

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	FDA	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	FDA	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	FDA	Z-1223-2009	Class II	2010/01/04	FLIR Systems Co., Ltd.	2792 8955
GE Healthcare CT Systems Table Model Number 2225283, 227124, 22269165	FDA	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	FDA	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)	FDA	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	FDA	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)	FDA	Z-1931-2009	Class II	2010/01/04	N.A.	N.A.
BioTek Gen5CL Microplate Data Collection and Analysis Software	FDA	Z-2223-2009	Class II	2010/01/04	N.A.	N.A.
St. Jude Medical (SJM) FAST-CATH Hemostasis Introducer (REF 406702, 406709)	FDA	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)	MHRA	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	MHRA	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	MHRA	2009/010/028/401/002	FSCA	2010/01/04	Shun On Healthcare Limited	N.A.
AGA Medical Corporation Amplatzer TorqVue 45° Delivery System	MHRA	2009/012/022/081/005	FSCA	2010/01/04	N.A.	N.A.
bioMérieux chromID Salmonella agar	MHRA	2009/012/001/601/002	FSCA	2010/01/04	bioMérieux China Ltd.	2195 9348
bioMérieux Vidas TPSA	MHRA	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)	FDA	N.A.	Class I	2010/01/06	Sinomed Company Ltd.	2887 7640
Agfa Mamoray HDR-C Plus DLF1 - 37780023	MHRA	2009/011/017/401/013	FSCA	2010/01/06	AGFA Hong Kong Limited	2555 9421
Siemens Healthcare Diagnostics Dade Hepzyme B4240-10, lot 528752	MHRA	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)	MHRA	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	FDA	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	FDA	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)	FDA	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)	FDA	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)	FDA	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	MHRA	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	N.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	MHRA	2009/012/015/081/016	FSCA	2010/01/12	N.A.	N.A.
Cardia Atrisept II ASD and PFO devices	MHRA	2010/001/007/291/004	FSCA	2010/01/12	N.A.	N.A.
Invacare Action 3 and Action 4 manual wheelchairs	MHRA	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)	MHRA	2009/012/016/081/010	FSCA	2010/01/13	Stryker China Ltd	2518 6915
GE Healthcare Solar 8000I System - Patient Monitor	Health Canada	43880	Type II	2010/01/14	GE Medical Systems Hong Kong Ltd.	2783 1838
Ossur Total Knee Prosthetic Device (Model : TK1100)	Health Canada	50746	Type II	2010/01/14	N.A.	N.A.
Siemens Medical Solutions Acuson X300 (Model : 10037409)	Health Canada	50794	Type II	2010/01/14	Siemens Healthcare Diagnostic Limited	2810 7533
Beckman Coulter Immage Alpha2-Macroglobulin AMG Reagent	Health Canada	50959	Type II	2010/01/14	Beckman Coulter Hong Kong Ltd	2240 6150
Baxter Syndeo PCA Syringe Pump (Model : 2L3113, 2L3113R)	Health Canada	50978	Type II	2010/01/14	Baxter Healthcare Ltd	2807 8555
GE Medical Systems A) Omega 1V Table, B) Omega V Table	Health Canada	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)	Health Canada	51667	Type II	2010/01/14	Siemens Healthcare Diagnostic Limited	2810 7533
Sorin Clearguide Precision Bipolar Devices (Model : KTV15, PBD01)	Health Canada	51914	Type II	2010/01/14	N.A.	N.A.
Toshiba Aplio Artida Ultrasound System (Model : SSH-880CV)	Health Canada	51965	Type II	2010/01/14	Sanko Medical Systems (HK) LTD	23840688
Dixtal Pulse Oximetry Products (Model : A) 2001, B) 515B, 520A	Health Canada	52058	Type II	2010/01/14	N.A.	N.A.
Millipore Millex 33 Syringe Filter Unit (Model : SLGVM33RS)	Health Canada	52075	Type II	2010/01/14	N.A.	N.A.
