PMA Final Decisions for June 2011

U.S. Food & Drug Administration

Below are Premarket Approvals (PMA), Product Development Protocols (PDP), Supplement and Notice Decisions. This list is generated on a monthly basis.

A PDF document that contains the "Approval letter and Summary of Safety and Effectiveness" is being added to this listing for each PMA. The PMA number will appear as a link if this document is available.

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
P090002 **[1] 6/13/11**	Pinnacle® CoMplete® Acetabular Hip System	DePuy Orthopaedics, Inc. Warsaw, IN 46581	Approval for the Pinnacle® CoMplete® Acetabular Hip System. This device is indicated for: The Pinnacle® CoMplete® Acetabular Hip System is a single use device intended for uncemented fixation. The Pinnacle® CoMplete® Acetabular Hip System is intended as a primary joint replacement prosthesis in total hip arthroplasty for skeletally mature patients suffering at least moderate pain in the hip joint from non-inflammatory degenerative joint disease (NIDJD) and its composite diagnoses of osteoarthritis (OA) or post-traumatic arthritis.

			Pinnacle®" CoMplete® Acetabular Hip System's inserts (Pinnacle® Ultamet®) are only intended for use with DePuy's femoral and acetabular components having matching outer and inner diameters.
P100027 **[2]** **6/14/11**	INFORM® HER2 Dual ISH DNA Probe Cocktail	Ventana Medical Systems, Inc. Tucson, AZ 85755	Approval for the INFORM® HER2 Dual ISH DNA Probe Cocktail. This device is indicated for: The INFORM® HER2 Dual ISH DNA Probe Cocktail is intended for use in determining HER2 gene status by enumeration of the ratio of the HER2 gene to Chromosome 17. The HER2 and Chromosome 17 probes are detected using two color chromogenic *in situ* hybridization (ISH) in formalin-fixed. paraffin-embedded human breast cancer tissue specimens following staining on Ventana BenchMark® XT automated slide stainers (using NeXES software), by light microscopy. The I NFORM® H ER2 Dual ISH DNA

			Probe Cocktail is indicated as an aid in the assessment of patients for whom I-HERPCEPTIN (trastuzumab) treatment is being considered. This product should be interpreted by a qualified reader in conjunction with histological examination, relevant clinical information, and proper controls. This reagent is intended for *in vitro* diagnostic (IVD) use.
P100031 **[3] 6/22/11**	Elecsys® Anti-HBc Immunoassay and Elecsys® PreciControl Anti-HBc for use on the MODULAR ANALYTICS E170 Immunoassay Analyzer	Roche Diagnostics Corporation Indianapolis, IN 46250	Approval for the Elecsys® Anti-HBc Immunoassay & Elecsys® PreciControl Anti-HBc for use on the MODULAR ANALYTICS E170 Immunoassay Analyzer. This device is indicated for the *in vitro* qualitative determination of total antibodies to hepatitis B core antigen (anti-HBc) in human serum and plasma (lithium-heparin, sodium-citrate, K 2 -EDTA) in adult patients with the symptoms of hepatitis or who may be at risk for hepatitis B (HBV) infection. The detection of total

			anti-HBc is indicative of a laboratory diagnosis for HBV infection. Further HBV serological marker testing is required to define the specific disease state. The Elecsys Anti-HBc immunoassay's performance has not been established for the monitoring HBV disease or therapy. The electro-chemiluminescence immunoassay "ECLIA" is intended for use on the MODULAR ANALYTICS EI70 Immunoassay Analyzer. The Elecsys Preci-Control Anti-HBc is used for quality control of the Elecsys Anti-HBc immunoassay on the MODULAR ANALYTICS E170 immunoassay analyzer.
P100032 **[4]** **6/27/11**	Elecsys® Anti-HBc Immunoassay and Elecsys® PreciControl Anti-HBc for use on the Elecsys® 2010 Immunoassay Analyzer	Roche Diagnostics Corporation Indianapolis, IN 46250	Approval for the Elecsys® Anti-HBc Immunoassay & Elecsys® PreciControl Anti-HBc for use on the Elecsys® 2010 Immunoassay Analyzer. This device is indicated for the *in vitro* qualitative determination of

