

## **Major Safety Alerts in April 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 April 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

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.
ConMed Electrosurgery 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	2010/04/09	N.A.	N.A.
ArjoHuntleigh Minstrel patient hoist (non scale type)	<a href="#">MHRA</a>	2009/011/003/401/001	FSCA	2010/04/12	Arjo Huntleigh (Hong Kong) Ltd.	2508 1416
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.	N.A.	Firm Initiated Field Action	2010/04/13	BrainLAB Ltd	2417 1881
Kimal Long Term Haemodialysis Catheters	<a href="#">MHRA</a>	2010/002/010/401/007	FSCA	2010/04/15	N.A.	N.A.
Fresenius Medical Care Disinfection block (spare part) for 5008 & 5008S d	<a href="#">MHRA</a>	2010/004/008/081/015	FSCA	2010/04/15	Fresenius Medical Care Hong Kong Limited	2583 0813
Precision Medical Flow Selector (Model : PM1000)	<a href="#">Health Canada</a>	53663	Type I	2010/04/15	N.A.	N.A.
Animas A) 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	2010/04/15	Johnson & Johnson Medical (HK)	2738 6027

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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.
StatSpin (IRIS Sample Processing) StatSpin Express 4 Centrifuges (Model #510)	<a href="#">FDA</a>	N.A.	Class I	2010/03/01	Vastec Medical Ltd.	2897 1912
Beckman Coulter Olympus PK7200 Blood Grouping System	<a href="#">MHRA</a>	2010/002/023/081/005	FSCA	2010/03/02	Beckman Coulter Hong Kong Ltd	2240 6150
Siemens Versacell Connectivity With Advia 1800 Systems	<a href="#">MHRA</a>	2010/002/024/081/001	FSCA	2010/03/02	Siemens Healthcare Diagnostic Limited	2810 7533
Hill-Rom ROLKO Monkey Pole equipped with a roller, Type: TGN-R100GR	<a href="#">MHRA</a>	2010/001/005/291/006	FSCA	2010/03/03	N.A.	N.A.
Wassenburg WD440 and Wassenburg WD440-PT endoscope washer disinfectors	<a href="#">MHRA</a>	2010/002/025/081/004	FSCA	2010/03/03	N.A.	N.A.
PMVL 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 (Broth)	<a href="#">Health Canada</a>	49997	Type II	2010/03/03	N.A.	N.A.
Technidata TD-Synergy software (TD-SYN-01)	<a href="#">Health Canada</a>	52749	Type II	2010/03/03	N.A.	N.A.
Philips Medical Systems A) HeartStart MRx Monitor/Defibrillator, B) HeartStart MRx AC Power Module Kit	<a href="#">Health Canada</a>	52858	Type II	2010/03/03	Philips Electronic Hong Kong Ltd	2821 5480
Wallac OY Lifecycle For Prenatal Screening	<a href="#">Health Canada</a>	52863	Type II	2010/03/03	N.A.	N.A.
Medline Industries Medline Self Sealing Sterilization Pouches	<a href="#">Health Canada</a>	52864	Type II	2010/03/03	N.A.	N.A.
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	2010/03/03	N.A.	N.A.
Zimmer Nexgen Complete Knee, Stemmed Tibial	<a href="#">Health Canada</a>	52954	Type II	2010/03/03	Zimmer PTE Ltd. (Hong Kong branch)	2992 0968
Smiths Medical Cadd-Solis Infusion Pump-AC Power Cord	<a href="#">Health Canada</a>	52967	Type II	2010/03/03	N.A.	N.A.
Smith & Nephew Wound Management Division EZCARE Negative Pressure Wound Therapy System	<a href="#">Health Canada</a>	53008	Type II	2010/03/03	Smith & Nephew LTD	2648 7700
Whatman 903 Newborn Screening Card	<a href="#">Health Canada</a>	53017	Type II	2010/03/03	N.A.	N.A.

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	2010/03/03	N.A.	N.A.
Tyco Healthcare Handi-Fil Disposable Syringe Fill Tube	<a href="#">Health Canada</a>	53027	Type II	2010/03/03	Tyco Healthcare (HKSAR) LTD	3157 7220
Olympus A) Olympus Trocar Spikes (Conical Tip), B) Olympus Trocar Spikes (Triangular Tip)	<a href="#">Health Canada</a>	53040	Type II	2010/03/03	Medical Systems Division, Olympus Hong Kong and China Limited	2170 5603
The Laryngeal Mask Company Limited A) LMA Pain Care 3000, B) LMA Pain Care 4200	<a href="#">Health Canada</a>	53106	Type II	2010/03/03	N.A.	N.A.
Wright Medical Technology Advance Tibial Wedge Augment	<a href="#">Health Canada</a>	53128	Type II	2010/03/03	N.A.	N.A.
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	2010/03/04	King Health Limited	2481 3787
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	2010/03/04	Hospira Limited	2898 2886
Biomet 3i Locator Restorative Abutment, ILOA002	<a href="#">FDA</a>	Z-0810-2010	Class II	2010/03/04	Ositek (HK), Inc. Ltd	3157 1757
Encore Medical Foundation Knee Revision Baseplate, Part Number 321-01-106	<a href="#">FDA</a>	Z-0826-2010	Class II	2010/03/04	N.A.	N.A.
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	2010/03/04	N.A.	N.A.
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	2010/03/04	N.A.	N.A.
Maquet Cardiovascular EXXCEL Soft Standard Wall EPTFE Vascular Graft, Product Code: M002004910580	<a href="#">FDA</a>	Z-0866-2010	Class II	2010/03/04	Maquet Hong Kong Ltd.	2393 9511
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	2010/03/04	Beckman Coulter Hong Kong Ltd	2240 6150
Novacare Alternating pressure mattress overlay (ASX)	<a href="#">MHRA</a>	2009/011/012/081/004	FSCA	2010/03/04	N.A.	N.A.
Synthes compression connecting screw (Part number: 358.610)	<a href="#">MHRA</a>	2010/003/001/081/015	FSCA	2010/03/05	Synthes (Hong Kong) Ltd	2724 2032
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	2010/03/05	Bio-Asia Diagnostics Co. Ltd.	2787 0906
Sysmex CA-1500 coagulation analyser (art. No. 97347516, 98306210, 99324211, 99324815)	<a href="#">MHRA</a>	2010/002/009/081/005	FSCA	2010/03/05	N.A.	N.A.
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	2010/03/05	N.A.	N.A.