Lumenis One (Model : GAL 150000)	Health Canada	52100	Type II	2010/01/14	N.A.	N.A.
Siemens Healthcare Diagnostics Crotor	Health Canada	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)	Health Canada	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	Health Canada	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	Health Canada	52122	Type II	2010/01/14	N.A.	N.A.
Teleflex Medical One Way Valve (Model : 1665)	Health Canada	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	Health Canada	52133	Type II	2010/01/14	B Braun Medical Hong Kong	2277 6125
Zimmer Nexgen Complete Knee Solution, MIS (Model : 00-5954-057-02)	Health Canada	52161	Type II	2010/01/14	Zimmer PTE Ltd. (Hong Kong branch)	2992 0968

Baxa Exactamix Empty Eva Container (Model : 738, 739, 740)	Health Canada	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	Health Canada	52186	Type II	2010/01/14	Stryker China Ltd	2518 6988
Howmedica Osteonics Triathlon Total Stabilizer Femur (Model : 5512-F-301, 5512-F-501)	Health Canada	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	Health Canada	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	Health Canada	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	Health Canada	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)	MHRA	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	MHRA	2010/001/006/601/006	FSCA	2010/01/14	N.A.	N.A.
Thermo Fisher Scientific PO0152A Mueller Hinton Agar, 4mm depth	MHRA	2010/001/006/601/005	FSCA	2010/01/14	N.A.	N.A.
Beckman Coulter Access Free T3 Calibrators A13430	MHRA	2010/001/005/601/001	FSCA	2010/01/14	Beckman Coulter Hong Kong Ltd	2240 6150
Merit Medical Systems Mistique Infusion Catheters	MHRA	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	MHRA	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,	FDA	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; Surg300; 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;	FDA	Z-0392-2010 to Z-0412-2010	Class II	2010/01/18	Covidien	3157 7220
Numed IMPACT Catheters (Model No. 307)	FDA	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)	FDA	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)	FDA	Z-0542-2010	Class II	2010/01/18	N.A.	N.A.
Invacare Storm TDX SR Power wheelchair with Stability Lock, model numbers: TDXSR, TDXSR-CG, TDXSR-CG-HD, TDXSR-HD, TDXSR-MCG, TDXSR-MCG-HD, TDXSRV-HD	FDA	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)	FDA	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)	FDA	Z-0585-2010	Class II	2010/01/18	N.A.	N.A.
BD 30 ml Syringe Luer-Lok Tip (Catalog # 309650)	FDA	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)	FDA	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)	FDA	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)	FDA	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	FDA	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	MHRA	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)	MHRA	2010/001/014/601/001	FSCA	2010/01/20	N.A.	N.A.
Siemens Axiom Iconos R200	MHRA	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)	MHRA	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	MHRA	2010/001/015/081/004	FSCA	2010/01/21	GE Medical Systems Hong Kong Ltd.	2783 1838
Unomedical Diathermy cables 3405M and 3508M	MHRA	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	MHRA	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)	Health Canada	52179	Type II	2010/01/21	N.A.	N.A.
Philips A) Heartstart FRx AED (861304) B) Heartstart HS1 Onsite Defibrillator (M5066A)	Health Canada	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)	Health Canada		Type II	2010/01/21	Abbott Laboratories LTD.	2593 2211
Draeger A) Radiant Warmer (RW82, RW82-1) B) Birthing Room Warmer (WBR82, WBR82-1)	Health Canada	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)	Health Canada	51955	Type II	2010/01/21	Hospira Limited	2898 2886
Nipro Blood Tubing Set for Hemodialysis (A231TR/V811TR)	Health Canada	52178	Type II	2010/01/21	N.A.	N.A.
