

## **Major Safety Alerts in September 2010 (This page is subject to further review)**

The following safety alerts has a reasonable chance that the product will cause serious health problems or death. These cases will be forming part of the summary of September 2010 and more details will be provided when available

\*Note: FDA = Food and Drug Administration, United States of America; MHRA = Medicines and Healthcare products Regulatory Agency, United Kingdom; Health Canada = Health Canada, Canada

<b>Date of Issue (YYYY/MM/DD)</b>	<b>Description of Product</b>	<b>Source of Information*</b>	<b>Reference No. by Source</b>	<b>Alert Type by Source</b>	<b>Local Agent</b>	<b>Agent Contact Telephone No.</b>
2010/09/01	Stryker Scorpio /NRG 4-in-1 Cutting Blocks	Stryker China Limited	RA 2010-205	Firm Initiated Field Action	Stryker China Ltd	2518 6915
2010/09/02	GE Centricity Laboratory Core Lab, Software Versions: 3.3A, 3.3GA & Customers using version of label program	<a href="#">MHRA</a>	2010/008/016/081/005	FSCA	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/09/02	GE Centricity Laboratory; Software Versions: Versions 3.3 GA and prior	<a href="#">MHRA</a>	2010/008/016/291/014	FSCA	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/09/02	GE Giraffe OmniBed / Giraffe Incubator / Giraffe Warmer, In Bed Scales	<a href="#">MHRA</a>	2010/007/021/601/003	FSCA	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/09/02	GE Centricity Laboratory Instrument Interface; Software Versions: 4.0.0 series (4.0.0.9 or higher only) and 4.1.0 or higher	<a href="#">MHRA</a>	2010/008/016/291/015	FSCA	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/09/02	Siemens Dimension Vista V-LYTE Standard A – Impact on Potassium Results (K820) lot KA0C03, KA0D01, KA0E01, KA0E02, KA0F01, and/or KA0G01	<a href="#">MHRA</a>	2010/008/020/601/001	FSCA	Siemens Healthcare Diagnostic Limited	28707827
2010/09/02	Optovue iVue100 OCT	<a href="#">MHRA</a>	2010/008/020/081/013	FSCA	N.A.	N.A.
2010/09/02	BD MGIT AST Starter Kit, Set Carrier, Label Spares	BD	MC 640	Firm Initiated Field Action	BD	2575 8668
2010/09/03	Fresenius USA, Inc Fresenius 2008H Dialysate Delivery Machine; Fresenius 2008K, 2008K2 and 2008 K2@home Hemodialysis Machines; Fresenius Granuflo 1 Mixer Dissolution Unit; Main Power Supply Assembly (50 and 60 Hz) and AC Power cord assembly	<a href="#">FDA</a>	Z-2224-2010; Z-2225-2010; Z-2226-2010; Z-2227-2010	Class II	Fresenius Medical Care Hong Kong Limited	2583 0813
2010/09/03	Siemens AG AXIOM Artis MP/Artis dMP and Artis zee Multipurpose. Angiographic x-ray system. Model numbers: 10094139, 5904466, 7555365	<a href="#">FDA</a>	Z-2233-2010	Class II	Siemens Healthcare Diagnostic Limited	28707827
2010/09/03	Encore Medical 3DKnee Baseplates, Size 8, Left, Part # 333-01-108. Size 8, Left, Part # 333-01-108. Lot number: A1000003	<a href="#">FDA</a>	Z-2244-2010	Class II	N.A.	N.A.
2010/09/03	Availmed Medtronic Everest 20 / 30 Disposable Inflation Device AC 2200, AC 3200, AC3205P; 1) Lot numbers: 50517330, 50517331, 50517332, 50517333, 50517334, 50519716, 50519717, 50519718, and 50519679; 2) Lot numbers: 50517324; 3) Lot numbers: 50517336, 50517337, and 50517339	<a href="#">FDA</a>	Z-2271-2010; Z-2272-2010; Z-2273-2010	Class II	N.A.	N.A.
2010/09/03	Arrow Arrow Percutaneous Sheath Introducer Kit with Integral Hemostasis Valve/Side Port for use with 7.5 Fr. Catheters; Catalog number AJ-09801; RF0018145, RF0021641, RF9044164, RF9069739, RF9070837, RF9100262	<a href="#">FDA</a>	Z-2274-2010	Class II	N.A.	N.A.

2010/09/03	Seisa Medical ABC Bend-A-Beam Handpiece REF 134003; ABC Bend-A-Beam Handpiece REF 134006; ABC Bend-A-Beam Handpiece REF 134009; ABC Probe REF 160656 5 mm Handswitching Probe; ABC Probe REF 160636 5 mm Handswitching Probe; ABC Probe REF 160644 5 mm Handswitching Probe, 44 cm; ABC PROBE REF 160655 5 mm Footswitching Probe,	<a href="#">FDA</a>	Z-2276-2010; Z-2277-2010; Z-2278-2010; Z-2279-2010; Z-2280-2010; Z-2281-2010; Z-2282-2010	Class II	N.A.	N.A.
2010/09/03	Genzyme Corp Genzyme Biosurgery Essentials Kit, Item Number 82004; Lot Numbers Affected: RM00654 RM00664 RM00672 RM00687 RM00690 RM00698 RM00700 RM00711 RM00714 RM00727 RM00732 RM00741 RM00748 RM00757 RM00773 RM00781 RM00791 RM00802 RM00820 RM00835	<a href="#">FDA</a>	Z-2310-2010	Class II	N.A.	N.A.
2010/09/03	AdvanDx, Inc E. faecalis/OE PNA FISH" (Cat. No. KT003)	<a href="#">FDA</a>	Z-2315-2010	Class II	N.A.	N.A.
2010/09/03	Interpore Cross International LLC Sterile Bio-Eye Hydroxyapatite Orbital Implant and Conformer	<a href="#">FDA</a>	Z-2292-2010	Class III	N.A.	N.A.
2010/09/03	Smith & Nephew Orthopaedics Genesis II LIS Sizer (Product Code 75018966, Lot Number C66858)	<a href="#">MHRA</a>	2010/008/023/601/001	FSCA	Smith & Nephew Ltd.	2648 7700
2010/09/06	Prism Medical Freeway T40 Shower Chair Drop down armrests	<a href="#">MHRA</a>	2009/009/018/401/013	FSCA	N.A.	N.A.
2010/09/07	Various Manufacturer IV Extension sets with multiple ports and vented caps	<a href="#">MHRA</a>	MDA/2010/068	MDA	N.A.	N.A.
2010/09/07	Abbott Diagnostics Architect Pre-Trigger Solution	<a href="#">MHRA</a>	2010/008/027/601/001	FSCA	Abbott Laboratories LTD.	2593 2211
2010/09/08	Hologic ATEC Breast Bippy and Excision System / ATEC Handpiece (Lot 003016 and only the handpiece)	<a href="#">MHRA</a>	2010/008/027/291/001	FSCA	Prism Technologies Limited	2786 3233
2010/09/08	Medtronic Neuromodulation Intrathecal Catheters Catheters (Models : 8709, 8709SC, 8703, 8703W, 8731, 8731SC, 8711, 8749) Catheter repair kits (Models : 8598, 8598A)	<a href="#">Medtronic International Ltd.</a>	N.A.	Firm Initiated Field Action	Medtronic International, Ltd.	2919 1300
2010/09/09	Maquet Connector Ref#0286 (1/2"x1/2")	<a href="#">MHRA</a>	2010/009/001/291/016	FSCA	Maquet Hong Kong Ltd.	2393 9511
2010/09/09	RehaMed PAL 1000 (Portable Aquatic Lift)	<a href="#">MHRA</a>	2009/001/016/401/015	FSCA	N.A.	N.A.
2010/09/09	AngioScore AngioSculpt Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter, cutting/scoring, Easy Exchange (EX) delivery system	<a href="#">FDA</a>	Z-2218-2010	Class I	N.A.	N.A.
2010/09/09	Medical Components medCOMP(R) MRCTI66841 6.6F Plastic Dignity Low Profile CT Port with Pre-Attached Chronoflex(R) Polyurethane Catheter - 1 Unit	<a href="#">FDA</a>	Z-2235-2010	Class II	N.A.	N.A.
2010/09/09	Olympus SD Snares, Reusable Electrosurgical Snares. Models: SD-9L/U-1, SD-11L/U-1, SD-12L/U-1, SD-13L/U-1, SD-13L/U-1, & SD-16L/U-1. Snare tube model numbers: MAJ-13 and MAJ-15.	<a href="#">FDA</a>	Z-2236-2010	Class II	Olympus Hong Kong and China Ltd	2170 5678
2010/09/09	Philips and Neusoft NeuViz Dual series Computed Tomography (CT) Scanner System, X-Ray System. Part Number: 989605651321.	<a href="#">FDA</a>	Z-2237-2010	Class II	N.A.	N.A.

2010/09/09	Greatbatch Medical OptiSeal Valved PTFE Peelable Introducer, Model 1000093-001, 1000093-002, 1000093-003, 1000093-004, 1000093-005, 1000093-006, 1000093-007.	<a href="#">FDA</a>	Z-2294-2010	Class II	N.A.	N.A.
2010/09/09	Biomerieux VITEK TWO AST-N085 REF 22 225 For In Vitro Diagnostic Use	<a href="#">FDA</a>	Z-2295-2010	Class II	bioMerieux China Ltd.	2195 9348
2010/09/09	G3 Medical V. Mueller Peanut Sponges, Catalog number 23275-470	<a href="#">FDA</a>	Z-2296-2010	Class II	N.A.	N.A.
2010/09/09	Abbott Laboratories VP 2000 Processor Heated Reagent Basins; automated slide stainer	<a href="#">FDA</a>	Z-2313-2010	Class II	Abbott Laboratories LTD.	2593 2211
2010/09/09	Boston Scientific Ultraflex Uncovered Esophageal Stent System ; Tracheobronchial Stent System ; Colonic Stent System	<a href="#">FDA</a>	Z-2316-2010 through Z-2331-2010	Class II	Boston Scientific Hong Kong Ltd	2960 7136
2010/09/09	Stryker Worldwide Long Nail Kit R2.0, Ti RIGHT 011x360 mm x 125 degrees; Sterile, Ti Alloy, Implant; Catalog number 3225-0360S.	<a href="#">FDA</a>	Z-2340-2010	Class II	Stryker China Ltd	2518 6915
2010/09/09	Abbott Laboratories 1) CELL-DYN 3200 CS and SL, Hematology Analyzer. Waste Reservoir Assembly Part number 8921174802; 2) CELL-DYN 3700 CS and SL, Hematology Analyzer. Waste Reservoir Assembly Part number 8921174802; 3) CELL-DYN Ruby, Hematology Analyzer. Waste Reservoir Assembly Part number 8921174802; 4) CELL-DYN Sapphire, Hematology Analyzer. Waste Reservoir Assembly Part number 8921174802.	<a href="#">FDA</a>	Z-2350-2010 through Z-2353-2010	Class II	Abbott Laboratories LTD.	2593 2211
2010/09/09	Stryker Pain Pump; Stryker Sheath ; Poly Stim II Nerve Stimulator ; Single Shot Needle; Tuohy Catheter Kit ; Tuohy Stimulation Catheter Kit ; Stimulation Catheter Continuous Nerve Block Tray	<a href="#">FDA</a>	Z-2356-2010 through Z-2379-2010	Class II	N.A.	N.A.
2010/09/09	Vital Signs enFlow Disposable IV Fluid/Blood Warmer Cartridge. Medical point-of-care device designed to warm blood and IV fluids. Model numbers: 9800200, 9800202, 9800200EU, 9800202EU, 9100020010, 9100020210, 91000153, 91000154, 91000156.	<a href="#">FDA</a>	Z-2380-2010	Class II	N.A.	N.A.
2010/09/09	Dental EZ Stardental Division Titan 3 5K Low-Speed Motor - Star Titan 3, 5,000 rpm- Lube Free. Part number 262261.	<a href="#">FDA</a>	Z-2354-2010	Class III	N.A.	N.A.
2010/09/10	Aesculap Hydrolift Implants SV004T (Batch 51658397), SV010T (Batch 51647369, 51653357), SV011T (Batch 51660087, 51654664, 51651709), SV012T(Batch 51652387)	<a href="#">MHRA</a>	2010/009/001/081/004	FSCA	B. Braun Medical Hong Kong	2529 2009
2010/09/13	Roche Diagnostics A) Tina-Quant D-Dimer Gen.2 for Cobas Integra and Cobas C-System B) Tina-Quant D-Dimer Gen.2 for Roche/Hitachi 917 and Modular P Analyzers C) Tina-Quant D-Dimer Gen.2 for Roche Cobas C111 Analyzers	<a href="#">Health Canada</a>	51661	Type I	Roche Diagnostics (Hong Kong) Ltd	2485 7510
2010/09/13	Biomerieux, Inc. A) Vitek 2 Compact 30 System - Test Cards B) Vitek 2 Compact 60 System - Test Cards C) Vitek 2 System - Test Cards	<a href="#">Health Canada</a>	55961	Type II	bioMerieux China Ltd.	2195 9348
2010/09/13	Technidata S.A.S. TD-Synergy	<a href="#">Health Canada</a>	55962	Type II	N.A.	N.A.
2010/09/13	Technidata S.A.S. A) TDLims B) TD-Synergy	<a href="#">Health Canada</a>	55963	Type II	N.A.	N.A.
2010/09/13	Beckman Coulter, Inc. Sex Hormone Binding Globulin (SHBG) Reagent	<a href="#">Health Canada</a>	55983	Type II	Beckman Coulter Hong Kong Ltd	2240 6150
2010/09/13	Gyrus Acmi, Inc. Pleatman Sac Tissue Removal System	<a href="#">Health Canada</a>	56025	Type II	N.A.	N.A.
2010/09/13	Stryker Orthopedics Scorpio T72 Insert Tibial Trials	<a href="#">Health Canada</a>	55981	Type II	Stryker China Ltd	2518 6915

2010/09/13	Howmedica Osteonics Corporation Osteonics Series 7000 Total Knee Standard Tibial Tray	<a href="#">Health Canada</a>	56012	Type II	Stryker China Ltd	2518 6915
2010/09/13	Bio-Rad Laboratories Deeside IN2IT - A1C Test Cartridges	<a href="#">Health Canada</a>	56054	Type II	Bio-Rad Pacific Ltd.	N.A.
2010/09/13	Stryker Instruments Instructions for use (IFU) for Painpump2 Block-Aid	<a href="#">Health Canada</a>	56046	Type II	Stryker China Ltd	2518 6915
2010/09/13	Cardinal Health A) Sterile Craniotomy Pack B) Sterile Ear Pack	<a href="#">Health Canada</a>	56051	Type II	CareFusion Hong Kong Ltd.	2891 8730
2010/09/13	Roche Diagnostics GMBH A) Coaguheck XS Monitor B) Coaguheck XS Plus Monitor	<a href="#">Health Canada</a>	56053	Type II	Roche Diagnostics (Hong Kong) Ltd	2485 7510
2010/09/13	Ortho-Clinical Diagnostics Inc. Vitros Chemistry Products MALB Reagent	<a href="#">Health Canada</a>	56101	Type II	Ortho Clinical Diagnostics	2737 5504
2010/09/13	Immuontech A.S. IGFBP-3 Immunoradiometric Assay (IRMA)	<a href="#">Health Canada</a>	56099	Type II	Beckman Coulter Hong Kong Ltd	2240 6150
2010/09/13	Diasorin Inc. Liason Analyzer	<a href="#">Health Canada</a>	56139	Type II	N.A.	N.A.
2010/09/13	Prolenium Medical Technologies Inc. Dermal Roller SR	<a href="#">Health Canada</a>	56052	Type III	N.A.	N.A.
2010/09/13	Roche Diagnostics GMBH Precicontrol Universal	<a href="#">Health Canada</a>	55469	Type II	Roche Diagnostics (Hong Kong) Ltd	2485 7510
2010/09/13	Beckman Coulter, Inc. Synchron Systems Glucose Reagent (GLU)	<a href="#">Health Canada</a>	56165	Type II	Beckman Coulter Hong Kong Ltd	2240 6150
2010/09/13	Trinity Biotech PDQ 1 Reagent, 940ml, Lot No. 3339	<a href="#">MHRA</a>	2010/008/031/291/014	FSCA	N.A.	N.A.
2010/09/13	Roche Diagnostics GMBH Elecsys Vitamin D3 assay	<a href="#">Health Canada</a>	55964	Type III	Roche Diagnostics (Hong Kong) Ltd	2485 7510
2010/09/13	Roche Diagnostics GMBH Elecsys Free T4	<a href="#">Health Canada</a>	56041	Type III	Roche Diagnostics (Hong Kong) Ltd	2485 7510
2010/09/13	Vital Diagnostics, Inc. Excyte Sliders	<a href="#">Health Canada</a>	54156	Type III	N.A.	N.A.
2010/09/13	Siemens Healthcare Diagnostics Inc. A) ADVIA Centaur Hepatitis B Core Total (HBCT) Assay B) ADVIA Centaur XP System-HBC Total (HBCT) assay (donor screening for transplantation) C) Advia Centaur CP System-HBC Total (HBCT) assay (donor screening for transplantation)	<a href="#">Health Canada</a>	55559	Type III	Siemens Healthcare Diagnostic Limited	28707827
2010/09/13	Johnson & Johnson Vision Care, Inc. Acuvue Oasys Brand Contact Lenses for Astigmatism	<a href="#">Health Canada</a>	56160	Type III	Johnson & Johnson Vision Care, Johnson & Johnson (Hong Kong) Ltd.	2737 5718
2010/09/13	Boston Scientific Corporation A) Sterling Monorail PTA Balloon B) Sterling Over-The-Wire PTA Balloon	<a href="#">Health Canada</a>	54721	Type III	Boston Scientific Hong Kong Ltd	2960 7136
2010/09/13	Siemens AG A) Mevatron Linear Accelerators B) Artiste MV-Linear Accelerator-Main Unit	<a href="#">Health Canada</a>	56152	Type III	Siemens Healthcare Diagnostic Limited	28707827
2010/09/13	Prolenium Medical Technologies Inc. Dermal Roller SR	<a href="#">Health Canada</a>	56052	Type III	N.A.	N.A.
2010/09/14	Immucor Panocell 20	<a href="#">NCAR</a>	BE-2010-09-08-010	FSCA/Recall	Uninet Technology LTD	2838 8423
2010/09/14	Varian Oncology Systems, USA Varian Eclipse™ Treatment Planning System and RT Chart (Aria™ Radiation Oncology)	<a href="#">MHRA</a>	2010/009/006/291/009	FSCA	Varian Medical Systems Pacific Inc.	2724 2836
2010/09/14	Elekta Ltd Linear Accelerator – XVI, Applicable to XVI R4.2.1 or XVI R4.5 with MOSAIQ@ 2.00T2SP5 or later, in the SYNERGISTIQ. configuration.	<a href="#">MHRA</a>	2010/009/006/081/005	FSCA	Elekta Ltd.	2891 2208
2010/09/14	Rociale RFEO10-1001 - Umbilical Cord Clamp	<a href="#">MHRA</a>	2010/007/001/401/016	FSCA	N.A.	N.A.
2010/09/14	Pentax Europe GmbH Pentax Light Sources BS-LH1, BS-LH2 and BS-LL1	<a href="#">MHRA</a>	2010/009/009/081/011	FSCA	N.A.	N.A.
2010/09/14	Merck Serono Limited Lubricant Gel - Corflo CuBBY and Gastrostomy Kits (various sizes, manufactured from 2004 through 2006)	<a href="#">MHRA</a>	2010/009/003/081/001	FSCA	N.A.	N.A.
2010/09/14	Freeway Healthcare Transactive Xtra Hoist - All Models Manufactured with serial numbers between 11761 & 12316 (inclusive)	<a href="#">MHRA</a>	2010/007/016/261/001	FSCA	N.A.	N.A.

## Monthly Summary of Medical Device Safety Alerts - August 2010

\*Note: FDA = Food and Drug Administration, United States of America; MHRA = Medicines and Healthcare products Regulatory Agency, United Kingdom; Health Canada = Health Canada, Canada

Date of Issue (YYYY/MM/DD)	Description of Product	Source of Information*	Reference No. by Source	Alert Type by Source	Local Agent	Agent Contact Telephone No.
2010/08/02	Medtronic Sutureless Unipolar Myocardial Lead	<a href="#">Health Canada</a>	53385	Type II	Medtronic International, Ltd.	2919 1300
2010/08/02	Siemens Dimension Vista System-Enzymatic Creatinine Assay (ECREA)	<a href="#">Health Canada</a>	55520	Type II	Siemens Healthcare Diagnostic Limited	2870 7533
2010/08/02	Philips Heartstart HS1 Onsite Defibrillator, Heartstart HS1 Home Defibrillator	<a href="#">Health Canada</a>	55525	Type II	Philips Electronic Hong Kong Ltd	2821 5480
2010/08/02	Liko Scale Adapters	<a href="#">Health Canada</a>	55601	Type II	Solutions Health Care Products	2688 2933
2010/08/02	Minntech Endoscope Disinfectant	<a href="#">Health Canada</a>	55606	Type II	Schmidt BioMedTech (H.K.) Limited	2620 8329
2010/08/02	Immunotech Estrone Radioimmunoassay (RIA) Kit	<a href="#">Health Canada</a>	55630	Type II	N.A.	N.A.
2010/08/02	Zimmer Versys Hip System Femoral Head 12/14	<a href="#">Health Canada</a>	55632	Type II	Zimmer PTE Ltd. (Hong Kong branch)	2992 0968
2010/08/02	Zimmer ITST Fixation Locking Bolt Extractor	<a href="#">Health Canada</a>	55641	Type II	Zimmer PTE Ltd. (Hong Kong branch)	2992 0968
2010/08/02	Teleflex Medical Rusch Care Premium Drain Bag	<a href="#">Health Canada</a>	55666	Type II	N.A.	N.A.
2010/08/02	Depuy Summit Broach Handle	<a href="#">Health Canada</a>	55756	Type III	Johnson & Johnson Medical (HK)	2738 6027
2010/08/02	CaridianBCT A) COBE Spectra White Blood Cell Sets B) COBE Spectra Therapeutic Plasma Exchange Sets	<a href="#">Health Canada</a>	55784	Type II	CaridianBCT (Asia Pacific) Ltd.	2576 1366
2010/08/02	Digiterm Comfort 4 Eco	<a href="#">MHRA</a>	2009/009/001/291/028	FSCA	N.A.	N.A.
2010/08/02	Activate Corgi Sprint (size 3 only)	<a href="#">MHRA</a>	2009/012/008/401/004	FSCA	N.A.	N.A.
2010/08/02	Fisher & Paykel Sleepstyle	<a href="#">MHRA</a>	2010/005/019/081/010	FSCA	N.A.	N.A.
2010/08/03	BioMérieux VIDAS RUB IGG II, ref 30221, Lot 837810801	<a href="#">MHRA</a>	2010/007/023/601/003	FSCA	bioMerieux China Ltd.	2195 9348
2010/08/03	Medtronic Everest Inflation device/ survival kit, models AC2200, AC3200 and AC3205P	<a href="#">MHRA</a>	2010/007/022/081/011	FSCA	Medtronic International, Ltd.	2919 1300
2010/08/04	DiaSorin Liaison Analyser	<a href="#">MHRA</a>	2010/006/028/401/011	FSCA	N.A.	N.A.
2010/08/04	Siemens ADVIA centaur HIV Ag/Ab combo (CHIV) assay	<a href="#">MHRA</a>	2010/007/019/601/003	FSCA	Siemens Healthcare Diagnostic Limited	2870 7533
2010/08/04	Stryker Crossfire Consoles	<a href="#">MHRA</a>	2010/007/027/291/013	FSCA	Stryker China Ltd	2518 6915
2010/08/04	Beckman Coulter SYNCHRON rheumatoid factor (RF) reagent -- PN 475136 lot numbers M907325	<a href="#">MHRA</a>	2010/007/023/601/004	FSCA	Beckman Coulter Hong Kong Ltd	2240 6150
2010/08/04	Wescott Sae-Flo MD Extension Set with Y-Connector Product Code WFC2000AY	<a href="#">MHRA</a>	2010/007/029/601/006	FSCA	N.A.	N.A.
2010/08/04	Activate Corgi Sprint (size 2 only)	<a href="#">MHRA</a>	2010/003/002/081/007	FSCA	N.A.	N.A.
2010/08/04	Invacare Instructions for use - XLT	<a href="#">MHRA</a>	2009/003/010/301/001	FSCA	Direct Health LTD	2528 1109
2010/08/04	Coloplast Self-Cath Nelaton CH12 Catheter	<a href="#">MHRA</a>	2010/008/002/291/019	FSCA	Coloplast (Hong Kong) Ltd	3628 7428
2010/08/05	Biomet Artificial ligament fixation device # 7PE ZIPLOOP Extended Toggle (REF 904755), Toggleloc Artificial ligament fixation device ZIPLOOP Technology Implant Kit (REF 909848)	<a href="#">FDA</a>	Z-1952-2010 to Z-1953-2010	Class II	N.A.	N.A.

2010/08/05	Terumo Cardiovascular Procedure Kit (P/N 64937, 65246, 65503/70881-02, 70608-01, 71544-01, 71546-01, 71733, 71766PP, 71934, 72642, 72790, 72846, 131351-02, 70608-01, 71032)	<a href="#">FDA</a>	Z-2149-2010 to Z-2163-2010	Class II	TERUMO CHINA (H.K.) LTD.	2866 0811
2010/08/05	Baxa Exacta-Mix EVA Container, sterile (REF: 137, 138, 139, 140, 141, 142, 143), Halobag EVA Dual-Chamber Bag (REF: 341), Exacta-Mix Calibration Bag (Recorder No. H938 371 3), Exacta-Mix 2400 Valve Assembly w/ Calibration Bag (REF: 724), Exacta-Mix Valve Set (REF 706, 706D)	<a href="#">FDA</a>	Z-2137-2010 to Z-2148-2010	Class II	N.A.	N.A.
2010/08/05	Siemens Healthcare Diagnostics Dimension Vista LOCI Reaction Vessels, catalog number KS855.	<a href="#">FDA</a>	Z-2117-2010	Class III	Siemens Healthcare Diagnostic Limited	2810 7533
2010/08/05	Stryker Howmedica Osteonics Exeter Femoral head 26mm diameter standard neck	<a href="#">MHRA</a>	2009/006/001/081/003	FSCA	Stryker China Ltd	2518 6915
2010/08/05	Newdeal Forefoot Sterile Cannulated Drill (specific lots)	<a href="#">MHRA</a>	2010/007/027/291/010	FSCA	N.A.	N.A.
2010/08/05	Philips M1013A IntelliVue G1, M1019A IntelliVue G5, M1026B/BT Anesthesia Gas Modules with M1657B manifolds shipped from Jan 01, 2009 to May 25, 2010 (M1013A / M1019A) respectively Jun 10, 2010 (M1026B / M1026BT) (1) M1013A: Serial Number range ARYE-0014 to ASBC-0013; (2) M1019A: Serial Number range ARZC-0202 to ASBE-0086; (3) M1026B: Serial Number range 4614H27003 to 4614H28158; (4) M1026BT: Serial Number range 4614H27160 to 4614H28184	Philips Electronic Hong Kong Ltd	FSN86201138	Firm Initiated Field Action	Philips Electronic Hong Kong Ltd	2821 5480
2010/08/06	Codman Surgical Patties -1/4 X 1/4 and 5/16 round sizes (Model : 80-1396, 80-1399)	<a href="#">MHRA</a>	2010/007/027/291/012	FSCA	Johnson & Johnson Medical (HK)	2738 6027
2010/08/09	Varian Eclipse Client software versions with build numbers from 7.3.10 through 8.6.15 (i.e. excluding 8.6.17)	<a href="#">Varian Medical Systems Pacific Inc.</a>	CP-01785	Firm Initiated Field Action	Varian Medical Systems Pacific Inc.	2724 2836
2010/08/10	Trinity Biotech Captia VZV IgM kit (Product Code : 2325650)	<a href="#">MHRA</a>	2010/008/002/291/013	FSCA	N.A.	N.A.
2010/08/10	Karl Storz Calcuson & Endomat LC units used in combination, Karl Storz Suction Tubing Set, Item No. 20330342	<a href="#">MHRA</a>	2010/008/004/081/013	FSCA	KARL STORZ Endoscopy China Ltd.	2865 2411
2010/08/10	Fresenius Bloodline for 4008 Dialysis Machine, Product : AV-SET FMC (FA404E/FV404E), Code : 5016481	<a href="#">MHRA</a>	2010/008/005/081/016	FSCA	Fresenius Medical Care Hong Kong Limited	2583 0813
2010/08/10	Rociale InHealth Ophthalmic Procedure Pack (Code: RMT8761-REVE)	<a href="#">MHRA</a>	2010/005/006/291/010	FSCA	N.A.	N.A.
2010/08/10	Hospira Gemstar Pump Set (List No. 13261-0401, Lot no. 670695H, 691805H, 760665H; List No. 13261-6102, Lot No. 740545H)	Hospira Limited	N.A.	Firm Initiated Field Action	Hospira Limited	2898 2886
2010/08/11	Roma Medical Aids All mobility scooters	<a href="#">MHRA</a>	2009/007/003/301/002	FSCA	N.A.	N.A.
2010/08/11	Ikaria INOMAX DS drug-delivery systems	<a href="#">FDA</a>	N.A.	Class I	N.A.	N.A.
2010/08/11	Hospital Metalcraft Bristol Maid Baby Crib Trolleys, BA/3/B and BA/6	<a href="#">MHRA</a>	2010/005/025/081/019	FSCA	N.A.	N.A.
2010/08/11	Karl Storz MTP Rhino Fiberscope Cover (code 041310-50 Lot-no. 0907/05)	<a href="#">MHRA</a>	2010/008/004/081/012	FSCA	KARL STORZ Endoscopy China Ltd.	2865 2411
2010/08/11	Baxter HomeChoice Automated Peritoneal Dialysis System (Product Code: 5C4474)	Baxter Healthcare Ltd	N.A.	Firm Initiated Field Action	Baxter Healthcare Ltd	2807 8555
2010/08/12	Philips AC power cords manufactured by Electri-Cord with tall bridge design. Used across all Philips product lines, as well as Respiroics/Philips products, Dixtel owned products and Dixtal (formerly Novamatrix or Respiroics/Novamatrix products)	<a href="#">FDA</a>	Z-1257-2010 to Z-1309-2010	Class II	Philips Electronic Hong Kong Ltd	2821 5480
2010/08/12	GE Healthcare GE Centricity PACS-IW software (version 3.7.3), GE Centricity Web Diagnostic (WebDX) software (version 1.0.0.2)	<a href="#">FDA</a>	Z-1402-2010 to Z-1403-2010	Class II	GE Medical Systems Hong Kong Ltd.	2783 1838

2010/08/12	Elekta Synergy XVI Medical Linear Accelerator. Model Numbers R3.5, R4.0 and R4.2.	<a href="#">FDA</a>	Z-1405-2010	Class II	Elekta Ltd.	2891 2208
2010/08/12	Merit Medical Systems Vessel Sizing Angiographic Catheter, REF 7602-2M65, 5F PIG-VSC-2B, UHF Pigtail, Performa, Sterile EO. (lot no. G775032)	<a href="#">FDA</a>	Z-1731-2010	Class II	King Health Limited	2481 3787
2010/08/12	Dreamcon Fancy i Color cosmetic lens, Contents: A pair of sterile soft color contact lens immersed in buffered isotonic saline solution, Size: B.C. 8.6mm DIA. 14.5mm. a) Includes models Amber, Amethyst, Blueberry Crush, BumbleBee Yellow, Denim Blue, Envious Green, Honey, Pebble Gray, Marble Swirl, Royal Blue, Ultraviolet, HA11, HA12, HA13, HA14, HA16, HL21, HL22, HL23, HL24, HL26, Fierce Fandango and Holiday Green (Lot no. D01704); b) includes models Copper, Gotham Gray, HJ31, HW21, HW22, Jade and Natural Hazel (lot no. D01711); c) includes models Aquamist, Artic Blue, Deep Ocean Blue, HJ35, HJ36 and HW26 (lot no. D01712); d) includes models HJ33, HJ34, HW23, HW24, Lavender, Lazer Green, Sour Apple Green and Vibrant Violet (lot no. D01713); and e) includes models 011, 015, 024, 029, 032, 033, 035, 043-1, 044, 046, 047, 049, 055, 063-1, 064, 071, 079, 085 and 088 (lot no. unidentified). CODE a) Lot Number D01704; b) Lot Number D01711; c) Lot Number D01712; d) Lot Number D01713; e) Lot (unidentified)	<a href="#">FDA</a>	Z-1756-2010	Class II	N.A.	N.A.
2010/08/12	Orthohelix Surgical Designs Modular Foot System 3.5mm x 22mm Locking Screw M/N: MFT-021-35-22, Lot no. 0964081	<a href="#">FDA</a>	Z-1784-2010	Class II	N.A.	N.A.
2010/08/12	Mindray Passport V Monitor, Part Number 6100F.	<a href="#">FDA</a>	Z-1785-2010	Class II	MR Holdings (HK) Limited	2511 0701
2010/08/12	Fresenius Medical Care Optiflux F180NR Dialyzers, Catalog Number: 0500318E., Lot no. 10AU04011	<a href="#">FDA</a>	Z-1951-2010	Class II	Fresenius Medical Care Hong Kong Limited	2583 0813
2010/08/12	Microtek Medical Stackhouse Laser Resistant Suction Probe, Size: 1/4" x 9" (0.64cm x 22.9cm), REF 24014, qty 10 ea, Sterile EO, 2015-05.	<a href="#">FDA</a>	Z-2109-2010	Class II	N.A.	N.A.
2010/08/12	Wright Medical Technology Claw Hex Screw Charlotte " F&A System Contents: 1 each Foot and Ankle Screw ... Implant Material: Stainless Steel Ref: 4013-3520 ... Size 3.5MM, Length 20 MM, Use with Clava 3.5MM - Non-Sterile. Item # 40133520	<a href="#">FDA</a>	Z-2188-2010	Class II	N.A.	N.A.
2010/08/12	Ascent Healthcare Solutions Reprocessed Femoral Compression Device, Model 11165, Lot numbers: 869509, 878402, 878439, 879762, 879990, 880274	<a href="#">FDA</a>	Z-2196-2010	Class III	N.A.	N.A.
2010/08/12	DIMA Incontinence Sling - Contasure Needleless	<a href="#">MHRA</a>	2010/006/021/291/009	FSCA	N.A.	N.A.
2010/08/12	Smith & Nephew Orthopaedics Ltd Peri-Loc 3.5mm Anterolateral Distal Tibial Plate - Single Lot number 08GM01799	<a href="#">MHRA</a>	2010/005/011/601/002	FSCA	Smith & Nephew LTD	N.A.
2010/08/12	Siemens Medical Solutions e.cam SPECT Camera Systems with Profile AC option	<a href="#">MHRA</a>	2010/002/003/081/016	FSCA	Siemens Healthcare Diagnostic Limited	2870 7533
2010/08/12	Invacare Stability - TDX SP	<a href="#">MHRA</a>	2010/004/030/301/001	FSCA	Direct Health Ltd.	25281109
2010/08/12	Smith & Nephew Healthcare Ltd Dyonics Bonecutter Electroblade - Item code: 7205962 and 72202213 Lot number: All	<a href="#">MHRA</a>	2010/008/010/081/002	FSCA	Smith & Nephew LTD	N.A.