			total antibodies to hepatitis B core antigen (anti-HBc) in human serum and plasma (lithium-heparin, sodium-citrate, K 2 -EDTA) in adult patients with the symptoms of hepatitis or who may be at risk for hepatitis B (HBV) infection. The detection of total anti-HBc is indicative of a laboratory diagnosis for HBV infection. Further HBV serological marker testing is required to define the specific disease state. The Elecsys Anti-HBc immunoassay's performance has not been established for the monitoring of HBV disease or therapy. The electrochemilu mi-nescence immunoassay "ECLIA" is intended for use on the Elecsys 2010 Immunoassay Analyzer. The Elecsys PreciControl Anti-HBc is used for quality control of the Elecsys Anti-HBc immunoassay on the Elecsys 2010 immunoassay analyzer.
APPLICATION NUMBER / DATE	**DEVICE TRADE NAME**	**COMPANY NAME CITY, STATE, &**	**DEVICE DESCRIPTION /**

of APPROVAL		ZIP	INDICATIONS
P820060/S027 **6/10/11** **180-Day**	AxSYM AFP	Abbott Laboratories Abbott Park, IL 60064	Approval for a manufacturing site located at Abbott Ireland Diagnostics Division in Sligo, Ireland.
P830061/S061 **6/16/11** **135-Day**	CapSure, CapSure SP Novus, Vitatron Crystaline, Vitatron Excellence PS+ Leads	Medtronic, Inc. Mounds View, MN 55112	Approval for an alternate supplier for the sterile barrier trays and change in orientation of tooling ID number on the tray.
P830061/S062 **6/27/11** **135-Day**	CapSure SP Novus Leads, CapSure, CapSure Sense Leads, Vitatron Excellence PS+, Vitatron Crystalline	Medtronic, Inc. Mounds View, MN 55112	Approval for the change of the cleaning control area and the associated processes.
P830063/S006 **6/17/11** **Real-Time**	PRISMAFLEX TPE 2000 Set	Gambro Renal Products Lakewood, CO 80401	Approval for modifications to the Gambro Prisma TPE 2000 Set with Plasmafilter PF 2000N to permit the use of the plasmafilter with the Gambro PRISMAFLEX System. The device, as modified, will be marketed under the trade name PRISMAFLEX TPE 2000 Set and is indicated for therapeutic plasmapheresis.
P850089/S074 **6/16/11** **135-Day**	CapSure Z Novus, CapSure SP Novus, Vitatron Excellence SS+, Vitatron Impulse II Leads	Medtronic, Inc. Mounds View, MN 55112	Approval for an alternate supplier for the sterile barrier trays and change in orientation of tooling ID number on the tray.

P850089/S075 **6/27/11** **135-Day**	CapSure Z Novus Leads, CapSure SP Novus Leads, CapSure, Vitatron Excellence, Vitatron Excellence SS+, Vitatron Impluse II, CapSure SP Z Leads	Medtronic, Inc. Mounds View, MN 55112	Approval for the change of the cleaning control area and the associated processes.
P880047/S015 **6/17/11** **Real-Time**	GYNECARE INTERCEED® Absorbable Adhesion Barrier	Ethicon, Inc. Somerville, NJ 08876	Approval for a larger INTERCEED® product that measures 5”x6” in size. The device, as modified, is indicated as an adjuvant in open (laparotomy) gynecologic pelvic surgery for reducing the incidence of postoperative pelvic adhesions after meticulous hemostasis is achieved.
P880086/S204 **6/8/11** **Real-Time**	Sustain XL Family of Pacemakers	St. Jude Medical, Inc. Sunnyvale, CA 94086	Approval for the new Sustain XL Pacemaker Models, predicated off the Victory/Zephyr family of pacemaker. The device, as modified, will be marketed under the trade name Sustain XL DR/SR and Sustain XL DC/SC and is indicated for **Indications and** Usage • Implantation of Sustain™ pulse generators is indicated in the following permanent conditions, when