Fresenius 2008H Hemodialysis Machine (150254, 501228, 507115)	Health Canada	49355	Type II	2010/01/21	Fresenius Medical Care Asia Pacific Ltd.	2802 2900
Abbott i-Stat 1 Analyzer (06F16-10)	Health Canada	52261	Type II	2010/01/21	Abbott Laboratories LTD.	2593 2211
GE OEC 9800 Plus Mobile Digital Imaging (00-870632-05, 2274023)	Health Canada	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)	Health Canada	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	MHRA	2009/012/022/081/001	FSCA	2010/01/21	N.A.	N.A.
Medtronic Sofamor Danek Extended Length Trocar (Item No.: 7578013, 7578014)	FDA	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	FDA	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)	FDA	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)	FDA	Z-0641-2010		2010/01/22	N.A.	N.A.
Remel Mueller Hinton Agar w/4% NaCl w/6 mcg/ml Oxacillin (Ref R01626)	FDA	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)	FDA	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	Health Canada	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)	FDA	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)	FDA	N.A.	Press Release	2010/01/25	N.A.	N.A.
Accuray Cyberknife Robotic Radiosurgery System (MultiPlan Treatment Planning System Version 3.5)	MHRA	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	MHRA	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)	MHRA	2009/012/031/081/007	FSCA	2010/01/26	Invitrogen Hong Kong Limited	N.A.
Roche Elecsys Folate III (Material No. 04476433190)	MHRA	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)	MHRA	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)	FDA	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)	FDA	N.A.	News Release	2010/01/29	N.A.	N.A.
Stelkast Unicondylar Knee Femoral Component SC2462-1, Lot no. 20210-100108	FDA	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)	FDA	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)	FDA	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

Major Safety Alerts in March 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 March 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.
StatSpin (IRIS Sample Processing) StatSpin Express 4 Centrifuges (Model #510)	FDA	N.A.	Class I	2010/03/01	Vastec Medical Ltd.	2897 1912
Novacare Alternating pressure mattress overlay (ASX)	MHRA	2009/011/012/081/004	N.A.	2010/03/04	N.A.	N.A.
Medtronic Physio-Control LIFEPAK 15	Medtronic International, Ltd.	N.A.	Firm Initiated Field Action	2010/03/05	Medtronic International, Ltd.	2919 1300
Thomas Medical Products Transseptal Sheath Introducer Kit (also under the trade names: HeartSpan, CHANNEL FX, Torflex, Braided Guiding Introducer Kit)	FDA	N.A.	Class I	2010/03/08	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	FDA	N.A.	Class I	2010/03/09	Pacific Medical Systems Limited	2108 4005
Abiomed AB5000 Circulatory Support System (Cat. No. 0015-0000, Serial No. AD5001 through AD5496 except AD5006 & AD5018)	FDA	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)	FDA	N.A.	Class I	2010/03/11	Beckman Coulter Hong Kong Ltd	2240 6150
Baylis Medical Torflex Transseptal Guiding Sheath (Model no. TF8-38-62-S, Lot no. S21244, S21903, S21940, S22739, and S22739X1)	FDA	N.A.	Class I	2010/03/12	N.A.	N.A.
Teleflex Medical Arrow Select IV Tubing Sets, Accessories, and Certain Embolectomy Catheters	FDA	N.A.	Class I	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	MHRA	2010/003/009/601/001	FSCA	2010/03/16	Medical Systems Hong Kong	2783 1838
Unomedical (Convatec) Unilect ECG Electrodes	MHRA	2010/003/010/291/001	FSCA	2010/03/17	N.A.	N.A.
Nova Medical Nova Statstrip Glucose Test Strips (lot no. 0309019249)	MHRA	2010/002/019/601/003	FSCA	2010/03/17	N.A.	N.A.
Gyrus Medical Micron Bobbin Vent Tube T, 1.27 mm, Catalog (REF) Number 145281-ENT, Lot Number MH136952	FDA	N.A.	Class I	2010/03/18	Olympus Hong Kong and China Ltd	2170 5678
Medical Action Industries 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)	FDA	N.A.	Class I	2010/03/18	N.A.	N.A.