2010/08/14	St. Jude Medical Engage TR Introducer, 6 Fr. (Batch: 3109782, 3105838, 3107645, 3103891, 3110889, 3110892, 3118794, 3123051, 3107789, 3107790)	<a href="#">FDA</a>	N.A.	Class I	St. Jude Medical (Hong Kong) Ltd.	2996 7688
2010/08/16	Drive Medical Walking frame (Model : 10281W-1 to 10287W-1)	<a href="#">MHRA</a>	2010/006/014/301/001	FSCA	N.A.	N.A.
2010/08/16	MIPM TeslaPlus MRI-compatible Patient Monitor with New ECG leads	<a href="#">MHRA</a>	2010/008/003/291/022	FSCA	N.A.	N.A.
2010/08/16	Philips All Bucky Diagnost with Optimus X-ray Generator	<a href="#">MHRA</a>	2010/002/012/401/018	FSCA	Philips Electronic Hong Kong Ltd	2821 5480
2010/08/17	Kimal Extension Set Product No K39/10/100 and K39/10/200	<a href="#">MHRA</a>	2010/006/016/401/005	FSCA	N.A.	N.A.
2010/08/17	Varian BrachyVision (Versions 8.2 through 8.9)	<a href="#">MHRA</a>	2010/008/013/081/003	FSCA	Varian Medical Systems Pacific Inc.	2724 2836
2010/08/18	Abbot CELL-DYN 4000 and Sapphire vent head assembly	<a href="#">MHRA</a>	2010/008/006/601/001	FSCA	Abbott Laboratories LTD.	2593 2211
2010/08/18	Stryker Scorpio T72 Tibial Insert Trial	<a href="#">MHRA</a>	2010/008/006/081/027	FSCA	Stryker China Ltd	2518 6915
2010/08/19	Ortho-Clinical Diagnostics mALB Reagent, GENs 2, 3, and 4 Cat. No 6801740	<a href="#">MHRA</a>	2010/006/011/401/005	FSCA	Ortho Clinical Diagnostics	2737 5504
2010/08/19	Swissimplant solysafe septal occluder - all diameters - type 15rRef 010.0001, type 20 Ref 010.0002, type 25 ref 010.0003, type 30 Ref 010.0004, type 35 ref 010.0005	<a href="#">MHRA</a>	2010/008/006/081/020	FSCA	N.A.	N.A.
2010/08/19	Siemens Medical Solutions AXIOM Luminos TF and Sireskop SD	<a href="#">MHRA</a>	2010/008/010/081/005	FSCA	Siemens Healthcare Diagnostic Limited	2810 7533
2010/08/19	BD GasPak EZ Large Incubation Container (Cat No. 260672, Lot No. 7110573)	BD	N.A.	Firm Initiated Field Action	BD	2575 8668
2010/08/19	Cardinal Health Medi-Vac® Non-Conductive Suction Tubing (Cat No. N510, N512, N56A, N610, N612, N66A, N710, N712, N76A, NEX510; NEX512; NEX56A; NEX610; NEX612, NEX66A; NEX710, NEX712; NEX76A) (All lot numbers prior to Y10KXXXX)	Solar-Med Limited	FCA 2010236	Firm Initiated Field Action	Solar-Med Limited	2425 0926
2010/08/19	Johnson & Johnson Acuvue (Narafilcon A) contact lens 1 Day Acuvue TruEye (Lot No. 492237, 492238, 492250, 492251, 492287, 492288, 492289, 492268, 492241, 492282, 492283, 492280, 492281, 492252, 492254, 492245)	<a href="#">Johnson &amp; Johnson Vision Care, Johnson &amp; Johnson (Hong Kong) Ltd.</a>	N.A.	Firm Initiated Field Action	Johnson & Johnson Vision Care, Johnson & Johnson (Hong Kong) Ltd.	2737 5718
2010/08/20	Sonosite SonoSite TEE, 8-3 MHz Transducer labeled: "Tee Transducer" Part number P05813 and P06841.	<a href="#">FDA</a>	Z-2191-2010	Class II	N.A.	N.A.
2010/08/20	ConMed Linvatec REF 87100 87k Arthroscopy Tubing Set (Lot 0904151 through 1005201), for use with the 87k Arthroscopy Pump (87000)	<a href="#">FDA</a>	Z-2192-2010	Class II	ConMed Limited	N.A.



2010/08/20	Wright Medical Technology Dynasty A-Class Poly Liner, REF DLXP-LD36	<a href="#">FDA</a>	Z-2212-2010	Class II	N.A.	N.A.
2010/08/20	Minntech DSD Application Guide (MG04-0001 revision M) for the Pentax Universal Video Scope Hookup (DSD-110-HU0109) only when used with the DSD automated endoscope reprocessor (AER) and the Pentax EG-3630U endoscope.	<a href="#">FDA</a>	Z-2213-2010	Class II	Schmidt BioMedTech (H.K.) Limited	2620 8329
2010/08/20	Beckman Coulter Access Immunoassay Systems AFP QC, Part Number: 33219, Lot Numbers: 911158, 911581, and 917631	<a href="#">FDA</a>	Z-2208-2010	Class III	N.A.	N.A.
2010/08/20	St. Jude Medical Engage TR Introducer, 6 Fr. (Batch: 3109782, 3105838, 3107645, 3103891, 3110889, 3110892, 3118794, 3123051, 3110892, 3118797, 3107789, 3107790)	<a href="#">FDA</a>	Z-2178-2010 to Z-2182-2010	Class I	St. Jude Medical (Hong Kong) Ltd.	2996 7688
2010/08/21	Immuncor Panoscreen I, II & III	<a href="#">Health Canada</a>	55873	Type I	Uninet Technology LTD	2838 8423
2010/08/23	GE Healthcare CARESCAPE™ Monitor B850	<a href="#">MHRA</a>	2010/007/007/601/001	FSCA	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/08/23	Fujirebio Mesomark Kits	<a href="#">Health Canada</a>	55955	Type II	N.A.	N.A.
2010/08/23	Teleflex IMA / ENT Blade Electrode	<a href="#">Health Canada</a>	55952	Type II	N.A.	N.A.
2010/08/23	Immucor Galileo Blood Bank Analyzer	<a href="#">Health Canada</a>	55949	Type II	Uninet Technology LTD	2838 8423
2010/08/23	Siemens Syngo Dynamics	<a href="#">Health Canada</a>	55938	Type III	Siemens Healthcare Diagnostic Limited	2810 7533
2010/08/23	Gyrus Dissector PlasmaKnife (DPK)	<a href="#">Health Canada</a>	55925	Type II	Olympus Hong Kong and China Ltd	2170 5678
2010/08/23	Heine Optotechnik XP Laryngoscope Blabe Mac 3	<a href="#">Health Canada</a>	55909	Type III	N.A.	N.A.
2010/08/23	Sybron Endo K3 Gutta Percha	<a href="#">Health Canada</a>	55901	Type III	N.A.	N.A.
2010/08/23	Roche Anti-CCP for Elecsys and Cobas E	<a href="#">Health Canada</a>	55874	Type III	Roche Diagnostics (Hong Kong) Ltd	2485 7510
2010/08/23	Toshiba Aquilion One System - Main Unit	<a href="#">Health Canada</a>	55835	Type II	Sanko Medical Systems (HK) LTD	23840688
2010/08/23	Stryker Sonopet Ultrasonic Aspirator Console	<a href="#">Health Canada</a>	55828	Type II	Stryker China Ltd	2518 6915
2010/08/23	Medtronic Polestar N-20 - Magnetic Resonance Diagnostic Device	<a href="#">Health Canada</a>	55746	Type II	Medtronic International, Ltd.	2919 1300
2010/08/23	Roche (Tina Quant IgG Gen.2)	<a href="#">Health Canada</a>	55734	Type III	Roche Diagnostics (Hong Kong) Ltd	2485 7510

2010/08/23	AGFA A) NX8000 workstations used in combination with 19" Barco monitor and mounting stand, B) NX8200 workstations used in combination with 19" Barco monitor and mounting stand	<a href="#">Health Canada</a>	55730	Type II	AGFA Hong Kong Limited	2555 9421
2010/08/23	GE HiSpeed DX/I LX/I CT System	<a href="#">Health Canada</a>	55695	Type III	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/08/23	Siemens Immulite 2500 System-Human Chorionic Gonadotropin (HCG) Assay	<a href="#">Health Canada</a>	55581	Type III	N.A.	N.A.
2010/08/23	OridionA) Filterline Set B) Smart Capnoline Plus ADU/INT 25/100 UN C) Smart Capnoline Plus O2 ADU/INT 25UN D) Smart Capnoline H Plus O2 ADU/INT 25UN E) Niv-Line Adult 25UN	<a href="#">Health Canada</a>	55493	Type II	N.A.	N.A.
2010/08/23	Varian A) Clinac Linear Accelerator B) Trilogy Radiotherapy Delivery System C) Clinac IX Radio Therapy Delivery System D) Novalis TX Linear Accelerator	<a href="#">Health Canada</a>	55377	Type II	Varian Medical Systems Pacific Inc.	2724 2836
2010/08/23	Biomerieux O-F Dextrose Tubed Media	<a href="#">Health Canada</a>	55201	Type III	bioMerieux China Ltd.	2195 9348
2010/08/24	Draeger Oxylog 3000 emergency / transport ventilators	<a href="#">MHRA</a>	2010/008/016/081/002	FSCA	Draeger Medical Hong Kong Ltd.	2877 3077
2010/08/24	Varian Optical Guidance Platform used for Clinac or Novalis TX	Varian Medical Systems Pacific Inc.	CP-00356	Firm Initiated Field Action	Varian Medical Systems Pacific Inc.	2724 2836
2010/08/25	BrainLAB 19506B, 19506C KOLIBRI NAVIGATION STATION 2.0 (WITH MOBILE CAMERA STAND 2.0); 19801A KOLIBRI MOBILE CAMERA STAND 2.0	BrainLAB Ltd	10-06-02.SEL.3 (III)	Firm Initiated Field Action	BrainLAB Ltd	2417 1881
2010/08/25	Allergan UK Easyband - Version 2 and Version 3	<a href="#">MHRA</a>	2010/003/026/081/004	FSCA	Allergan Asia Limited	2610 2525
2010/08/25	Allergan UK Easyband - Gen0	<a href="#">MHRA</a>	2010/003/026/081/004	FSCA	Allergan Asia Limited	2610 2525
2010/08/25	Aesculap AG Tibia Offset Cemented Stem (Model Number: NR196K)	<a href="#">MHRA</a>	2010/008/006/081/005	FSCA	B. Braun Medical Hong Kong	2529 2009
2010/08/25	Aesculap AG Hydrolift instrumentation	<a href="#">MHRA</a>	2010/008/006/081/006	FSCA	B. Braun Medical Hong Kong	2529 2009
2010/08/25	Smith & Nephew VLP Compression Plate 7 Hole 56mm (Product code 72824014S Lot Number: all batches)	<a href="#">MHRA</a>	2010/008/016/081/007	FSCA	Smith & Nephew LTD	2645 8706
2010/08/25	Beckman Synchron® Systems LX®20 & UniCel® DxC Systems	<a href="#">MHRA</a>	2010/008/006/601/004	FSCA	Beckman Coulter Hong Kong Ltd	2240 6150
2010/08/26	Abbott Point of Care i-STAT Level 2 Control Value Assignment Sheets & i-STAT CLEW A20 Software/System Manual Update Compact Disc	<a href="#">MHRA</a>	2010/008/009/291/003	FSCA	Abbott Laboratories LTD.	2593 2211

2010/08/26	ThermoFisher PB0226A, Oxoid G.C. Selective Agar with Lysed Blood and LCAT, lot numbers 1140346, 1140347	<a href="#">MHRA</a>	2010/008/017/601/001	FSCA	N.A.	N.A.
2010/08/26	SonoSite NanoMaxx Ultrasound system	<a href="#">MHRA</a>	2010/008/020/601/005	FSCA	N.A.	N.A.
2010/08/26	BD BACTEC FX - Top Unit (Cat. No. 441385, All sequential serial numbers between and including FT001 to FT0906 and FT0922), BD BACTEC FX - Software (Cat. No. 441398, Serial No. V100E, V101F, V200B, V210A, V220B, V221A, V230B, V300A; Cat. No. 441750, Serial No. V100A)	BD	N.A.	Firm Initiated Field Action	BD	2575 8668
2010/08/27	Boston Scientific Wingspan Stent System 3.0x15mm (Cat. No. WE030015, Lot 13192372, 13215033)	Boston Scientific Hong Kong Ltd	N.A.	Firm Initiated Field Action	Boston Scientific Hong Kong Ltd	2960 7136
2010/08/27	AGFA 19" Barco MFCD 1219 (Touch Screen) + Low Profile Stand and Rack with LCD Arm Agfa's Computed Radiography Systems with NX2.X software (Lot: LU8QJ000)	<a href="#">FDA</a>	Z-2100-2010	Class II	AGFA Hong Kong Limited	2555 9421
2010/08/27	International Technidyne Corporation (ITC) RQCHRT HRT Control Level 1 & 2; Whole Blood controls for use with Hemochron Kaolin and Celite HRT Test Tubes. (Test kit lot numbers: H9KHR002, Exp 07/2010 and BOKHR001, Exp 1/2011; RAF 10-016)	<a href="#">FDA</a>	Z-2110-2010	Class II	Vastec Medical Ltd.	2897 1912
2010/08/27	Cardinal Health Temno Coaxial Chiba Fine Needle Aspiration; a coaxial introducer needle (20G x 15 cm) with a Chiba biopsy needle (22G x 20 cm) (REF CCH2220, Lot D09121745)	<a href="#">FDA</a>	Z-2111-2010	Class II	CareFusion Hong Kong Ltd.	2891 8730
2010/08/27	International Technidyne Corporation (ITC) directCheck Whole Blood Quality Controls Plasma, Coagulation Control. (Catalog number: DCJLR-N; Lot number: M9DNL055, exp. 9/2010)	<a href="#">FDA</a>	Z-2200-2010	Class II	Vastec Medical Ltd.	2897 1912
2010/08/27	Biomet Vanguard CR femoral 57.5 mm left interlok, Sterile, Knee prosthesis component. (REF 183022, Lot: M402080)	<a href="#">FDA</a>	Z-2204-2010	Class II	N.A.	N.A.
2010/08/27	CareFusion Pulmonetic Systems P/N 19189-001 Patient Circuit SPU W/O PEEP 15 FT 5/Pkg. (Units: Y09D1922 Y09H0564 Y09H0565 Y09K0491 Y09K0492 Y09S1283 Y09S1284 Y10A1230)	<a href="#">FDA</a>	Z-2205-2010	Class II	CareFusion Hong Kong Ltd.	2891 8730
2010/08/27	Zimmer Trabecular Metal acetabular revision system buttress augment (00-4898-001-54, 00-4898-001-58, 00-4894-300-00, 00-4894-400-00)	<a href="#">FDA</a>	Z-2214-2010 to Z-2217-2010	Class II	Zimmer PTE Ltd. (Hong Kong branch)	2992 0968
2010/08/27	Pride Electric rise and recline chair - models C1, C5, C6, C11, C15, LC101, D30, 560, 660, 670 & T3	<a href="#">MHRA</a>	2009/009/021/261/001	FSCA	N.A.	N.A.
2010/08/27	Seca 955 & 959	<a href="#">MHRA</a>	2009/009/014/401/010	FSCA	N.A.	N.A.
2010/08/30	Beckman COULTER® AC•T™ 5diff, COULTER® AC•T™ 5diff Cap Pierce, and COULTER® AC•T™ 5diff Autoloader Hematology Analyzers	<a href="#">MHRA</a>	2010/008/009/601/003	FSCA	N.A.	N.A.

2010/08/30	Beckman SYNCHRON® System(s) Modular Creatinine Reagent Kit (472525) Buffer lot M911427 and M911518	<a href="#">MHRA</a>	2010/008/009/601/004	FSCA	Beckman Coulter Hong Kong Ltd	2240 6150
2010/08/30	Aesculap Targon Tx Access Reamer, part no. KH451R	<a href="#">MHRA</a>	2010/008/016/081/015	FSCA	B. Braun Medical Hong Kong	2529 2009
2010/08/30	Schulke Thermosept Alka Clean Forte/Thermosept Nkz	<a href="#">MHRA</a>	2010/008/016/291/011	FSCA	N.A.	N.A.
2010/08/30	Hill-Rom TotalCare Duo2 Therapy System	<a href="#">MHRA</a>	2009/008/017/261/003	FSCA	Solar-Med Limited	2425 0926
2010/08/30	Joerns Oxford Hoist Weigh-scales OP97000 models	<a href="#">MHRA</a>	2010/007/009/401/005	FSCA	N.A.	N.A.

## Monthly Summary of Medical Device Safety Alerts -July 2010

\*Note: FDA = Food and Drug Administration, United States of America; MHRA = Medicines and Healthcare products Regulatory Agency, United Kingdom; Health Canada = Health Canada, Canada

Date of Issue (YYYY/MM/DD)	Description of Product	Source of Information*	Reference No. by Source	Alert Type by Source	Local Agent	Agent Contact Telephone No.
2010/07/02	Medtronic Orthopedic Dovetail Clamp, REF 9730289.	<a href="#">FDA</a>	Z-0923-2010	Class II	N.A.	N.A.
2010/07/02	Pointe Scientific Creatinine Reagent Set (Catalog # C7539-150, C7539-625, C7539-625-S, C7539-1250, HC939-756, HC939-1340, 12-C7539-98, 8-C7539-R1-120, 8-C7539-R1-500, 8-C7539-R1-1000, 7-C7539-R1-120, 7-C7539-R1-1000, and 7-C7539-R1-500), Creatinine Reagent R2 (Catalog # 3-C7539-L, 7-C7539-R2-30, 7-C7539-R2-125, 7-C7539-R2-250, 8-C7539-R2-30, 8-C7539-R2-125 and 8-7539-R2-250). All lots numbers containing the numbers 923202; exp. 2011-08.	<a href="#">FDA</a>	Z-1035-2010 to Z-1036-2010	Class II	N.A.	N.A.
2010/07/02	FHC Micro Targeting Guideline 4000 version 1.4 (GL4K) Software, Catalog # MT GL4K. Serial Numbers: 19454, 14423, 17349, 19215, 15573, 19424, 17583, 17589, 17588, and 17581.	<a href="#">FDA</a>	Z-1143-2010	Class II	N.A.	N.A.
2010/07/02	Lockheed-Martin Aculight Corporation Perseus Pulsed Fiber Laser, Model number: ML36L-1541. Additional Model numbers with non-defective type"A" fiber: M22L-1540, M27L-1541, M281-1540, M30PL-1541, & M33L-1541. Serial Numbers: 00001, 00002, and 00003	<a href="#">FDA</a>	Z-1170-2010	Class II	N.A.	N.A.
2010/07/02	ev3 Protg EverFlex Self-Expanding Biliary Stent System (REF: PRB35-06-150-080, REF PRB35-06-120-120 and PRB35-06-150-120, Lot Numbers: 7857377, 7856788 and 7858698)	<a href="#">FDA</a>	Z-1598-2010	Class II	Sinomed Company Ltd.	28877640
2010/07/02	Advanced Neuromodulation Systems (St. Jude Medical) Eon Mini Implantable Pulse Generator (IPG) (Code: 65-3788-01, Serial Numbers: 703271, 703287, 703050, 703051, 704169, 704476 and 704520)	<a href="#">FDA</a>	Z-1599-2010	Class II	N.A.	N.A.
2010/07/02	Cardinal Health Disposable Skin Stapler (catalog number FS-35W, Lot Numbers: 090203-SH and 091008-SH)	<a href="#">FDA</a>	Z-1610-2010	Class II	CareFusion Hong Kong Ltd.	2891 8730
2010/07/02	Orthofix 4.5MM, 5.5MM, 6.5MM, 7.5MM, 8.5MM Bone Tap, Modular (Part Number 52-1024, 52-1025, 52-1026, 52-1027, 52-1028)	<a href="#">FDA</a>	Z-1611-2010 to Z-1615-2010	Class II	N.A.	N.A.
2010/07/02	Wright Medical Technology Advance Duramer Tibial Insert (REF: Kimp-312L, Kimp-312R, Lot Number: 679391, 681644)	<a href="#">FDA</a>	Z-16356-2010 to Z-1637-2010	Class II	N.A.	N.A.
2010/07/02	Churchill Medical Systems Bag Access Device w/Smartsite Needleless Injection Site, Sterile, Non pyrogenic, Latex Free (Product Code: KSA-140. Lot Numbers: 903005, 904057, 904060, 904061, 904062, 904063, 905089, 905090, 905091, 906199, 907005, 907006, 907007, 909014, 909015, 909016, 909017, 909018, 909026, 909031, 909032, 909033, 909034, 909035, 909036 and 909037)	<a href="#">FDA</a>	Z-1639-2010	Class II	N.A.	N.A.
2010/07/02	Biomet Mallory Head Calcar Provisional replacement stem (REF 104773, 104986, 11-104902, 11-104904, 11-104905, 11-104939, 11-104947, 11-104953, 11-104954, 11-104971, 11-104972, CP154591, CP154593, CP154599, CP154604)	<a href="#">FDA</a>	Z-1665-2010 to Z-1679-2010	Class II	N.A.	N.A.
2010/07/02	Cepheid Xpert Flu A Panel (GXFLUPANEL-10, GXFLUPANEL-CE-10) (Lot Numbers: 00401, 00502, 00701, 00702, 00501)	<a href="#">FDA</a>	Z-1651-2010 to Z-1652-2010	Class III	N.A.	N.A.
2010/07/02	Churchill Medical Systems Vycon Nutrisafe 2 syringe 5 ml (Product Code: 1015.062M, Lot Numbers: 910118), 10 ml (Product Code: 1015.122M, Lot Numbers: 910107, 911165)	<a href="#">FDA</a>	Z-1203-2010 to Z-1204-2010	Class III	N.A.	N.A.

2010/07/02	Ferring Pharmaceuticals Euflexxa (1% sodium hyaluronate). Pre-filled syringe (Lot Numbers: RC0101A, RC0102A, RC0107A, RC0114A, RC0118A, RC0122A, RC0123A, RC0127A, and RC0131A)	<a href="#">FDA</a>	Z-1635-2010	Class III	N.A.	N.A.
2010/07/02	Stryker Orthopaedics Passport A.R. Knee Instrumentation Anterior Skim Guide (Scorpio Anterior Skim Cut Guide, product code 7650-5003; Distal Femoral Resection Guide Stand, product code 7650-5005; Punch Thru Tibial Baseplates, product codes 3750-0003, 3750-0004, 3750-0005, 3750-0006, 3750-0007, 3750-0009, 3750-0011 and 3750-0013)	<a href="#">MHRA</a>	2010/004/013/081/013	FSCA	Stryker China Ltd	2518 6915
2010/07/02	Nova Biomedical Ionized Calcium and Ionized Magnesium Sensors (27813, 37272, 42458) on Nova Stat Profile pHox, Stat Profile Critical Care Xpress, Nova 8 and BioProfile FLEX analyzers	<a href="#">MHRA</a>	2010/006/028/601/002	FSCA	N.A.	N.A.
2010/07/02	Beckman Coulter IOTest 3 CD5- FITC / CD-10 PE / CD-19 ECD (Part number: A07707, Lot number: 27)	<a href="#">MHRA</a>	2010/006/029/601/001	FSCA	Beckman Coulter Hong Kong Ltd.	2240 6150
2010/07/02	Gebrueder Martin Molina Pin Driver (Reference number: 51-600-85)	<a href="#">MHRA</a>	2010/006/028/081/014	FSCA	N.A.	N.A.
2010/07/02	Kapitex Trachidress (Model: Trachidress TR DRE 0001; Lot number: WO 25700 – WO 25702)	<a href="#">MHRA</a>	2010/002/010/401/021	FSCA	N.A.	N.A.
2010/07/02	BD Beaver Xstar Slit Blade 3.0mm Straight Blades (REF 375521, Lot 9138996)	BD	N.A.	Firm Initiated Field Action	BD	2575 8668
2010/07/02	BD Vacutainer ACD Solution A tube (Cat No. 364606, Lot 0077189)	BD	N.A.	Firm Initiated Field Action	BD	2575 8668
2010/07/03	Cepheid Xpert Flu A Panel (GXFLUPANEL-10, GXFLUPANEL-CE-10) (Lot Numbers: 00401, 00502, 00701, 00702, 00501)	<a href="#">FDA</a>	N.A.	Class I	N.A.	N.A.
2010/07/05	Elekta CMS Software XiO Patient Scan Position and Treatment Orientation Designation in XiO	<a href="#">MHRA</a>	2010/006/003/081/003	FSCA	Elekta Ltd.	2891 2208
2010/07/05	Karl Storz Cart Trolley (Model : 29003xxx)	<a href="#">MHRA</a>	2010/002/002/401/007	FSCA	KARL STORZ Endoscopy China Ltd.	2865 2411
2010/07/05	Volcano pcFM Software Kit (Model 6830 ComboMap System pcFM)	<a href="#">MHRA</a>	2010/006/025/081/001	FSCA	N.A.	N.A.
2010/07/05	Zimmer Trabecular Metal Acetabular Revision System Buttress Augments And Trabecular Metal	<a href="#">MHRA</a>	2010/004/009/081/007	FSCA	Zimmer PTE Ltd. (Hong Kong branch)	2992 0968
2010/07/05	Draeger Blood Pressure Monitors Cuff, Neonatal ; Sizes 1 to 5 (Model : MP00901, MP00902, MP00903, MP00904, MP00905)	<a href="#">MHRA</a>	2010/006/028/081/023	FSCA	Draeger Medical Hong Kong Ltd.	2877 3077
2010/07/06	GE A) Prospeed Scanner System, B) Sytec 6000 (Model : a)B7970YZ, b)P9183AH)	<a href="#">Health Canada</a>	47109	Type II	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/07/06	Technidata TD-Synergy Software (Model : TD-SYN-01)	<a href="#">Health Canada</a>	52751	Type III	N.A.	N.A.
2010/07/06	Biomet Sports Medicine Artificial Ligament Fixation Device (Model : 904755 )	<a href="#">Health Canada</a>	53910	Type II	Swedish Trading Co., Ltd	2953 5111
2010/07/06	Mizuho America Mizuha Doppler Probe (Model : 07-150-10)	<a href="#">Health Canada</a>	53996	Type III	Keymax Technology (HK) Ltd.	3150 8413
2010/07/06	Hill-Rom 100 Low Bed	<a href="#">Health Canada</a>	54548	Type II	N.A.	N.A.

2010/07/06	Hill-Rom A) Hill-Rom 1000 Beds, B) Care Assist P1170	<a href="#">Health Canada</a>	54567	Type II	N.A.	N.A.
2010/07/06	GE Medical Systems Innova 2000 Cardiovascular System	<a href="#">Health Canada</a>	54810	Type II	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/07/06	Ohmeda Giraffe In-Bed Scales	<a href="#">Health Canada</a>	55120	Type II	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/07/06	Stryker Instruments A) Commandf II Microelectric System, B) Core Drills	<a href="#">Health Canada</a>	55206	Type II	Stryker China Ltd	2518 6915
2010/07/06	Philips Medical Systems 1.5T Edge Eclipse system - Main Unit	<a href="#">Health Canada</a>	55221	Type II	Philips Electronic Hong Kong Ltd	2821 5480
2010/07/06	Bio-Rad Strep B Select (Model: 63750)	<a href="#">Health Canada</a>	55233	Type II	Bio-Rad Pacific Ltd.	N.A.
2010/07/06	Elekta Focal Software (Release 4.40.00 & Up)	<a href="#">Health Canada</a>	55234	Type II	Elekta Ltd.	2891 2208
2010/07/06	Haemonetics Plasma Bowl (Model : 0625B-00)	<a href="#">Health Canada</a>	55256	Type II	Haemonetics (Hong Kong) Limited	2116 3166
2010/07/06	Tyco Hydra Vision DR60/80 System, Generators	<a href="#">Health Canada</a>	55273	Type II	Tyco Healthcare (HKSAR) Ltd.	2574 3251
2010/07/06	Beckman Coulter A) P3, P4 Plates for the PK7200 Automated Microplate System-Microplate Reader B) P3, P4 Plates for the PK7200 Automated Microplate System-Analyzer Class 3 C) P3, P4 Plates for the PK7300 Automated Microplate System-Instrument Class 3	<a href="#">Health Canada</a>	55300	Type II	Beckman Coulter Hong Kong Ltd	2240 6150
2010/07/06	Smith & Nephew Gigli Saw Blade, 12 Inch (Model ; 210482)	<a href="#">Health Canada</a>	55302	Type II	Smith & Nephew LTD	
2010/07/06	Siemens Dimension Tacrolimus Flex Reagent Cartridge, DF107	<a href="#">Health Canada</a>	55304	Type III	Siemens Healthcare Diagnostic Limited	2870 7533
2010/07/06	International Technidyne Corporation (ITC) Hemochron Response Insrtument, IDMS	<a href="#">Health Canada</a>	55307	Type III	N.A.	N.A.
2010/07/06	Siemens Syngo Imaging PACS	<a href="#">MHRA</a>	2010/004/019/081/011	FSCA	Siemens Healthcare Diagnostic Limited	2870 7533
2010/07/07	Stryker Epic, Epic II, and Epic II+ Critical Care Bed Models 2030 and 2031 and Zoom II Critical Care Bed Model 2040	<a href="#">MHRA</a>	2010/006/007/081/016	FSCA	Stryker China Ltd	2518 6915
2010/07/07	Oxford Midi 150A Electrical Hoist	<a href="#">MHRA</a>	2010/001/013/401/006	FSCA	N.A.	N.A.
2010/07/08	DePuy (a JnJ company) P.F.C. Sigma Modular Tibial Tray SZ-4 N-8 (Model : 866024)	<a href="#">MHRA</a>	2010/006/022/291/008	FSCA	Johnson & Johnson Medical (HK)	2738 6027
2010/07/08	Bausch & Lomb Boston ES Rigid Gas Permeable Contact lens manufactured with Fluoro Silicone Acrylate Rigid Gas Permeable Contact Lens Material (Lot no. 156PTC05)	<a href="#">FDA</a>	Z-1705-2010	Class II	Bausch & Lomb (Hong Kong ) Ltd	2213 3371
2010/07/08	Ciba Vision AIR OPTIX (Iotrafilon B) for Astigmatism Soft Contact Lenses. (Lot Number: 8717082, Exp. 10/2013 and Lot Number: 8717066, Exp. 10/2013)	<a href="#">FDA</a>	Z-1706-2010	Class II	Ciba Vision (Hong Kong) Ltd.	3972 7300
2010/07/08	Angiodynamics PulseSpray Infusion System, 90 cm x 20 cm infusion length (Catalog No./Ref 12500402, Lot no. 991437)	<a href="#">FDA</a>	Z-1707-2010	Class II	N.A.	N.A.
2010/07/08	Siemens Axiom Artis systems with Motor Controller Unit (Model Numbers: 10094135, 10094137, 10094139, 10094141, 10094142, 10094143, 10280959, 7008605, 7412807, 7413078, 7555357, 7555365, 7555373, 7727717 and 7728392)	<a href="#">FDA</a>	Z-1732-2010	Class II	Siemens Healthcare Diagnostic Limited	2810 7533