Newdeal QWIX screws 4.3mm diameter, Cat. no. 111432S and 111434S	<a href="#">MHRA</a>	2010/002/008/081/016	FSCA	2010/03/05	N.A.	N.A.
Physio-Control LIFEPAK 15	Medtronic International, Ltd.	N.A.	Firm Initiated Field Action	2010/03/05	Medtronic International, Ltd.	2919 1300
Philips Healthcare HeartStart MRx Monitor/Defibrillator	Philips Electronic Hong Kong Ltd	FSN86100090A	Firm Initiated Field Action	2010/03/05	Philips Electronic Hong Kong Ltd	2821 5480
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	2010/03/08	GE Medical Systems Hong Kong Ltd.	2783 1838
Eurovema Alvema ITO pushchair	<a href="#">MHRA</a>	2010/001/005/081/002	FSCA	2010/03/08	N.A.	N.A.
SmitCare Ringwood Bathseat, Product code SNE343	<a href="#">MHRA</a>	2009/008/026/401/002	FSCA	2010/03/08	N.A.	N.A.
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	2010/03/08	Invitrogen Hong Kong Limited	2407 8450
Stryker Implant Extraction Set Brochure / Guide B1000057 (Extraction Hook Large)	<a href="#">MHRA</a>	2010/002/009/081/002	FSCA	2010/03/08	Stryker China Ltd	2522 6915
Unipath Clearview hCG Combo pregnancy test for professional use (Product code: 506760)	<a href="#">MHRA</a>	MDA/2010/016	MDA	2010/03/09	N.A.	N.A.
Steris Harmony LA, LC 500 and LA 700 Surgical Lighting and Media System	<a href="#">MHRA</a>	2010/003/002/081/008	FSCA	2010/03/09	Swedish Trading Co. Ltd.	6199 0634
Naniwa Rubber Tubing Set for Blood Purification (Model: DFPP-SGL, Lot: 980425, 992624)	<a href="#">MHRA</a>	2010/003/005/081/021	FSCA	2010/03/09	N.A.	N.A.
Aidapt VR231 Lenham adjustable height commode (manufactured in November 2008)	<a href="#">MHRA</a>	2010/002/001/401/017	FSCA	2010/03/09	N.A.	N.A.
Farla Medical Disposable Long Scissors (Product code: 4003201, batch no. 091003)	<a href="#">MHRA</a>	2010/003/001/081/002	FSCA	2010/03/09	N.A.	N.A.
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	2010/03/09	Pacific Medical Systems Limited	2108 4005
Balt Extrusion Silk intracranial stent	<a href="#">MHRA</a>	2009/012/003/401/010	FSCA	2010/03/10	N.A.	N.A.
Biomet M2A-magnum modular heads - size 44mm part #157444 (batch #1793089)	<a href="#">MHRA</a>	2010/003/004/081/017	FSCA	2010/03/10	N.A.	N.A.

Biodiagnostics MPO QuickCard lot # M683	<a href="#">MHRA</a>	2010/002/024/601/002	FSCA	2010/03/10	N.A.	N.A.
Abbott Diagnostics ARCHITECT HAVAb IgM reagent (List no. 6C30-20 and 6C30-25)	<a href="#">MHRA</a>	2010/003/002/601/007	FSCA	2010/03/10	Abbott Laboratories LTD.	2593 2211
BD GeneOhm Cdiff Assay, Cat. No. 441401	BD	N.A.	Firm Initiated Field Action	2010/03/11	BD	2575 8668
Stryker Eye Surgery Stretcher 1069 / Stryker Eye Surgery Stretcher 1079 (Product No. 1069000000 & 1079000000)	<a href="#">MHRA</a>	2010/003/004/081/010	FSCA	2010/03/11	Stryker China Ltd	2522 6915
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	2010/03/11	Arjo Huntleigh (Hong Kong) Ltd.	2508 1416
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	2010/03/11	N.A.	N.A.
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	2010/03/11	Beckman Coulter Hong Kong Ltd	2240 6150
Newdeal IPP on interphalangeal implant (Ref no. 230 001S, 230 002S)	<a href="#">MHRA</a>	2009/012/004/081/003	FSCA	2010/03/12	N.A.	N.A.
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	2010/03/12	Beckman Coulter Hong Kong Ltd	2240 6150
Biodiagnostics PR3 ANCA Serine proteinase 3 QuickCard, Part no. CS014, CS014A, Batch no. M695	<a href="#">MHRA</a>	2010/001/028/601/002	FSCA	2010/03/12	N.A.	N.A.
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	2010/03/12	N.A.	N.A.
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	2010/03/15	N.A.	N.A.
ThermoFisher Scientific Oxoid Ready Poured Plate, Yersinia Agar (CIN Medium), PO0287A, lot number 1118247	<a href="#">MHRA</a>	2010/003/005/601/002	FSCA	2010/03/15	N.A.	N.A.
DePuy (JNJ) ASR Articular Surface Replacement and ASR XI Monoblock Metal-On-Metal System	<a href="#">MHRA</a>	2010/003/009/081/036	FSCA	2010/03/15	Johnson & Johnson Medical (HK)	2738 6027
Micromedical Technologies Aquastar Water Caloric Irrigator	<a href="#">Health Canada</a>	52635	Type II	2010/03/16	N.A.	N.A.
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	2010/03/16	N.A.	N.A.