<p>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 Flex- Tip(R), ARROWg+ard Blue PLUS (R) Catheter (Catalog/Part # ASK-45703-</p>	<p>FDA</p>	<p>N.A.</p>	<p>Class I</p>	<p>2010/03/18</p>	<p>N.A.</p>	<p>N.A.</p>
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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)	MHRA	2010/001/015/081/006	FSCA	2010/02/01	N.A.	N.A.
Trinity Biotech Captia Measles IgM Kit (Product Code: 2326050)	MHRA	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)	MHRA	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)	MHRA	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)	FDA	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	FDA	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	FDA	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)	FDA	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).	FDA	Z-0577-2010 to Z-0578-2010	Class II	2010/02/04	N.A.	N.A.
Zap Lasers SoftLase Pro Dental Lasers	FDA	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.	FDA	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.	FDA	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).	FDA	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	FDA	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)	FDA	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	MHRA	2009/009/023/081/001	FSCA	2010/02/04	N.A.	N.A.
ev3 Silverhawk cutter driver (Catalogue number FG 02550)	MHRA	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	Health Canada	52078	Type II	2010/02/04	Hospira Limited	2898 2886
Dana Douglas Nexus 3 Model : 4500185F, 4500225F, 4500245F	Health Canada	52174	Type II	2010/02/04	N.A.	N.A.
Howmedica Osteonics Scorpio 4:1 Ceramic Blocks	Health Canada	52242	Type II	2010/02/04	N.A.	N.A.
Abaxis Piccolo Comprehensive Metabolic Panel	Health Canada	52289	Type II	2010/02/04	N.A.	N.A.
Toshiba Aquilion One TSX-301A/2	Health Canada	52445	Type II	2010/02/04	Sanko Medical Systems (HK) LTD	2384 0688
Stryker Spine Jam Shidi Needles	Health Canada	52532	Type II	2010/02/04	N.A.	N.A.
Dana Douglas A) Nexus 1, B) Nexus 2	Health Canada	52535	Type I	2010/02/04	N.A.	N.A.
Baxter Y-Type Blood Solution Sets	Health Canada	52558	Type II	2010/02/04	Baxter Healthcare Ltd	2807 8516
Howmedica Osteonics Restoration Modular Plasma Distal Stem	Health Canada	52681	Type II	2010/02/04	N.A.	N.A.
Dorel Juvenile Ear Thermometer Model 49531	Health Canada	49531	Type II	2010/02/04	N.A.	N.A.
Fimet F1 Dental Chair	MHRA	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)	MHRA	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	MHRA	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	MHRA	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	MHRA	2010/001/020/081/001	FSCA	2010/02/09	Covidien	3157 7220

Philips Panorama HFO systems on software release R2.5.3 and higher	MHRA	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)	FDA	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)	FDA	N.A.	Press Release	2010/02/10	N.A.	N.A.
Elekta IMPAC Medical Systems SEQUENCER for MOSAIQ	MHRA	2010/002/001/081/029	FSCA	2010/02/12	N.A.	N.A.
Cook Novy Cornual Cannulation Set	MHRA	2010/001/020/081/002	FSCA	2010/02/12	N.A.	N.A.
diaDexus PLAC Test Reagent Kit (10-0112, 10-0113, 10-0115)	MHRA	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	MHRA	2010/001/025/291/002	FSCA	2010/02/17	Invitrogen Hong Kong Limited	2407 8450
Beckman Coulter PrepPlus (PN 286600) Coulter Preplus	MHRA	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	MHRA	2010/002/008/601/002	FSCA	2010/02/17	N.A.	N.A.
Stryker Femoral Sponges	MHRA	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	MHRA	2010/001/012/601/001	FSCA	2010/02/17	N.A.	N.A.