2010/07/08	Angiodynamics BENEPHIT(TM) XT Infusion System, (Model/REF Number 70035, Batch Numbers: P909081, P909291, P910092, P910262, P911053, P911163, P911243, P912083, P912293 and P001203), ANGIODYNAMICS BENEPHIT(TM) CV Infusion System, 35 cm (Catalog/Model/REF Number 60035, Batch Number: P909231)	<a href="#">FDA</a>	Z-1733-2010 to Z-1734-2010	Class II	N.A.	N.A.
2010/07/08	Argon Medical Devices ARTERIAL LINE KIT (REF/REORDER NO. 194284, 496185, 496413Y, 498104, 498410B, 498411B, 498412B, 498439, 498447; Lot No. 99737820, 99738261, 99737884, 99737777, 99737665, 99736745, 99716572, 99734514, 99738189)	<a href="#">FDA</a>	Z-1737-2010 to Z-1745-2010	Class II	N.A.	N.A.
2010/07/08	Medtronic Hospital Grade Power Cord, UL, Part # 66319, 055476, manufactured by Electri-Cord Manufacturing Co. beginning in February 2003. (The cords are a detachable unit, supplied with the instruments listed below: Medtronic Bio-Console 550 centrifugal pump console, Model #95180, Catalogue # 95180, E95180, R95180. Medtronic Bio-Console 560 centrifugal pump consoles Model # 560BC, Catalogue # 560BC, 560BCS, 560BCS1. Medtronic autoLog, Model # ATLG110, Catalogue # ATLG110, ATLG110E ATLG110R. Medtronic Sequestra 1000, Model #SEQ1000, Catalogue # SEQ1000, SEQ1000E, SEQ1000R.)	<a href="#">FDA</a>	Z-1939-2010	Class II	Medtronic International Ltd.	2919 1300
2010/07/08	STERIS 4085, 5085 & 5085SRT Surgical Tables (Model #: 4085, 5085 & 5085SRT).	<a href="#">FDA</a>	Z-1941-2010	Class II	Swedish Trading Co. Ltd.	6199 0634
2010/07/08	Inova Diagnostics BINDAZYME Human C1q binding Circulating Immune Complex EIA Kit, Part#: MK021.	<a href="#">FDA</a>	Z-1942-2010	Class III	N.A.	N.A.
2010/07/08	Biomet Microfixation "1.5MM" System High Torque (HT), SD, X-DR, Screw 1.5MM X 3.5MM (WXL) Titanium, Non Sterile Product. (Ref: 91-6103, Lot no. 829760)	<a href="#">FDA</a>	Z-1943-2010	Class III	Swedish Trading Co., Ltd	2953 5111
2010/07/09	Merit Medical Systems Laureate Hydrophilic Guide Wire - LWSTDA35180, LWSTFA35180, LWSTFS35180, LWSTDA35260EX, LWSTFA35260EX, LWSTFS35260EX	<a href="#">MHRA</a>	2010/007/005/291/021	FSCA	King Health Limited	2481 3787
2010/07/09	BrainLAB Digital Lightbox	<a href="#">MHRA</a>	2010/006/030/081/022	FSCA	BrainLAB Ltd	2417 1881
2010/07/12	Accuray CyberKnife System (securing the LINAC Cover)	Accuray Asia Ltd.	N.A.	Firm Initiated Field Action	Accuray Asia Ltd	2247 8628
2010/07/12	Various FDA Safety Notification: Risk of Air or Gas Embolism When Using Air- or Gas- Pressurized Spray Devices	<a href="#">FDA</a>	N.A.	News Release	N.A.	N.A.
2010/07/13	Siemens Immunitite 2000/2500 Chemiluminiscent Substract (Lots No. lots L2SUBX 253, 254, 255, 256A, 257A, 258, 259S)	<a href="#">MHRA</a>	2010/005/027/081/013	FSCA	Siemens Healthcare Diagnostic Limited	2870 7827
2010/07/13	Boots All In One Contact Lens Solution	<a href="#">MHRA</a>	2010/007/006/291/001	FSCA	N.A.	N.A.
2010/07/13	HAAG-STREIT Tonometer Measuring Prism	<a href="#">HAAG-STREIT</a>	Field Safety Notice No. 2010-01/01	FSCA	The Vita Company Ltd.	2548 7483
2010/07/14	Integra Lifesciences Integra Neuroballoon Catheters (Model:7CBD10)	<a href="#">MHRA</a>	2010/007/006/291/021	FSCA	N.A.	N.A.
2010/07/14	Terumo Destination Carotid Guiding Sheath	<a href="#">MHRA</a>	2010/007/006/291/006	FSCA	TERUMO CHINA (H.K.) LTD.	2866 0811



2010/07/14	ArjoHuntleigh Atlas Skull Traction Unit (Model : SA9085)	<a href="#">MHRA</a>	2010/003/030/601/001	FSCA	Arjo Huntleigh (Hong Kong) Ltd.	2508 1416
2010/07/14	Roma Medical Aids All models of mobility scooter and powered wheelchair	<a href="#">MHRA</a>	2009/011/004/301/001	FSCA	N.A.	N.A.
2010/07/14	Spectranetics QuickCat Extraction Catheter (Model : 60090-01)	<a href="#">MHRA</a>	2010/006/017/401/013	FSCA	N.A.	N.A.
2010/07/14	Single Use Surgical (SUS) Vein Hook/Phlebectomy Hook Codes - S090, S106, S134, and S135 Sterile -Single Use Devices	<a href="#">MHRA</a>	2010/006/030/601/003	FSCA	N.A.	N.A.
2010/07/15	Merivaara Promerix Operating Table (product code 100060000)	<a href="#">MHRA</a>	2010/007/008/291/002	FSCA	N.A.	N.A.
2010/07/15	Cardiac Science Powerheart 9390A automated external defibrillator	<a href="#">FDA</a>	Z-1810-2010	Class II	Pacific Medical Systems Limited	2108 4005
2010/07/15	Cardiac Science Treadmill models TM55, TM65, and CR60 (brand names include Quinton, Burdick, and Cardiac Science).	<a href="#">FDA</a>	Z-0985-2005 & Z-1757-2010	Class II	Shun On Healthcare Limited	N.A.
2010/07/15	Romedic EVA 450 Patient Lift Battery Charger. (Serial numbers: 373317696102209, 373317696102210, 373317696102224, 373317696102227, 373317696102228, 373317696102232, 373317696102235, 373317696102242, and 373317696102244)	<a href="#">FDA</a>	Z-1736-2010	Class II	N.A.	N.A.
2010/07/15	DiaDexus PLAC Test Reagent Kit, immuno-turbidimetric method (part no. 90107, 90110, 90112, 90115, 90116, 10-112, 10-0113, 10-115)	<a href="#">FDA</a>	Z-1748-2010 to Z-1753-2010	Class II	N.A.	N.A.
2010/07/15	International Technidyne Corporation (ITC) directCHECK Whole Blood Control for Hemochron J. Microcoagulation Systems (Catalog number: DCJPT-A, Lot no. G9DPA005).	<a href="#">FDA</a>	Z-1786-2010	Class II	N.A.	N.A.
2010/07/15	Inviro Medical Devices InviroSnap Retractable Safety Syringes, Single use, Sterile. (Catalog number: 100002, 100017, 100018, 100019, 100032, 100034, 100019, 100032, 100038, 100047, 100055).	<a href="#">FDA</a>	Z-1800-2010	Class II	N.A.	N.A.
2010/07/15	Maquet (Datascope) CS100 Intra-Aortic Balloon Pump (Product number 0998-00-3023-XX), CS300 Intra-Aortic Balloon Pump (Product number 0998-00-3013-XX), System 98XT/98 Intra-Aortic Balloon Pump (Product number 0998-00-0446-XX and 0998-00-0479-XX).	<a href="#">FDA</a>	Z-1811-2010 to Z-1813-2010	Class II	N.A.	N.A.
2010/07/15	Biomet 3i GS300 Gold Slotted Screw-3mm (Lot no. 868517, 865348, 868515)	<a href="#">FDA</a>	Z-1956-2010	Class II	Ositek (HK), Inc. Ltd	3157 1757
2010/07/15	Biokit biokit HSV-2 Rapid test (Catalogue Number: 3000-28001), Sure-Vue HSV-2 Rapid Test (Catalogue No: 23-046395) In Vitro Diagnostic test for Herpes Simplex Virus 2.	<a href="#">FDA</a>	Z-1970-2010 to Z-1971-2010	Class II	N.A.	N.A.
2010/07/16	Stryker Model 6200 M1 Ambulance Cot (Model : 6100-xxx-xxx)	<a href="#">MHRA</a>	2010/006/029/081/009	FSCA	Stryker China Ltd	2518 6915
2010/07/16	SMS O2 Hose Assembly BS5682/NIST 3m Part No SMS0062386, Air-4 Hose Assembly BS5682/NIST 3m Part No SMS0062387 and O2 Hose Assembly BS5682/NIST 30" Part No SMS0062388	<a href="#">MHRA</a>	2010/007/008/081/007	FSCA	N.A.	N.A.
2010/07/16	Philips Respironics V60 Ventilator	<a href="#">MHRA</a>	2010/007/008/291/009	FSCA	Philips Electronic Hong Kong Ltd	2821 5480
2010/07/16	Volcano s5 Family Software Version 3.2 Intravascular Ultrasound Scanner	<a href="#">MHRA</a>	2010/007/008/291/008	FSCA	N.A.	N.A.

2010/07/16	Osypka Pace 203H/300 Model 3085 in the range from S/N 0706101 to S/N 1001210 Pace 203H/300 Model 3085 in the range from S/N 0706101 to S/N 1001210	<a href="#">MHRA</a>	2010/006/029/081/001	FSCA	N.A.	N.A.
2010/07/19	Beckman Coulter SYNCHRON Immunoglobulin A (Ig-A) Reagent	<a href="#">MHRA</a>	2010/007/002/601/003	FSCA	Beckman Coulter Hong Kong Ltd	2240 6150
2010/07/19	Drive Medical Mercury M36 Powered Scooter (Batch : WU-4726)	<a href="#">MHRA</a>	2009/006/008/261/001	FSCA	N.A.	N.A.
2010/07/19	Siemens E-CAM Patient Handling System	<a href="#">MHRA</a>	2010/007/007/291/008	FSCA	Siemens Healthcare Diagnostic Limited	2870 7533
2010/07/19	Boston Scientific Ultraflex Esophageal Stent System, Ultraflex Tracheobronchial Stent System and Ultraflex Precision Colonic Stent System	Boston Scientific Hong Kong Ltd	NA	Firm Initiated Field Action	Boston Scientific Hong Kong Ltd	2960 7136
		<a href="#">MHRA</a>	2010/007/021/081/011			
2010/07/19	Philips IntelliVue Patient Monitors MP60 (M8005A) (Serial no. DE22701289 – DE84316576), MP70 (M8007A) (Serial No. DE22702728 – DE84399581)	Philips Electronic Hong Kong Ltd	FSN86201147 (FSN dated 24 Jun 2010)	Firm Initiated Field Action	Philips Electronic Hong Kong Ltd	2821 5364
2010/07/21	Cory Bros Purple Surgical Ultimate Endo Retrieval Pouch	<a href="#">MHRA</a>	2010/006/014/401/012	FSCA	N.A.	N.A.
2010/07/21	CIBA VISION Softperm (synergicon A) contact lenses	<a href="#">MHRA</a>	2010/006/008/081/004	FSCA	Ciba Vision (Hong Kong) Ltd.	3972 7300
2010/07/21	Siemens Healthcare Diagnostics ADVIA Centaur Hepatitis B core Total (HBcT) Assay (Cat. No. 07566733, Lot No. 49471033, 50694033, 51071033, 51628033, 52260033, 52809033, 53674033)	<a href="#">MHRA</a>	2010/007/009/081/008	FSCA	Siemens Healthcare Diagnostic Limited	2810 7533
2010/07/21	Ethicon Endo-Surgery (EES) (a J & J Company) PROXIMATE® PPH Procedure for Prolapse and Hemorrhoids Set (product code PPH03, lot number F4N12N)	<a href="#">MHRA</a>	2010/007/007/291/006	FSCA	Johnson & Johnson Medical (HK)	2738 6027
2010/07/21	BD BBL Staphyloslide Latex Test Kit (Cat no. 240952, 240953)	BD	N.A.	Firm Initiated Field Action	BD	2575 8668
2010/07/21	Liko Viking M Patient Lift	<a href="#">Health Canada</a>	54859	Type II	N.A.	N.A.
2010/07/21	GE Centricity Ultra Laboratory Information System	<a href="#">Health Canada</a>	55072	Type II	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/07/21	Roche MagNa Pure Compact Instrument	<a href="#">Health Canada</a>	55083	Type III	Roche Diagnostics (Hong Kong) Ltd	2485 7510
2010/07/21	Brentwood IQManager Diagnostic Workstation	<a href="#">Health Canada</a>	55107	Type III	N.A.	N.A.
2010/07/21	Medtronic Carelink - Monitor	<a href="#">Health Canada</a>	55207	Type II	Medtronic International, Ltd.	2919 1300
2010/07/21	Hill-Rom A) Hill-Rom 1000 Beds, B) Careassist Hospital Bed	<a href="#">Health Canada</a>	55218	Type II	Solar-Med Limited	2425 0926
2010/07/21	Boston Scientific A) Synchro 2 Soft Guidewire, B) Synchro 2 Standard Guidewire, C) Synchro PVS 1300 Neuro Guidewire	<a href="#">Health Canada</a>	55223	Type II	Boston Scientific Hong Kong Ltd	2960 7136
2010/07/21	Remel TB Potassium Permanganate Counterstain	<a href="#">Health Canada</a>	55303	Type II	Hong Kong South East Chemicals & Instruments Ltd	2802 6333
2010/07/21	Smiths Medical A) Medfusion Syringe Infusion Pump, 3010, B) Medfusion Syringe Infusion Pump, 3010A	<a href="#">Health Canada</a>	55335	Type II	Goodman Medical Supplies Ltd	2332 4455

2010/07/21	Immucor Anti-FY Blood Grouping Reagent	<a href="#">Health Canada</a>	55381	Type III	Uninet Technology LTD	2838 8423
2010/07/21	Tomotherapy HI-ART System	<a href="#">Health Canada</a>	55439	Type II	Transmedic Pte Ltd	(608) 824 2867
2010/07/21	Toshiba Kalare	<a href="#">Health Canada</a>	55449	Type II	Sanko Medical Systems (HK) LTD	23840688
2010/07/21	Medtronic Sofamor Danek Nim-Eclipse System - Module, Surface Preamp	<a href="#">Health Canada</a>	55529	Type II	Medtronic International, Ltd.	2919 1300
2010/07/21	Beckman Coulter Access Thyroglobulin Antibody II Reagent	<a href="#">Health Canada</a>	55500	Type II	Beckman Coulter Hong Kong Ltd	2240 6150
2010/07/22	DiaSorin Liaison VZV (Varicella Zoster Virus) IgG; Liaison VZV IgM	<a href="#">MHRA</a>	2010/007/014/081/002	FSCA	N.A.	N.A.
2010/07/22	Invitrogen 7500Fast Dx Real-Time PCR Instrument With Sds V1.4 Software	<a href="#">MHRA</a>	2010/007/013/081/001	FSCA	Invitrogen Hong Kong Limited	N.A.
2010/07/22	Boston Scientific CONTAK RENEWAL 3 / 3 RF / 4 / 4 RF and VITALITY HE implantable defibrillators manufactured between Jan 2006 and Nov 2007	Boston Scientific Hong Kong Ltd	N.A.	Firm Initiated Field Action	Boston Scientific Hong Kong Ltd	2960 7136
		<a href="#">MHRA</a>	2010/007/022/081/006			
2010/07/22	Varian Clinac 2100 (All C series Clinacs Equipped for Rapid Arc Treatment delivery)	Varian Medical Systems Pacific Inc.	CP-02334	Firm Initiated Field Action	Varian Medical Systems Pacific Inc.	2724 2836
2010/07/22	Biosite Triage Total Controls 5, Level 1 (Model 88753), Level 2 (Model 88754), Triage Total Controls Calibration Verification 5 (Model 88755)	<a href="#">FDA</a>	Z-1788-2010 to Z-1790-2010	Class II	N.A.	N.A.
2010/07/22	Medtrol CaviBleach Wipes (Reorder No. 10-1155, Lot number: F29, Exp June 2010)	<a href="#">FDA</a>	Z-1815-2010	Class II	N.A.	N.A.
2010/07/22	Respironics Trilogy 100 Ventilator, Model/Catalog Number 1054260	<a href="#">FDA</a>	Z-1896-2010	Class II	Celki Medical Company	2332 3366
2010/07/22	Haag-Streit Lenstar LS 900, Biomicroscope, Slit-Lamp, AC-powered.	<a href="#">FDA</a>	Z-1897-2010	Class II	The Vita Company Ltd.	N.A.
2010/07/22	Smith & Nephew Genesis II Tibial Drill Guide, REF 71440238	<a href="#">FDA</a>	Z-1900-2010	Class II	Smith & Nephew LTD	N.A.
2010/07/22	Bio-Rad VARIANT II Hemoglobin Testing System with CDM 3.5 Software Version 3.5 (Model Number: 270-2000), VARIANT II TURBO Hemoglobin Testing System with CDM 3.6T Software Version 3.5 (Model Number: 270-2600)	<a href="#">FDA</a>	Z-1901-2010 to Z-1902-2010	Class II	Bio-Rad Pacific Ltd.	N.A.
2010/07/22	Sedecal Hydradjust IV DR Urological Table Sedecal Generator ( a) p/n 750732 - 64W generator & b) p/n 750733 80W generator).	<a href="#">FDA</a>	Z-1904-2010	Class II	N.A.	N.A.
2010/07/22	DiaSorin GammaCoat Plasma Renin Activity 125 I RIA Kit, REF: CA-1533 (100 test kit), CA-1553 (500 test kit).	<a href="#">FDA</a>	Z-1914-2010	Class II	N.A.	N.A.
2010/07/22	Philips HeartStart FRx AED (Model number 861304), HeartStart HS1 OnSite* (Model number M5066A), HeartStart HS1 Home (Model Number M5068A)	<a href="#">FDA</a>	Z-1915-2010 to Z-1917-2010	Class II	Philips Electronic Hong Kong Ltd	2821 5364
2010/07/22	MIRA CR4050 12mm Finger Probe, CR4055 25mm Finger Probe, CR4060 68 mm Finger Probe	<a href="#">FDA</a>	Z-1918-2010 to Z-1920-2010	Class II	N.A.	N.A.

2010/07/22	SpineMatrix Lumbar Matrix Scan, Diagnostic Electromyography System consisting of the CERSR Electromyography System and Electrode Array	<a href="#">FDA</a>	Z-1935-2010	Class II	N.A.	N.A.
2010/07/22	Centurion Medical Products Dialysis On/Off Kit (DT11300), C.A.P.D. Tubing Exchange Tray (HT80), Dialysis Tray (SP560)	<a href="#">FDA</a>	Z-1936-2010 to Z-1938-2010	Class II	N.A.	N.A.
2010/07/22	Stanley Security Solutions Tabs Professional Monitor (Model 25022, 25023, 25223)	<a href="#">FDA</a>	Z-1944-2010 to Z-1947-2010	Class II	N.A.	N.A.
2010/07/22	Bio-Rad Monolisa (TM) Anti-HBs EIA test kit, Labeled as, "MONOLISA TM Anti-HBs EIA 25220; MONOLISA TM Anti-HBs Calibrator Kit 25219.	<a href="#">FDA</a>	Z-1620-2010	Class III	Bio-Rad Pacific Ltd.	N.A.
2010/07/22	Wilden Excyte Slider Barcode Tube Adapter used with Excyte Vacuum or Non-Vacuum ESR (erythrocyte sedimentation rate) Tubes. (Product Number: EX-I0552).	<a href="#">FDA</a>	Z-1816-2010	Class III	N.A.	N.A.
2010/07/23	Siemens ACUSON and SONOLINE Antares™ Ultrasound Systems versions 4.0, 5.0 and Acuson S2000	<a href="#">MHRA</a>	2010/007/012/081/003	FSCA	Siemens Healthcare Diagnostic Limited	2810 7533
2010/07/23	Fresenius 5008/5008S Bloodlines, 4008 E-Beam Bloodlines, 4008 ETO Bloodlines, Genius Bloodlines and MultiFiltrate Bloodlines	<a href="#">MHRA</a>	2010/007/020/081/015	FSCA	Fresenius Medical Care Hong Kong Limited	2583 0813
2010/07/23	Heraeus PALAMIX uno 1x80 Vacuum mixing system (Ref. no. 66036743; lot no. 200177, 200178, 200179, 200180, 200181, 200182, 200183, 200184, 200185); PALAMIX duo 2x80 (Ref. no. 66036746; lot no. 500040); PALAMIX Hip Set (Ref. no. 66044411; lot no. 800011, 800012)	<a href="#">MHRA</a>	2010/007/021/291/019	FSCA	N.A.	N.A.
2010/07/26	Zimmer Trabecular Metal Femoral Cone Augment, Left & Right	<a href="#">MHRA</a>	2010/007/012/081/006	FSCA	Zimmer PTE Ltd. (Hong Kong branch)	2992 0968
2010/07/26	Synovis PSD Gel with Peri-Strips Dry Staple Line Reinforcement with Apex Processing & Peri-Strips Dry with Veritas Collagen Matrix Staple line Reinforcement Replacement Fel 3-packs	<a href="#">MHRA</a>	2010/007/020/081/007	FSCA	N.A.	N.A.
2010/07/26	Scan Mobility ScanBeta Cot Velcro	<a href="#">MHRA</a>	2010/002/012/401/001	FSCA	N.A.	N.A.
2010/07/27	Beckman Coulter UniCel Dxl 600 and 800 Systems Running System Software Version 4.3	<a href="#">MHRA</a>	2010/007/016/601/006	FSCA	Beckman Coulter Hong Kong Ltd	2240 6150
2010/07/27	Beckman Coulter Active® I-PTH ELISA, DSL-10-8000 & Active® Intact PTH DSL-8000	<a href="#">MHRA</a>	2010/007/009/601/003	FSCA	Beckman Coulter Hong Kong Ltd	2240 6150
2010/07/27	LeMaitre Vascular The Unballoon Non-Occlusive Modeling Catheter	<a href="#">MHRA</a>	2010/007/020/081/017	FSCA	N.A.	N.A.
2010/07/28	Permobil Instructions for use for all Permobil wheelchairs	<a href="#">MHRA</a>	2010/003/002/401/015	FSCA	N.A.	N.A.
2010/07/28	Siemens VARTA Microbattery rechargeable battery type p312 and charger, used in hearing aid applications with the family name Siemens Pure and its derivatives	<a href="#">MHRA</a>	2010/005/006/081/020	FSCA	Siemens Healthcare Diagnostic Limited	2810 7533
2010/07/28	B.R.A.H.M.S. fBhCG KRYPTOR lot 09045 (reagent unit) in combination with calibrator B.R.A.H.M.S. fBhCG KRYPTOR CAL lot 09033	<a href="#">MHRA</a>	2010/007/021/291/018	FSCA	N.A.	N.A.
2010/07/28	Abbott Medical Optics (AMO) AMO WaveScan WaveFront Systems and Offline Programming Module (OPM), software versions 3.67 and 3.671	AMO Asia Limited	N.A.	Firm Initiated Field Action	AMO Asia Limited	2401 5711
2010/07/29	CU Medical Paramedic CU-ER1, CU-ER2, CU-ER3, CU-ER5 Non-implantable Defibrillator	<a href="#">MHRA</a>	2010/007/022/081/004	FSCA	N.A.	N.A.



## Monthly Summary of Medical Device Safety Alerts - June 2010

\*Note: FDA = Food and Drug Administration, United States of America; MHRA = Medicines and Healthcare products Regulatory Agency, United Kingdom; Health Canada = Health Canada, Canada

Date of Issue (YYYY/MM/DD)	Description of Product	Source of Information*	Reference No. by Source	Alert Type by Source	Local Agent	Agent Contact Telephone No.
2010/06/01	Vital Images Vitrea 5.1, Vitrea fX 3.0, Vitrea Enterprise Suite 1.2 with the licensing of CT lung or CT Colon	<a href="#">FDA</a>	Z-1600-2010	Class II	N.A.	N.A.
2010/06/01	Endotec Prosthesis Knee, Prosthesis Shoulder, Prosthesis Hip, Prosthesis Ankle, TMJ Components	<a href="#">FDA</a>	Z-1621-2010 to Z-1627-2010	Class II	N.A.	N.A.
2010/06/01	Philips HeartStart FR2+ Automated External Defibrillator	<a href="#">Philips Electronic Hong Kong Ltd</a>	N.A.	Firm Initiated Field Action	Philips Electronic Hong Kong Ltd	2821 5480
2010/06/02	Centurion Medical Products Basic Core Pack # OR1805, Sterile (Lots: 2009100590, 2009110990, 2009121490, 2010011190 and 2010031590)	<a href="#">FDA</a>	Z-1595-2010	Class II	N.A.	N.A.
2010/06/02	Stryker Accolade Distal Centralizers 14 mm Large (Catalog No.: 1059-6714) & 13 mm Medium (Catalog No.: 1059-4513) (Lot no. WDYMLE & WDXMLE)	<a href="#">FDA</a>	Z-1593-2010 to Z-1594-2010	Class II	Stryker China Ltd	2518 6915
2010/06/02	Animas (JNJ) One Touch Ping Insulin Pump using ezManager Max diabetes management software.	<a href="#">FDA</a>	Z-1560-2010	Class III	Johnson & Johnson Medical (HK)	2738 6027
2010/06/03	Cutera Titan XL handpieces (Serial no. TX2183)	<a href="#">MHRA</a>	2010/005/011/081/003	FSCA	N.A.	N.A.
2010/06/03	Beckman Coulter IMAGE Systems Buffer 1 (BUF 1) (REF: 447650, Lot: T908069, T908104, T909110, T001036)	<a href="#">MHRA</a>	2010/005/024/061/002	FSCA	Beckman Coulter Hong Kong Ltd	2240 6150
2010/06/04	DJO Surgical (Encore Medical) MIKA (Minimally Invasive Knee Arthroplasty) Instrumentation System - MIKA Speedblocks Size 8-12 (Cat no. 8000-01-368, 800-01-369-, 800-01-370, 800-02-343, 800-02-344, 800-02-345)	<a href="#">MHRA</a>	2010/005/017/291/025	FSCA	N.A.	N.A.
2010/06/04	Sanofi-Aventis Sculptra Apyrogenic Suspension (Poly-L-lactic Acid) - batch number 1A9032	<a href="#">MHRA</a>	2010/005/026/081/017	FSCA	Sanofi-Aventis HK	2506 8333
2010/06/04	Hospira Receptal PVC Liner (List no. OL2129701, OL21297W1, OF8079701, OG6619701, OG9159701, OE0989701, OF8069701)	<a href="#">MHRA</a>	2010/005/028/081/037	FSCA	Hospira Limited	2898 2886
2010/06/04	Elekta Linear Accelerator Software - XVI R4.5	<a href="#">MHRA</a>	2010/005/027/081/004	FSCA	Elekta Ltd.	2891 2208
2010/06/04	Elekta XiO Release 4.50.00 and higher	<a href="#">MHRA</a>	2010/005/027/601/001	FSCA	Elekta Ltd.	2891 2208
2010/06/05	NERL Diagnostics Lifesign Staph Latex Kits / Wampole Staph Latex Test	<a href="#">FDA</a>	Z-1111-2010	Class II	N.A.	N.A.
2010/06/05	Galt Medical Micro Introducer Kit 5F, Model number: KIT-014-29	<a href="#">FDA</a>	Z-1592-2010	Class II	N.A.	N.A.
2010/06/05	Stryker Distal Centralizer, Exeter II Hip System. Catalog number - 0920-2-920	<a href="#">FDA</a>	Z-1601-2010	Class II	Stryker China Ltd	2518 6915
2010/06/05	Hitachi AIRIS, AIRIS II, AIRIS Elite MRI Scanner Compensation Coil. Part numbers: MR-FC-2EO, MR-FC-3EO	<a href="#">FDA</a>	Z-1616-2010	Class II	N.A.	N.A.

2010/06/05	Stryker VISUM LED Surgical Lights (Ceiling Mounted Surgical Light); 2) Stryker Equipment Delivery System (EDS), Ceiling Mounted Equipment Booms, the booms are ceiling mounted devices; 3) Stryker VISUM Halogen Surgical Lights (Ceiling Mounted Surgical Lights); 4) SwitchPoint Element (SPE) Control System. Control System for audio/video, surgical, and room equipment; 5) SwitchPoint Infinity (SPI) Control System; 6) Ceiling Suspensions (Surgical Light and Flat Panel Suspensions);	<a href="#">FDA</a>	Z-1640-2010	Class II	Stryker China Ltd	2518 6915
2010/06/05	Blackstone Medical Orthofix Spinal Implants, Hallmark Anterior Cervical Plate System; Plate Bender Part number 62-0070. Non Sterile. Part number 62-0070	<a href="#">FDA</a>	Z-1653-2010	Class II	N.A.	N.A.
2010/06/05	GE Innova 4100 IQ: 4100 / 4100 IQ, Innova 3100 IQ: Innova 3100 / 3100 IQ, Innova 2100IQ	<a href="#">FDA</a>	Z-1659-2010 to Z-1661-2010	Class II	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/06/05	InSound Medical Lyric in-canal hearing aid	<a href="#">FDA</a>	Z-1681-2010	Class II	N.A.	N.A.
2010/06/05	Circaid Juxta-Lite compression wrap (various sizes)	<a href="#">FDA</a>	Z-1684-2010 to Z-1702-2010	Class II	N.A.	N.A.
2010/06/05	3m Imtec Sendax MDI Mini Dental Implant O-Ball Prosthetic Head	<a href="#">FDA</a>	Z-1703-2010	Class II		
2010/06/05	Imaxeon Avidia Angiograph Contrast Injector	<a href="#">MHRA</a>	2010/005/028/081/031	FSCA	N.A.	N.A.
2010/06/05	DeRoyal Custom Procedure Trays (CPT) Angio Pack (Code: 55-012953, Lot no. 195336, 191453, 191454, 191455, 195335)	<a href="#">MHRA</a>	2010/005/028/081/032	FSCA	N.A.	N.A.
2010/06/07	Draeger Delta and Gamma XXL	Draeger Medical Hong Kong Ltd.	N.A.	Firm Initiated Field Action	Draeger Medical Hong Kong Ltd.	2877 3077
2010/06/07	Siemens 550 TXT Table (Model: 07346534, Lot: 1108, 1109, 1110, 1121, 1122, 1123, 1216, 1345, 1354, 1421, 1481)	<a href="#">Health Canada</a>	54154	Type III	Siemens Healthcare Diagnostic Limited	2810 7533
2010/06/07	Stryker A) Autoclavable Camera Tray (0233-410-000), B) 45cm Laparoscopic Tray (0250-015-704), C) 23 Instrument Tray (0242-000-024), D) Dilator Tray (0234-020-124), E) Bio-Absorbable Tray (0234-020-123)	<a href="#">Health Canada</a>	54622	Type II	Stryker China Ltd	2518 6915
2010/06/07	Oridion Medical A) Capnostream 20 (US) N with Printer (CS08657, CS08659), B) Capnostream 20 (US) N (CS08651), C) Capnostream 20 (US) M (CS08653)	<a href="#">Health Canada</a>	54790	Type II	N.A.	N.A.
2010/06/07	Coopersurgical INCA Infant Nasal Cannulae Assembly for CPAP (continuous positive airway pressure) 9F, 10.5F, 12F, 15F and 7.5F (Model: AL-44-2709, AL-44-2710, AL-44-2712, AL-44-2715, AL-44-2707)	<a href="#">Health Canada</a>	54701	Type II	N.A.	N.A.
2010/06/07	Stryker Small Joint Handpiece (275-601-500) and Hand Control Shaver	<a href="#">Health Canada</a>	54355	Type II	Stryker China Ltd	2518 6915
2010/06/07	Stryker Switchpoint Infinity 2 Standard With DVI With PIP Control System (0678-000-537), Stryker Switchpoint Infinity 2 Standard With Hi-Res With DVI (0678-000-536)	<a href="#">Health Canada</a>	54569	Type II	Stryker China Ltd	2518 6915
2010/06/07	Hospira Symbiq One Channel Infuser (16026), Symbiq Two Channel Infuser (16027)	<a href="#">Health Canada</a>	54403	Type II	Hospira Limited	2898 2886
2010/06/07	Baxter 1550 Hemodialysis Instruments (Model: 5M5538, 6001238147, 6001238148, 6001238149, 6001238218)	<a href="#">Health Canada</a>	54625	Type III	Baxter Healthcare Ltd	2807 8555
2010/06/07	Bioplate Bioplate Titanium Fixation System, Sterile Kits	<a href="#">Health Canada</a>	54690	Type II	N.A.	N.A.