Siemens Medical Solutions Artiste MV System	<a href="#">Health Canada</a>	53047	Type II	2010/03/16	Siemens Healthcare Diagnostic Limited	2810 7533
Diagnostica Stago A) Staclot LA 20, B) Start 4 NG DSI 115V	<a href="#">Health Canada</a>	53133	Type II	2010/03/16	Healthpro Technology Co. Ltd	2575 2028
Teleflex Arrow Select IV Tubing Sets, Accessories, and Certain Embolectomy Catheters	<a href="#">FDA</a>	N.A.	Press Release	2010/03/16	N.A.	N.A.
Zimmer NextGen Knee Gender Solutions CR-Flex Femoral Component (00-5750-014-01)	<a href="#">FDA</a>	Z-0915-2010	Class II	2010/03/16	Zimmer PTE Ltd. (Hong Kong branch)	2992 0968
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	2010/03/16	Smith & Nephew LTD	2648 7700
Siemens Healthcare Diagnostics Dimension Vista System BUN Flex Reagent Cartridge, Catalog number K1021	<a href="#">FDA</a>	Z-1017-2010	Class II	2010/03/16	Siemens Healthcare Diagnostic Limited	2810 7533
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	2010/03/16	N.A.	N.A.
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	2010/03/16	N.A.	N.A.
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	2010/03/16	GE Medical Systems Hong Kong Ltd.	2783 1838
GE Healthcare Centricity PACS-IW, software version 3.7.3	<a href="#">MHRA</a>	2010/003/009/081/010	FSCA	2010/03/16	GE Medical Systems Hong Kong Ltd.	2783 1838
BrainLAB IMRI OR Power Management / Uninterruptible Power Supply	<a href="#">MHRA</a>	2010/003/009/081/035	FSCA	2010/03/16	BrainLAB Ltd	2417 1881
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	2010/03/16	Invitrogen Hong Kong Limited	2407 8450
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	2010/03/16	N.A.	N.A.
Convatec (Unomedical) Unilect ECG Electrodes	<a href="#">MHRA</a>	2010/003/010/291/001	FSCA	2010/03/17	N.A.	N.A.
Nova Biomedical Nova Statstrip Glucose Test Strips (lot no. 0309019249)	<a href="#">MHRA</a>	2010/002/019/601/003	FSCA	2010/03/17	N.A.	N.A.
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	2010/03/17	N.A.	N.A.
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	2010/03/18	Olympus Hong Kong and China Ltd	2170 5678

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	2010/03/18	N.A.	N.A.
Arrow International (Terix 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 Flex- Tip(R), ARROWg+ard Blue PLUS (R) Catheter (Catalog/Part # ASK-45703-SHB)	<a href="#">FDA</a>	N.A.	Class I	2010/03/18	N.A.	N.A.
Stryker Xia 3 Polyaxial Screw, 8.5mm x 65mm (Catalog number: 482318565)	<a href="#">FDA</a>	Z-0823-2010	Class II	2010/03/19	Stryker China Ltd	2519 6915
Synthes in situ bender / Cutter kit-wide-sterile (Cat. number: 530.512S)	<a href="#">FDA</a>	Z-0825-2010	Class II	2010/03/19	Synthes (Hong Kong) Ltd	2724 2032
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	2010/03/19	Beckman Coulter Hong Kong Ltd	2240 6150
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	2010/03/19	N.A.	N.A.
Bio-Rad Variant II Turbo Hemoglobin A1c Program, model number 270 2417	<a href="#">FDA</a>	Z-0867-2010	Class II	2010/03/19	Bio-Rad Pacific Ltd.	2789 3300
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	2010/03/19	Ultronics Enterprise Limited	2764 5208
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	2010/03/19	Stryker China Ltd	2519 6915
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	2010/03/19	N.A.	N.A.
Beckman Coulter Access Peristaltic Pump component of: UniCel DxI 800, UniCel DxI 600 and UniCel Dx C 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	2010/03/19	Beckman Coulter Hong Kong Ltd	2240 6150
Sybron Dental Specialties Sealapex Express, Part Number: 33639	<a href="#">FDA</a>	Z-0917-2010	Class II	2010/03/19	N.A.	N.A.
Kamiya Biomedical "K-ASSAY CRP (3) Calibrator E". (Catalog number: "KAI-084C")	<a href="#">FDA</a>	Z-0973-2010	Class II	2010/03/19	N.A.	N.A.
Sigma-Aldrich Histopaque-1077 (Ref. 10771), Histopaque-1119 (Ref. 11191)	<a href="#">FDA</a>	Z-0976-2010 to Z-0977-2010	Class II	2010/03/19	N.A.	N.A.
Boston Scientific Clinician Programmer M400 (SC-7150-4) Battery Pack	N.A.	N.A.	Firm Initiated Field Action	2010/03/22	Boston Scientific Hong Kong Ltd	2960 7136
Lifescan (Johnson & Johnson) Onetouch Ultrasmart Meter (Catalogue number 020-890, Lot number V0903003X)	<a href="#">MHRA</a>	2010/001/029/081/007	FSCA	2010/03/22	Johnson & Johnson Medical (HK)	2738 6027