GE Centricity PACS RA1000 Workstation	MHRA	2010/002/004/291/013	FSCA	2010/02/17	N.A.	N.A.
Roche Diagnostics Accu-Chek Inform II meter	MHRA	2010/002/011/081/004	FSCA	2010/02/17	N.A.	N.A.
ConMed Linvatec TS8850 concept grafix tendon stripper	MHRA	2010/002/008/081/018	FSCA	2010/02/17	N.A.	N.A.
Invacare Scanbed 750 Hospital Bed	MHRA	2008/002/011/061/019	FSCA	2010/02/17	N.A.	N.A.
Beckman Coulter Access AccuTnl Reagent Kit	MHRA	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	MHRA	2009/012/031/081/014	FSCA	2010/02/18	N.A.	N.A.
Jointmedica Birmingham Knee Replacement bearing insert re. 300003-10	MHRA	2010/001/019/081/006	FSCA	2010/02/18	N.A.	N.A.
Stryker Tessier Osseous Microtome (TOM) bone mill	MHRA	2010/002/011/081/015	FSCA	2010/02/18	N.A.	N.A.

Cincinnati Sub-Zero Products Warmair Cardiac Blanket	Health Canada	52127	Type II	2010/02/18	N.A.	N.A.
Beckman Coulter Unicel DXC 600, 800, 600I, 880I, 660I, 680I, 860I	Health Canada	52600	Type II	2010/02/18	N.A.	N.A.
Smiths Medical AC Power Cords used with 9200 Advisor / 8400 Capnocheck / BC1 3180 Pulse	Health Canada	52815	Type II	2010/02/18	N.A.	N.A.
EMCM Artesense (PMMA Collagen Dermal Implant)	Health Canada	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	FDA	Z-0104-2010	Class I	2010/02/18	N.A.	N.A.
Stryker Instruments Navigation System II CART / PC SPC-1	FDA	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	FDA	Z-0134-2010	Class II	2010/02/18	N.A.	N.A.
Medcomp 10F Bioflex Tesio Kit with cutting trocar, BFR-6CTT	FDA	Z-0161-2010	Class II	2010/02/18	N.A.	N.A.
STERIS Harmony LL 500/700 Surgical Light, Vertical Spring-Loaded Arm	FDA	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	FDA	Z-0779-2010	Class II	2010/02/18	N.A.	N.A.
Cincinnati Sub-Zero Products FilteredFlo Cardiac Blanket / TempPad Cold Therapy Pad	FDA	Z-0781-2010 to Z-0782-2010	Class II	2010/02/18	N.A.	N.A.
Edwards Lifesciences Fogarty Occlusion Catheter Ref. 6208022F	FDA	Z-0002-2010	Class II	2010/02/18	N.A.	N.A.
Philips HeartStart MRx(M3535A/M3536A) Defibrillator / Monitor Serial No. US00533518 to US00535118	FDA	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	FDA	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	MHRA	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	MHRA	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	MHRA	2010/001/026/081/006	FSCA	2010/02/24	N.A.	N.A.
Maquet Cardiopulmonary Vasoview Hemopro Endoscopic Vessel Harvesting System	MHRA	2010/002/001/081/024	FSCA	2010/02/24	Maquet Hong Kong Ltd.	2393 9511
Solafeet Model ST-400 Solafeet Foot portable tanners	FDA	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.	FDA	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.	FDA	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).	FDA	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).	FDA	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).	FDA	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.	FDA	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.	FDA	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)	FDA	Z-0798-2010	Class II	2010/02/25	N.A.	N.A.
Wescor Hematology reagent C eosin stain SS-035C	MHRA	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	MHRA	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	MHRA	2010/002/015/081/016	FSCA	2010/02/26	BD	2575 8668
Trumpf Ondal spring arm AC2000 in Helicon and Xenion surgical lights	MHRA	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)	MHRA	2010/002/004/601/004	FSCA	2010/02/26	Abbott Laboratories LTD.	2593 2211