2010/06/07	Teleflex Medical Blade Electrode (Model: 809315)	<a href="#">Health Canada</a>	53866	Type II	N.A.	N.A.
2010/06/07	Siemens Healthcare Diagnostics Dimension Vista System-1500 Analyzer (Model: 1000035896)	<a href="#">Health Canada</a>	54568	Type III	Siemens Healthcare Diagnostic Limited	2810 7533
2010/06/07	Roche Diagnostics Elecsys-Antibodies to Thyroid Peroxidas (Model: 11820818191)	<a href="#">Health Canada</a>	54002	Type III	Roche Diagnostics (Hong Kong) Ltd	2485 7510
2010/06/07	Rochester Medical Femsoft Insert (Model: 71201, 71202, 71203, 72201, 72202, 72203)	<a href="#">Health Canada</a>	54707	Type II	N.A.	N.A.
2010/06/07	Restorative Therapies FES Leg / Arm Cycle Ergometer, RT300 (Model: FA100052, FA102011, FA104581)	<a href="#">Health Canada</a>	54668	Type II	N.A.	N.A.
2010/06/07	Thermo Anatomical Pathology Microm HM355S Microtome (Model: 36 101 6409)	<a href="#">Health Canada</a>	54338	Type II	N.A.	N.A.
2010/06/07	Abbott IMX Sirolimus Reagent (List No. 5C91-21)	<a href="#">Health Canada</a>	54481	Type III	Abbott Laboratories LTD.	2593 2211
2010/06/07	Stryker Infravision Esophageal Kit (Model: 0220-180-548)	<a href="#">Health Canada</a>	54720	Type II	Stryker China Ltd	2518 6915
2010/06/07	Integra Lifesciences Mayfield Infinity XR2 radiolucent Base Unit (Model: A2079)	<a href="#">Health Canada</a>	54531	Type III	N.A.	N.A.
2010/06/07	Micro Typing Systems Ortho Provue (Model: MTS213784)	<a href="#">Health Canada</a>	36665	Type III	N.A.	N.A.
2010/06/07	Roche Diagnostics PSM Software Version 2.01.05b and above (Model: 04944607001)	<a href="#">Health Canada</a>	54207	Type II	Roche Diagnostics (Hong Kong) Ltd	2485 7510
2010/06/07	Philips QCPR - CPR Meter Upgrade Kit (Model: 861444)	<a href="#">Health Canada</a>	54745	Type II	Philips Electronic Hong Kong Ltd	2821 5480
2010/06/07	Stryker Video Carts With Isolation Transformers (Model: 240-099-001, 240-099-011, 240-099-011K, 240-099-020, 240-099-020K)	<a href="#">Health Canada</a>	54347	Type II	Stryker China Ltd	2518 6915
2010/06/07	Leica Microsystems Surgical Microscope Footswitch (Model: 10445599, 10446000, 10448164, 10448406, 10448407)	<a href="#">Health Canada</a>	54029	Type II	Leica Microsystems Limited	2564 6699
2010/06/07	GE Healthcare, Bio-Sciences Corp. Whatman 903 Newborn Screening Card (Model: 10534567, 10534678, 10534732, 10534751, 10534784, 10534785, 10534804)	<a href="#">Health Canada</a>	54741	Type III	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/06/07	Varian Ximatron (Model: CX)	<a href="#">Health Canada</a>	54560	Type II	Varian Medical Systems Pacific Inc.	2724 2836
2010/06/07	Navilyst Vaxcel Port and Vaxcel Port with PASV Valve	Boston Scientific Hong Kong Ltd	N.A.	Firm Initiated Field Action	Boston Scientific Hong Kong Ltd	2960 7136
2010/06/08	Abbott ARCHITECT Sirolimus Reagent (List no. 01L76-25, Lot 80162M100)	<a href="#">MHRA</a>	2010/006/001/601/001	FSCA	Abbott Laboratories LTD.	2593 2211
2010/06/09	Roche Cobas Amplicor HIV-1 Monitor Test, v1.5, CE-IVD (Material No. 21118390123, Lot No. M04255)	<a href="#">MHRA</a>	2010/006/003/081/004	FSCA	Roche Diagnostics (Hong Kong) Ltd	2485 7510
2010/06/09	Roche Cobas AmpliPrep/Cobas TaqMan HBV Test, Version 2.0 (Material No. 04894570190)	<a href="#">MHRA</a>	2010/006/003/081/005	FSCA	Roche Diagnostics (Hong Kong) Ltd	2485 7510



2010/06/09	C.R. Bard/Davol Counterfeit flat sheets of polypropylene surgical mesh labeled with C.R. Bard/Davol brand names (product no. 0112650, 0112660, 0112680, 0112720 Bard Flat Mesh with lot no. 48HVS036, 43APD007, HUSD0629, HURL0336, 43HPD027, 43HPD032, 43HPD034, HUSG0540, 43HDP027, HUSE0532, 43LPD507, HUSF0763, 43IOD011, 43IPD038, 43FQD327) are not Bard-manufactured products	<a href="#">FDA</a>	N.A.	Class I	N.A.	N.A.
2010/06/09	Boston Scientific Fathom - 14 Steerable Guidewire (Lot No. B17404, B18118, B18485, B18595, B18702, B18746, B18596, B18747, B19308, B18947, B17847 & B18948)	Boston Scientific Hong Kong Ltd	90599507FA	Firm Initiated Field Action	Boston Scientific Hong Kong Ltd	2960 7136
2010/06/09	Sorin Paradym DR, CRT-D & CRT-D sonR ICD (Models:8550, 8750 & 8770)	Innotronik Hong Kong Limited	N.A.	Firm Initiated Field Action	Innotronik Hong Kong Limited	2877 6787
2010/06/09	BD Hypromellose Ophthalmic Solution USP 2% w/v BD HPMC, 2ml Sterile Solution (REF 585306, Lot: 9A005BD, 9A006BD, 9J237BD, 0A019BD, and 0A021BD)	<a href="#">MHRA</a>	2010/005/028/081/017	FSCA	BD	2575 8668
2010/06/09	DePuy (JNJ) Corail Hip Cemented Femoral Stem Without Collar Size 11 (Product code: L96411, Lot No. 3028743) and Size 9 (Product code: L96409, Lot No. 3028308)	<a href="#">MHRA</a>	2010/006/004/081/005	FSCA	Johnson & Johnson Medical (HK)	2738 6027
2010/06/10	Philips Intera and Achieva systems with "Basic T1 Perfusion Package" (Software Releases R1.8.1, R2.1.5, R2.5, R2.6, R11.8.1, R12.1.5 and R12.6)	<a href="#">MHRA</a>	2010/003/005/081/024	FSCA	Philips Electronic Hong Kong Ltd	2821 5480
2010/06/10	Roche LightCycler MRSA Advanced Test (P/N: 05352894190)	<a href="#">MHRA</a>	2010/005/028/081/036	FSCA	Roche Diagnostics (Hong Kong) Ltd	2485 7510
2010/06/10	Wright Medical Technology Rayhack Drill Guide Angled, Ref 4010-0206	<a href="#">FDA</a>	Z-1779-2010	Class II	N.A.	N.A.
2010/06/10	Ohio Medical MobilVac Portable Wound Care Pump (Models 769600, 759600, 769600, 769601, 769602, and 769610); NPWT Small Mobile Bag (Model 769709)	<a href="#">FDA</a>	Z-1777-2010 to Z-1778-2010	Class II	N.A.	N.A.
2010/06/10	Angiodynamics DURAMAX Hemodialysis Catheters (Cat. no. 10302802, 10302803, 10302804, 10302805, 10302806, 10302807, 10302809, 10302812, 10302813, 10302814, 10302815)	<a href="#">FDA</a>	Z-1761-2010 to Z-1771-2010	Class II	N.A.	N.A.
2010/06/10	Baylis LumbarCool Pain Management Kit (Model/Catalogue Number: LUK-17-150-4, Lot No. LKFA160310)	<a href="#">FDA</a>	Z-1755-2010	Class II	N.A.	N.A.
2010/06/10	Continental Medical Labs Xenon Diagnostic Circuit Kits labeled as "Xenon Diagnostic Circuit", "Xenon Circuit", and Needleless Xenon Diagnostic Circuit" Manufactured for RAF MEDICAL, INC. or Medico-Mart, Inc.	<a href="#">FDA</a>	Z-1754-2010	Class II	N.A.	N.A.
2010/06/10	GE Healthcare Seno Advantage 2.2 workstations with software version 22_01 and 22_02	<a href="#">FDA</a>	Z-1747-2010	Class II	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/06/10	Terumo Sarns Cardioplegia Set with MP-4 Module (Catalog Nos. 6375, 165720, 15501 and 16010)	Terumo China (Hong Kong) Limited	MD-2010-002-C	Firm Initiated Field Action	Terumo China (Hong Kong) Limited	2866 0811

2010/06/10	Boston Scientific Synchro-14 and Synchro2 Guidewire	Boston Scientific Hong Kong Ltd	90599507FA	Firm Initiated Field Action	Boston Scientific Hong Kong Ltd	2960 7136
2010/06/11	Patterson Medical Liftmaster 160 (AA8974) and Liftmaster 190 (AA8943)	<a href="#">MHRA</a>	2009/011/012/301/001	FSCA	N.A.	N.A.
2010/06/11	DePuy (JNJ) Mitek VAPR Integrated Handpiece Electrode (Product Code: 225370, 227355, 227504, 227204, 227301, 227312, 227302, 227305, 227211, 227202, 227203, 227213 and 227252)	Johnson & Johnson (Hong Kong) Ltd.	N.A.	Firm Initiated Field Action	Johnson & Johnson (Hong Kong) Ltd.	2738 6027
2010/06/11	Stryker SwitchPoint Infinity 2 & SwitchPoint Element DOM Cards, Product Reference: 0100224307 (SPI2 DOM Card), 0100224592 (SPE DOM Card)	<a href="#">MHRA</a>	2010/006/003/081/014	FSCA	Stryker China Ltd	2518 6915
2010/06/11	Varian DIC / Fiches de traitement version 1.54.09d and ARIA Standard version 1.1	<a href="#">MHRA</a>	2010/006/008/081/006 (CP-01953)	FSCA	Varian Medical Systems Pacific Inc.	2724 2836
2010/06/11	Park House Healthcare Atlantic Bed Rails, Product code EBA013	<a href="#">MHRA</a>	2010/005/019/301/002	FSCA	N.A.	N.A.
2010/06/14	Thermo Fisher Scientific Eb0212E Oxoid Cooked Meat Medium (Lot Number: 1084871)	<a href="#">MHRA</a>	2009/010/014/601/004	FSCA	N.A.	N.A.
2010/06/15	Elekta XiO Release 4.50.00	<a href="#">MHRA</a>	2010/005/028/081/038	FSCA	Elekta Ltd.	2891 2208
2010/06/15	Elekta XiO Release 4.0.2	<a href="#">MHRA</a>	2010/006/003/081/019	FSCA	Elekta Ltd.	2891 2208
2010/06/15	Codan Argus Infusion pumps A707 and A708 (Article numbers: 18.0110, 18.011)	<a href="#">MHRA</a>	2010/003/022/081/024	FSCA	N.A.	N.A.
2010/06/15	Oxoid Giolitti-Cantoni Broth CM0523 (Lot: 793642)	<a href="#">MHRA</a>	2010/005/018/601/002	FSCA	N.A.	N.A.
2010/06/15	Medtronic StealthStation S7 System Retractable Power Cable	Medtronic International Ltd.	N.A.	Firm Initiated Field Action	Medtronic International Ltd.	2919 1300
2010/06/17	Activate Corgi Power Hi-Lo	<a href="#">MHRA</a>	2009/010/029/081/001	FSCA	N.A.	N.A.
2010/06/18	Abbott i-STAT ACT Celite Cartridges (Catalog No. 07G01-1), i-STAT ACT Kaolin Cartridges (Catalog No. 07G81-01)	<a href="#">FDA</a>	Z-0813-2010 to Z-0814-2010	Class II	Bio-Asia Diagnostics Co. Ltd.	N.A.
2010/06/18	Oxoid dry Spot Staphylect Plus (Catalog #DR0100M, DR0850M, DR0850B, Lot No. J055610, J539110, J591710, J577920, J610620)	<a href="#">FDA</a>	Z-0817-2010 to Z-0818-2010	Class II	N.A.	N.A.
2010/06/18	Ortho Development 10 degree Tibial Augment Wedge and 5mm Tibial Augment Block, component of Balanced Knee Modular Tibial System	<a href="#">FDA</a>	Z-1228-2010 to Z-1229-2010	Class II	N.A.	N.A.
2010/06/18	Vital Diagnostics Envoy 500 Serum Control Kit and ATAC Serum Control Kit	<a href="#">FDA</a>	Z-1233-2010 to Z-1234-2010	Class II	N.A.	N.A.

2010/06/18	Abbott ARCHITECT System Software v5.00 and v5.10 (List Number 5F48-22 and 5F48-23)	<a href="#">FDA</a>	Z-1316-2010	Class II	Abbott Laboratories LTD.	2593 2211
2010/06/18	Endocare Cryo V Probe (Model # Cryo 206V, CVA2400)	<a href="#">FDA</a>	Z-1400-2010 to Z-1401-2010	Class II	N.A.	N.A.
2010/06/18	Abbott CELL-DYN 1700 (list numbers 03H5301 and 03H53-03), CELL-DYN 1700CS (Closed Sampler) (list numbers 03H57-01, 03H57-03), CELL-DYN 1800 (list numbers 07H77-01, 07H77-03)	<a href="#">FDA</a>	Z-1628-2010 to Z-1630-2010	Class II	Abbott Laboratories LTD.	2593 2211
2010/06/18	Mckesson Medical Imaging Voiceware clip software update to certain Horizon Medical Imaging Systems.	<a href="#">FDA</a>	Z-1735-2010	Class II	N.A.	N.A.
2010/06/18	Diagnostic Hybrids Rabbit Kidney Culture with brand name 'FreshCells' (Catalog No. 48-0600, Lot no. 480109)	<a href="#">FDA</a>	Z-0822-2010	Class III	N.A.	N.A.
2010/06/19	Cardiac Pacemakers Altrua 20, 40, 50 and 60 Implantable Pulse Generator (S20	<a href="#">Health Canada</a>	54496	Type II	Boston Scientific Hong Kong Ltd	2960 7136
2010/06/19	Ace Surgical Supply Calcium Sulfate Hemihydrate Kit, 1g (Model or Catalog#505	<a href="#">Health Canada</a>	54873	Type I	N.A.	N.A.
2010/06/19	Philips Heartstart FRX AED (Model No. 861304) and Heartstart HS1 Onsite Defi	<a href="#">Health Canada</a>	54809	Type II	Philips Electronic Hong Kong Ltd	9101 3077
2010/06/19	Siemens Immulite 2000 System and Immulite 2500 System (Model/Catalog# L23	<a href="#">Health Canada</a>	54811	Type II	Siemens Healthcare Diagnostic Limited	2810 7533
2010/06/19	Navilyst Vaxcel Port/Mini/T/PU/6F/1.1/1.9 (Model or Catalog # 45-303, 45-305, 4	<a href="#">Health Canada</a>	54921	Type II	N.A.	N.A.
2010/06/19	Toshiba Aplio XG Ultrasound System (Model# SSA-790A)	<a href="#">Health Canada</a>	55073	Type II	Sanko Medical Systems (HK) LTD	
2010/06/19	Datascope CS300 Intra-Aortic Balloon Pump (Model or Catalog# 0998-00-3023-	<a href="#">Health Canada</a>	54614	Type III	N.A.	N.A.
2010/06/19	Remington Disposable Surgical Extension Cable (Model or Catalog# FL-601-97, Lot or Serial# 100701)	<a href="#">Health Canada</a>	54899	Type I	N.A.	N.A.
2010/06/19	Varian Flexible Probe with Blocking Washer (part of the Segmented Cylinder Set) (Model or Catalog# GM11002420, Lot or Serial# Y01 to E19)	<a href="#">Health Canada</a>	54886	Type II	Varian Medical Systems Pacific Inc.	2724 2836
2010/06/19	Boston Scientific Flexima Biliary Stent System (Model or Catalog# 3922, 3925, 3	<a href="#">Health Canada</a>	54480	Type III	Boston Scientific Hong Kong Ltd	2960 7136
2010/06/19	Voco Futurabond NR Single Dose (Model or Catalog# 1153, Lot or Serial# 1006	<a href="#">Health Canada</a>	54852	Type II	N.A.	N.A.
2010/06/19	Smith & Nephew Genesis II Resection Cutting Blocks (Model or Catalog # 71440	<a href="#">Health Canada</a>	54935	Type I	Smith & Nephew LTD	2648 7700
2010/06/19	Abbott i-STAT PT/INR Cartridges (Model or Catalog # 04J50-01, 04J50-02, Lot	<a href="#">Health Canada</a>	54626	Type III	Abbott Laboratories LTD.	2593 2211
2010/06/19	Medrad Stellant CT Dual Syringe Kits (Model or Catalog# SDS-CTP-QFT, SDS-	<a href="#">Health Canada</a>	55065	Type II	Prism Technologies Ltd.	2786 3233
2010/06/19	Micro Typing Systems Ortho Provue Analyzer Software V. 3.1 (Model or Catalog	<a href="#">Health Canada</a>	55074	Type II	Johnson & Johnson Medical (HK)	2738 6027

2010/06/19	Micro Typing Systems Ortho Provue Analyzer Software V. 3.1 (Model or Catalog # 55075)	<a href="#">Health Canada</a>	55075	Type II	Johnson & Johnson Medical (HK)	2738 6027
2010/06/19	Escalon PD Access 18 Gauge Vascular Access Device (Model or Catalog # 780)	<a href="#">Health Canada</a>	54858	Type II	N.A.	N.A.
2010/06/19	Medrad Sterile Disposable Syringe Kit (Model or Catalog # 150-FT-Q, Lot or Ser # 54929)	<a href="#">Health Canada</a>	54929	Type II	Prism Technologies Ltd.	2786 3233
2010/06/19	Elekta XiO Radiation Treatment Planning System (Release 2.1.0 & Higher)	<a href="#">Health Canada</a>	54897	Type II	N.A.	N.A.
2010/06/22	Siemens Healthcare Diagnostics VERSANT Sample Preparation 1.0 Reagent - Lot number B005X, Box 1 and Box 2 (Ref 04801677 and 04801685)	<a href="#">MHRA</a>	2010/006/009/081/002	FSCA	Siemens Healthcare Diagnostic Limited	28707827
2010/06/23	St. Jude Medical Exclaim (Model no. 3224) and Lamitrode Paddle Leads (Model no. 3243, 3246, 3266, 3267, 3268, 3269, 3283, 3286, 3208, 3210, 3219, 3214, 3240, 3254, 3255, 3244, 3262, 3263, 3245, 3264, 3265, 3280, 3288, 3289 and 3228)	<a href="#">MHRA</a>	2010/006/015/081/011	FSCA	St. Jude Medical (Hong Kong) Ltd.	2996 7651
2010/06/24	Medela Symphony Double Pumping Kit; the instructions were packaged with the following non-sterile single user accessory kits for use with Symphony breast pumps: a) Model 67023, Harmony to Symphony Conversion Kit; b) Model 67091, Lactina to Symphony Conversion Retail Kit; c) Model 67099, Symphony Retail Kit; d) Model 67099-06, Symphony Retail Kit - case of 6 kits; e) Model 67099NA, Symphony Retail Kit - case of 6 kits for national accounts.	<a href="#">FDA</a>	Z-1442-2010	Class II	N.A.	N.A.
2010/06/24	Leica Peloris Rapid Tissue Processor; catalog number 26.0001 and 26.0005.	<a href="#">FDA</a>	Z-1551-2010	Class II	Leica Microsystems Limited	2564 6699
2010/06/24	Acumed Intramedullary Fixation Rod, common name Fibula Rod, labeled IM Rod System: a) Model # 40-0028-S; b) Model # 40-0029-S; and c) Model # 40-0031-S.	<a href="#">FDA</a>	Z-1552-2010	Class II	N.A.	N.A.
2010/06/24	Acumed Polarus(R) Humeral Fixation System, size: 3.5mm x 25.0mm Cortical Screw, Ref: HCO3250-S.	<a href="#">FDA</a>	Z-1602-2010	Class II	N.A.	N.A.
2010/06/24	Maquet EXXCEL Soft Standard Wall EPTFE Vascular Graft (UPN M002004810260), EXXCEL Soft Thin Wall EPTFE Vascular Graft (UPN M002004948580).	<a href="#">FDA</a>	Z-1606-2010 to Z-1607-2010	Class II	Maquet Hong Kong Ltd.	2393 9511
2010/06/24	PerMedics Odyssey treatment planning system version 4.4 through 4.6.	<a href="#">FDA</a>	Z-1609-2010	Class II	N.A.	N.A.
2010/06/24	Newport e360 Ventilator (All serial numbers beginning with N093609XXXXX, N093610XXXXX, N093611XXXXX, and N093612XXXXX)	<a href="#">FDA</a>	Z-1617-2010	Class II	N.A.	N.A.
2010/06/24	I2s Micro Implantable Systems Inserter Wand Holder (Serial # 4273-0001 through 4273-0061)	<a href="#">FDA</a>	Z-1619-2010	Class II	N.A.	N.A.
2010/06/24	Cardiac Science Responder 2000 Defibrillator/Monitor Models: 2025653, 2026109, and 2026114.	<a href="#">FDA</a>	Z-1683-2010	Class II	Pacific Medical Systems Limited	2108 4005
2010/06/24	DATEX-Ohmeda TruSat Oximeter and Accessories, Model 3500	<a href="#">FDA</a>	Z-1814-2010	Class II	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/06/24	Bausch & Lomb Millennium Microsurgical System Vit Enhancer (MVE), Stellaris Vision Enhancement System	<a href="#">FDA</a>	Z-1662-2010 to Z-1664-2010	Class II	Bausch & Lomb (Hong Kong ) Ltd	2213 3371

2010/06/24	Cambridge Heart Alternans Sensor Kit Assembly	<a href="#">FDA</a>	Z-1776-2010	Class II	N.A.	N.A.
2010/06/24	Pelton & Crane Spirit 3000 Dental Chair, Catalog number: 3003, Model number: SP30.	<a href="#">FDA</a>	Z-1311-2010	Class III	N.A.	N.A.
2010/06/25	Tosoh Bioscience G8 Hemoglobin F&A2 Control Set (lots: 8BKITP3, level 1 and 8BKITP4, level 1)	<a href="#">MHRA</a>	2010/006/008/081/002	FSCA	N.A.	N.A.
2010/06/25	Innogenetics LiRAS for Infectious Diseases v2.01 (lot: 2009090901) and all previous versions of the software	<a href="#">MHRA</a>	2010/006/014/291/009	FSCA	N.A.	N.A.
2010/06/29	Fresenius 5008 and 5008S Haemodialysis Machines	<a href="#">MHRA</a>	MDA/2010/053	MDA	Fresenius Medical Care Hong Kong Limited	2583 0813
2010/06/29	Innogenetics Innostest Beta-Amyloid(1-42) (Product codes: 80324 & 80177, Batchnumbers: 196524, 204108, 206189, 196526, 201230, 204109 & 206205)	<a href="#">MHRA</a>	2010/006/015/081/001	FSCA	N.A.	N.A.
2010/06/29	Fresenius 5008 Dialysis Machines	<a href="#">MHRA</a>	2010/001/011/081/013	FSCA	Fresenius Medical Care Hong Kong Limited	2583 0813
2010/06/29	B. Braun Online Substitution Line for Dialog 7210558 and 721055A	<a href="#">MHRA</a>	2010/006/003/081/023	FSCA	B. Braun Medical (Hong Kong) Ltd.	2529 2009
2010/06/29	Siemens Dimension Tacr Flex Reagent Cartridges (DF107) (lots: DC0306, CA0320, DA0334 and GA0348)	<a href="#">MHRA</a>	2010/006/018/291/014	FSCA	Siemens Healthcare Diagnostics Limited	2870 7888
2010/06/29	Peacocks Skylux C4VS Theatre Operating Light	<a href="#">MHRA</a>	2009/011/016/401/004	FSCA	N.A.	N.A.
2010/06/29	Ultimate T-Bag Oxygen Enrichment Device (Code: 7000T)	<a href="#">MHRA</a>	2010/002/025/401/009	FSCA	N.A.	N.A.
2010/06/29	Bard DORADO PTA Balloon Dilatation Catheter (Product code# DR135412, DR135415, DR135417, DR135420, DR135512, DR135515, DR135517, DR135520, DR135612, DR135615, DR135620, DR135712, DR135715, DR135717 and DR135720)	<a href="#">MHRA</a>	2010/005/026/081/030	FSCA	N.A.	N.A.
2010/06/29	Olympus KeyMed Lens Cleaning Sheath - MAJ 1537	<a href="#">MHRA</a>	2010/005/004/401/017	FSCA	Olympus Hong Kong and China Ltd	2170 5678
2010/06/29	Fresenius Orchestra Base Primea Infusion System	<a href="#">MHRA</a>	2010/006/009/081/013	FSCA	N.A.	N.A.
2010/06/30	ArjoHuntleigh / Huntleigh Healthcare Contoura 800 series beds (Model nos. 200	<a href="#">MHRA</a>	2009/007/009/401/011	FSCA	Arjo Huntleigh (Hong Kong) Ltd.	2508 1416
2010/06/30	Acumed Ulnar Shortening Saw Blade - Hub Style S (Part No. 80-0499-S) (Lot no	<a href="#">MHRA</a>	2010/004/020/291/009	FSCA	N.A.	N.A.
2010/06/30	Roche Diagnostics AMPLILINK Software v 3.1.x and v 3.2.x for COBAS AmpliPr	<a href="#">MHRA</a>	2010/006/023/291/003	FSCA	Roche Diagnostics (Hong Kong) Ltd	2485 7510
2010/06/30	Siemens Dimension Enzymatic Creatinine (EZCR) Flex reagent cartridges, DF2	<a href="#">MHRA</a>	2010/006/022/081/002	FSCA	Siemens Healthcare Diagnostic Limited	2810 7533
2010/06/30	Varian C-Series Clinacs	<a href="#">MHRA</a>	2010/006/018/291/009	FSCA	Varian Medical Systems Pacific Inc.	2724 2836
2010/06/30	Olympus KeyMed 5.5mm TroQ Trocar Spike (Product Codes: A5816, A5821, A5948, A5949, A5968, A5979, WA58341L and WA58343L)	<a href="#">MHRA</a>	2010/006/021/291/021	FSCA	Olympus Hong Kong and China Ltd	2170 5678
2010/06/30	CIVCO Universal Couchtop Rectangular Extension (Part number: MTIL6600; Lo	<a href="#">MHRA</a>	2010/006/024/291/003	FSCA	N.A.	N.A.
2010/06/30	TomoTherapy Hi-Art Treatment System Software (Versions 4.0.0, 4.0.1 and 4.0.	<a href="#">MHRA</a>	2010/006/023/291/002	FSCA	N.A.	N.A.

2010/06/30	Fresenius AV-SET FMC (FA404E/FV404E) Bloodline (Product Code: 5016481;	<a href="#">MHRA</a>	2010/006/024/291/021	FSCA	Fresenius Medical Care Hong Kong Limited	2583 0813
2010/06/30	Stryker Pkg. Disposable Scope Warmer (Part No. 502-360-000)	Stryker China Limited	N.A.	Firm Initiated Field Action	Stryker China Limited	2518 6915

## Monthly Summary of Medical Device Safety Alerts - May 2010

\*Note: FDA = Food and Drug Administration, United States of America; MHRA = Medicines and Healthcare products Regulatory Agency, United Kingdom; Health Canada = Health Canada, Canada

Date of Issue (YYYY/MM/DD)	Description of Product	Source of Information*	Reference No. by Source	Alert Type by Source	Local Agent	Agent Contact Telephone No.
2010/05/04	Diopsys Enfant Pediatric VEP Vision Testing System, Product number: 8510-0001-00 Rev 1	<a href="#">FDA</a>	Z-1437-2010	Class III	N.A.	N.A.
2010/05/04	CareFusion NicoletOne vEEG System.	<a href="#">FDA</a>	Z-1256-2010	Class II	CareFusion Hong Kong Ltd.	2891 8730
2010/05/04	Novasys Medical Renessa RF System, model PR0918.	<a href="#">FDA</a>	Z-1404-2010	Class II	N.A.	N.A.
2010/05/04	3M Micropore Single Use Rolls (REF 1530S-1), 3M Micropore Paper Tape (Cat. No. 1530-118, 1530-136, 1530-154, 1530-12Y, 1530-15Y, 1530-254, 1530-226)	<a href="#">FDA</a>	Z-1413-2010 to Z-1420-2010	Class II	3M Hong Kong Ltd	2806 6111
2010/05/04	Cordis AVANTI+ Introducer (Catalog # 402656X, 504606X, 504656X).	<a href="#">FDA</a>	Z-1421-2010	Class II	Johnson & Johnson Medical (HK)	2738 6027
2010/05/04	Integra LifeSciences Integra Licox Ref 1P2.P; 1P2; CC1/P1.	<a href="#">FDA</a>	Z-1422-2010	Class II	N.A.	N.A.
2010/05/04	Advanced Neuromodulation Systems Swift-Lock (TM) Anchor Accessory Kit, Directions For Use Model 1192.	<a href="#">FDA</a>	Z-1425-2010	Class II	St. Jude Medical (Hong Kong) Ltd.	2996 7688
2010/05/04	American Diagnostica REF 822 IMUBIND(R) Plasma PAI-1 ELISA.	<a href="#">FDA</a>	Z-1426-2010	Class II	N.A.	N.A.
2010/05/04	Elekta iView GT Electronic Portal Imaging Device	<a href="#">FDA</a>	Z-1436-2010	Class II	Elekta Ltd.	2891 2208
2010/05/05	Baxter Colleague Volumetric Infusion Pump  Remark : FDA has further issued Questions and Answers about the Baxter Colleague Infusion Pump Recall on 5 May 2010. According to FDA's recommendations, users may continue to use the Colleague pumps during the transition period. In view of the numerous software and hardware defects reported since 2005, users are advised to seek replacement for their Colleague Pumps.  <a href="#">Questions and Answers issued by FDA</a>	<a href="#">FDA</a>	N.A.	Press Release	Baxter Healthcare Ltd	2807 8555
2010/05/05	Philips Heartstart MRx Defibrillator Monitors	<a href="#">MHRA</a>	2010/004/029/081/009	FSCA	Philips Electronic Hong Kong Ltd	2821 5480
2010/05/05	Smith & Nephew Dyonics II Shaver Controller (Item code: 7220873, lot no. AAX2448)	<a href="#">MHRA</a>	2010/004/029/081/018	FSCA	Smith & Nephew LTD	2648 7700
2010/05/05	Medtronic Consulta CRT-D (D234TRK), Secura DR/VR (D234DRG, D234VRC), Maximo II CRT-D (D284TRK), Maximo II DR/VR (D284DRC, D284VRC)	Medtronic International Ltd.	N.A.	Firm Initiated Field Action	Medtronic International, Ltd.	2919 1300
2010/05/06	B. Braun Infusomat space lines Cyto-Set (REF 8250910SP), Neutrapur (REF 8700110SP, 8250731SP, 8700095SP), Original Infusomat Line type Neutrapur (REF 8250731T)	<a href="#">MHRA</a>	2010/001/026/601/001	FSCA	B. Braun Medical (Hong Kong) Ltd.	2529 2009
2010/05/06	DePuy Corail AMT HA Femoral Stem Std With Collar S11 and Without Collar S8 (Model: 3L92501, 3L92507)	<a href="#">MHRA</a>	2010/004/027/081/022	FSCA	Johnson & Johnson Medical (HK)	2738 6027
2010/05/06	Codman & Shurtleff (JNJ) Medstream Implantable Drug Pump (Model: 91-4200, 91-4201)	<a href="#">MHRA</a>	2010/004/012/291/014	FSCA	Johnson & Johnson Medical (HK)	2738 6027

2010/05/06	Beckman Coulter Synchron Systems Modular Glucose (GLUCm) Reagent (Model 472500)	<a href="#">MHRA</a>	2010/004/023/601/003	FSCA	Beckman Coulter Hong Kong Ltd	2240 6150
2010/05/06	St. Jude Medical Convert+ Model V-195 Implantable Cardioverter-Defibrillator	St Jude Medical (Hong Kong) Ltd.	N.A.	Firm Initiated Field Action	St. Jude Medical (Hong Kong) Ltd.	2996 7651
2010/05/07	Cook Medical Ciaglia Blue Dolphin and Ciaglia Blue Rhino Balloon Percutaneous Tracheostomy Introducer Set (with Shiley Percutaneous	<a href="#">MHRA</a>	2010/004/028/081/022	FSCA	AR Burkill & Sons (HK) Ltd	2541 1041
2010/05/07	Newdeal LARGE QWIX screws (diameter 7.5mm, lg 65mm) (Cat: 111765S and 121765S; Batches EGH5 and EGJK)	<a href="#">MHRA</a>	2010/004/022/081/005	FSCA	N.A.	N.A.
2010/05/07	Varian Varisource iX Console	<a href="#">MHRA</a>	2010/003/031/081/002	FSCA	Varian Medical Systems Pacific Inc.	2724 2836
2010/05/07	Teleflex Medical AQUA+FLEX Hygroscopic Condenser Humidifier (Catalog Number 1570)	<a href="#">FDA</a>	N.A.	Press Release	N.A.	N.A.
2010/05/10	The Helping Hand Company Acheeva Learning Station	<a href="#">MHRA</a>	2010/003/031/401/002	FSCA	N.A.	N.A.
2010/05/10	Orthofix US XCaliber Meta-Diaphyseal Complete Kit, 99-91600; Orthofix US XCaliber Ankle Complete Kit, 99-91647.	<a href="#">FDA</a>	Z-1434-2010 to Z-1435-2010	Class II	N.A.	N.A.
2010/05/10	Elekta Synergy	<a href="#">FDA</a>	Z-1441-2010	Class II	Elekta Ltd.	2891 2208
2010/05/10	Elekta Leksell Gamma Knife C.	<a href="#">FDA</a>	Z-1533-2010	Class II	Elekta Ltd.	2891 2208
2010/05/10	Stryker Literature for Implant Extraction Set - Implant Extraction Guide Module One & Two.	<a href="#">FDA</a>	Z-1443-2010	Class II	Stryker China Ltd.	2814 7463
2010/05/10	Baxter RenAmin (Amino Acid) Injection (product code 2A6222); Baxter Evacuated Containers (product code 1A8502, 1A8503).	<a href="#">FDA</a>	Z-1528-2010 to Z-1530-2010	Class II	Baxter Healthcare Ltd	2807 8555
2010/05/10	Medtronic HMS PLUS Hemostasis Management System (Catalog Number: 30514).	<a href="#">FDA</a>	Z-1537-2010	Class II	Medtronic International Ltd.	2919 1362
2010/05/10	Arrow International Percutaneous Sheath Introducer (PSI) Kit with Integral Hemostasis Valve/Side Port for use with 7.5 - 8 Fr. Catheters (Catalog number: ASK-09903-CMC).	<a href="#">FDA</a>	Z-1538-2010	Class II	N.A.	N.A.
2010/05/10	Ortho-Clinical Diagnostics VITROS Immunodiagnostic Products CA 125 II Reagent Packs, Lot 1060 (CAT No. 6800038)	<a href="#">MHRA</a>	2010/004/022/081/004	FSCA	Ortho Clinical Diagnostics	2737 5504
2010/05/10	Boston Scientific Radial Jaw 4 Large Capacity w/ Needle Biopsy Forceps (Cat. No. M00513331, M00513334, M00513330, Lot No. 13244654, 13361332, 13361334, 13244654)	Boston Scientific Hong Kong Ltd	90596143FA	Firm Initiated Field Action	Boston Scientific Hong Kong Ltd	2960 7136
2010/05/11	Zimmer Nexgen Complete Knee Solution, Mis Total Knee Procedure, Stemmed Tibial Component, Fixed Bearing (Part no. 00-5950-027-01/02, 00-5950-037-01/02, 00-5950-037-12, 00-5950-047-01/02, 00-5950-057-01/02, 00-5950-057-03-04)	<a href="#">MHRA</a>	2010/004/029/081/010	FSCA	Zimmer PTE Ltd. (Hong Kong branch)	2992 0968
2010/05/11	Smith & Nephew Aimer endofemoral (Item code: 72201714, 72201715, 72201716, 72201717, 72201713)	<a href="#">MHRA</a>	2010/005/006/081/014	FSCA	Smith & Nephew Ltd.	2648 7700
2010/05/11	GE Healthcare CARESCAPE Monitor B850 version 1.0.1.13 and 1.0.2.1	<a href="#">MHRA</a>	2010/004/030/601/002	FSCA	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/05/11	GE Centricity Laboratory; Software Versions: v4.1	<a href="#">MHRA</a>	2010/004/028/081/013	FSCA	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/05/11	Siemens MicroScan Gram Negative MIC Type 37 (B1016-147) Panels	<a href="#">MHRA</a>	2010/005/005/081/025	FSCA	Siemens Healthcare Diagnostics Limited	2870 7888



2010/05/11	Abbott CELL-DYN Sapphire System, List Number 08H00-01 and 08H00-03	<a href="#">MHRA</a>	2010/004/014/601/001	FSCA	Abbott Laboratories LTD.	2593 2211
2010/05/11	Caledonian Medical CalMed custom procedure packs - various	<a href="#">MHRA</a>	2010/004/028/601/001	FSCA	N.A.	N.A.
2010/05/11	Zimmer Nexgen complete knee solution stemmed & rotating hinge knee tibial broach impactor	<a href="#">MHRA</a>	2010/004/019/081/007	FSCA	Zimmer PTE Ltd. (Hong Kong branch)	2992 0968
2010/05/11	Hill-Rom Totalcare Bed System (Model : P1900)	<a href="#">Health Canada</a>	52322	Type II	N.A.	N.A.
2010/05/11	Cardinal Health DIS/NIC1 VEEG 32CHNL ETHNT (Model : V EEG)	<a href="#">Health Canada</a>	53613	Type II	CareFusion Hong Kong Ltd.	2891 8730
2010/05/11	GE Datex Ohmeda Network and iCentral	<a href="#">Health Canada</a>	53807	Type II	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/05/11	Therakos Cellex Procedural Kits (Model : CLXECP)	<a href="#">Health Canada</a>	53868	Type II	N.A.	N.A.
2010/05/11	Zimmer A) TMARS - Buttress Augments B) TMARS - Column Buttress Augments	<a href="#">Health Canada</a>	53937	Type II	Zimmer PTE Ltd. (Hong Kong branch)	2992 0968
2010/05/11	Cardinal Health A) Sterile CABG Pack B) Ensemble Sterile Total Hip C) Sterile Pacemaker Pack D) Urology Vaginal With Champs E) Sterile Thoracic Pack F) Sterile Plastic Extremity Pack G) Ensemble Total Knee H) Ensemble Sterile Plastics I) Sterile Cesarean Section Pack J) Sterile Major Laparotomy Pack K) Sterile Vascular Pack L) Sterile Minor Set Up Pack M) Sterile Major ABD Pack	<a href="#">Health Canada</a>	54000	Type II	CareFusion Hong Kong Ltd.	2891 8730
2010/05/11	Medibo Ministrel Patient Lift (Model : HMA0001, HMA0011)	<a href="#">Health Canada</a>	54019	Type II	N.A.	N.A.
2010/05/11	Medline Cardiac Sternal Pack (Model : DYNJ32436X)	<a href="#">Health Canada</a>	54033	Type II	N.A.	N.A.
2010/05/11	Advanced Sterilization Products Automatic Endoscope Reprocessor (Model : 20300, 20301)	<a href="#">Health Canada</a>	54046	Type II	Johnson & Johnson Medical (HK)	2738 6027
2010/05/11	Elekta XIO Radiation Treatment Planning System (Model : 9200)	<a href="#">Health Canada</a>	54227	Type II	Elekta Ltd.	2891 2208
2010/05/11	A) Stryker Smart-Pump Dual Channel B) Stryker Smart-Pump Printer	<a href="#">Health Canada</a>	54263	Type II	Stryker China Ltd	2518 6915
2010/05/11	Medtronic O-ARM Imaging System (Part # 9732719, 9733346, BI-700-00027-100, BI-700-00027-120, BI-700-00027-230)	Medtronic International Ltd.	N.A.	Firm Initiated Field Action	Medtronic International Ltd.	2919 1300
2010/05/12	Heartware Ventricular Assist System Controller	<a href="#">MHRA</a>	2010/005/004/291/011	FSCA	N.A.	N.A.
2010/05/12	Arrow International (Teleflex Medical) Arrow 4 Fr Peripherally Inserted Central Catheter (PICCs) Kits	<a href="#">MHRA</a>	2010/005/007/081/014	FSCA	N.A.	N.A.
2010/05/12	Edwards Lifesciences Swan Ganz Continuous Cardiac Output (CCO) Catheters (Models 744HF75 and 746HF8)	<a href="#">MHRA</a>	2010/005/006/081/004	FSCA	N.A.	N.A.
2010/05/13	Baxter All Aquarius Haemofiltration Machines	<a href="#">MHRA</a>	MDA/2010/039	MDA	Baxter Healthcare Ltd	2807 8555
2010/05/13	Optovue RTVue Optical Coherence Tomography (OCT), Model-RT100	<a href="#">FDA</a>	Z-1131-2010	Class II	N.A.	N.A.