Centurion Medical Products Pump Fill Kit DT10175	<a href="#">FDA</a>	Z-1140-2010	Class I	2010/03/25	N.A.	N.A.
Remel Oxoid CM0225 Brain Heart Infusion IVD	<a href="#">FDA</a>	Z-0979-2010	Class II	2010/03/25	Hong Kong South East Chemicals & Instruments Ltd	2802 6333
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	2010/03/25	N.A.	N.A.
Elekta PrecisePLAN 2.15 Treatment Planning System	<a href="#">FDA</a>	Z-1109-2010	Class II	2010/03/25	Elekta Ltd.	2891 2208
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	2010/03/25	A.R. Burkill & Sons (Hong Kong) Ltd	2541 1041
Remel A.C.T. II Sterile Pack Tube, Collection and Transport System, Ref 12402	<a href="#">FDA</a>	Z-1139-2010	Class II	2010/03/25	Hong Kong South East Chemicals & Instruments Ltd	2802 6333
ConvaTec (Unomedical) Neutralect Diathermy Cable, Ref code 3508M and 3405M.	<a href="#">FDA</a>	Z-1142-2010	Class II	2010/03/25	N.A.	N.A.
Sybron Dental Specialties Bond-1 Primer/Adhesive	<a href="#">FDA</a>	Z-1150-2010	Class II	2010/03/25	N.A.	N.A.
R.O. Gulden Image Consultant (IC) Software	<a href="#">FDA</a>	Z-1176-2010-2010	Class II	2010/03/25	N.A.	N.A.
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	2010/03/25	N.A.	N.A.
Nucletron Oncentra Brachy	<a href="#">MHRA</a>	2010/003/015/081/003	FSCA	2010/03/26	Nucletron Asia Pacific Ltd.	2311 2683 / 2311 2684 / 2311 3025
Animas (JNJ) 2020 Insulin Pumps	<a href="#">MHRA</a>	2010/003/022/081/014	FSCA	2010/03/26	Johnson & Johnson Medical (HK)	2738 6027
Synthes Awl 2,5 mm with Trocar tip Article Number: 324.111 All Batches	<a href="#">MHRA</a>	2010/003/016/291/010	FSCA	2010/03/26	Synthes (Hong Kong) Ltd	2724 2032
Biotest Medical Diagnostics Seraclone Anti-k (KEL2)	<a href="#">MHRA</a>	2010/003/017/291/018	FSCA	2010/03/26	Chong Lap (HK) Co. Ltd.	2736 3078
Biosite Triage TOX Drug Screen, PN 94400	<a href="#">MHRA</a>	2010/003/015/081/006	FSCA	2010/03/26	N.A.	N.A.
GE Healthcare Innova 2100IQ, 3100IQ and 4100IQ	<a href="#">MHRA</a>	2010/003/019/291/008	FSCA	2010/03/26	GE Medical Systems Hong Kong Ltd.	2783 1838
Trinity Biotech Captia Mumps IgM Kit (product code: 2325950 and 2325960)	<a href="#">MHRA</a>	2010/003/024/081/020	FSCA	2010/03/26	N.A.	N.A.
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	2010/03/26	Fresenius Kabi Hong Kong Ltd.	2116 2683
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	2010/03/29	Siemens Healthcare Diagnostic Limited	2810 7533
Beckman Coulter UniCel DxH 800 system	<a href="#">MHRA</a>	2010/003/015/601/001	FSCA	2010/03/29	Beckman Coulter Hong Kong Ltd	2240 6150
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	2010/03/29	Siemens Healthcare Diagnostic Limited	2810 7533
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	2010/03/29	Invitrogen Hong Kong Limited	2407 8450
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, 342899)	<a href="#">MHRA</a>	2010/003/025/081/018	FSCA	2010/03/29	Becton Dickinson Asia Ltd.	2575 8668

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	2010/03/29	Abbott Laboratories LTD.	2593 2211
Varian FastPlan Conical Collimator Plans	Varian Medical Systems Pacific Inc.	CP-02191	Firm Initiated Field Action	2010/03/29	Varian Medical Systems Pacific Inc.	2724 2836
Oxoid Antimicrobial Susceptibility Testing Discs Ciprofloxacin 1ug, code CT0623B, lot 843801	<a href="#">MHRA</a>	2010/003/024/601/001	FSCA	2010/03/30	Hong Kong South East Chemicals & Instruments Ltd	2802 6333
Lancer Fibro Cleaner Automatic Endoscope Reprocessors FC4	<a href="#">MHRA</a>	2009/009/002/291/012	FSCA	2010/03/30	N.A.	N.A.
Bayer Healthcare 5-second CONTOUR and CONTOUR TS Blood Glucose Monitoring System	<a href="#">MHRA</a>	2010/003/024/601/002	FSCA	2010/03/30	Bayer HealthCare Ltd.	28144815/ 28145220
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	2010/03/30	Abbott Laboratories LTD.	2593 2211
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	2010/03/30	N.A.	N.A.
Baxter Healthcare Coseal Surgical Sealant (certain serial numbers)	<a href="#">MHRA</a>	2010/001/013/081/014	FSCA	2010/03/31	Baxter Healthcare Ltd	2807 8555
Applied Medical Resources Corporation Surgical Trocars - Separator (Model : C0R36, C0R37)	<a href="#">Health Canada</a>	52934	Type II	2010/03/31	N.A.	N.A.
Stryker Trauma Implant Extraction Set	<a href="#">Health Canada</a>	53127	Type II	2010/03/31	Stryker China Ltd	2518 6915
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	2010/03/31	Beckman Coulter Hong Kong Ltd	2240 6150
Intersurgical Clear-Guard II Breathing Filter	<a href="#">Health Canada</a>	53292	Type II	2010/03/31	Shun On Healthcare Limited	3123 8000
Smith & Nephew Dyonics 25 Fluid Management System-Patient Tube Set	<a href="#">Health Canada</a>	53313	Type II	2010/03/31	Smith & Nephew LTD	2648 7700
GE Healthcare Finland OY A) Trusat Oximeter, B) Trusat Oximeter - With Expansion Option	<a href="#">Health Canada</a>	53326	Type I	2010/03/31	GE Medical Systems Hong Kong Ltd.	2783 1838
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	2010/03/31	N.A.	N.A.
Immucor Galileo Echo Blood Bank Analyzer (Model : 0087000)	<a href="#">Health Canada</a>	53353	Type II	2010/03/31	Uninet Technology LTD	2838 8423
Conmed Endoscopic Technologies Entake Tri-Funnel G-Tube	<a href="#">Health Canada</a>	53424	Type II	2010/03/31	N.A.	N.A.
Tomotherapy Hi-Art System (S/N: 10169, 10037)	<a href="#">Health Canada</a>	53493	Type II	2010/03/31	N.A.	N.A.
<a href="#">Poly Implant Prothese IMGHC-TX, IMGHC-MX, IMGHC-LS</a>	N.A.	FR-2010-03-007	FSCA	2010/03/31	N.A.	N.A.