2010/05/13	Elekta Leksell GammaPlan	<a href="#">FDA</a>	Z-1134-2010	Class II	Elekta Ltd.	2891 2208
2010/05/13	Leica Microsystems Shutter HX SP5. a component of the Leica Point Scanning Confocal Microscope Models TCS SP5 and TCS SP5 X. Material No: 1531160006 Spare Part No: 15000904000093	<a href="#">FDA</a>	Z-1221-2010	Class II	Leica Microsystems Limited	2564 6699
2010/05/13	Stryker Vertier Surgical Table, Catalog numbers 0788100000, 0788100000S, 0788100001, and 0788100001S.	<a href="#">FDA</a>	Z-1238-2010	Class II	Stryker China Ltd.	2814 7463
2010/05/13	Biomet Microfixation Patient Distractor Driver 10.87cm (Part Number SP-1918).	<a href="#">FDA</a>	Z-1319-2010	Class II	Swedish Trading Co., Ltd	2953 5111
2010/05/13	Orthohelix Surgical Designs Mini Max Torque 2.6 mm diameter Drill Bit, Model #HCS-072-26 & 3.8 mm Countersink, Model # HCS-070-38.	<a href="#">FDA</a>	Z-1430-2010	Class II	N.A.	N.A.
2010/05/13	Philips Heartstart FRx AED (Model 861304), Heartstart (HS1) Onsite AED (Model M5066A), Heartstart (HS1) Laerdal brand onsite AED (Model M5067A), HeartStart HS1 Defibrillator (Model M5068A).	<a href="#">FDA</a>	Z-1193-2010 to Z-1196-2010	Class II	Philips Electronic Hong Kong Ltd	2821 5480
2010/05/14	Immucor Gamma Antibody identification cell panel Panocell-10, Cat. No. 0003032 Lot: 13083	<a href="#">MHRA</a>	2010/005/007/081/011	FSCA	Uninet Technology LTD	2838 8423
2010/05/14	Zimmer Cannulated modular screwdriver (part no. 1160-2)	<a href="#">MHRA</a>	2010/004/028/081/010	FSCA	Zimmer PTE Ltd. (Hong Kong branch)	2992 0968
2010/05/14	Zimmer End screw extender sleeve (Part no. 1165-10)	<a href="#">MHRA</a>	2010/004/028/081/011	FSCA	Zimmer PTE Ltd. (Hong Kong branch)	2992 0968
2010/05/18	Defibtech DBP-2800 Battery Packs used with DDU-100 series AEDs sold under the brand names Lifeline AED and ReviveR AED (serial no.: between 202001005 and 202005916, or between 206001001 and 206009871.)	<a href="#">MHRA</a>	2010/005/010/291/011	FSCA	Defib China	3750 7464
2010/05/18	Stryker a) HMRS Curved Anchorage Stems 12 mm to 19mm (6365-5-012 to 6365-5-019), b) HMRS Straight Anchorage Stems 11mm to 15mm (6367-4-011 to 6367-4-015), c) GMRS/HMRS PLUS Curved Anchorage Stems 12mm to 19mm (6365-5-112 to 6365-5-119).	<a href="#">MHRA</a>	2010/004/013/291/006	FSCA	Stryker China Ltd.	2814 7463
2010/05/18	GE Aespire 100/7100 (S/N: AMXL00100-AMXN01192), Aespire 7900 (ANCL00100-ANCN01565), Aespire View (APHN00100-APHN00179), Avance (ANBL00100-ANBN01719), Amingo (AMNM0100-AMNN00164), ADS 180 (AMXL01114, AMXL01115, AMXM00476, AMXM01233, AMXN00302) Anaesthesia Machines.	<a href="#">MHRA</a>	2009/007/017/401/007	FSCA	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/05/18	KaVo ESTETICA E70 and E80 units	<a href="#">MHRA</a>	2010/004/030/291/003	FSCA	N.A.	N.A.
2010/05/18	GE Innova 2100IQ, 3100, 3100IQ, 4100 and 4100IQ cardiovascular X-ray imaging systems with InnovalQ Table distributed from February 2008 to April	<a href="#">MHRA</a>	2010/005/010/081/021	FSCA	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/05/18	Varian Eclipse Version 7.310 (Multiple Workstations) or VARIS Vision system 7.x	Varian Medical Systems Pacific Inc.	CP-00648	Firm Initiated Field Action	Varian Medical Systems Pacific Inc.	2724 2836
2010/05/19	Biomet Stanmore Total Knee (Right & Left) (Part 3 125510 and 125511)	<a href="#">MHRA</a>	2010/004/027/081/006	FSCA	N.A.	N.A.
2010/05/19	DWA (Dialyse Wasser Aufbereitungsanlagen) Central Concentrate Supply Systems CeCon 3000	<a href="#">MHRA</a>	2010/004/022/081/003	FSCA	N.A.	N.A.
2010/05/19	Pronefro Therapy chair (supplied by Hemotion UK Ltd.)	<a href="#">MHRA</a>	MDA/2010/042	MDA	N.A.	N.A.
2010/05/19	Brainlab Digital Lightbox 2.0 with data export	<a href="#">MHRA</a>	2010/005/012/291/003 (10-04-09.DWI.1)	FSCA	BrainLAB Ltd	2417 1881
2010/05/19	CareFusion NicoletOne System vEEG/ nEEG/ LTM/ Sleep/ ICU Monitor/ Ambulatory Software Version 5.3, 5.4 & 5.7	<a href="#">MHRA</a>	2010/005/010/081/027 (RA2010-04)	FSCA	CareFusion Hong Kong Ltd.	2891 8730

2010/05/19	Spacelabs Healthcare Vital Signs Monitor Model 91220	<a href="#">MHRA</a>	2010/004/028/081/014	FSCA	Schmidt Bio Med Tech (H.K.)	2620 8329
2010/05/20	Abbott Freestyle Navigator Continuous Glucose Monitor System (Item no. 70684-01, 70684-02, 70684-03, 70791-01, 70791-02, 70791-20, 70965-01, 70965-02, 70965-03, 70966-01, 70966-02, 70966-03, 70966-04, 71036-01, 71036-02, PRT: 03415-001, 03831-001, 03831-002, 03831-091)	<a href="#">FDA</a>	Z-0820-2010 to Z-1461-2010	Class II	Abbott Laboratories Ltd.	2593 2211
2010/05/20	Elekta Precise Treatment Table	<a href="#">FDA</a>	Z-1432-2010	Class II	Elekta Ltd.	2891 2208
2010/05/20	Encore Medical 3DKNEE SYSTEM, 3D Knee Tibial Insert-DCM (Cat. no. 392-11-604)	<a href="#">FDA</a>	Z-1433-2010	Class II	N.A.	N.A.
2010/05/20	Ascension PyroCarbon PIP Total Joint - Trials; Ascension PIP, sizes 10P, 20P, 30P and 40P.	<a href="#">FDA</a>	Z-1524-2010	Class II	N.A.	N.A.
2010/05/20	Bard Access Systems PowerPort isp M.R.I Implanted Port without Suture Plugs with attachable 6F Chronoflex Polyurethane Open-ended Single -Lumen Venous Catheter REF#1806061.	<a href="#">FDA</a>	Z-1525-2010	Class II	Senrex International Ltd.	2311 8938
2010/05/20	Siemens Dimension Vista CHEM 3 calibrator, Catalog number KC130.	<a href="#">FDA</a>	Z-1535-2010	Class II	Siemens Healthcare Diagnostic Limited	2870 7533
2010/05/20	Davol Bard Ventrilo Small Oval Hernia Patch 8cm X 12cm (3.1" x 4.7"), Product Code: 0010211.	<a href="#">FDA</a>	Z-1536-2010	Class II	N.A.	N.A.
2010/05/20	Excision AEM Disposable Electrode (REF ES0301, ES0301-45, ES0309, ES0310, ES0310-45, ES0311, ES0312, ES0312-45)	<a href="#">FDA</a>	Z-1539-2010 to Z-1546-2010	Class II	N.A.	N.A.
2010/05/20	Synthes 7.5mm Ti Solid Humeral Nail 230 mm and 250 mm, Catalog number 462.723S and 462.725S	<a href="#">FDA</a>	Z-1548-2010 to Z-1549-2010	Class II	Synthes (Hong Kong) Ltd	2724 2032
2010/05/20	Alcon Constellation Vision System	<a href="#">MHRA</a>	2010/005/017/291/007	FSCA	Alcon Hong Kong, Ltd.	2568 0636
2010/05/20	Olympus Electrosurgical Snare Tube Models: MAJ-13, MAJ-15, SD-9L/U-1, SD-11 L/U -1, SD-12 L/U -1, SD-13 L/U -1, SD-16 L/U -1, SD-17 L/U -1.	<a href="#">MHRA</a>	2010/005/017/291/016	FSCA	Olympus Hong Kong and China Ltd	2170 5678
2010/05/20	Terumo Sarns Disposable Centrifugal Pump (Cat. Nos. 164275 & 16427X) and Cardiovascular Procedure Kits containing pumps from affected lots	Terumo China (Hong Kong) Limited	MD-2010-001-R-E	Firm Initiated Field Action	Terumo China (Hong Kong) Limited	2866 0811
2010/05/24	Acumed Trial Gage (Part number TR-TG01, Lots : 211365, 214346, 220365, 222678, & 224183)	<a href="#">MHRA</a>	2010/005/018/081/016	FSCA	N.A.	N.A.
2010/05/24	Abbott Diagnostics Clinical Chemistry Phosphorus (List no. 7D71-21, all lots)	<a href="#">MHRA</a>	2010/005/011/601/004	FSCA	Abbott Laboratories Ltd.	2566 8711
2010/05/24	Smith & Nephew Reflection Liner Adapter (Product code: 71323144, 71323145)	<a href="#">MHRA</a>	2010/005/011/601/003	FSCA	Smith & Nephew LTD	2648 7700
2010/05/24	Siemens ADVIA Centaur Systems Calibrator A Lot 068 and 069 for FT4 Value Assignment	<a href="#">MHRA</a>	2010/005/011/081/007 (078D0959-01)	FSCA	Siemens Healthcare Diagnostic Limited	2810 7533
2010/05/24	Possum Nickel Metal Hydride Battery Pack HC2000B/HC1800A/B Model 131-214 (Used in the Freeway and Companion A and B Environmental Aids)	<a href="#">MHRA</a>	2010/005/010/301/001	FSCA	N.A.	N.A.
2010/05/24	BD Phoenix PMIC/ID Panels, PMIC/ID-107 (Cat# 448607, Lot# 0083198)	BD	N.A.	Firm Initiated Field Action	BD	2575 8668
2010/05/24	AliMed IQ Cupid Pull Cord Alarm	<a href="#">Health Canada</a>	54333	Type II	N.A.	N.A.
2010/05/24	Stryker Universal Flat Panel Yoke	<a href="#">Health Canada</a>	54351	Type II	Stryker China Ltd	2518 6915
2010/05/24	USA Instruments Breast Biopsy Plates	<a href="#">Health Canada</a>	54354	Type II	N.A.	N.A.

2010/05/24	Zimmer Spine Nexlink Polyaxial Screw Driver	<a href="#">Health Canada</a>	54444	Type II	Zimmer PTE Ltd. (Hong Kong branch)	2992 0968
2010/05/24	Johnson & Johnson Coated Vicryl Rapide Suture (Model : VR416, VR417, VR917, VR935, VR944 )	<a href="#">Health Canada</a>	54468	Type II	Johnson & Johnson Medical (HK)	2738 6027
2010/05/24	Stryker Zoom Stretcher-SM-304	<a href="#">Health Canada</a>	54479	Type II	Stryker China Ltd	2518 6915
2010/05/24	Coloplast Saline Filled Testicular Prosthesis	<a href="#">Health Canada</a>	54489	Type II	Coloplast (Hong Kong) Ltd	3628 7428
2010/05/25	GS Elektromedizinische Geräte G. Stemple GmbH Corpuls3 Defibrillator / Monitoring System pertaining to software 1.4.0, 1.5.0 and 1.6.0	<a href="#">MHRA</a>	2010/004/009/081/009	FSCA	N.A.	N.A.
2010/05/25	James Spencer Ventnor shower chairs	<a href="#">MHRA</a>	2009/007/029/401/005	FSCA	N.A.	N.A.
2010/05/27	Stryker OIC PEEK Cage (Product Ref: 6731304S, Lot Ref: 52952)	<a href="#">MHRA</a>	2010/005/018/081/005 (RA 2010-016)	FSCA	Stryker China Ltd.	2814 7463
2010/05/28	Novartis Chiron RIBA HCV 3.0 SIA (Product code: 930600, Lot YA1209, YA1691, YA1758, YA1804, 98290, 98743)	<a href="#">MHRA</a>	2010/005/018/081/021	FSCA	Ortho Clinical Diagnostics	2737 5504
2010/05/28	Veridex (JNJ) CellTracks AutoPrep System (Product code: 9541)	<a href="#">MHRA</a>	2010/005/025/081/001 (CL10-156_EU)	FSCA	Ortho Clinical Diagnostics	2737 5504
2010/05/28	Stryker AVS (Adaptive Vertebral PEEK Spacer) TL Spacer Trial 7-18 (Product Ref: from 48389407 to 48389418)	<a href="#">MHRA</a>	2010/005/021/081/021 & 2010/005/010/291/002 (RA 2009-224)	FSCA	Stryker China Ltd.	2814 7463
2010/05/31	Talley G3 Quattro Plus mattresses, 99-01-05-306 (from April 2006) fitted to Linet Eleganza Smart bed frames with 3/4 (three quarter) side rails.	<a href="#">MHRA</a>	2009/006/004/401/010	FSCA	N.A.	N.A.
2010/05/31	Medtronic LIFEPAK 20 and LIFEPAK 20e Defibrillator/Monitors	Medtronic International Ltd.	N.A.	Firm Initiated Field Action	Medtronic International Ltd.	2919 1300

## Monthly Summary of Medical Device Safety Alerts - April 2010

\*Note: FDA = Food and Drug Administration, United States of America; MHRA = Medicines and Healthcare products Regulatory Agency, United Kingdom; Health Canada = Health Canada, Canada

Date of Issue (YYYY/MM/DD)	Description of Product	Source of Information*	Reference No. by Source	Alert Type by Source	Local Agent	Agent Contact Telephone No.
2010/04/07	Covidien Auto Suture ProTack Fixation 5 mm Product Catalogue # 174006.	<a href="#">FDA</a>	Z-1157-2010	Class II	Covidien	3157 7220
2010/04/07	Elekta Leksell Gamma Knife Perfexion, Article #715000.	<a href="#">FDA</a>	Z-1158-2010	Class II	Elekta Ltd.	2891 2208
2010/04/07	Toshiba Aplio 50 (SSA-700A; software version 5.5r002); Aplio 80 (SSA-770A; software version 5.5r002), Xario (SSA-660A; software version 1.0 r002).	<a href="#">FDA</a>	-1171-2010 to Z-1173-201	Class II	Sanko Medical Systems (HK) LTD	23840688
2010/04/07	Advanced Orthopaedic Solutions (AOS) Trochanteric Nail (Product Part Number: 1034-170, 1034-200, 1036-170, 1036-200, 1037-200, 1038-200, 1040-170, 1040-200, 1041-170, 1041-200, 1042-200, 1043-200).	<a href="#">FDA</a>	-1181-2010 to Z-1192-201	Class II	N.A.	N.A.
2010/04/07	Medrad Avanta Fluid Management Injection System, Avanta Multi-Patient Disposable Set (MPAT) High Pressure Check Valve, Catalog number AVA 500 MPAT, Material number 3018231.	<a href="#">FDA</a>	Z-1199-2010	Class II	Prism Technologies Ltd.	2786 3233
2010/04/08	Intuitive Surgical Da Vinci S Surgical System IS2000	<a href="#">FDA</a>	Z-1161-2010	Class II	Chindex	N.A.
2010/04/08	Olympus Trocar Spikes, Model numbers: A5821, A5948, A5949, WA58341L, and WA58343L	<a href="#">FDA</a>	Z-1163-2010	Class II	Olympus Hong Kong and China Ltd	2170 5678
2010/04/08	UROLOGIX CTC Advance" Standard Microwave Catheter (3.0-5.0 cm), CTC Advance" Long Microwave Catheter (4.5+ cm), CTC Advance" Short Microwave Catheter (2.5 -3.5 cm), RTU Plus Balloon, and RTU Plus Handle	<a href="#">FDA</a>	Z-1174-2010	Class II	N.A.	N.A.
2010/04/08	Pelton & Crane Chairman 5000, Spirit 1500, Spirit 1800, Spirit 2000 and Spirit 3000 Dental Chairs with magnetic headrests. (Model # L5, SP15, SP18, SP20, SP30)	<a href="#">FDA</a>	-1179-2010 to Z-1180-201	Class II	N.A.	N.A.
2010/04/08	Encompass Therapeutic Support Systems AccuMax Quantum Complete (Model CU3/CU4)	<a href="#">FDA</a>	Z-1216-2010	Class II	N.A.	N.A.
2010/04/08	Ulti Med Live Better 1cc, 31 gauge x 5/16 inch U-100 Insulin Syringe short needle	<a href="#">FDA</a>	Z-1217-2010	Class II	N.A.	N.A.
2010/04/08	K C Pharmaceuticals Publix Sterile Preserved Saline Solution SKU#041415-003767, Top Care Sterile Preserved Saline Solution SKU#0036800-16040, Safeway Sterile Preserved Saline Solution SKU#321130-700707, Hannaford Sterile Preserved Saline Solution SKU#041268-029297, Kroger Sterile Preserved Saline Solution SKU#011110-385956, CVS Sterile Preserved Saline Solution SKU#050428-253793	<a href="#">FDA</a>	-1222-2010 to Z-1227-201	Class II	N.A.	N.A.
2010/04/08	Trinity Biotech Auto D-Dimer control, level 2 (Product code: A8096, Lot no: T159027, T090006)	<a href="#">MHRA</a>	2010/003/026/081/017	FSCA	N.A.	N.A.
2010/04/08	Beckman Coulter Access Estradiol Reagent Kit (REF 33540, Lot 913016, 915171, 917766)	<a href="#">MHRA</a>	2010/003/025/601/006	FSCA	Beckman Coulter Hong Kong Ltd	2240 6150
2010/04/08	Zimmer Trauma Ti - interference screws and dynamic hip screw plates	<a href="#">MHRA</a>	2010/003/018/291/003	FSCA	Zimmer PTE Ltd. (Hong Kong branch)	2992 0968

2010/04/08	Zimmer Continuum Acetabular Systems Shell Inserter Adapter with and without rotational control (part no. 00-8790-003-00, 00-8790-003-10)	<a href="#">MHRA</a>	2010/003/023/081/005	FSCA	Zimmer PTE Ltd. (Hong Kong branch)	2992 0968
2010/04/08	Zimmer Universal clamp instrument (part no. SN2027-1-02200, SN2027-1-02201)	<a href="#">MHRA</a>	2010/002/005/081/010	FSCA	Zimmer PTE Ltd. (Hong Kong branch)	2992 0968
2010/04/08	Siemens Healthcare Diagnostics Chloride electrode (REF 07097504, PN 073-0049-01) used with ADVIA Chemistry Systems 1200, 1650, 1800, 2400	<a href="#">MHRA</a>	2010/003/016/291/017	FSCA	Siemens Healthcare Diagnostic Limited	2810 7533
2010/04/09	Marshall Visionary Single Use Laryngeal Airway Device Size 1.5, Size 2, Size 3, Size 4 and Size 5 (product code: 707150, 707200, 707300, 707400, 707500)	<a href="#">MHRA</a>	2010/003/026/081/016	FSCA	N.A.	N.A.
2010/04/09	ConMed Goldline Rocker Switch Pencil (Cat. # 130301A, 130304A, 130307A, 130319A, 130327A, 130337A, 130339A, 131307A, 131319A, 131327A, 60-6829-001A, 60-6829-005A)	<a href="#">MHRA</a>	2010/003/031/291/009	FSCA	N.A.	N.A.
2010/04/12	ArjoHuntleigh Minstrel patient hoist (non scale type)	<a href="#">MHRA</a>	2009/011/003/401/001	FSCA	Arjo Huntleigh (Hong Kong) Ltd.	2508 1416
2010/04/12	Smith & Nephew IV Cap/Obturator (Product code: 72201846, lot 50282872 & 50304125)	<a href="#">MHRA</a>	2010/003/030/291/007	FSCA	N.A.	N.A.
2010/04/12	Madrimed (W&H) VINCI 600Ss (Ref: 17306010)	<a href="#">MHRA</a>	2010/003/030/291/013	FSCA	N.A.	N.A.
2010/04/13	BrainLAB iPlan RT Dose software versions 4.0, 4.1.0 and 4.1.1 (Model No. 21213C, 21213D and 21213E) used with Monte Carlo Dose Algorithm 23071	BrainLAB Ltd.	10-03-01.ALV.2	m Initiated Field Act	BrainLAB Ltd	2417 1881
2010/04/14	Stryker Crossfire Consoles (Product Ref: 0475000000)	<a href="#">MHRA</a>	2010/004/008/081/018	FSCA	Stryker China Ltd	2518 6915
2010/04/14	Abbott CELL-DYN Emerald System (List no. 09H39-01)	<a href="#">MHRA</a>	2010/004/002/601/002	FSCA	Abbott Laboratories LTD.	2593 2211
2010/04/15	Stryker Dual Irrigation Adaptor (Product Ref: 250-070-419)	<a href="#">MHRA</a>	2010/003/024/081/021	FSCA	Stryker China Ltd	2518 6915
2010/04/15	Kimal Long Term Haemodialysis Catheters	<a href="#">MHRA</a>	2010/002/010/401/007	FSCA	N.A.	N.A.
2010/04/15	American Medical Systems GreenLight PV Fiber Guard Assembly 0126-7300	<a href="#">MHRA</a>	2010/003/024/081/005	FSCA	N.A.	N.A.
2010/04/15	Fresenius Medical Care Disinfection block (spare part) for 5008 & 5008S dialysis system	<a href="#">MHRA</a>	2010/004/008/081/015	FSCA	Fresenius Medical Care Hong Kong Limited	2583 0813
2010/04/15	Respironics A) Model 860 Transcutaneous CO2/O2 Monitor System B) Capnogard Model 1265 End Tidal Monitor C) End Tidal Monitor System Cosmo 7100 D) Cosmo Plus Model 8100 (Model : A) 6590-00, U6590-00 B) 5555-00, U5555-00 C) 5758-00 D) 6758-00)	<a href="#">Health Canada</a>	52213	Type II	Celki Medical Company	2332 3366
2010/04/15	Newport Medical Instruments e360 Ventilator	<a href="#">Health Canada</a>	52740	Type II	N.A.	N.A.

2010/04/15	Hospira A) Symbiq One-Channel Infuser B) Symbiq Two-Channel Infuser (Model : A) 16026, B) 16027)	<a href="#">Health Canada</a>	53355	Type II	Hospira Limited	2898 2886
2010/04/15	Bomimed Reusable Fiber Optic LED Medium Laryngoscope Handle	<a href="#">Health Canada</a>	53524	Type II	N.A.	N.A.
2010/04/15	HILL-ROM Excel Care ES Bariatric Bed (Model : P610B)	<a href="#">Health Canada</a>	53527	Type II	N.A.	N.A.
2010/04/15	Linvatec Corporation Video Carts & Replacement Cord Reel (Model : VP6501, VP6502, VP6504, VP6547, VP8500)	<a href="#">Health Canada</a>	53530	Type II	N.A.	N.A.
2010/04/15	Vital Images Vitrea 5.1 (Model : VPMC-11725)	<a href="#">Health Canada</a>	53571	Type II	N.A.	N.A.
2010/04/15	Toshiba Aquilion 64 System With Optional Software (Model : TSX-101A/H)	<a href="#">Health Canada</a>	53582	Type II	Sanko Medical Systems (HK) LTD	23840688
2010/04/15	Baxter A) Colleague Volumetric Infusion Pump B) Colleague 3 Volumetric Infusion Pump C) Colleague Guardian CXE Color Pump D) Colleague Guardian 3 CXE Color Pump E) French Colleague CXE Volumetric Pump F) French Colleague 3 CXE Volumetric Pump (Model : A) 2M8151, 2M8151KL, 2M8161, 2M8161L, 2M8161LU, DNM8151, DNM8151L B) 2M8153, 2M8163, 2M8163LU, DNM8153, DNM8153L C) 2M9161, 2M9161L D) 2M9163, 2M9163L, 2M9163LU E) DNM9161, DNM9161L F) DNM9163, DNM9163L)	<a href="#">Health Canada</a>	53616	Type II	Baxter Healthcare Ltd	2807 8555
2010/04/15	Biomet Microfixation 1.5mm Bone Screw (Model : 91-1504, 95-1504)	<a href="#">Health Canada</a>	53651	Type II	Swedish Trading Co., Ltd	2953 5111
2010/04/15	Precision Medical Flow Selector (Model : PM1000)	<a href="#">Health Canada</a>	53663	Type I	N.A.	N.A.
2010/04/15	Picis A) Caresuite Anesthesia Manager B) Caresuite PACU Manager C) Caresuite Critical Care Manager (Model : A) 4220, B) 4245, C) 1110)	<a href="#">Health Canada</a>	53683	Type II	N.A.	N.A.
2010/04/15	Animas A) Animas 2020 Insulin Pump B) OneTouch Ping Insulin Pump (Model : A) 100-380-51, 100-381-51, 100-382-51, 100-384-51, 100-385-51, 200-260-51, 200-261-51, 200-262-51, 200-263-51, 200-264-51, 200-265-51, 200-370-00, 200-371-00, 200-372-00, 200-374-00, 200-375-00 B) 100-420-51, 100-421-51, 100-422-51, 100-424-51, 100-425-51, 100-430-51, 100-431-51, 100-432-51, 100-434-51, 100-435-51)	<a href="#">Health Canada</a>	53695	Type I	Johnson & Johnson Medical (HK)	2738 6027
2010/04/16	Philips DigitalDiagnost General radiographic examinations, BuckyDiagnost General Radiography and Tomography, EasyDiagnost Multi-functional R/F systems	<a href="#">FDA</a>	-0847-2010 to Z-0849-201	Class II	Philips Electronic Hong Kong Ltd	2821 5480

2010/04/16	CareFusion Cardinal Health EnVe Ventilator Cat # 19250-001.	<a href="#">FDA</a>	Z-0857-2010	Class II	CareFusion Hong Kong Ltd.	2891 8730
2010/04/16	Bard Access Systems Huber Plus Non-Coring Needle Safety Infusion Set, REF 011901NY, 011901	<a href="#">FDA</a>	-0861-2010 to Z-0862-201	Class II	Senrex International Ltd.	2311 8938
2010/04/16	Integra LifeSciences Qwix 4.3mm Stabilization Screws (Part Number: 111432SND, 111434SND)	<a href="#">FDA</a>	-1253-2010 to Z-1254-201	Class II	N.A.	N.A.
2010/04/16	Encore Medical Foundation Knee System, Patella Trial, 26 mm, part number 802-01-019.	<a href="#">FDA</a>	Z-1255-2010	Class II	N.A.	N.A.
2010/04/16	Siemens Axiom Artis Systems Operating with VB22, VB23, VB30, and VB31. Model number 5917054, 7008605, 7412807, 7413078, 7555357, 7555365, 7555373, and 7728392.	<a href="#">FDA</a>	Z-1312-2010	Class II	Siemens Healthcare Diagnostic Limited	2810 7533
2010/04/16	Mindray Datascope AS3000 Anesthesia System (Product numbers 0998-00-3024-01).	<a href="#">FDA</a>	Z-1313-2010	Class II	MR Holdings (HK) Limited	
2010/04/16	Orthofix Xcaliber meta-diaphyseal kit with dynamic compression-distraction unit	<a href="#">MHRA</a>	2010/002/023/081/021	FSCA	N.A.	N.A.
2010/04/16	Philips Diagnost 76, EasyDiagnost and EasyDiagnost Digital Systems	Philips Electronic Hong	FSN-70600049	Firm Initiated Field Action	Philips Electronic Hong Kong Ltd	2821 5480
2010/04/16	Medtronic U-CLIP V100D Approximation Device	Medtronic	N.A.	Firm Initiated Field Action	Medtronic International, Ltd.	2919 1300
2010/04/10	Siemens AXIOM Artis	<a href="#">MHRA</a>	2010/003/026/081/006	FSCA	Siemens Healthcare Diagnostic Limited	2810 7533
2010/04/10	Randox Laboratories CH203 RX Monza	<a href="#">MHRA</a>	2009/011/009/601/001	FSCA	Randox Laboratories Hong Kong	3595 0515
2010/04/10	Edwards Lifesciences Ascendra Balloon Catheter Loader Assembly (Model No. 9100BCL23 and Model No. 9100BCL26)	<a href="#">MHRA</a>	2010/004/008/081/007	FSCA	N.A.	N.A.
2010/04/10	Smith & Nephew PERI-LOC 3.5mm X14mm Self Tapping Non Locking Cortex Screw - Product Code 71804014	<a href="#">MHRA</a>	2010/004/001/601/003	FSCA	Smith & Nephew LTD	2648 7700
2010/04/20	Edwards Lifesciences NovaFlex Delivery System (Models 9350FS23 & 9350FS26)	<a href="#">MHRA</a>	2010/004/013/291/019	FSCA	N.A.	N.A.
2010/04/20	Immunodiagnostic Systems IDS ostase BAP ELISA, cat AC-20F1, lot 5117	<a href="#">MHRA</a>	2010/004/012/291/005	FSCA	N.A.	N.A.
2010/04/20	Cyberonics VNS Therapy Model 250 Programming Software (version 7.1) for demipulse and demipulse duo generators	<a href="#">MHRA</a>	2010/004/008/081/020	FSCA	N.A.	N.A.
2010/04/20	Draeger Sola 300 examination lights installed between 2001 and 2003	Draeger Medical Hong Kong Ltd.	N.A.	Firm Initiated Field Act	Draeger Medical Hong Kong Ltd.	2877 3077
2010/04/21	Covidien Shiley tracheostomy products (lot no. in the range of 0810XXXXXX to 0908XXXXXX)	<a href="#">MHRA</a>	2009/009/023/401/009	FSCA	Tyco Healthcare (HKSAR) Ltd.	2574 3251
2010/04/21	Boston Scientific Back-up Meier Steerable Guidewire RVTF	Boston Scientific Hong Kong Ltd	N.A.	Firm Initiated Field Action	Boston Scientific Hong Kong Ltd	2960 7136
2010/04/21	Inion CPS Biodegradable Fixation System and CPS Baby Biodegradable Fixation System (Model Nos. PLT-1000 to PLT-1062, SCR-1200 to SCR-2225, PCK-6001 to PCK-6101)	Inion Oy	N.A.	Firm Initiated Field Action	Minton Supplies Company	2271 7709
2010/04/22	International Technidyne Corporation (ITC) Hemochron Signature Elite (serial no.: SE2830 to SE2854 and SE2880 to SE4789)	<a href="#">MHRA</a>	2010/004/015/291/003	FSCA	N.A.	N.A.



2010/04/22	Beckman Coulter Integrated UniCel DxC 600i/660i/680i/860i/880i Synchron Systems (with serial numbers <2760) Software version 4.9 build 01 (REF: A84500, A86646)	<a href="#">MHRA</a>	2010/003/002/601/008	FSCA	Beckman Coulter Hong Kong Ltd	2240 6150
2010/04/23	William Cook Wayne Pneumothorax Sets or Trays (Global product no. G09922, G44035, G11183, G07910, G11182, G12032)	<a href="#">MHRA</a>	2010/003/017/291/020	FSCA	AR Burkill & Sons (HK) Ltd	2541 1041
2010/04/23	Welch Allyn CP200 (Electrocardiograph with optional Spirometry)	<a href="#">MHRA</a>	2010/004/020/291/002	FSCA	N.A.	N.A.
2010/04/23	Stryker Howmedica Restoration ADM Trial Cup Holder (Catalog number: 1235-0-000).	<a href="#">FDA</a>	Z-1201-2010	Class II	N.A.	N.A.
2010/04/23	Elekta Leksell Gamma Knife Perfexion, Product Number: 715000. (Reason: Frame Adaptor)	<a href="#">FDA</a>	Z-1232-2010	Class II	Elekta Ltd.	2891 2208
2010/04/23	Elekta Leksell Gamma Knife (code: LGK 4203, LGK 4309, LGK 4333, LGK 4343 and LGK 4354)	<a href="#">FDA</a>	Z-1236-2010	Class II	Elekta Ltd.	2891 2208
2010/04/23	Agendia MammaPrint, Catalog Numbers MP01, MP US version 03.	<a href="#">FDA</a>	Z-1321-2010	Class II	N.A.	N.A.
2010/04/23	Baxter 1550 Single Patient System Hemodialysis Machines; product codes 5M5538, 5M5538R, 5M5575, 5M5551 and 5M5551R.	<a href="#">FDA</a>	Z-1322-2010	Class II	Baxter Healthcare Ltd.	2807 8555
2010/04/23	Circulatory Technology Bigger Better-Bladder, Catalog Number BBB38 (with 3/8 inch ID tubing).	<a href="#">FDA</a>	Z-1323-2010	Class II	N.A.	N.A.
2010/04/23	GE Centricity PACS-IW software & GE Centricity Web Diagnostic 1.0 (WebDX) software (version 3.x & 3.7.7.x)	<a href="#">FDA</a>	-1394-2010 to Z-1395-201	Class II	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/04/23	Mindray SmarTemp Probe Covers for use with the Accutorr V Monitor, DPM3 Monitor, VS-800 Monitor (model ST010)	<a href="#">FDA</a>	-1396-2010 to Z-1398-201	Class II	MR Holdings (HK) Limited	N.A.
2010/04/23	Orthohelix Surgical Designs Quick Connect Adapter Model #CSS-QA-Adapter MaxTorque(R) Maxtorque Quick, Mat: 17-4PH.	<a href="#">FDA</a>	Z-1399-2010	Class II	N.A.	N.A.
2010/04/23	Boston Scientific Bionic NAVIGATOR Clinician Programmer Model Number SC-7150-4.	<a href="#">FDA</a>	Z-1409-2010	Class II	Boston Scientific Hong Kong Ltd	2960 7136
2010/04/23	Siemens Syngo Imaging XS model number 10496279. The intended use: image processing radiological.	<a href="#">FDA</a>	Z-1423-2010	Class II	Siemens Healthcare Diagnostic Limited	2810 7533
2010/04/26	Covidien Shiley tracheostomy products (lot no. in the range of 0810XXXXXX to 0908XXXXXX); Custom/Specialty Shiley tracheostomy tubes (lot no. in the range of 0904XXXXXX to 0912XXXXXX)	<a href="#">FDA</a>	N.A.	Press Release	Tyco Healthcare (HKSAR) Ltd.	2574 3251
2010/04/26	Ethicon Vicryl Rapide* (Polyglactin 910) Suture	Johnson & Johnson	N.A.	Firm Initiated Field Action	Johnson & Johnson Medical (HK)	2738 6027
2010/04/26	Welch Allyn Illuminated sigmoidoscope and anoscope systems and accessories	<a href="#">MHRA</a>	2009/012/008/081/012	FSCA	N.A.	N.A.
2010/04/26	Siemens Stratus CS STAT Fluorometric Analyzer	<a href="#">MHRA</a>	2010/004/021/081/010	FSCA	Siemens Healthcare Diagnostic Limited	2810 7533
2010/04/27	Medtronic Vascular Cannula and Catheters : Catheter Introducer - Input TS and PS Introducer Sets with Puncture Needle (Model : 070A11)	<a href="#">MHRA</a>	2010/003/015/291/001	FSCA	Medtronic International, Ltd.	2919 1300
2010/04/27	Invitrogen IVDs, genetic testing : Nucleic Acid - Res Unitray, B High Res ASG, B22 Unitray and B22 ASG	<a href="#">MHRA</a>	2010/004/013/291/010	FSCA	Invitrogen Hong Kong Limited	2407 8450
2010/04/27	Abbott IVDs, Clinical Chemistry : Murex HIV 1.2.O - 9E25-02, batches L325710 and L325810	<a href="#">MHRA</a>	2010/004/020/601/001	FSCA	Abbott Laboratories LTD.	2593 2211
2010/04/28	BD Visitec EdgeAhead MVR Knife 0.90mm (20G), REF 585230, Lot 9202221	<a href="#">MHRA</a>	2010/004/021/081/006	FSCA	BD	2575 8668

2010/04/28	Cardiac Science Powerheart 9300A, 9300C, 9300D, 9300E, 9300P, 9390A, 9390E; CardioVive 92531, 92532, 92533; Nihon Kohden 9200G, 9231; and GE Responder 2019198, 2023440 External Defibrillators	<a href="#">FDA</a>	N.A.	News Release	N.A.	N.A.
2010/04/28	Medtronic A) HMS System - Instrument, B) HMS System - Test Cartridges & Controls	<a href="#">Health Canada</a>	52320	Type II	Medtronic International, Ltd.	2919 1300
2010/04/28	Arrow International A) Stopcocks, B) Stopcock With Male Luer Lock, C) Stopcock 4-Gang 4-Way Luer Lock, D) 4-Gang Stopcock Manifold, E) 5-Gang Stopcock Manifold, F) Triple Hi Flo 4-way Stopcock With Manifold, G) Double 4-Way Stopcock With Male Luer Lock, H) Hi Flo 3-Way Stopcock With Male Luer Lock, I) 3-Gang 4-Way Hi Flo 9 FR Stockcock, J) Stopcock With Extension, K) Stopcock With Monitoring Line, L) Stopcock Extension With Anesthesia Induction, M) T-Connector With Microbore Extension, N) Microbore IV Extension Set, O) Extension With Anti-Siphon Valve For Syringe, P) IV Set With Double H-F Stopcock 72 HR, Q) Hi-Flo Y Type Blood Pump Set, R) Y Type Positive Pressure Blood Set, S) Triple Anesthesia Induction Valve, T) Monitoring Line Male Extension, U) Hi-Flo Stopcock With Luer-Lock Extension, V) Y Type Positive Pressure Pump Set, W) 4-Gang 4-Way H-F Stopcock Manifold	<a href="#">Health Canada</a>	53437	Type II	Cemma Enterprise Co., Ltd	2412 2310
2010/04/28	Bio-Rad MRSA Select (Model : 63747, 63749)	<a href="#">Health Canada</a>	53591	Type II	Bio-Rad Pacific Ltd.	2789 3300
2010/04/28	Medline Cardiac Procedure Pack (Model : DYNJ31903X)	<a href="#">Health Canada</a>	53612	Type II	N.A.	N.A.
2010/04/28	Stryker Heated Insufflators (Model : 0620-030-407)	<a href="#">Health Canada</a>	53729	Type II	Stryker China Ltd	2518 6915
2010/04/28	Stryker Disposable Strykerprobe (Model : 0250-070-550)	<a href="#">Health Canada</a>	53731	Type II	Stryker China Ltd	2518 6915
2010/04/28	Beckman Coulter A) Access System - Free T4 Assay, B) Unicel DXI 600 Access Immunoassay System -Free T-4 Assay, C) Unicel DXI 800 Access Immunoassay System Free T-4 Assay	<a href="#">Health Canada</a>	53734	Type II	Beckman Coulter Hong Kong Ltd	2240 6150
2010/04/28	Carestream Health A) T MAT L Film, B) T MAT G Film	<a href="#">Health Canada</a>	53792	Type II	Carestream Health Hong Kong Limited	2564 9759
2010/04/28	Zoll E Series BLS Defibrillator	<a href="#">Health Canada</a>	53801	Type II	Suburfarm Investment & Trading Co.	2780 9421
2010/04/28	Synthes Medullary Tube Part (Model : 355.01)	<a href="#">Health Canada</a>	53804	Type II	Synthes (Hong Kong) Ltd	2724 2032
2010/04/28	Stryker Endoscopy Infravision IR Illuminator (Model : 220-180-521)	<a href="#">Health Canada</a>	53805	Type II	Stryker China Ltd	2518 6915
2010/04/28	Howmedica Osteonics Anterior Skim Cutting Guide	<a href="#">Health Canada</a>	53876	Type II	Stryker China Ltd	2518 6915
2010/04/28	Howmedica Osteonics Distal Femoral Resection Guide (Model : 7650-5005)	<a href="#">Health Canada</a>	53907	Type II	Stryker China Ltd	2518 6915
2010/04/28	Howmedica Osteonics Scorpio Punch Thru Tibial Base-Plates	<a href="#">Health Canada</a>	53909	Type II	Stryker China Ltd	2518 6915
2010/04/29	Johnson & Johnson Bioplate Cranial Fixation Sterile Kits	<a href="#">MHRA</a>	2010/003/031/291/008	FSCA	Johnson & Johnson Medical (HK)	2738 6027
2010/04/29	Siemens Medical Solutions 3gAllergy Specific IgE Universal Kit (Model : IMMULITE 2000)	<a href="#">MHRA</a>	2010/004/023/081/019	FSCA	Siemens Healthcare Diagnostic Limited	2810 7533

2010/04/29	Edwards Lifesciences NovaFlex Delivery System (Models 9350FS23 & 9350FS26)	<a href="#">MHRA</a>	2010/004/013/291/018	FSCA	N.A.	N.A.
2010/04/29	Boston Scientific FleximaR Biliary Stent System	Boston Scientific Hong Kong Ltd	N.A.	Firm Initiated Field Action	Boston Scientific Hong Kong Ltd	2960 7136

## Monthly Summary of Medical Device Safety Alerts - March 2010

\*Note: FDA = Food and Drug Administration, United States of America; MHRA = Medicines and Healthcare products Regulatory Agency, United Kingdom; Health Canada = Health Canada, Canada

Date of Issue (YYYY/MM/DD)	Description of Product	Source of Information*	Reference No. by Source	Alert Type by Source	Local Agent	Agent Contact Telephone No.
2010/03/01	StatSpin (IRIS Sample Processing) StatSpin Express 4 Centrifuges (Model #510)	<a href="#">FDA</a>	N.A.	Class I	Vastec Medical Ltd.	2897 1912
2010/03/02	Beckman Coulter Olympus PK7200 Blood Grouping System	<a href="#">MHRA</a>	2010/002/023/081/005	FSCA	Beckman Coulter Hong Kong Ltd	2240 6150
2010/03/02	Siemens Versacell Connectivity With Advia 1800 Systems	<a href="#">MHRA</a>	2010/002/024/081/001	FSCA	Siemens Healthcare Diagnostic Limited	2810 7533
2010/03/03	Hill-Rom ROLKO Monkey Pole equipped with a roller, Type: TGN-R100GR	<a href="#">MHRA</a>	2010/001/005/291/006	FSCA	N.A.	N.A.
2010/03/03	Wassenburg WD440 and Wassenburg WD440-PT endoscope washer disinfectors	<a href="#">MHRA</a>	2010/002/025/081/004	FSCA	N.A.	N.A.
2010/03/03	PML Micrologicals A) Campylobacter CVA Agar B) Campylobacter CCDA-Preston Agar, C) Campylobacter Agar, Blood-Free, D) PEA Agar + 5% Sheep Blood (SB), E) Columbia CNA/Macconkey, F) Sabouraud Liquid	<a href="#">Health Canada</a>	49997	Type II	N.A.	N.A.
2010/03/03	Technidata TD-Synergy software (TD-SYN-01)	<a href="#">Health Canada</a>	52749	Type II	N.A.	N.A.
2010/03/03	Philips Medical Systems A) HeartStart MRx Monitor/Defibrillator, B) HeartStart MRx AC Power Module Kit	<a href="#">Health Canada</a>	52858	Type II	Philips Electronic Hong Kong Ltd	2821 5480
2010/03/03	Wallac OY Lifecycle For Prenatal Screening	<a href="#">Health Canada</a>	52863	Type II	N.A.	N.A.
2010/03/03	Medline Industries Medline Self Sealing Sterilization Pouches	<a href="#">Health Canada</a>	52864	Type II	N.A.	N.A.
2010/03/03	Drive Medical Design A) Economy Dual Channel Tens B) Self-Adhesive Electrodes, C) Neb to Go, D) Deluxe Dual Channel Tens, E) APP Pad, F) Fingertip Pulse Oximeter	<a href="#">Health Canada</a>	52943	Type II	N.A.	N.A.
2010/03/03	Zimmer Nexgen Complete Knee, Stemmed Tibial	<a href="#">Health Canada</a>	52954	Type II	Zimmer PTE Ltd. (Hong Kong branch)	2992 0968
2010/03/03	Smiths Medical Cadd-Solis Infusion Pump-AC Power Cord	<a href="#">Health Canada</a>	52967	Type II	N.A.	N.A.
2010/03/03	Smith & Nephew Wound Management Division EZCARE Negative Pressure Wound Therapy System	<a href="#">Health Canada</a>	53008	Type II	Smith & Nephew LTD	2648 7700
2010/03/03	Whatman 903 Newborn Screening Card	<a href="#">Health Canada</a>	53017	Type II	N.A.	N.A.
2010/03/03	Linvatec A) C-Reamer Cannulated, 9 and 10 mm B) Digit Trap Finger Grasping Device, C) Arthro-Knife Banana Serrated, Straight, D) Arthro-Knife Banana Serrated, Left, E) Arthro-Knife Hook, Straight, F) Arthro-Knife Retro, Straight, G) Arthro-Knife Serrated, Straight Rosette, H) Arthro-Knife Mini Meniscus, Straight, I) Arthro-Knife Serrated, Straight 2-Sided, J) Arthro-Knife Serrated, Straight, Round	<a href="#">Health Canada</a>	53019	Type II	N.A.	N.A.

2010/03/03	Tyco Healthcare Handi-Fil Disposable Syringe Fill Tube	<a href="#">Health Canada</a>	53027	Type II	Tyco Healthcare (HKSAR) LTD	3157 7220
2010/03/03	Olympus A) Olympus Trocar Spikes (Conical Tip), B) Olympus Trocar Spikes (Triangular Tip)	<a href="#">Health Canada</a>	53040	Type II	Medical Systems Division, Olympus Hong Kong and China Limited	2170 5603
2010/03/03	The Laryngeal Mask Company Limited A) LMA Pain Care 3000, B) LMA Pain Care 4200	<a href="#">Health Canada</a>	53106	Type II	N.A.	N.A.
2010/03/03	Wright Medical Technology Advance Tibial Wedge Augment	<a href="#">Health Canada</a>	53128	Type II	N.A.	N.A.
2010/03/04	Merit Medical Systems Endotek Alimaxx-B Uncovered Biliary Stent for Endoscopic Delivery, REF 70129-204, 70129-205, 70129-206, 70129-208, 70129-209, 70129-210	<a href="#">FDA</a>	Z-0801-2010 to Z-0806-2010	Class II	King Health Limited	2481 3787
2010/03/04	Hospira LifeShield Latex-Free Primary SYMBIQ Set, list number 16096-28, LifeShield Latex-free Primary I.V. Set, list number 19689-01	<a href="#">FDA</a>	Z-0808-2010 to Z-0809-2010	Class II	Hospira Limited	2898 2886
2010/03/04	Biomet 3i Locator Restorative Abutment, ILOA002	<a href="#">FDA</a>	Z-0810-2010	Class II	Ositek (HK), Inc. Ltd	3157 1757
2010/03/04	Encore Medical Foundation Knee Revision Baseplate, Part Number 321-01-106	<a href="#">FDA</a>	Z-0826-2010	Class II	N.A.	N.A.
2010/03/04	Gibson Laboratories RambaChrom KPC M/N 11500, RambaChrom VRE M/N 11600	<a href="#">FDA</a>	Z-0827-2010 to Z-0828-2010	Class II	N.A.	N.A.
2010/03/04	Cybernet Systems MedStar Telemedicine System Model 533-210, 533-380, 533-386, 533-381	<a href="#">FDA</a>	Z-0852-2010 to Z-0855-2010	Class II	N.A.	N.A.
2010/03/04	Maquet Cardiovascular EXXCEL Soft Standard Wall EPTFE Vascular Graft, Product Code: M002004910580	<a href="#">FDA</a>	Z-0866-2010	Class II	Maquet Hong Kong Ltd.	2393 9511
2010/03/04	Beckman Coulter Access progesterone reagent kit (REF 33550) and Access cortisol reagent kits (REF 33600)	<a href="#">MHRA</a>	2010/002/022/601/001	FSCA	Beckman Coulter Hong Kong Ltd	2240 6150
2010/03/04	Novacare Alternating pressure mattress overlay (ASX)	<a href="#">MHRA</a>	2009/011/012/081/004	FSCA	N.A.	N.A.
2010/03/05	Synthes compression connecting screw (Part number: 358.610)	<a href="#">MHRA</a>	2010/003/001/081/015	FSCA	Synthes (Hong Kong) Ltd	2724 2032
2010/03/05	Emergo (Abbott) i-STAT EC8+ cartridges 06F04-02, i-STAT 6+ cartridges 06F05-02, i-STAT EC4+ cartridges 06F07-02, i-STAT E3+ cartridges 06F08-02, i-STAT CHEM8+ cartridges 03M88-02, i-STAT CG8+ cartridges 03M86-02, i-STAT EG7+ cartridges 06F01-02, i-STAT EG6+ cartridges 06F02-02	<a href="#">MHRA</a>	2010/002/017/081/005	FSCA	Bio-Asia Diagnostics Co. Ltd.	2787 0906
2010/03/05	Sysmex CA-1500 coagulation analyser (art. No. 97347516, 98306210, 99324211, 99324815)	<a href="#">MHRA</a>	2010/002/009/081/005	FSCA	N.A.	N.A.
2010/03/05	Newdeal Right Hallu-C plates size 1-40 mm non sterile, Ref no. 117340, Lot no. EF44	<a href="#">MHRA</a>	2010/002/023/081/013	FSCA	N.A.	N.A.
2010/03/05	Newdeal QWIX screws 4.3mm diameter, Cat. no. 111432S and 111434S	<a href="#">MHRA</a>	2010/002/008/081/016	FSCA	N.A.	N.A.

2010/03/05	Physio-Control LIFEPAK 15	Medtronic International, Ltd.	N.A.	Firm Initiated Field Action	Medtronic International, Ltd.	2919 1300
2010/03/05	Philips Healthcare HeartStart MRx Monitor/Defibrillator	Philips Electronic Hong Kong Ltd	FSN86100090A	Firm Initiated Field Action	Philips Electronic Hong Kong Ltd	2821 5480
2010/03/08	Thomas Medical Products Transseptal Sheath Introducer Kit (also under the trade names: HeartSpan, CHANNEL FX, Torflex, Braided Guiding Introducer Kit)	<a href="#">FDA</a>	N.A.	Class I	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/03/08	Eurovema Alvema ITO pushchair	<a href="#">MHRA</a>	2010/001/005/081/002	FSCA	N.A.	N.A.
2010/03/08	SmitCare Ringwood Bathseat, Product code SNE343	<a href="#">MHRA</a>	2009/008/026/401/002	FSCA	N.A.	N.A.
2010/03/08	Invitrogen All set gold and SSP unitray low resolution kits (product code: 7800010, 7800110, 54340D, 7810010, 7810110, 54350D, 7850010, 7850110, 54360D, 7870010, 7870110, 54320D)	<a href="#">MHRA</a>	2010/003/001/081/006	FSCA	Invitrogen Hong Kong Limited	2407 8450
2010/03/08	Stryker Implant Extraction Set Brochure / Guide B1000057 (Extraction Hook Large)	<a href="#">MHRA</a>	2010/002/009/081/002	FSCA	Stryker China Ltd	2522 6915
2010/03/09	Unipath Clearview hCG Combo pregnancy test for professional use (Product code: 506760)	<a href="#">MHRA</a>	MDA/2010/016	MDA	N.A.	N.A.
2010/03/09	Steris Harmony LA, LC 500 and LA 700 Surgical Lighting and Media System	<a href="#">MHRA</a>	2010/003/002/081/008	FSCA	Swedish Trading Co. Ltd.	6199 0634
2010/03/09	Naniwa Rubber Tubing Set for Blood Purification (Model: DFPP-SGL, Lot: 980425, 992624)	<a href="#">MHRA</a>	2010/003/005/081/021	FSCA	N.A.	N.A.
2010/03/09	Aidapt VR231 Lenham adjustable height commode (manufactured in November 2008)	<a href="#">MHRA</a>	2010/002/001/401/017	FSCA	N.A.	N.A.
2010/03/09	Farla Medical Disposable Long Scissors (Product code: 4003201, batch no. 091003)	<a href="#">MHRA</a>	2010/003/001/081/002	FSCA	N.A.	N.A.
2010/03/09	Cardiac Science Powerheart 9300A, 9300C, 9300D, 9300E, 9300P, 9390A, 9390E; CardioVive 92531, 92532, 92533; NK 9200G, 9231; Responder 2019198 and 2023440	<a href="#">FDA</a>	N.A.	Class I	Pacific Medical Systems Limited	2108 4005
2010/03/10	Balt Extrusion Silk intracranial stent	<a href="#">MHRA</a>	2009/012/003/401/010	FSCA	N.A.	N.A.
2010/03/10	Biomet M2A-magnum modular heads - size 44mm part #157444 (batch #1793089)	<a href="#">MHRA</a>	2010/003/004/081/017	FSCA	N.A.	N.A.
2010/03/10	Biodiagnostics MPO QuickCard lot # M683	<a href="#">MHRA</a>	2010/002/024/601/002	FSCA	N.A.	N.A.

2010/03/10	Abbott Diagnostics ARCHITECT HAVAb IgM reagent (List no. 6C30-20 and 6C30-25)	<a href="#">MHRA</a>	2010/003/002/601/007	FSCA	Abbott Laboratories LTD.	2593 2211
2010/03/11	BD GeneOhm Cdiff Assay, Cat. No. 441401	BD	N.A.	Firm Initiated Field Action	BD	2575 8668
2010/03/11	Stryker Eye Surgery Stretcher 1069 / Stryker Eye Surgery Stretcher 1079 (Product No. 1069000000 & 1079000000)	<a href="#">MHRA</a>	2010/003/004/081/010	FSCA	Stryker China Ltd	2522 6915
2010/03/11	BHM Medical Cricket-3, Cypress-2, Ergolift, Ergolift 600, Ergostand, Explorer, Explorer 600, Graduate, Junior, Medilifter-IV, Mezzo, Ministand, ML-4, Primo, Sherpa, SSL-2, Standup, Trekker and Xtreme hoists and standing aids	<a href="#">MHRA</a>	MDA/2010/022	MDA	Arjo Huntleigh (Hong Kong) Ltd.	2508 1416
2010/03/11	Abiomed AB5000 Circulatory Support System (Cat. No. 0015-0000, Serial No. AD5001 through AD5496 except AD5006 & AD5018)	<a href="#">FDA</a>	N.A.	Class I	N.A.	N.A.
2010/03/11	Beckman Coulter UniCel DxC Synchron Clinical System - Ion Selective Electrode (ISE) Flow Cell. UniCel DxC 600 (PN No. A10405), 600 PRO (A11810), 600i (A27318), 800 (A11816), 800 PRO (A11812), 880i (A59102), 680i (A64903), 660i (A64871), 860i (A64935)	<a href="#">FDA</a>	N.A.	Class I	Beckman Coulter Hong Kong Ltd	2240 6150
2010/03/12	Newdeal IPP on interphalangeal implant (Ref no. 230 001S, 230 002S)	<a href="#">MHRA</a>	2009/012/004/081/003	FSCA	N.A.	N.A.
2010/03/12	Beckman Coulter LH 500 Analyzer, LH 750 Analyzer, LH 780 Analyzer, GENS Analyzer, UniCel DxH 800 Coulter Cellular Analysis System	<a href="#">MHRA</a>	2010/002/018/601/001	FSCA	Beckman Coulter Hong Kong Ltd	2240 6150
2010/03/12	Biodiagnostics PR3 ANCA Serine proteinase 3 QuickCard, Part no. CS014, CS014A, Batch no. M695	<a href="#">MHRA</a>	2010/001/028/601/002	FSCA	N.A.	N.A.
2010/03/12	Baylis Medical Torflex Transseptal Guiding Sheath (Model no. TF8-38-62-S, Lot no. S21244, S21903, S21940, S22739, and S22739X1)	<a href="#">FDA</a>	N.A.	Class I	N.A.	N.A.
2010/03/15	Radiometer ABL505/555, EML105, ABL600, ABL700 Series, ABL800 Flex And ABL800 Basic Blood Gas Analyser	<a href="#">MHRA</a>	2010/002/002/081/018	FSCA	N.A.	N.A.
2010/03/15	ThermoFisher Scientific Oxoid Ready Poured Plate, Yersinia Agar (CIN Medium), PO0287A, lot number 1118247	<a href="#">MHRA</a>	2010/003/005/601/002	FSCA	N.A.	N.A.
2010/03/15	DePuy (JNJ) ASR Articular Surface Replacement and ASR XI Monoblock Metal-On-Metal System	<a href="#">MHRA</a>	2010/003/009/081/036	FSCA	Johnson & Johnson Medical (HK)	2738 6027
2010/03/16	Micromedical Technologies Aquastar Water Caloric Irrigator	<a href="#">Health Canada</a>	52635	Type II	N.A.	N.A.
2010/03/16	Advanced Meditech International A) CH-HI Ultrafyn Reusable Thermal Cautery, B) CT-2121 Disposable Thermal Cautery Tips	<a href="#">Health Canada</a>	52942	Type II	N.A.	N.A.
2010/03/16	Siemens Medical Solutions Artiste MV System	<a href="#">Health Canada</a>	53047	Type II	Siemens Healthcare Diagnostic Limited	2810 7533

2010/03/16	Diagnostica Stago A) Staclot LA 20, B) Start 4 NG DSI 115V	<a href="#">Health Canada</a>	53133	Type II	Healthpro Technology Co. Ltd	2575 2028
2010/03/16	Teleflex Arrow Select IV Tubing Sets, Accessories, and Certain Embolectomy Catheters	<a href="#">FDA</a>	N.A.	Press Release	N.A.	N.A.
2010/03/16	Zimmer NextGen Knee Gender Solutions CR-Flex Femoral Component (00-5750-014-01)	<a href="#">FDA</a>	Z-0915-2010	Class II	Zimmer PTE Ltd. (Hong Kong branch)	2992 0968
2010/03/16	Smith & Nephew JOURNEY " UNI TIBIAL BASEPLATE (REF 71422221 through 71422226, 71422231 through 71422248, 71422251 through 71422258, 71422261 through 71422268, 71933296 through 71933303)	<a href="#">FDA</a>	Z-0924-2010 to Z-0967-2010	Class II	Smith & Nephew LTD	2648 7700
2010/03/16	Siemens Healthcare Diagnostics Dimension Vista System BUN Flex Reagent Cartridge, Catalog number K1021	<a href="#">FDA</a>	Z-1017-2010	Class II	Siemens Healthcare Diagnostic Limited	2810 7533
2010/03/16	Smartinfuser (Hsmg, Inc.) PainPump, part numbers P49230, P49220, P49224-D, P49224N, P49230-D and P49234; SmartBlock Pain Management System, Part numbers P49524, P49534, P49624, and P49634	<a href="#">FDA</a>	Z-1021-2010 to Z-1022-2010	Class II	N.A.	N.A.
2010/03/16	Baxa Exacta Mix TPN (total parenteral nutrition) Bag, Model 738, 739, 740	<a href="#">FDA</a>	Z-1030-2010 to Z-1032-2010	Class II	N.A.	N.A.
2010/03/16	GE Healthcare 1011-9000-000 Aisys Anesthesia Machine and Monitor, 1009-9002-000 Avance Anesthesia Machine and Monitor	<a href="#">MHRA</a>	2010/003/009/601/001	FSCA	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/03/16	GE Healthcare Centricity PACS-IW, software version 3.7.3	<a href="#">MHRA</a>	2010/003/009/081/010	FSCA	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/03/16	BrainLAB IMRI OR Power Management / Uninterruptible Power Supply	<a href="#">MHRA</a>	2010/003/009/081/035	FSCA	BrainLAB Ltd	2417 1881
2010/03/16	Invitrogen A High Res SSP Unitray (item code: 4729010, 4729110), AllSet Gold A High Res SSP Kit (item code: 54010D)	<a href="#">MHRA</a>	2010/003/005/081/015	FSCA	Invitrogen Hong Kong Limited	2407 8450
2010/03/16	C.R. Bard/Davol Counterfeit flat sheets of polypropylene surgical mesh labeled with C.R. Bard/Davol brand names (product no. 0112650, 0112660, 0112680, 0112720 Bard Flat Mesh with lot no. 48HVS036, 43APD007, HUSD0629, HURL0336, 43HPD027, 43HPD032, HUSG0540, 43HDP027, HUSE0532, 43LPD507, HUSF0763, 43IOD011, 43IPD038, 43FQD327) are not Bard-manufactured products	<a href="#">FDA</a>	N.A.	Safety Notice	N.A.	N.A.
2010/03/17	Convatec (Unomedical) Unilect ECG Electrodes	<a href="#">MHRA</a>	2010/003/010/291/001	FSCA	N.A.	N.A.
2010/03/17	Nova Biomedical Nova Statstrip Glucose Test Strips (lot no. 0309019249)	<a href="#">MHRA</a>	2010/002/019/601/003	FSCA	N.A.	N.A.
2010/03/17	Newdeal Hallu-C Plate - Size 3-50 mm, Non-Sterile, reference number 117 350 (Lots EF4A and EF4B)	<a href="#">MHRA</a>	2010/002/018/081/015	FSCA	N.A.	N.A.
2010/03/18	Gyrus ACMI Micron Bobbin Vent Tube T, 1.27 mm, Catalog (REF) Number 145281-ENT, Lot Number MH136952	<a href="#">FDA</a>	N.A.	Class I	Olympus Hong Kong and China Ltd	2170 5678



2010/03/18	Medical Action Bundle Kit, using MPS Acacia with Q-Syte BD#385151 (Cat. no. 69946B), Venous Access Tray, using BD Q-Syte Luer Access Split Septum BD #385100 (Cat. no. 69498), Dialysis Kit, using BD Q-Syte Luer Access Split Septum BD #385100 (Cat. no. 57977)	<a href="#">FDA</a>	N.A.	Class I	N.A.	N.A.
2010/03/18	Arrow International (Teleflex Medical) MAC Two Lumen Central Venous Access Kit with ARROWg+ard Blue (R) Access Device (Catalog/Part # ASK-21242-UVA2), Percutaneous Sheath Introducer Kit with ARROWg+ard Blue (R) Sheath (Catalog/Part # ASK-29803-SJH), Multi-Lumen Central Venous Catheterization Kit with Blue Flex- Tip(R), ARROWg+ard Blue PLUS (R) Catheter (Catalog/Part # ASK-42703-SJH), Two-Lumen Central Venous Catheterization Kit with Blue Flex-Tip(R), ARROWg+ard Blue PLUS (R) Catheter (Catalog/Part # ASK-42802-SHB), Multi-Lumen Central Venous Catheterization Kit with Blue Flex-Tip(R), ARROWg+ard Blue PLUS (R) Catheter (Catalog/Part # ASK-45703-SHB), Multi-Lumen Central Venous Catheterization Kit with Blue	<a href="#">FDA</a>	N.A.	Class I	N.A.	N.A.
2010/03/19	Stryker Xia 3 Polyaxial Screw, 8.5mm x 65mm (Catalog number: 482318565)	<a href="#">FDA</a>	Z-0823-2010	Class II	Stryker China Ltd	2519 6915
2010/03/19	Synthes in situ bender / Cutter kit-wide-sterile (Cat. number: 530.512S)	<a href="#">FDA</a>	Z-0825-2010	Class II	Synthes (Hong Kong) Ltd	2724 2032
2010/03/19	Beckman Coulter LH SlideMaker (Part Number 6605633), GEN*S SlideMaker (Part Numbers 6605360)	<a href="#">FDA</a>	Z-0850-2010 to Z-0851-2010	Class II	Beckman Coulter Hong Kong Ltd	2240 6150
2010/03/19	Pointe Scientific Liquid HDL (PEG) Cholesterol Reagent Set (Catalog # H7511-60, H7511-SAM, 7-H7511-30, 8-H7511-30, 3-H-7511-L)	<a href="#">FDA</a>	Z-0859-2010 to Z-0860-2010	Class II	N.A.	N.A.
2010/03/19	Bio-Rad Variant II Turbo Hemoglobin A1c Program, model number 270 2417	<a href="#">FDA</a>	Z-0867-2010	Class II	Bio-Rad Pacific Ltd.	2789 3300
2010/03/19	Polymer Technology Systems Panels Cholesterol test strips for self-testing or professional use with CardioChek analyzers, Catalog # 1711.	<a href="#">FDA</a>	Z-0871-2010	Class II	Ultronics Enterprise Limited	2764 5208
2010/03/19	Stryker Trident Acetabular Hip System Polyethylene Inserts, Triathlon X3 UHMWPE Tibial Inserts and Patellar Components, Scorpio X3 UHMWPE Tibial Inserts and Scorpio X3 UHMWPE Patellar Components	<a href="#">FDA</a>	Z-0909-2010 to Z-0911-2010	Class II	Stryker China Ltd	2519 6915
2010/03/19	Pointe Scientific Uric Acid (Liquid) Reagent Set (Catalog # HU782-246 and HU982-615), Liquid Uric Acid (R1) Reagent Set (Catalog # HU482-R1)	<a href="#">FDA</a>	Z-0912-2010 to Z-0913-2010	Class II	N.A.	N.A.
2010/03/19	Beckman Coulter Access Peristaltic Pump component of: UniCel Dxl 800, UniCel Dxl 600 and UniCel DxC 880i SYNCHRON Access Clinical Systems. (Pump Part Numbers A62712, A62839, A62840, A62841, and A63124) (Instrument Part Numbers: 973100, A30260, and A59102)	<a href="#">FDA</a>	Z-0914-2010	Class II	Beckman Coulter Hong Kong Ltd	2240 6150
2010/03/19	Sybron Dental Specialties Sealapex Express, Part Number: 33639	<a href="#">FDA</a>	Z-0917-2010	Class II	N.A.	N.A.
2010/03/19	Kamiya Biomedical "K-ASSAY CRP (3) Calibrator E". (Catalog number: "KAI-084C")	<a href="#">FDA</a>	Z-0973-2010	Class II	N.A.	N.A.
2010/03/19	Sigma-Aldrich Histopaque-1077 (Ref. 10771), Histopaque-1119 (Ref. 11191)	<a href="#">FDA</a>	Z-0976-2010 to Z-0977-2010	Class II	N.A.	N.A.
2010/03/22	Boston Scientific Clinician Programmer M400 (SC-7150-4) Battery Pack	N.A.	N.A.	Firm Initiated Field Action	Boston Scientific Hong Kong Ltd	2960 7136
2010/03/22	Lifescan (Johnson & Johnson) Onetouch Ultrasmart Meter (Catalogue number 020-890, Lot number V0903003X)	<a href="#">MHRA</a>	2010/001/029/081/007	FSCA	Johnson & Johnson Medical (HK)	2738 6027