## Major Safety Alerts in February 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 February 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

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.
Inion CPS baby screw (REF: SCR-1221, Lot no. 0809009 and 0809069)	<a href="#">MHRA</a>	2010/001/015/081/006	FSCA	2010/02/01	N.A.	N.A.
Trinity Biotech Captia Measles IgM Kit (Product Code: 2326050)	<a href="#">MHRA</a>	2010/001/025/291/009	FSCA	2010/02/01	N.A.	N.A.
Beckman Coulter Closed tube aliquotter (CTA) for synchron LXi725 (REF: 388982, 389695) and UniCel Dx600i (REF: A25637, A25633)	<a href="#">MHRA</a>	2010/001/025/601/001	FSCA	2010/02/01	Beckman Coulter Hong Kong Ltd	2240 6150
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	2010/02/01	Stryker China Ltd	2518 6915
Philips Switched Reusable Internal Defibrillation Paddles (Product Numbers M4741A, M4742A, M4743A and M4744A)	Philips Electronic Hong Kong Ltd	FSN86100088A	Firm Initiated Field Action	2010/02/02	Philips Electronic Hong Kong Ltd	2821 5480
Centurion Healthcare Products (code no. LM110, LM115)	<a href="#">FDA</a>	Z-0105-2010 to Z-0106-2010	Class I	2010/02/04	N.A.	N.A.
GE OEC 9900 Elite ESP, GE OEC 9900 Elite GSP Fluoroscopes	<a href="#">FDA</a>	Z-0004-2010 to Z-0005-2010	Class II	2010/02/04	GE Medical Systems Hong Kong Ltd.	2783 1838
Richard Wolf Hulka Clip, item 4986.90	<a href="#">FDA</a>	Z-0272-2010	Class II	2010/02/04	N.A.	N.A.
GE Infinia with Hawkeye 1 (model no.: H2508PW, H2508PY, H3000WN, H3000WR, H3000WW, 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	2010/02/04	GE Medical Systems Hong Kong Ltd.	2783 1838
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	2010/02/04	N.A.	N.A.
Zap Lasers SoftLase Pro Dental Lasers	<a href="#">FDA</a>	Z-0587-2010	Class II	2010/02/04	N.A.	N.A.
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	2010/02/04	GE Medical Systems Hong Kong Ltd.	2783 1838
GE MAC 800 RESTING ECG ANALYSIS SYSTEM.	<a href="#">FDA</a>	Z-0645-2010	Class II	2010/02/04	GE Medical Systems Hong Kong Ltd.	2784 1838
KCI AC Power Cords (#4100079, 4102204, M4268840, 340225, M4268882, M4268884).	<a href="#">FDA</a>	Z-0662-2010 to Z-0667-2010	Class II	2010/02/04	N.A.	N.A.
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	2010/02/04	N.A.	N.A.

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	2010/02/04	N.A.	N.A.
Merivaara Merilux X3, Merilux X5, Merilux Duo 320, Merilux Trio 360	<a href="#">MHRA</a>	2009/009/023/081/001	FSCA	2010/02/04	N.A.	N.A.
ev3 Silverhawk cutter driver (Catalogue number FG 02550)	<a href="#">MHRA</a>	2010/001/029/081/008	FSCA	2010/02/04	Sinomed Company Ltd.	28877640
Hospira A) Lifeshield Nonvented Primary IV Set, B) Lifeshield Microdrip Primary Piggyback	<a href="#">Health Canada</a>	52078	Type II	2010/02/04	Hospira Limited	2898 2886
Dana Douglas Nexus 3 Model : 4500185F, 4500225F, 4500245F	<a href="#">Health Canada</a>	52174	Type II	2010/02/04	N.A.	N.A.
Howmedica Osteonics Scorpio 4:1 Ceramic Blocks	<a href="#">Health Canada</a>	52242	Type II	2010/02/04	N.A.	N.A.
Abaxis Piccolo Comprehensive Metabolic Panel	<a href="#">Health Canada</a>	52289	Type II	2010/02/04	N.A.	N.A.
Toshiba Aquilion One TSX-301A/2	<a href="#">Health Canada</a>	52445	Type II	2010/02/04	Sanko Medical Systems (HK) LTD	2384 0688
Stryker Spine Jam Shidi Needles	<a href="#">Health Canada</a>	52532	Type II	2010/02/04	N.A.	N.A.
Dana Douglas A) Nexus 1, B) Nexus 2	<a href="#">Health Canada</a>	52535	Type I	2010/02/04	N.A.	N.A.
Baxter Y-Type Blood Solution Sets	<a href="#">Health Canada</a>	52558	Type II	2010/02/04	Baxter Healthcare Ltd	2807 8516
Howmedica Osteonics Restoration Modular Plasma Distal Stem	<a href="#">Health Canada</a>	52681	Type II	2010/02/04	N.A.	N.A.
Dorel Juvenile Ear Thermometer Model 49531	<a href="#">Health Canada</a>	49531	Type II	2010/02/04	N.A.	N.A.
Fimet F1 Dental Chair	<a href="#">MHRA</a>	2009/001/014/291/002	FSCA	2010/02/04	N.A.	N.A.
Thomas Medical Products Safesheath CSG Coronary Sinus Guide Hemostatic Introducer System with Infusion Sideport	FDA	N.A.	News Release	2010/02/05	N.A.	N.A.
Bound Tree Economy vacuum splints (Product code: SP040, SP041, SP042, SP043)	<a href="#">MHRA</a>	2009/009/010/401/001	FSCA	2010/02/05	N.A.	N.A.
Cardiac Science Powerheart 9300A, 9300E, 9300P, 9390A, 9390E, CardioVive 92532, CardioLife 9200G and 9231 (manufactured/serviced between Oct 19, 2009 and Jan 15, 2010)	Pacific Medical Systems Limited	N.A.	Firm Initiated Field Action	2010/02/08	Pacific Medical Systems Limited	2108 4005
Reva Elegance, Excalibur ,Appollo and Highgrove baths	<a href="#">MHRA</a>	2008/011/013/301/002	FSCA	2010/02/08	N.A.	N.A.
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	2010/02/08	GE Medical Systems Hong Kong Ltd.	2783 1838
BD Shigella poly Group D Antiserum S. sonnei; types I,II, 241031 (Lot # 8032036 & 9110319)	BD	N.A.	Firm Initiated Field Action	2010/02/08	BD	2575 8668
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	2010/02/09	Covidien	3157 7220