2010/03/25	Centurion Medical Products Pump Fill Kit DT10175	<a href="#">FDA</a>	Z-1140-2010	Class I	N.A.	N.A.
2010/03/25	Remel Oxoid CM0225 Brain Heart Infusion IVD	<a href="#">FDA</a>	Z-0979-2010	Class II	Hong Kong South East Chemicals & Instruments	2802 6333
2010/03/25	Pointe Scientific Calcium Reagent, Calcium (CPC) R1 and (CPC) R2 Reagent Set (Cat.# HC902-576, HC902-1000, HC902-SAM-911, HC402-R1, 3-HC902-R1, HC402-R2, 3-HC902-R2	<a href="#">FDA</a>	Z-1041-2010 to Z-1043-2010	Class II	N.A.	N.A.
2010/03/25	Elekta PrecisePLAN 2.15 Treatment Planning System	<a href="#">FDA</a>	Z-1109-2010	Class II	Elekta Ltd.	2891 2208
2010/03/25	Cook Modified Novy Cornual Cannulation Set with clear tip, G17558, REF J-NCS-504070	<a href="#">FDA</a>	Z-1137-2010 to Z-1138-2010	Class II	A.R. Burkill & Sons (Hong Kong) Ltd	2541 1041
2010/03/25	Remel A.C.T. II Sterile Pack Tube, Collection and Transport System, Ref 12402	<a href="#">FDA</a>	Z-1139-2010	Class II	Hong Kong South East Chemicals & Instruments	2802 6333
2010/03/25	ConvaTec (Unomedical) Neutralect Diathermy Cable, Ref code 3508M and 3405M.	<a href="#">FDA</a>	Z-1142-2010	Class II	N.A.	N.A.
2010/03/25	Sybron Dental Specialties Bond-1 Primer/Adhesive	<a href="#">FDA</a>	Z-1150-2010	Class II	N.A.	N.A.
2010/03/25	R.O. Gulden Image Consultant (IC) Software	<a href="#">FDA</a>	Z-1176-2010-2010	Class II	N.A.	N.A.
2010/03/25	Stryker Femoral Sponge REF 206-715, 206-730, 306-563S10, 306-705-000S8, 0306-708-000S4	<a href="#">FDA</a>	Z-1104-2010 to Z-1108-2010	Class II	N.A.	N.A.
2010/03/26	Nucletron Oncentra Brachy	<a href="#">MHRA</a>	2010/003/015/081/003	FSCA	Nucletron Asia Pacific Ltd.	2311 2683 / 2311 2684 / 2311 3025
2010/03/26	Animas (JNJ) 2020 Insulin Pumps	<a href="#">MHRA</a>	2010/003/022/081/014	FSCA	Johnson & Johnson Medical (HK)	2738 6027
2010/03/26	Synthes Awl 2,5 mm with Trocar tip Article Number: 324.111 All Batches	<a href="#">MHRA</a>	2010/003/016/291/010	FSCA	Synthes (Hong Kong) Ltd	2724 2032
2010/03/26	Biotest Medical Diagnostics Seraclone Anti-k (KEL2)	<a href="#">MHRA</a>	2010/003/017/291/018	FSCA	Chong Lap (HK) Co. Ltd.	2736 3078
2010/03/26	Biosite Triage TOX Drug Screen, PN 94400	<a href="#">MHRA</a>	2010/003/015/081/006	FSCA	N.A.	N.A.
2010/03/26	GE Healthcare Innova 2100IQ, 3100IQ and 4100IQ	<a href="#">MHRA</a>	2010/003/019/291/008	FSCA	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/03/26	Trinity Biotech Captia Mumps IgM Kit (product code: 2325950 and 2325960)	<a href="#">MHRA</a>	2010/003/024/081/020	FSCA	N.A.	N.A.
2010/03/26	Fresenius Kabi C.A.T.S. Auto Transfusion System (AT-1 disposables 9005101 and C.A.T.S. machine)	<a href="#">MHRA</a>	2010/003/012/601/004	FSCA	Fresenius Kabi Hong Kong Ltd.	2116 2683
2010/03/29	Siemens Healthcare Diagnostics ADVIA Centaur System version 4.0 (078-A002R02) / ADVIA Centaur XP System version 6.0 (078-A011-03)	<a href="#">MHRA</a>	2010/003/016/291/018	FSCA	Siemens Healthcare Diagnostic Limited	2810 7533
2010/03/29	Beckman Coulter UniCel DxH 800 system	<a href="#">MHRA</a>	2010/003/015/601/001	FSCA	Beckman Coulter Hong Kong Ltd	2240 6150
2010/03/29	Siemens Healthcare Diagnostics Dimension clinical chemistry system Open Well Instability with Lipase (LIP) Flex reagent cartridges (DF55A)	<a href="#">MHRA</a>	2010/003/011/291/009	FSCA	Siemens Healthcare Diagnostic Limited	2810 7533
2010/03/29	Invitrogen Unitray B*52 SSP (472602 and 472612) and AllSet Gold B*51/52 Hi Res SSP (54180D)	<a href="#">MHRA</a>	2010/003/012/291/012	FSCA	Invitrogen Hong Kong Limited	2407 8450
2010/03/29	Becton Dickinson CD7 (M-T701) PE, CD7 (M-T701) FITC, CD7 (M-T701) V450, and CD7 (M-T701) PE-Cy7 (Part no. 332773, 332774, 642916,	<a href="#">MHRA</a>	2010/003/025/081/018	FSCA	Becton Dickinson Asia Ltd.	2575 8668

2010/03/29	Abbott Diagnostics ARCHITECT Anti-HCV Reagents List numbers: 6C37-20, 6C37-25 and 6C37-30	<a href="#">MHRA</a>	2010/003/023/601/001	FSCA	Abbott Laboratories LTD.	2593 2211
2010/03/29	Varian FastPlan Conical Collimator Plans	Varian Medical Systems Pacific Inc.	CP-02191	Firm Initiated Field Action	Varian Medical Systems Pacific Inc.	2724 2836
2010/03/30	Oxoid Antimicrobial Susceptibility Testing Discs Ciprofloxacin 1ug, code CT0623B, lot 843801	<a href="#">MHRA</a>	2010/003/024/601/001	FSCA	Hong Kong South East Chemicals & Instruments	2802 6333
2010/03/30	Lancer Fibro Cleaner Automatic Endoscope Reprocessors FC4	<a href="#">MHRA</a>	2009/009/002/291/012	FSCA	N.A.	N.A.
2010/03/30	Bayer Healthcare 5-second CONTOUR and CONTOUR TS Blood Glucose Monitoring System	<a href="#">MHRA</a>	2010/003/024/601/002	FSCA	Bayer HealthCare Ltd.	28144815/ 28145220
2010/03/30	Abbott Diagnostics Clinical Chemistry Albumin BCG (AlbG), List No. 7D53-21, lot no. 77056HW00, 80051HW00, 83030HW00	<a href="#">MHRA</a>	2010/003/017/601/003	FSCA	Abbott Laboratories LTD.	2593 2211
2010/03/30	DÜRR DENTAL CA 4 Amalgam Separator (Ref: 7805-100-50, 7805-100-50E, 7805-08)	<a href="#">MHRA</a>	2010/003/016/291/015	FSCA	N.A.	N.A.
2010/03/31	Baxter Healthcare Coseal Surgical Sealant (certain serial numbers)	<a href="#">MHRA</a>	2010/001/013/081/014	FSCA	Baxter Healthcare Ltd	2807 8555
2010/03/31	Applied Medical Resources Corporation Surgical Trocars - Separator (Model : C0R36, C0R37)	<a href="#">Health Canada</a>	52934	Type II	N.A.	N.A.
2010/03/31	Stryker Trauma Implant Extraction Set	<a href="#">Health Canada</a>	53127	Type II	Stryker China Ltd	2518 6915
2010/03/31	Beckman Coulter A) Access System - Cortisol Assay B) Access System - Progesterone Assay, C) Unicel DXI600 Acc.Immuno.Sys.-Cortisol, D) Unicel DXI600 Acc.Imm.Sys.-Progesterone, E) Unicel DXI800 Acc.Imm.Sys.-Cortisol, F) Unicel DXI800 Acc.Imm.Sys.-Progesterone	<a href="#">Health Canada</a>	53210	Type II	Beckman Coulter Hong Kong Ltd	2240 6150
2010/03/31	Intersurgical Clear-Guard II Breathing Filter	<a href="#">Health Canada</a>	53292	Type II	Shun On Healthcare Limited	3123 8000
2010/03/31	Smith & Nephew Dyonics 25 Fluid Management System-Patient Tube Set	<a href="#">Health Canada</a>	53313	Type II	Smith & Nephew LTD	2648 7700
2010/03/31	GE Healthcare Finland OY A) Trusat Oximeter, B) Trusat Oximeter - With Expansion Option	<a href="#">Health Canada</a>	53326	Type I	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/03/31	Maddak A) Bath Safe Adjustable Shower Seat w/o Back and Arms, B) Bath Safe Adjustable Shower Seat with Back, C) Bath Safe Shower Seat w/Back and Arms, Blue, D) Bath Safe Adjustable Transfer Bench, Brown Box	<a href="#">Health Canada</a>	53348	Type II	N.A.	N.A.
2010/03/31	Immucor Galileo Echo Blood Bank Analyzer (Model : 0087000)	<a href="#">Health Canada</a>	53353	Type II	Uninet Technology LTD	2838 8423
2010/03/31	Conmed Endoscopic Technologies Entake Tri-Funnel G-Tube	<a href="#">Health Canada</a>	53424	Type II	N.A.	N.A.
2010/03/31	Tomotherapy Hi-Art System (S/N: 10169, 10037)	<a href="#">Health Canada</a>	53493	Type II	N.A.	N.A.
2010/03/31	<a href="#">Poly Implant Prothese IMGHC-TX, IMGHC-MX, IMGHC-LS</a>	N.A.	FR-2010-03-007	FSCA	N.A.	N.A.

## Monthly Summary of Medical Device Safety Alerts - February 2010

\*Note: FDA = Food and Drug Administration, United States of America; MHRA = Medicines and Healthcare products Regulatory Agency, United Kingdom; Health Canada = Health Canada, Canada

Date of Issue (YYYY/MM/DD)	Description of Product	Source of Information*	Reference No. by Source	Alert Type by Source	Local Agent	Agent Contact Telephone No.
2010/02/01	Inion CPS baby screw (REF: SCR-1221, Lot no. 0809009 and 0809069)	<a href="#">MHRA</a>	2010/001/015/081/006	FSCA	N.A.	N.A.
2010/02/01	Trinity Biotech Captia Measles IgM Kit (Product Code: 2326050)	<a href="#">MHRA</a>	2010/001/025/291/009	FSCA	N.A.	N.A.
2010/02/01	Beckman Coulter Closed tube aliquotter (CTA) for synchron LXi725 (REF: 388982, 389695) and UniCel DxC600i (REF: A25637, A25633)	<a href="#">MHRA</a>	2010/001/025/601/001	FSCA	Beckman Coulter Hong Kong Ltd	2240 6150
2010/02/01	Stryker Xcelerate ceramic 4:1 cutting blocks (Scorpio: 8000-0003, 8000-0004, 8000-0005, 8000-0006, 8000-0007, 8000-0008, 8000-0009, 8000-0011, 8000-0013 ; Duracon: 8000-7005, 8000-7010, 8000-7020, 8000-7030, 8000-7040, 8000-7050, 8000-7060)	<a href="#">MHRA</a>	2009/012/015/081/011	FSCA	Stryker China Ltd	2518 6915
2010/02/02	Philips Switched Reusable Internal Defibrillation Paddles (Product Numbers M4741A, M4742A, M4743A and M4744A)	Philips Electronic Hong Kong Ltd	FSN86100088A	Firm Initiated Field Action	Philips Electronic Hong Kong Ltd	2821 5480
2010/02/04	Centurion Healthcare Products (code no. LM110, LM115)	<a href="#">FDA</a>	Z-0105-2010 to Z-0106-2010	Class I	N.A.	N.A.
2010/02/04	GE OEC 9900 Elite ESP, GE OEC 9900 Elite GSP Fluoroscopes	<a href="#">FDA</a>	Z-0004-2010 to Z-0005-2010	Class II	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/02/04	Richard Wolf Hulka Clip, item 4986.90	<a href="#">FDA</a>	Z-0272-2010	Class II	N.A.	N.A.
2010/02/04	GE Infinia with Hawkeye 1 (model no.: H2508PW, H2508PY, H3000WN, H3000WR, H3000VW, H3000WY, H3000WZ, H3000YM, and H3000YS), Infinia with Hawkeye 4 (model no.: H3000WC and H3000WD), Millenium VG with Hawkeye/Discovery VH with Hawkeye (model no.: BR321000008)	<a href="#">FDA</a>	Z-0494-2010 to Z-0496-2010	Class II	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/02/04	Ellex Motorized Safety Filter, Zeiss; (Model no. 6339585), Motorized Safety Filter, Wild (Model no. 6339590).	<a href="#">FDA</a>	Z-0577-2010 to Z-0578-2010	Class II	N.A.	N.A.
2010/02/04	Zap Lasers SoftLase Pro Dental Lasers	<a href="#">FDA</a>	Z-0587-2010	Class II	N.A.	N.A.
2010/02/04	GE iDXA, Prodigy 1-8 series, DPX-NT series, DPX-MD series, DPX-Bravo/Duo, GE Lunar DEXA bone densitometers operating with enCORE software versions 12.0, 12.1, 12.2, 13.0, & 13.1.	<a href="#">FDA</a>	Z-0600-2010 to Z-0604-2010	Class II	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/02/04	GE MAC 800 RESTING ECG ANALYSIS SYSTEM.	<a href="#">FDA</a>	Z-0645-2010	Class II	GE Medical Systems Hong Kong Ltd.	2784 1838
2010/02/04	KCI AC Power Cords (#4100079, 4102204, M4268840, 340225, M4268882, M4268884).	<a href="#">FDA</a>	Z-0662-2010 to Z-0667-2010	Class II	N.A.	N.A.
2010/02/04	B. Braun Outlook Pump IV Set w/Universal Spike, Outlook Pump Add On Set, Outlook Pump Set, Drop Universal IV Admin Set, Safeline Y Type Blood Set for Outlook Pump, Outlook Pump Syringe Add On Set, Outlook Pump Nitroglycerin	<a href="#">FDA</a>	Z-0670-2010 to Z-0718-2010	Class II	N.A.	N.A.

2010/02/04	Stryker CBCII ConstaVac Blood conservation system (REF 225-28E), CBCII collection only (REF 225-28-S20), CBC Blood Conservation Kit (REF 225-28-85), CBCII (REF225-28-85S1, 225-28-85S4, REF 225-28-S5), CBCII Blood Conservation Kit (REF 225-28-514, 225-28-516, 225-28-526), CBCII Double Trocar Kit (REF 225-28-614, 225-28-616, 225-28-626, 225-28-626S1, CBCII ConstaVac Blood Conservagtion System w/ Quick Disconnect and 1/8in. (3.2mm) PVC Drain (REF 225-28-914, 225-28-916, 225-28-926), CBCII ConstaVac Blood Collection Only (REF 225-29), CBCII ConstaVAc Blood Conservatin Kit (REF 225-414, 225-414S2, 225-414-W, 225-416, 225-426, 225-426-W), CBCII with 3/16 in. Silicone Drain, (REF 0225-028-S16), CBCII Collection (REF 0225-028-S21)	<a href="#">FDA</a>	Z-0719-2010 to Z-0743-2010	Class II	N.A.	N.A.
2010/02/04	Merivaara Merilux X3, Merilux X5, Merilux Duo 320, Merilux Trio 360	<a href="#">MHRA</a>	2009/009/023/081/001	FSCA	N.A.	N.A.
2010/02/04	ev3 Silverhawk cutter driver (Catalogue number FG 02550)	<a href="#">MHRA</a>	2010/001/029/081/008	FSCA	Sinomed Company Ltd.	28877640
2010/02/04	Hospira A) Lifeshield Nonvented Primary IV Set, B) Lifeshield Microdrip Primary Piggyback	<a href="#">Health Canada</a>	52078	Type II	Hospira Limited	2898 2886
2010/02/04	Dana Douglas Nexus 3 Model : 4500185F, 4500225F, 4500245F	<a href="#">Health Canada</a>	52174	Type II	N.A.	N.A.
2010/02/04	Howmedica Osteonics Scorpio 4:1 Ceramic Blocks	<a href="#">Health Canada</a>	52242	Type II	N.A.	N.A.
2010/02/04	Abaxis Piccolo Comprehensive Metabolic Panel	<a href="#">Health Canada</a>	52289	Type II	N.A.	N.A.
2010/02/04	Toshiba Aquilion One TSX-301A/2	<a href="#">Health Canada</a>	52445	Type II	Sanko Medical Systems (HK) LTD	2384 0688
2010/02/04	Stryker Spine Jam Shidi Needles	<a href="#">Health Canada</a>	52532	Type II	N.A.	N.A.
2010/02/04	Dana Douglas A) Nexus 1, B) Nexus 2	<a href="#">Health Canada</a>	52535	Type I	N.A.	N.A.
2010/02/04	Baxter Y-Type Blood Solution Sets	<a href="#">Health Canada</a>	52558	Type II	Baxter Healthcare Ltd	2807 8516
2010/02/04	Howmedica Osteonics Restoration Modular Plasma Distal Stem	<a href="#">Health Canada</a>	52681	Type II	N.A.	N.A.
2010/02/04	Dorel Juvenile Ear Thermometer Model 49531	<a href="#">Health Canada</a>	49531	Type II	N.A.	N.A.
2010/02/04	Fimet F1 Dental Chair	<a href="#">MHRA</a>	2009/001/014/291/002	FSCA	N.A.	N.A.
2010/02/05	Thomas Medical Products Safesheath CSG Coronary Sinus Guide Hemostatic Introducer System with Infusion Sideport	FDA	N.A.	News Release	N.A.	N.A.
2010/02/05	Bound Tree Economy vacuum splints (Product code: SP040, SP041, SP042, SP043)	<a href="#">MHRA</a>	2009/009/010/401/001	FSCA	N.A.	N.A.
2010/02/08	Cardiac Science Powerheart 9300A, 9300E, 9300P, 9390A, 9390E, CardioVive 92532, CardioliLife 9200G and 9231 (manufactured/serviced between Oct 19, 2009 and Jan 15, 2010)	Pacific Medical Systems Limited	N.A.	Firm Initiated Field Action	Pacific Medical Systems Limited	2108 4005
2010/02/08	Reva Elegance, Excalibur ,Appollo and Highgrove baths	<a href="#">MHRA</a>	2008/011/013/301/002	FSCA	N.A.	N.A.
2010/02/08	GE Instatrak button probe, debrider attachments, biopsy and shunt guides, articulating arm and transmitter arms used with InstaTrak 3500, ENTrak 2500 and other GE Healthcare Surgery Navigation Systems	<a href="#">MHRA</a>	2010/002/002/081/019	FSCA	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/02/08	BD Shigella poly Group D Antiserum S. sonnei; types I,II, 241031 (Lot # 8032036 & 9110319)	BD	N.A.	Firm Initiated Field Action	BD	2575 8668
2010/02/09	Covidien Moltech/Accutronics Battery (Rev. D & E) used in Legendair and Supportair ventilators and Associated Accessory-Open Pack	<a href="#">MHRA</a>	2010/001/020/081/001	FSCA	Covidien	3157 7220

2010/02/09	Philips Panorama HFO systems on software release R2.5.3 and higher	<a href="#">MHRA</a>	2010/002/001/081/028	FSCA	Philips Electronic Hong Kong Ltd	2821 5480
2010/02/09	Accuray Cyberknife Robotic Radiosurgery System (MultiPlan Treatment Planning System Version 3.0, 3.1, 3.5.0, 3.5.1)	Accuray Asia Ltd.	N.A.	Firm Initiated Field Action	Accuray Asia Ltd	2247 8628
2010/02/10	BD Q-Syte Luer Access (Cat no. 380510, 385100, 385101) and BD Nexiva Closed IV Catheter Systems (Cat. No. 383530, 383531, 383532, 383533, 383534, 383536, 383537, 383538, 383539, 383540, 383647, 383649)	<a href="#">FDA</a>	N.A.	Press Release	BD	2575 8668
2010/02/10	Acacia IV Extension Sets with BD Q-Syte Luer Access Device (REF: 385150, 385151, 385164, 385165, 385166)	<a href="#">FDA</a>	N.A.	Press Release	N.A.	N.A.
2010/02/12	Elekta IMPAC Medical Systems SEQUENCER for MOSAIQ	<a href="#">MHRA</a>	2010/002/001/081/029	FSCA	N.A.	N.A.
2010/02/12	Cook Novy Cornual Cannulation Set	<a href="#">MHRA</a>	2010/001/020/081/002	FSCA	N.A.	N.A.
2010/02/12	diaDexus PLAC Test Reagent Kit (10-0112, 10-0113, 10-0115)	<a href="#">MHRA</a>	2010/001/025/081/001	FSCA	N.A.	N.A.
2010/02/12	Medtronic EnRhythm & EnRhythm MRI pacemakers	Medtronic	N.A.	Firm Initiated Field Action	Medtronic International, Ltd.	2919 1300
2010/02/12	Johnson & Johnson LifeScan OneTOuch SUREStep and OneTouch SUREStep Hospital Test Strips	Johnson & Johnson Medical (HK)	N.A.	Firm Initiated Field Action	Johnson & Johnson Medical (HK)	2738 6027
2010/02/17	Invitrogen DRB1*11 SSP Unitray, DRB1*11 SSP niTray with Taq, DRB1*11 AllSet Gold SSP	<a href="#">MHRA</a>	2010/001/025/291/002	FSCA	Invitrogen Hong Kong Limited	2407 8450
2010/02/17	Beckman Coulter PrepPlus (PN 286600) Coulter Preplus	<a href="#">MHRA</a>	2010/002/004/601/002	FSCA	N.A.	N.A.
2010/02/17	Smith & Nephew Orthopaedics Promos Standard Inclination Set - Model Numbers 75006722, 75006723, 75006724, 75006725, 75006722	<a href="#">MHRA</a>	2010/002/008/601/002	FSCA	N.A.	N.A.
2010/02/17	Stryker Femoral Sponges	<a href="#">MHRA</a>	2010/002/004/291/016	FSCA	N.A.	N.A.
2010/02/17	Beckman Coulter Clinical Chemistry Instrumentation A10405, A11810, A27318, A11816, A11812, A59102, A64903, A64871, A64935	<a href="#">MHRA</a>	2010/001/012/601/001	FSCA	N.A.	N.A.
2010/02/17	GE Centricity PACS RA1000 Workstation	<a href="#">MHRA</a>	2010/002/004/291/013	FSCA	N.A.	N.A.
2010/02/17	Roche Diagnostics Accu-Chek Inform II meter	<a href="#">MHRA</a>	2010/002/011/081/004	FSCA	N.A.	N.A.
2010/02/17	ConMed Linvatec TS8850 concept grafix tendon stripper	<a href="#">MHRA</a>	2010/002/008/081/018	FSCA	N.A.	N.A.
2010/02/17	Invacare Scanbed 750 Hospital Bed	<a href="#">MHRA</a>	2008/002/011/061/019	FSCA	N.A.	N.A.
2010/02/17	Beckman Coulter Access AccuTnl Reagent Kit	<a href="#">MHRA</a>	2010/002/010/601/003	FSCA	N.A.	N.A.
2010/02/17	Baxter HomeChoice Automated PD System / HomeChoice PRO Automated PD	Baxter Healthcare Ltd.	N.A.	Firm Initiated Field Action	Baxter Healthcare Ltd	2807 8516
2010/02/17	Philips Allura Xper Systems / Allura Integris Systems with Velara Generator	Philips Electronic Hong Kong Ltd	N.A.	Firm Initiated Field Action	Philips Electronic Hong Kong Ltd	2821 5480
2010/02/17	BD 10ml LS Plastipak Syringe, 302188	BD	N.A.	Firm Initiated Field Action	BD	2575 8668
2010/02/18	Eden Medical Portable IV Infusion Pumps	<a href="#">MHRA</a>	2009/012/031/081/014	FSCA	N.A.	N.A.
2010/02/18	Jointmedica Birmingham Knee Replacement bearing insert re. 300003-10	<a href="#">MHRA</a>	2010/001/019/081/006	FSCA	N.A.	N.A.
2010/02/18	Stryker Tessier Osseous Microtome (TOM) bone mill	<a href="#">MHRA</a>	2010/002/011/081/015	FSCA	N.A.	N.A.

2010/02/18	Cincinnati Sub-Zero Products Warmair Cardiac Blanket	<a href="#">Health Canada</a>	52127	Type II	N.A.	N.A.
2010/02/18	Beckman Coulter Unicel DXC 600, 800, 600I, 880I, 660I, 680I, 860I	<a href="#">Health Canada</a>	52600	Type II	N.A.	N.A.
2010/02/18	Smiths Medical AC Power Cords used with 9200 Advisor / 8400 Capnocheck / BCI 3180 Pulse	<a href="#">Health Canada</a>	52815	Type II	N.A.	N.A.
2010/02/18	EMCM Artesense (PMMA Collagen Dermal Implant)	<a href="#">Health Canada</a>	52836	Type II	N.A.	N.A.
2010/02/18	Pointe Scientific Liquid Glucose (HEXO) Reagent Set - 814301, 820502, 823901, 826801, 829401, 814301, 820502, 831502	<a href="#">FDA</a>	Z-0104-2010	Class I	N.A.	N.A.
2010/02/18	Stryker Instruments Navigation System II CART / PC SPC-1	<a href="#">FDA</a>	Z-0123-2010 to Z-0123-2010	Class I	N.A.	N.A.
2010/02/18	Stryker Imaging Guradian Services Software 0240-009-430, 0240-020-013, 0240-020-022	<a href="#">FDA</a>	Z-0134-2010	Class II	N.A.	N.A.
2010/02/18	Medcomp 10F Bioflex Tesio Kit with cutting trocar, BFR-6CTT	<a href="#">FDA</a>	Z-0161-2010	Class II	N.A.	N.A.
2010/02/18	STERIS Harmony LL 500/700 Surgical Light, Vertical Spring-Loaded Arm	<a href="#">FDA</a>	Z-0414-2010	Class II	Swedish Trading Co. Ltd.	6199 0634
2010/02/18	Biomet bone mulch screw, 10.5mm x 20mm, TI-6AL-4V alloy, steril, Ref. 907320	<a href="#">FDA</a>	Z-0779-2010	Class II	N.A.	N.A.
2010/02/18	Cincinnati Sub-Zero Products FilteredFlo Cardiac Blanket / TempPad Cold Therapy Pad	<a href="#">FDA</a>	Z-0781-2010 to Z-0782-2010	Class II	N.A.	N.A.
2010/02/18	Edwards Lifesciences Fogarty Occlusion Catheter Ref. 6208022F	<a href="#">FDA</a>	Z-0002-2010	Class II	N.A.	N.A.
2010/02/18	Philips HeartStart MRx(M3535A/M3536A) Defibrillator / Monitor Serial No. US00533518 to US00535118	<a href="#">FDA</a>	Z-0003-2010	Class II	Philips Electronic Hong Kong Ltd	2821 5480
2010/02/18	Synthes 2.0mm Screw Manipulation Forceps, Bending Pliers-straight for Craniofacial/Orthognathic, Plate Holding Forceps, TI Matrixmanible Sagittal, 2.0mm Drill bit Stryker J-latch	<a href="#">FDA</a>	Z-0075-2010 to Z-0082-2010	Class II	N.A.	N.A.
2010/02/19	SapiMed SMA 4545FP Sterile Rectoscopy Kit - Lot no. 9A010I	<a href="#">MHRA</a>	2010/001/026/401/023	FSCA	N.A.	N.A.
2010/02/19	GlaxoSmithKline (GSK) Polident Denture Adhesives (Zn)	GlaxoSmithKline Limited	N.A.	Firm Initiated Field Action	GlaxoSmithKline Limited	31898904
2010/02/22	Bredent Medical Dental Implant SKYFF002	<a href="#">MHRA</a>	2010/002/008/081/012	FSCA	N.A.	N.A.
2010/02/22	Leica Biosystems Peloris Rapid Tissue Processor Part Number 26.001	TGA	RC-2010-RN-00122-3	Class II	Leica Microsystems Limited	2564 6699
2010/02/22	Boston Scientific BLUE MAX and Ultra-thin Diamond Balloon Dilatation Catheters	Boston Scientific Hong Kong Ltd	N.A.	Firm Initiated Field Action	Boston Scientific Hong Kong Ltd	2960 7136
2010/02/24	American Medical Systems GreenLight HPS Fibre	<a href="#">MHRA</a>	2010/001/026/081/006	FSCA	N.A.	N.A.
2010/02/24	Maquet Cardiopulmonary Vasoview Hemopro Endoscopic Vessel Harvesting System	<a href="#">MHRA</a>	2010/002/001/081/024	FSCA	Maquet Hong Kong Ltd.	2393 9511
2010/02/25	Solafeet Model ST-400 Solafeet Foot portable tanners	<a href="#">FDA</a>	Z-0608-2010	Class II	N.A.	N.A.
2010/02/25	Merit Medical Systems University Health System Custom Cardiac Cath Pack, K09T-02178, Custom Cardiac Cath Pack Kit, K09-08945, Custom Angiographic Kit, K09-MS3084, Jeanes Hospital Custom Cath Procedure Tray, K09T-08945.	<a href="#">FDA</a>	Z-0744-2010 to Z-0748-2010	Class II	King Health Limited	2481 3787
2010/02/25	Abbott Vascular (Guidant) RX ACCULINK Carotid Stent System, 10x40 mm, Product Number: 1011344-40.	<a href="#">FDA</a>	Z-0749-2010	Class II	Abbott Laboratories LTD.	2593 2211
2010/02/25	Stryker Triathlon Total Stabilizer Femoral Component (Catalog number: 5512-F-201, 5512-F-301, 5512-F-402, 5512-F-501, 5512-F-502).	<a href="#">FDA</a>	Z-0757-2010 to Z-0761-2010	Class II	Stryker China Ltd	2518 6915

2010/02/25	Stryker Xia Precision System (Catalog number: 48237110, 48237105, 48237115, 48237135).	<a href="#">FDA</a>	Z-0789-2010 to Z-0792-2010	Class II	Stryker China Ltd	2519 6915
2010/02/25	Stryker Reamer T-Handle (Catalog Number: 1101-2100), Navigation Reamer T-handle (Catalog Number: 2124-2100).	<a href="#">FDA</a>	Z-0793-2010 to Z-0794-2010	Class II	Stryker China Ltd	2520 6915
2010/02/25	Stryker Scorpio PS Femoral Waffle (No post) with LFIT, Product code 72-4107-L.	<a href="#">FDA</a>	Z-0795-2010	Class II	Stryker China Ltd	2521 6915
2010/02/25	Stryker Depth Gauge (Catalog Number: 703707). This product is sold separately or as part of Kit # 990256.	<a href="#">FDA</a>	Z-0796-2010	Class II	Stryker China Ltd	2522 6915
2010/02/25	Neurovision Medical Products 2-Channel Laryngeal Surface Electrode (Model LSE500DCS and LSE500DCL)	<a href="#">FDA</a>	Z-0798-2010	Class II	N.A.	N.A.
2010/02/25	Wescor Hematology reagent C eosin stain SS-035C	<a href="#">MHRA</a>	2010/002/015/081/003	FSCA	N.A.	N.A.
2010/02/25	Medartis A-2723.01 APTUS Radius 2.5 Drill Block, Left; A-2723.02 APTUS Radius 2.5 Drill Block, Right	<a href="#">MHRA</a>	2010/002/019/081/003	FSCA	N.A.	N.A.
2010/02/25	Zimmer Reconstruction System Tenaculum Instruments	Zimmer PTE Ltd. (Hong Kong branch)	N.A.	Firm Initiated Field Action	Zimmer PTE Ltd. (Hong Kong branch)	2992 0968
2010/02/26	BD FACS SAMPLE PREP ASSISTANT II SPA II Catalog No. 337170, Sample Probes Lot Numbers 92035 and 92036	<a href="#">MHRA</a>	2010/002/015/081/016	FSCA	BD	2575 8668
2010/02/26	Trumpf Ondal spring arm AC2000 in Helicon and Xenion surgical lights	<a href="#">MHRA</a>	2010/002/018/081/007	FSCA	N.A.	N.A.
2010/02/26	Abbott Paraffin Pretreatment Reagent Kit II (List No. 7J02-02) & Paraffin Pretreatment Reagent Kit III (List No. 7J02-03)	<a href="#">MHRA</a>	2010/002/004/601/004	FSCA	Abbott Laboratories LTD.	2593 2211



## Monthly Summary of Medical Device Safety Alerts - January 2010

\*Note: FDA = Food and Drug Administration, United States of America; MHRA = Medicines and Healthcare products Regulatory Agency, United Kingdom; Health Canada = Health Canada, Canada