Philips Panorama HFO systems on software release R2.5.3 and higher	<a href="#">MHRA</a>	2010/002/001/081/028	FSCA	2010/02/09	Philips Electronic Hong Kong Ltd	2821 5480
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	2010/02/09	Accuray Asia Ltd	2247 8628
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	2010/02/10	BD	2575 8668
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	2010/02/10	N.A.	N.A.
Elekta IMPAC Medical Systems SEQUENCER for MOSAIQ	<a href="#">MHRA</a>	2010/002/001/081/029	FSCA	2010/02/12	N.A.	N.A.
Cook Novy Cornual Cannulation Set	<a href="#">MHRA</a>	2010/001/020/081/002	FSCA	2010/02/12	N.A.	N.A.
diaDexus PLAC Test Reagent Kit (10-0112, 10-0113, 10-0115)	<a href="#">MHRA</a>	2010/001/025/081/001	FSCA	2010/02/12	N.A.	N.A.
Medtronic EnRhythm & EnRhythm MRI pacemakers	Medtronic	N.A.	Firm Initiated Field Action	2010/02/12	Medtronic International, Ltd.	2919 1300
Johnson & Johnson LifeScan OneTOuch SUreStep and OneTouch SUreStep Hospital Test Strips	Johnson & Johnson Medical (HK)	N.A.	Firm Initiated Field Action	2010/02/12	Johnson & Johnson Medical (HK)	2738 6027
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	2010/02/17	Invitrogen Hong Kong Limited	2407 8450
Beckman Coulter PrepPlus (PN 286600) Coulter Preplus	<a href="#">MHRA</a>	2010/002/004/601/002	FSCA	2010/02/17	N.A.	N.A.
Smith & Nephew Orthopaedics Promos Standard Inclination Set - Model Numbers 75006722, 75006723, 75006724, 75006725, 75006722	<a href="#">MHRA</a>	2010/002/008/601/002	FSCA	2010/02/17	N.A.	N.A.
Stryker Femoral Sponges	<a href="#">MHRA</a>	2010/002/004/291/016	FSCA	2010/02/17	N.A.	N.A.
Beckman Coulter Clinical Chemistry Instrumentation A10405, A11810, A27318, A11816, A11812, A59102, A64903, A64871, A64935	<a href="#">MHRA</a>	2010/001/012/601/001	FSCA	2010/02/17	N.A.	N.A.
GE Centricity PACS RA1000 Workstation	<a href="#">MHRA</a>	2010/002/004/291/013	FSCA	2010/02/17	N.A.	N.A.
Roche Diagnostics Accu-Chek Inform II meter	<a href="#">MHRA</a>	2010/002/011/081/004	FSCA	2010/02/17	N.A.	N.A.
ConMed Linvatec TS8850 concept grafix tendon stripper	<a href="#">MHRA</a>	2010/002/008/081/018	FSCA	2010/02/17	N.A.	N.A.
Invacare Scanbed 750 Hospital Bed	<a href="#">MHRA</a>	2008/002/011/061/019	FSCA	2010/02/17	N.A.	N.A.
Beckman Coulter Access AccuTnl Reagent Kit	<a href="#">MHRA</a>	2010/002/010/601/003	FSCA	2010/02/17	N.A.	N.A.
Baxter HomeChoice Automated PD System / HomeChoice PRO Automated PD	Baxter Healthcare Ltd.	N.A.	Firm Initiated Field Action	2010/02/17	Baxter Healthcare Ltd	2807 8516
Philips Allura Xper Systems / Allura Integris Systems with Velara Generator	Philips Electronic Hong Kong Ltd	N.A.	Firm Initiated Field Action	2010/02/17	Philips Electronic Hong Kong Ltd	2821 5480
BD 10ml LS Plastipak Syringe, 302188	BD	N.A.	Firm Initiated Field Action	2010/02/17	BD	2575 8668
Eden Medical Portable IV Infusion Pumps	<a href="#">MHRA</a>	2009/012/031/081/014	FSCA	2010/02/18	N.A.	N.A.
Jointmedica Birmingham Knee Replacement bearing insert re. 300003-10	<a href="#">MHRA</a>	2010/001/019/081/006	FSCA	2010/02/18	N.A.	N.A.
Stryker Tessier Osseous Microtome (TOM) bone mill	<a href="#">MHRA</a>	2010/002/011/081/015	FSCA	2010/02/18	N.A.	N.A.

Cincinnati Sub-Zero Products Warmair Cardiac Blanket	<a href="#">Health Canada</a>	52127	Type II	2010/02/18	N.A.	N.A.
Beckman Coulter Unicel DXC 600, 800, 600I, 880I, 660I, 680I, 860I	<a href="#">Health Canada</a>	52600	Type II	2010/02/18	N.A.	N.A.
Smiths Medical AC Power Cords used with 9200 Advisor / 8400 Capnocheck / BC1 3180 Pulse	<a href="#">Health Canada</a>	52815	Type II	2010/02/18	N.A.	N.A.
EMCM Artesense (PMMA Collagen Dermal Implant)	<a href="#">Health Canada</a>	52836	Type II	2010/02/18	N.A.	N.A.
Pointe Scientific Liquid Glucose (HEXO) Reagent Set - 814301, 820502, 823901, 826801, 829401, 814301, 820502, 831502	<a href="#">FDA</a>	Z-0104-2010	Class I	2010/02/18	N.A.	N.A.
Stryker Instruments Navigation System II CART / PC SPC-1	<a href="#">FDA</a>	Z-0123-2010 to Z-0123-2010	Class I	2010/02/18	N.A.	N.A.
Stryker Imaging Guradian Services Software 0240-009-430, 0240-020-013, 0240-020-022	<a href="#">FDA</a>	Z-0134-2010	Class II	2010/02/18	N.A.	N.A.
Medcomp 10F Bioflex Tesio Kit with cutting trocar, BFR-6CTT	<a href="#">FDA</a>	Z-0161-2010	Class II	2010/02/18	N.A.	N.A.
STERIS Harmony LL 500/700 Surgical Light, Vertical Spring-Loaded Arm	<a href="#">FDA</a>	Z-0414-2010	Class II	2010/02/18	Swedish Trading Co. Ltd.	6199 0634
Biomet bone mulch screw, 10.5mm x 20mm, TI-6AL-4V alloy, steril, Ref. 907320	<a href="#">FDA</a>	Z-0779-2010	Class II	2010/02/18	N.A.	N.A.
Cincinnati Sub-Zero Products FilteredFlo Cardiac Blanket / TempPad Cold Therapy Pad	<a href="#">FDA</a>	Z-0781-2010 to Z-0782-2010	Class II	2010/02/18	N.A.	N.A.
Edwards Lifesciences Fogarty Occlusion Catheter Ref. 6208022F	<a href="#">FDA</a>	Z-0002-2010	Class II	2010/02/18	N.A.	N.A.
Philips HeartStart MRx(M3535A/M3536A) Defibrillator / Monitor Serial No. US00533518 to US00535118	<a href="#">FDA</a>	Z-0003-2010	Class II	2010/02/18	Philips Electronic Hong Kong Ltd	2821 5480
Synthes 2.0mm Screw Manipulation Forceps, Bending Pliers-straight for Craniofacial/Orthognathic, Plate Holding Forceps, TI Matrixmanible Saggittal, 2.0mm Drill bit Stryker J-latch	<a href="#">FDA</a>	Z-0075-2010 to Z-0082-2010	Class II	2010/02/18	N.A.	N.A.
SapiMed SMA 4545FP Sterile Rectoscopy Kit - Lot no. 9A010I	<a href="#">MHRA</a>	2010/001/026/401/023	FSCA	2010/02/19	N.A.	N.A.
GlaxoSmithKline (GSK) Polident Dentrue Adhesives (Zn)	GlaxoSmithKline Limited	N.A.	Firm Initiated Field Action	2010/02/19	GlaxoSmithKline Limited	31898904
Bredent Medical Dental Implant SKYFF002	<a href="#">MHRA</a>	2010/002/008/081/012	FSCA	2010/02/22	N.A.	N.A.
Leica Biosystems Peloris Rapid Tissue Processor Part Number 26.001	TGA	RC-2010-RN-00122-3	Class II	2010/02/22	Leica Microsystems Limited	2564 6699
Boston Scientific BLUE MAX and Ultra-thin Diamond Balloon Dilatation Catheters	Boston Scientific Hong Kong Ltd	N.A.	Firm Initiated Field Action	2010/02/22	Boston Scientific Hong Kong Ltd	2960 7136
American Medical Systems GreenLight HPS Fibre	<a href="#">MHRA</a>	2010/001/026/081/006	FSCA	2010/02/24	N.A.	N.A.
Maquet Cardiopulmonary Vasoview Hemopro Endoscopic Vessel Harvesting System	<a href="#">MHRA</a>	2010/002/001/081/024	FSCA	2010/02/24	Maquet Hong Kong Ltd.	2393 9511
Solafeet Model ST-400 Solafeet Foot portable tanners	<a href="#">FDA</a>	Z-0608-2010	Class II	2010/02/25	N.A.	N.A.
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	2010/02/25	King Health Limited	2481 3787
Abbott Vascular (Guidant) RX ACCULINK Carotid Stent System, 10x40 mm, Product Number: 1011344-40.	<a href="#">FDA</a>	Z-0749-2010	Class II	2010/02/25	Abbott Laboratories LTD.	2593 2211
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	2010/02/25	Stryker China Ltd	2518 6915

Stryker Xia Precision System (Catalog number: 48237110, 48237105, 48237115, 48237135).	<a href="#">FDA</a>	Z-0789-2010 to Z-0792-2010	Class II	2010/02/25	Stryker China Ltd	2519 6915
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	2010/02/25	Stryker China Ltd	2520 6915
Stryker Scorpio PS Femoral Waffle (No post) with LFIT, Product code 72-4107-L.	<a href="#">FDA</a>	Z-0795-2010	Class II	2010/02/25	Stryker China Ltd	2521 6915
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	2010/02/25	Stryker China Ltd	2522 6915
Neurovision Medical Products 2-Channel Laryngeal Surface Electrode (Model LSE500DCS and LSE500DCL)	<a href="#">FDA</a>	Z-0798-2010	Class II	2010/02/25	N.A.	N.A.
Wescor Hematology reagent C eosin stain SS-035C	<a href="#">MHRA</a>	2010/002/015/081/003	FSCA	2010/02/25	N.A.	N.A.
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	2010/02/25	N.A.	N.A.
Zimmer Reconstruction System Tenaculum Instruments	Zimmer PTE Ltd. (Hong Kong branch)	N.A.	Firm Initiated Field Action	2010/02/25	Zimmer PTE Ltd. (Hong Kong branch)	2992 0968
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	2010/02/26	BD	2575 8668
Trumpf Ondal spring arm AC2000 in Helicon and Xenion surgical lights	<a href="#">MHRA</a>	2010/002/018/081/007	FSCA	2010/02/26	N.A.	N.A.
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	2010/02/26	Abbott Laboratories LTD.	2593 2211

## Major Safety Alerts in January 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 January 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