Date of Issue (YYYY/MM/DD)	Description of Product	Source of Information*	Reference No. by Source	Alert Type by Source	Date of Issue (YYYY/MM/DD)	Local Agent	Agent Contact Telephone No.
2010/01/04	GE Healthcare Revolution XR/d system control room PC model 5117866-2 with Software collector 5115434	<a href="#">FDA</a>	Z-0002-2009	Class II	2010/01/04	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/01/04	Flir MilCAM Recon III Model Family of IR Imagers that incorporates a Class I infrared laser for Laser Range Finding	<a href="#">FDA</a>	Z-0937-2009	Class II	2010/01/04	FLIR Systems Co., Ltd.	2792 8955
2010/01/04	Flir MilCAM Recon III, Family of IR Imagers that incorporates a Class IIb infrared laser pointer	<a href="#">FDA</a>	Z-1223-2009	Class II	2010/01/04	FLIR Systems Co., Ltd.	2792 8955
2010/01/04	GE Healthcare CT Systems Table Model Number 2225283, 227124, 22269165	<a href="#">FDA</a>	Z-1257-2009 to Z-1259-2009	Class II	2010/01/04	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/01/04	NRT - Nordisk Rontgen Teknik A/S Celex / GE Precision MPI, REF no.: 02980000	<a href="#">FDA</a>	Z-1658-2009	Class II	2010/01/04	N.A.	N.A.
2010/01/04	GE Healthcare Innova 2100IQ, Innova 3100, Innova 3100-IQ, Innova 4100, Innova 4100-IQ (Recall# Z-1687-2009 to Z-1691-2009)	<a href="#">FDA</a>	Z-1687-2009 to Z-1691-2009	Class II	2010/01/04	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/01/04	Cook Endoscopy Jejunal Feeding Set, Product Order number FLOWJ-9-20	<a href="#">FDA</a>	Z-1910-2009	Class II	2010/01/04	A.R. Burkill & Sons (Hong Kong) Ltd.	2298 1125
2010/01/04	Abiomed iPulse Circulatory Support System (Catalog number: 0036-0010)	<a href="#">FDA</a>	Z-1931-2009	Class II	2010/01/04	N.A.	N.A.
2010/01/04	BioTek Gen5CL Microplate Data Collection and Analysis Software	<a href="#">FDA</a>	Z-2223-2009	Class II	2010/01/04	N.A.	N.A.
2010/01/04	St. Jude Medical (SJM) FAST-CATH Hemostasis Introducer (REF 406702, 406709)	<a href="#">FDA</a>	Z-2228-200 to Z-2229-2009	Class II	2010/01/04	St. Jude Medical (Hong Kong) Ltd.	2996 7688
2010/01/04	Beckman Coulter Enhanced Access AccuTnl Reagent Kit (Part number A78803)	<a href="#">MHRA</a>	2009/012/023/601/004	FSCA	2010/01/04	Beckman Coulter Hong Kong Ltd	2240 6150
2010/01/04	Abbott Architect HIV Ag/Ab Combo Calibrator, list number 4J27-01, lot 73507HN00	<a href="#">MHRA</a>	2009/012/022/601/001	FSCA	2010/01/04	Abbott Laboratories LTD.	2593 2211
2010/01/04	Intersurgical T-pieces sized 22F, 22M and 22M/15F for various breathing systems	<a href="#">MHRA</a>	2009/010/028/401/002	FSCA	2010/01/04	Shun On Healthcare Limited	N.A.
2010/01/04	AGA Medical Corporation Amplatzer TorqVue 45° Delivery System	<a href="#">MHRA</a>	2009/012/022/081/005	FSCA	2010/01/04	N.A.	N.A.
2010/01/04	bioMérieux chromID Salmonella agar	<a href="#">MHRA</a>	2009/012/001/601/002	FSCA	2010/01/04	bioMérieux China Ltd.	2195 9348
2010/01/04	bioMérieux Vidas TPSA	<a href="#">MHRA</a>	2009/012/001/601/001	FSCA	2010/01/04	bioMérieux China Ltd.	2195 9348
2010/01/06	ev3 Trailblazer Support Catheter (Model no. SC-014-135, SC-018-090, SC-035-065, SC-035-135, SC-014-150, SC-018-150, SC-035-090, SC-035-150)	<a href="#">FDA</a>	N.A.	Class I	2010/01/06	Sinomed Company Ltd.	2887 7640
2010/01/06	Agfa Mamoray HDR-C Plus DLF1 - 37780023	<a href="#">MHRA</a>	2009/011/017/401/013	FSCA	2010/01/06	AGFA Hong Kong Limited	2555 9421
2010/01/06	Siemens Healthcare Diagnostics Dade Hepzyme B4240-10, lot 528752	<a href="#">MHRA</a>	2009/012/023/291/011	FSCA	2010/01/06	Siemens Healthcare Diagnostic Limited	2810 7533
2010/01/07	Philips Healthcare HeartStart Vehicle Wall Mount (Model M5528A) and DC Power Module (Model M5529A)	<a href="#">MHRA</a>	2009/012/022/081/007	FSCA	2010/01/07	Philips Electronic Hong Kong Ltd	2821 5480
2010/01/07	Siemens Biograph mCt-X, model number 10248670, 10248671, 10248672	<a href="#">FDA</a>	Z-0162-2010 to Z-0164-2010	Class II	2010/01/07	Siemens Healthcare Diagnostic Limited	2810 7533

2010/01/07	Biomet Microfixation LactoSorb Self Drilling Adjustable Tap Model Numbers 915-2075 Lot # 064350 and 915-2185 Lot # 885580	<a href="#">FDA</a>	Z-0489-2010 to Z-0490-2010	Class II	2010/01/07	Swedish Trading Co., Ltd	2953 5111
2010/01/07	Terumo Sarns Centrifugal Pump (Cat. no. 164275, 164275X)	<a href="#">FDA</a>	Z-0544-2010 to Z-0545-2010	Class II	2010/01/07	TERUMO CHINA (H.K.) LTD.	2866 0811
2010/01/07	Hill-Rom Affinity Four Birthing Bed (Model P3700B)	<a href="#">FDA</a>	Z-0548-2010	Class II	2010/01/07	N.A.	N.A.
2010/01/07	Siemens Symbia S Series SPECT System (Part: 8717741), Symbia T Series SPECT-CT (Part: 8717733, 10275007, 10275008, 10275009, 10275010)	<a href="#">FDA</a>	Z-0583-2010 to Z-0584-2010	Class II	2010/01/07	Siemens Healthcare Diagnostic Limited	2810 7533
2010/01/11	Philips Healthcare GXR Systems with SCP Generator and tube grid switch functionality	<a href="#">MHRA</a>	2009/012/030/081/001	FSCA	2010/01/11	Philips Electronic Hong Kong Ltd	2821 5480
2010/01/11	BD CD103 PE, BD CD103 FITC, and BD Oncomark CD103/CD22/CD20, 340944	<a href="#">N.A.</a>	N.A.	Firm Initiated Field Action	2010/01/11	BD	2575 8668
2010/01/12	General Medical Merate Opera, Precision RXi, Meratel, BRT-20, Clinodigit, Compact, Futura 2000 and Arkiton 90/20M systems	<a href="#">MHRA</a>	2009/012/015/081/016	FSCA	2010/01/12	N.A.	N.A.
2010/01/12	Cardia Atrisept II ASD and PFO devices	<a href="#">MHRA</a>	2010/001/007/291/004	FSCA	2010/01/12	N.A.	N.A.
2010/01/12	Invacare Action 3 and Action 4 manual wheelchairs	<a href="#">MHRA</a>	MDA/2010/004	MDA	2010/01/12	Direct Health Ltd.	N.A.
2010/01/13	Stryker Endoscopic Digital Image Storage System SDC HD (0240050888), SDC HDI (0240050888i) and SDC Pro 2 (0240050800, 0240050810)	<a href="#">MHRA</a>	2009/012/016/081/010	FSCA	2010/01/13	Stryker China Ltd	2518 6915
2010/01/14	GE Healthcare Solar 8000L System - Patient Monitor	<a href="#">Health Canada</a>	43880	Type II	2010/01/14	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/01/14	Ossur Total Knee Prosthetic Device (Model : TK1100)	<a href="#">Health Canada</a>	50746	Type II	2010/01/14	N.A.	N.A.
2010/01/14	Siemens Medical Solutions Acuson X300 (Model : 10037409)	<a href="#">Health Canada</a>	50794	Type II	2010/01/14	Siemens Healthcare Diagnostic Limited	2810 7533
2010/01/14	Beckman Coulter Immage Alpha2-Macroglobulin AMG Reagent	<a href="#">Health Canada</a>	50959	Type II	2010/01/14	Beckman Coulter Hong Kong Ltd	2240 6150
2010/01/14	Baxter Syndeo PCA Syringe Pump (Model : 2L3113, 2L3113R)	<a href="#">Health Canada</a>	50978	Type II	2010/01/14	Baxter Healthcare Ltd	2807 8555
2010/01/14	GE Medical Systems A) Omega 1V Table, B) Omega V Table	<a href="#">Health Canada</a>	51642	Type II	2010/01/14	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/01/14	Siemens Healthcare Diagnostics Rapidpoint 405 System Cartridges (Models : 10283221, 130520, 130521)	<a href="#">Health Canada</a>	51667	Type II	2010/01/14	Siemens Healthcare Diagnostic Limited	2810 7533
2010/01/14	Sorin Clearguide Precision Bipolar Devices (Model : KTV15, PBD01)	<a href="#">Health Canada</a>	51914	Type II	2010/01/14	N.A.	N.A.
2010/01/14	Toshiba Aplio Artida Ultrasound System (Model : SSH-880CV)	<a href="#">Health Canada</a>	51965	Type II	2010/01/14	Sanko Medical Systems (HK) LTD	23840688
2010/01/14	Dixtal Pulse Oximetry Products (Model : A) 2001, B) 515B, 520A	<a href="#">Health Canada</a>	52058	Type II	2010/01/14	N.A.	N.A.
2010/01/14	Millipore Millex 33 Syringe Filter Unit (Model : SLGVM33RS)	<a href="#">Health Canada</a>	52075	Type II	2010/01/14	N.A.	N.A.
2010/01/14	Lumenis One (Model : GAL 150000)	<a href="#">Health Canada</a>	52100	Type II	2010/01/14	N.A.	N.A.
2010/01/14	Siemens Healthcare Diagnostics Crotor	<a href="#">Health Canada</a>	52101	Type II	2010/01/14	Siemens Healthcare Diagnostic Limited	2810 7533
2010/01/14	Zimmer Trabecular Metal Reverse Shoulder System (Model : 00-4309-037-09, 00-4309-037-12)	<a href="#">Health Canada</a>	52106	Type II	2010/01/14	Zimmer PTE Ltd. (Hong Kong branch)	2992 0968
2010/01/14	Respironics Novamatrix A) Tidal Wave Model 610, B) Tidal Wave SP Model 710, C) Tidal Wave SP Model 715, D) NICO Model 7300, E) Tidal Wave Model 615	<a href="#">Health Canada</a>	52112	Type II	2010/01/14	Philips Health Care (Great China)	2821 5480
2010/01/14	Wallac OY A) Defia Neonatal Thyroid Stimulating Hormone Assay, B) Defia Neonatal IRT Assay, C) 1235 Auto Delfia System Plate Processor Class 2	<a href="#">Health Canada</a>	52122	Type II	2010/01/14	N.A.	N.A.
2010/01/14	Teleflex Medical One Way Valve (Model : 1665)	<a href="#">Health Canada</a>	52132	Type II	2010/01/14	N.A.	N.A.
2010/01/14	B. Braun Medical A) Horizon Pump Blood Set NF/US3120,V7490, B) Horizon Pump Set V7453 AND V7402, C) Horizon Pump Nitroglycerin Sets V7450, D) Horizon Pump IV Sets Numerous Cat.#, E) Outlook Pump Set NF3115M, F) Outlook Pump IV SET W/Univer.Spike V7416F	<a href="#">Health Canada</a>	52133	Type II	2010/01/14	B Braun Medical Hong Kong	2277 6125
2010/01/14	Zimmer Nexgen Complete Knee Solution, MIS (Model : 00-5954-057-02)	<a href="#">Health Canada</a>	52161	Type II	2010/01/14	Zimmer PTE Ltd. (Hong Kong branch)	2992 0968
2010/01/14	Baxa Exactamix Empty Eva Container (Model : 738, 739, 740)	<a href="#">Health Canada</a>	52180	Type II	2010/01/14	N.A.	N.A.

2010/01/14	Stryker Trauma A) T2 Ankle System-Arthrodesis Nails,Left, B) T2 Ankle System-Arthrodesis Nails,Right	<a href="#">Health Canada</a>	52186	Type II	2010/01/14	Stryker China Ltd	2518 6988
2010/01/14	Howmedica Osteonics Triathlon Total Stabilizer Femur (Model : 5512-F-301, 5512-F-501)	<a href="#">Health Canada</a>	52187	Type II	2010/01/14	N.A.	N.A.
2010/01/14	Arizant A) Bair Hugger Warming Unit, B) Bair Paws Patient Adj. Warming System, C) Ranger Irrigation Fluid Warming System, D) Bair Paws Model 875 Warming Unit, E) Ranger Blood/Fluid Warming System	<a href="#">Health Canada</a>	52223	Type II	2010/01/14	N.A.	N.A.
2010/01/14	Bausch & Lomb A) Arnold-Bruening Intracordal Injection, B) Trach Tube Jackson, C) Trocar Needle & Stylet, D) Speaking Tube, E) Visco-Expression Cannula, F) Terry IRR Scapper, G) Can FNT SNUS Van Alyea, H) Can Antrum Van Alyea, I) Arnold-Bruen Laryngeal Injection Set, J) Laryngeal Injection Set Needle Rubin, K) Lyrngeal Injector Set Arnold Adaptor, L) ENT Trocar Antrum Coakley, M) Trachea-Speaking Tube Sterling, N) Jackson Lacrimal Intubation Set, O) X-BLD F/N/N-250 DISP STORZ, P) Surgilens Corneal Shield, Q) Cannula Angled Graether	<a href="#">Health Canada</a>	51949	Type II	2010/01/14	Bausch & Lomb (Hong Kong ) Ltd	2213 3371
2010/01/14	Bausch & Lomb A) Ophthalmic Cannula, B) I/A Handpiece, C) Ophthalmic Surgical Cannulas-Reusable, D) Excellus Hanstome Microkeratome, E) Sharpoint Ultra Plug, F) Millenium Microsurgical System, G) Millenium Microsurgical System-Connecto, H) Ryan 90 Degree Pick, I) Antrum Killian Sterling, J) Can Antrum Killian Chrome Cannula, K) Needle Fascia Wright, L) Sceral Plugs, M) Suct TB Guilford-Wright, N) TB Silastic, O) Silicone Tubing, P) Suction Tube Tonsil Yankauer, Q) Suct TB Tonsil Goodhil-Pynchon, R) Suct TB Baron W/Cut-Off, S) TB Suct Ferg-Frazier, T) Suction Tube Rosen, U) Needle House, V) Needle Utility Rosen Type House, W) Needle Perforating McGee, X) Needle Schuknech Straight Rigid, Y) Algerbrush Rust Ring Cornea Burrs, Z) Tonsil Needle Luer-LK	<a href="#">Health Canada</a>	51949	Type II	2010/01/14	Bausch & Lomb (Hong Kong ) Ltd	2213 3371
2010/01/14	Biedermann Motech Ext Tandem Connector (Product code: 1725-197-17, 1725-197-18)	<a href="#">MHRA</a>	2009/012/014/081/010	FSCA	2010/01/14	N.A.	N.A.
2010/01/14	Thermo Fisher Scientific PB0378A Oxoid Ready Poured Plate, Iso-Sensitest Agar + 5% Blood + 20mg/l N.A.D., 4mm depth	<a href="#">MHRA</a>	2010/001/006/601/006	FSCA	2010/01/14	N.A.	N.A.
2010/01/14	Thermo Fisher Scientific PO0152A Mueller Hinton Agar, 4mm depth	<a href="#">MHRA</a>	2010/001/006/601/005	FSCA	2010/01/14	N.A.	N.A.
2010/01/14	Beckman Coulter Access Free T3 Calibrators A13430	<a href="#">MHRA</a>	2010/001/005/601/001	FSCA	2010/01/14	Beckman Coulter Hong Kong Ltd	2240 6150
2010/01/14	Merit Medical Systems Mistique Infusion Catheters	<a href="#">MHRA</a>	2009/012/030/081/016	FSCA	2010/01/14	King Health Limited	2481 3787
2010/01/15	Rociale InHealth RML122-044 10cm x 7.5cm 32ply XRD swab sterile	<a href="#">MHRA</a>	2010/001/007/291/005	FSCA	2010/01/15	N.A.	N.A.
2010/01/18	Spire Biomedical Decathalon (Model: DE19SH24 and DE19SH24-K, DE23SH28 and DE23SH28-K, DE27SH32 and DE27SH32-K, DE31SH36 and DE31SH36-K, DE35SH40 and DE35SH40-K, DE50SH55 and DE50SH55-K, DF19SH24, DF23SH28, DF27SH32, DF31SH36, DF35SH40, DF50SH55, DF19SH24-100, DF23SH28-100, DF27SH32-100, DM19SH24, DM23SH28, DM27SH32, DX19SH24-XP, DX23SH28-XP, DX27SH32-XP, DEC19SH24 and DEC19SH24-K, DEC23SH28 and DEC23SH28-K, DEC27SH32 and DEC27SH32-K, DEC31SH36 and DEC31SH36-K, DEC35SH40 and DEC35SH40-K, DEC50SH55 and DEC50SH55-K, DFC19SH24 and DFC19SH24-K, DFC23SH28 and DFC23SH28-K, DFC27SH32), ALTA (Model: AL19SH24, AL23SH28, AL27SH32, AL31SH36, AL35SH40, AL19NH24, AL23NH28, AL27NH32, AL31NH36, AL19SH24-XP, AL23SH28XP, AL27SH32XP, ALC19SH24, AL27SH32XP, ALC19SH24	<a href="#">FDA</a>	Z-0288-2010 to Z-0335-2010	Class II	2010/01/18	N.A.	N.A.
2010/01/18	Covidien Staplers, cutters and various products (product code: CART; SRVM; Surg200; Surg300; OPMA, CS21; CS25; CS29; CS33 RALC30; RALC30V; RALC45; RCW100; SLC55B; SLC55G; SLRCR55B; SLRCR55G; SLS55B4; .FS14; FS214; FS312; FS3SCG; FS214RC; MR14; PLC75; PLCR75B; PLCR75G; PES100; PES100RC; PEC200RC; PES200RC; PLCR45B; PLCR45G; PLC60; PLCR60B; PLCR60G; PLCR60GT; PLC60RC; PCS21; PCS29; PC100; PC100S; PC100RC. SS01; MCV1A; iR45B; iR45G; iR45MB; iR45MG; iR45V; iR60B; iR60G; iR60MB; iR60MG; iR60B4; iDriveS; iDriveC; iDriveF. i60S; i60SRC; i60; i60XXL; i45; i45V; iB100; iB1C1; iBIG-1; iBIT-1. RCP; RCPOR. T300; PSP;	<a href="#">FDA</a>	Z-0392-2010 to Z-0412-2010	Class II	2010/01/18	Covidien	3157 7220
2010/01/18	Numed IMPACT Catheters (Model No. 307)	<a href="#">FDA</a>	Z-0509-2010	Class II	2010/01/18	N.A.	N.A.
2010/01/18	Medtronic Repose G2 Bone Screw System (REF 76353200), Repose G2 Bone Screw (REF 76310200)	<a href="#">FDA</a>	Z-0535-2010 to Z-0536-2010	Class II	2010/01/18	Medtronic International, Ltd.	2919 1300
2010/01/18	Luxottica Polycarbonate prescription lenses (single vision, progressive, and trifocal)	<a href="#">FDA</a>	Z-0542-2010	Class II	2010/01/18	N.A.	N.A.
2010/01/18	Invacare Storm TDX SR Power Wheelchair with Stability Lock, Model numbers: TDXSR, TDXSR-CG, TDXSR-CG-HD, TDXSR-HD, TDXSR-MCG, TDXSR-MCG-	<a href="#">FDA</a>	Z-0579-2010	Class II	2010/01/18	Direct Health LTD	N.A.
2010/01/18	Greatbatch Medical Enpath Lead Adaptor (Ref: 501214), Enpath Myopore Sutureless Myocardial Pacing Lead (Ref: 511211)	<a href="#">FDA</a>	Z-0580-2010 to Z-0581-2010	Class II	2010/01/18	N.A.	N.A.

2010/01/18	Teleflex Medical Oxygen Sensor (Cat. no: 5804, Lot no. 906018 and 906003)	<a href="#">FDA</a>	Z-0585-2010	Class II	2010/01/18	N.A.	N.A.
2010/01/18	BD 30 ml Syringe Luer-Lok Tip (Catalog # 309650)	<a href="#">FDA</a>	Z-0586-2010	Class II	2010/01/18	BD	2575 8668
2010/01/18	Endologix Powerlink System with IntuiTrak Delivery System (Endovascular Graft) (Model Number 34-34-80L, 34-34-80LE)	<a href="#">FDA</a>	Z-0593-2010 to Z-0594-2010	Class II	2010/01/18	N.A.	N.A.
2010/01/18	Stryker MIS Bur (REF 8420-107-120, 8420-107-125, 8420-107-130, 8420-107-135, 8420-107-230)	<a href="#">FDA</a>	Z-0595-2010 to Z-0599-2010	Class II	2010/01/18	Stryker China Ltd	2518 6915
2010/01/18	Invitrogen DRB1*04 Locus High Res SSP UniTray (Code: 450404, 450414) and DRB1*04 Locus High Res AllSet Gold SSP (Code: 54230D)	<a href="#">FDA</a>	2009/012/015/081/026	FSCA	2010/01/18	Invitrogen Hong Kong Limited	N.A.
2010/01/18	Bausch & Lomb Phacoemulsification Needle Wrench in Stellaris or Millennium phacoemulsification units including DP4305 & DP4305E, DP4310 & DP4310E, CX5310, CX4320, BL5110, BL5111, BL5112, BL5120, BL5121, BL5122, BL5113, BL5113A, BL5114, BL5114A, BL5123, BL5123A, DP8130S, DP8145S, DP8230S, DP8245S, DP8330S, DP8345S, DP8430S, DP8430AS, DP8730S	<a href="#">FDA</a>	N.A.	Firm Initiated Field Action	2010/01/18	Bausch & Lomb (Hong Kong ) Ltd	2213 3371
2010/01/19	B. Braun All pole clamps for Infusomat Space and Perfusor Space infusion pumps	<a href="#">MHRA</a>	MDA/2010/007	MDA	2010/01/19	B Braun Medical Hong Kong	2277 6125
2010/01/20	Thermo Fisher Scientific PB0146A Iso-Sensitest agar + horse blood, 4mm depth (lot no. 1115822)	<a href="#">MHRA</a>	2010/001/014/601/001	FSCA	2010/01/20	N.A.	N.A.
2010/01/20	Siemens Axiom Iconos R200	<a href="#">MHRA</a>	2009/012/009/081/013	FSCA	2010/01/20	Siemens Healthcare Diagnostic Limited	2810 7533
2010/01/20	Abbott CELL-DYN 4000 vent head spring assembly (List no. 07H95-01)	<a href="#">MHRA</a>	2010/001/012/601/002	FSCA	2010/01/20	Abbott Laboratories LTD.	2593 2211
2010/01/21	GE Healthcare LightSpeed VCT 7.2 Vision and Discovery CT750 HD Computed Tomography X-ray systems	<a href="#">MHRA</a>	2010/001/015/081/004	FSCA	2010/01/21	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/01/21	Unomedical Diathermy cables 3405M and 3508M	<a href="#">MHRA</a>	2010/001/012/081/001	FSCA	2010/01/21	N.A.	N.A.
2010/01/21	Karl Storz MTP fluid irrigation filter MTP 031125 and CO2 gas filter 0311231-1	<a href="#">MHRA</a>	2009/012/004/081/004	FSCA	2010/01/21	N.A.	N.A.
2010/01/21	Berchold A) Chromophare Surgical Lighting System (C200, C300, C450, C450/452, C570, C571, C571/572, C950, D500, D530, D530LED, D540, D650, D660, E520, E550, E650, E655, E800, E805, LED 558, LED 668, LED 778, X65, X66) B) Chromoview Flat Panel Arm (224, 224 FP, FP, TRAGARM)	<a href="#">Health Canada</a>	52179	Type II	2010/01/21	N.A.	N.A.
2010/01/21	Philips A) Heartstart FRx AED (861304) B) Heartstart HS1 Onsite Defibrillator (M5066A)	<a href="#">Health Canada</a>	51902	Type II	2010/01/21	Philips Electronic Hong Kong Ltd	2821 5480
2010/01/21	Abbott A) i-Stat EG7+ Cartridges (06F01-01, 06F01-02) B) i-Stat EG6+ Cartridges (06F02-01, 06F02-02) C) i-Stat CG8+ Cartridges (3M86-01, 03M86-02) D) i-Stat CHEM8+ Cartridges (03M88-01, 03M88-02)	<a href="#">Health Canada</a>		Type II	2010/01/21	Abbott Laboratories LTD.	2593 2211
2010/01/21	Draeger A) Radiant Warmer (RW82, RW82-1) B) Birthing Room Warmer (WBR82, WBR82-1)	<a href="#">Health Canada</a>	50181	Type II	2010/01/21	N.A.	N.A.
2010/01/21	Hospira A) Symbiq Set Backcheck Valve Clave Port (16000, 16008, 16013, 16019, 16021, 16022) B) Lifeshield Latexfree Primary Symbiq (16089, 16090, 16093)	<a href="#">Health Canada</a>	51955	Type II	2010/01/21	Hospira Limited	2898 2886
2010/01/21	Nipro Blood Tubing Set for Hemodialysis (A231TR/V811TR)	<a href="#">Health Canada</a>	52178	Type II	2010/01/21	N.A.	N.A.
2010/01/21	Fresenius 2008H Hemodialysis Machine (150254, 501228, 507115)	<a href="#">Health Canada</a>	49355	Type II	2010/01/21	Fresenius Medical Care Asia Pacific Ltd.	2802 2900
2010/01/21	Abbott i-Stat 1 Analyzer (06F16-10)	<a href="#">Health Canada</a>	52261	Type II	2010/01/21	Abbott Laboratories LTD.	2593 2211
2010/01/21	GE OEC 9800 Plus Mobile Digital Imaging (00-870632-05, 2274023)	<a href="#">Health Canada</a>	51836	Type II	2010/01/21	GE Medical Systems Hong Kong Ltd.	2783 1838
2010/01/21	Bio-Rad Variant II Turbo Hemoglobin A1C Program (70291500, 70292239, 70292240)	<a href="#">Health Canada</a>	52177	Type II	2010/01/21	Bio-Rad Pacific Ltd.	N.A.
2010/01/21	Spiegelberg ICP probe 3 PN [SND 13.1.53/FV534P], serial numbers 12835 to 13393, and probe 3 PS [SND 13.1.63/FV535P], serial numbers 6937 to 7122	<a href="#">MHRA</a>	2009/012/022/081/001	FSCA	2010/01/21	N.A.	N.A.
2010/01/22	Medtronic Sofamor Danek Extended Length Trocar (Item No.: 7578013, 7578014)	<a href="#">FDA</a>	Z-0606-2010 to Z-0607-201	Class II	2010/01/22	Medtronic International, Ltd.	2919 1300
2010/01/22	Cordis Aquatrack Hydrophilic Nitinol Guidewire, REF C3526-SSA	<a href="#">FDA</a>	Z-0623-2010	Class II	2010/01/22	Johnson & Johnson Medical (HK)	2738 6027
2010/01/22	Sorin Clearglide EVH (REF: KTV15, KTV16, KTV17, KTV18, KTV22, KTV23), Clearglide Precision Bipolar (REF: PBD01)	<a href="#">FDA</a>	Z-0624-2010 to Z-0630-2010	Class II	2010/01/22	N.A.	N.A.

2010/01/22	Orthofix Pillar SA PEEK Spacer System Instrument Case (REF: 49-0021) (Pillar SA Insertion Instrument 49-1100)	<a href="#">FDA</a>	Z-0641-2010		2010/01/22	N.A.	N.A.
2010/01/22	Remel Mueller Hinton Agar w/4% NaCl w/6 mcg/ml Oxacillin (Ref R01626)	<a href="#">FDA</a>	Z-0644-2010	Class II	2010/01/22	Hong Kong South East Chemicals & Instruments Ltd	2802 6333
2010/01/22	Teleflex Medical Hudson RCI One Way Valve (REF 1665)	<a href="#">FDA</a>	Z-0652-2010	Class II	2010/01/22	N.A.	N.A.
2010/01/22	Welch Allyn A) Vital Signs 300 Monitor w/Pulse Rate B) Vital Signs 300 Monitor w/Pulse Rate/Printer C) Vital Signs 300 w/Pulse Rate/Map/Printer D) Vital Signs 300 w/Temperature and Printer E) Vital Signs 300 Monitor/Nellcor SPO2 F) Vital Signs 300 Monitor/Nellcor SPO2 Printer G) Vital Signs 300 Monitor/Nellcor SPO2/Temp H) Vital Signs 300 Monitor/SPO2/Temp/Printer	<a href="#">Health Canada</a>	52292	Type II	2010/01/22	N.A.	N.A.
2010/01/22	Mindray SmarTemp Probe for use with VS-800 Vital Signs Monitor	Mindray	N.A.	Firm Initiated Field Action	2010/01/22	N.A.	N.A.
2010/01/22	Varian Ximatron, all C-Series models	Varian Medical Systems Pacific Inc.	CP-01842	Firm Initiated Field Action	2010/01/22	Varian Medical Systems Pacific Inc.	2724 2836
2010/01/25	Hettich Plastic Hematocrit Rotors (201424-01 Haematocrit 20 with 2050 haematocrit rotor, 2004-01 Mikro 20 with 2076 haematocrit rotor, 2070 Mikro 12-24 with 2050 haematocrit rotor, 2075 Haematocrit 24 with 2050 haematocrit rotor)	<a href="#">FDA</a>	N.A.	Press Release	2010/01/25	N.A.	N.A.
2010/01/25	Nipro All GlucoPro Insulin Syringes (JD+01U3008-5C, JD+01U3013-5C, JD+01U3013-5C, JD+01U3108-5C, JD+01U3108-5C, JD+03U3008-5C, JD+03U3013-5C, JD+03U3013-5C, JD+03U3108-5C, JD+03U3108-5C, JD+05U3008-5C, JD+05U3013-5C, JD+05U3013-5C, JD+05U3108-5C)	<a href="#">FDA</a>	N.A.	Press Release	2010/01/25	N.A.	N.A.
2010/01/25	Accuray Cyberknife Robotic Radiosurgery System (MultiPlan Treatment Planning System Version 3.5)	<a href="#">MHRA</a>	2010/001/019/291/012	FSCA	2010/01/25	Accuray Asia Ltd	2247 8628
2010/01/25	ThermoFisher Scientific Oxoid Ready Poured Plate, Pseudomonas CFC Selective Agar, PO0291A, lot number 1113977	<a href="#">MHRA</a>	2010/001/019/601/001	FSCA	2010/01/25	N.A.	N.A.
2010/01/26	Invitrogen DRB3,4,5 SSP UniTray (451806D), DRB4 AllSet Gold SSP (542110D), DRB3,4,5 AllSet Gold SSP (54080D), Cw High Resolution SSP UniTray (4719010), Cw AllSet Gold SSP (54030D)	<a href="#">MHRA</a>	2009/012/031/081/007	FSCA	2010/01/26	Invitrogen Hong Kong Limited	N.A.
2010/01/26	Roche Elecsys Folate III (Material No. 04476433190)	<a href="#">MHRA</a>	2010/001/021/081/009	FSCA	2010/01/26	Roche Diagnostics (Hong Kong) Ltd	2485 7510
2010/01/26	Invitrogen SSP UniTray and AllSet Gold HLA typing kits (450303, 450504D, 450514, 450904, 450202D, 450212D, 54230D, 54240D, 54250D, 54260D, 54290D)	<a href="#">MHRA</a>	2009/012/022/081/019	FSCA	2010/01/26	Invitrogen Hong Kong Limited	N.A.
2010/01/27	Exelint Exel/Exelint Huber needles (Code: 26901, 26902, 26904, 26906, 26907, 26908, 26909, 26911, 26921, 26922, 26923, 26924, 26925), Exel/Exelint Huber Infusion Sets (Code: 27940R, 27941R, 27944R, 27945R, 27946R, 27948R, 27949R, 27950R, 27954R, 27955R, 27958R, 27959R) and Exel/Exelint "Securetouch+" Safety Huber Infusion Sets (Code: 37854S, 37855S, 37858S)	<a href="#">FDA</a>	N.A.	Press Release	2010/01/27	N.A.	N.A.
2010/01/28	Medtronic Pressure Products SafeSheath CSG Sheath Introducers	Medtronic International, Ltd.	N.A.	Firm Initiated Field Action	2010/01/28	Medtronic International, Ltd.	2919 1300
2010/01/29	Edwards Lifesciences Aquarius Hemodialysis System (Model no. GEF08200, GEF09500, GEF09600, GEF09700, and GEF09800, using Software version 6.00.04)	<a href="#">FDA</a>	N.A.	News Release	2010/01/29	N.A.	N.A.
2010/01/29	Stelkast Unicondylar Knee Femoral Component SC2462-1, Lot no. 20210-100108	<a href="#">FDA</a>	Z-0371-2010	Class II	2010/01/29	N.A.	N.A.
2010/01/29	Biomet 2.9 Micromax L-15 suture anchor (REF 905456. Lot no. 695710)	<a href="#">FDA</a>	Z-0611-2010	Class II	2010/01/29	N.A.	N.A.
2010/01/29	Tomier Arthro Tunneler (Cat. No. SMB000101, Lot No. 09K1, 09J5, 09J6, 09K3, 09K4, & 09K5)	<a href="#">FDA</a>	Z-0656-2010	Class II	2010/01/29	N.A.	N.A.
2001/01/29	Boston Scientific FasTrackerR-325 Infusion Catheter	Boston Scientific Hong Kong Ltd.	N.A.	Firm Initiated Field Action	2001/01/29	Boston Scientific Hong Kong Ltd	2960 7136