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.
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
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
Flir MilCAM Recon III, Family of IR Imagers that incorporates a Class IIIb infrared laser pointer	<a href="#">FDA</a>	Z-1223-2009	Class II	2010/01/04	FLIR Systems Co., Ltd.	2792 8955
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
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.
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
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
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.
BioTek Gen5CL Microplate Data Collection and Analysis Software	<a href="#">FDA</a>	Z-2223-2009	Class II	2010/01/04	N.A.	N.A.
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
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
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
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.
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.
bioMérieux chromID Salmonella agar	<a href="#">MHRA</a>	2009/012/001/601/002	FSCA	2010/01/04	bioMérieux China Ltd.	2195 9348
bioMérieux Vidas TPSA	<a href="#">MHRA</a>	2009/012/001/601/001	FSCA	2010/01/04	bioMérieux China Ltd.	2195 9348
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
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
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
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

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
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
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
Hill-Rom Affinity Four Birthing Bed (Model P3700B)	<a href="#">FDA</a>	Z-0548-2010	Class II	2010/01/07	N.A.	N.A.
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
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
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
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.
Cardia Atrisept II ASD and PFO devices	<a href="#">MHRA</a>	2010/001/007/291/004	FSCA	2010/01/12	N.A.	N.A.
Invacare Action 3 and Action 4 manual wheelchairs	<a href="#">MHRA</a>	MDA/2010/004	MDA	2010/01/12	Direct Health Ltd.	N.A.
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
GE Healthcare Solar 8000I System - Patient Monitor	<a href="#">Health Canada</a>	43880	Type II	2010/01/14	GE Medical Systems Hong Kong Ltd.	2783 1838
Ossur Total Knee Prosthetic Device (Model : TK1100)	<a href="#">Health Canada</a>	50746	Type II	2010/01/14	N.A.	N.A.
Siemens Medical Solutions Acuson X300 (Model : 10037409)	<a href="#">Health Canada</a>	50794	Type II	2010/01/14	Siemens Healthcare Diagnostic Limited	2810 7533
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
Baxter Syndeo PCA Syringe Pump (Model : 2L3113, 2L3113R)	<a href="#">Health Canada</a>	50978	Type II	2010/01/14	Baxter Healthcare Ltd	2807 8555
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
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
Sorin Clearguide Precision Bipolar Devices (Model : KTV15, PBD01)	<a href="#">Health Canada</a>	51914	Type II	2010/01/14	N.A.	N.A.
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
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.
Millipore Millex 33 Syringe Filter Unit (Model : SLGVM33RS)	<a href="#">Health Canada</a>	52075	Type II	2010/01/14	N.A.	N.A.
Lumenis One (Model : GAL 150000)	<a href="#">Health Canada</a>	52100	Type II	2010/01/14	N.A.	N.A.
Siemens Healthcare Diagnostics Crotor	<a href="#">Health Canada</a>	52101	Type II	2010/01/14	Siemens Healthcare Diagnostic Limited	2810 7533
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
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
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.
Teleflex Medical One Way Valve (Model : 1665)	<a href="#">Health Canada</a>	52132	Type II	2010/01/14	N.A.	N.A.
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
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

Baxa Exactamix Empty Eva Container (Model : 738, 739, 740)	<a href="#">Health Canada</a>	52180	Type II	2010/01/14	N.A.	N.A.
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
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.
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.
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
Bausch & Lomb A) Ophthalmic Cannula, B) IRR Manipiece, 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) Scleral 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
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.
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.
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.
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
Merit Medical Systems Mistique Infusion Catheters	<a href="#">MHRA</a>	2009/012/030/081/016	FSCA	2010/01/14	King Health Limited	2481 3787
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.
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.
Covidien Staplers, cutters and various products (product code: CART; SRVM; Surg200; Surg300; OPMA, CS21; CS25; CS29; CS33 RALC30; RALC30V; RALC45; RCW100; SLC55B; SLC55G; SLCR55B; SLCR55G; 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
Numed IMPACT Catheters (Model No. 307)	<a href="#">FDA</a>	Z-0509-2010	Class II	2010/01/18	N.A.	N.A.
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
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.
Inviscare Storm TDX SR Power Intraocular Lens with Stability Lock, Model numbers: TDXSR, TDXSR-CG, TDXSR-CG-HD, TDXSR-HD, TDXSR-MCG, TDXSR-MCG-HD, TDXSRV-HD	<a href="#">FDA</a>	Z-0579-2010	Class II	2010/01/18	Direct Health LTD	N.A.

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.
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.
BD 30 ml Syringe Luer-Lok Tip (Catalog # 309650)	<a href="#">FDA</a>	Z-0586-2010	Class II	2010/01/18	BD	2575 8668
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.
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
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.
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
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
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.
Siemens Axiom Iconos R200	<a href="#">MHRA</a>	2009/012/009/081/013	FSCA	2010/01/20	Siemens Healthcare Diagnostic Limited	2810 7533
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
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
Unomedical Diathermy cables 3405M and 3508M	<a href="#">MHRA</a>	2010/001/012/081/001	FSCA	2010/01/21	N.A.	N.A.
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.
Berchtold 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.
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
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
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.
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
Nipro Blood Tubing Set for Hemodialysis (A231TR/V811TR)	<a href="#">Health Canada</a>	52178	Type II	2010/01/21	N.A.	N.A.
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
Abbott i-Stat 1 Analyzer (06F16-10)	<a href="#">Health Canada</a>	52261	Type II	2010/01/21	Abbott Laboratories LTD.	2593 2211
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
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.
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.
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
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

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.
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.
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
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.
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.
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.
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
Hettich Plastic Hematocrit Rotors (201424-01 Haematokrit 20 with 2050 haematocrit rotor, 2004-01 Mikro 20 with 2076 haematocrit rotor, 2070 Mikro 12-24 with 2050 haematocrit rotor, 2075 Haematokrit 24 with 2050 haematocrit rotor)	<a href="#">FDA</a>	N.A.	Press Release	2010/01/25	N.A.	N.A.
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.
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
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.
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.
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
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.
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.
Medtronic Pressure Products SafeSheath CSG Sheath Introducers	Medtronic International, Ltd.	N.A.	Firm Initiated Field Action	2010/01/28	Medtronic International, Ltd.	2919 1300
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.
Stelkast Unicodylar 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.
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.
Tornier 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.
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