			associated with symptoms including, but not limited to: • Syncope • Presyncope • Fatigue • Disorientation • Or any combination of those symptoms. **Rate-Modulated Pacing** is indicated for patients with chronotropic incompetence and for those who would benefit from increased stimulation rates concurrent with physical activity. Dual-Chamber Pacing (Models PM2134 and PM2136 only) is indicated for those patients exhibiting: • Sick sinus syndrome • Chronic, symptomatic second- and third-degree AV block • Recurrent Adams-Stokes syndrome • Symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. Atrial Pacing is indicated for patients with sinus node dysfunction and normal AV and intraventricular

			conduction systems. Ventricular Pacing is indicated for patients with significant bradycardia and: • Normal sinus rhythm with only rare episodes of A-V block or sinus arrest • Chronic atrial fibrillation • Severe physical disability. AF Suppression (Models PM2134 and PM2136 only) is indicated for suppression of paroxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications.
P890003/S218 **6/16/11** **135-Day**	CapSure VDD2, Brilliant S+ Leads	Medtronic, Inc. Mounds View, MN 55112	Approval for an alternate supplier for the sterile barrier trays and change in orientation of tooling ID number on the tray.
P890003/S219 **6/27/11** **135-Day**	Prodigy lPG, Leads Wrench Kit, Leads Service Kit, Vitatron Brilliant S+, Capsure VDD Leads, Connector Port Pin-Plug	Medtronic, Inc. Mounds View, MN 55112	Approval for the change of the cleaning control area and the associated processes.
P890055/S034 **6/21/11** **Special**	MedStream Programmable Infusion System	Codman & Shurtleff, Incorporated Raynham, MA 02767	Approval to add a warning statement to the Instructions for Use.
P900061/S100 **6/27/11**	Ace Header, Patch Lead, Lead End Pin	Medtronic, Inc. Mounds View, MN	Approval for the change of the

135-Day	Cup	55112	cleaning control area and the associated processes.`
P910007/S023 **6/8/11** **180-Day**	ARCHITECT Total PSA	Abbott Laboratories Abbott Park, IL 60064	Approval for manufacturing site located at Abbott Ireland Diagnostic Division in Sligo, Ireland.
P910007/S025 **6/10/11** **180-Day**	AxSYM Total PSA	Abbott Laboratories Abbott Park, IL 60064	Approval for a manufacturing site located at Abbott Ireland Diagnostics Division in Sligo, Ireland.
P910007/S026 **6/22/11** **180-Day**	ARCHITECT Total PSA	Abbott Laboratories Abbott Park, IL 60064	Approval for a manufacturing site located at Abbott Ireland Diagnostics division in Sligo, Ireland.
P910023/S257 **6/21/11** **180-Day**	Cadence/Current/ Fortify Family of ICDs	St. Jude Medical Sunnyvale, CA 94086	Approval for Software Model MN5000 V.5.0 for use on the Merlin.net System and Model EX2000 V.5.0 for use on Merlin@ home Devices.
P910023/S266 **6/28/11** **180-Day**	Current Accel VR, DR ICDs and Fortify VR, DR ICDs	St. Jude Medical Sylmar, CA 91342	Approval for manufacturing site located at St. Jude Medical Puerto Rico LLC in Arecibo, Puerto Rico.
P910073/S089 **6/14/11** **135-Day**	Reliance IS-1 Family of Leads	Boston Scientific Corporation St. Paul, MN 55112	Approval for acceptance of an enhancement to the insulation and tri-lumen bond process, to include an upgrade of the bonding equipment and additional acceptance activity

			inspections to verify an adequate bond which will prevent fluid leakage.
P910077/S115 **6/21/11** **Real-Time**	LATITUDE Paceart Integration System	Boston Scientific Corporation St. Paul, MN 55112	Approval for modifications to the LATITUDE Paceart Integration (LPI) software, Model 6472 v1.01.
P920015/S074 **6/27/11** **135-Day**	IS-l Port Pin Plug, Y Adaptor Kit, Lead Adaptor, Sprint Lead, Sprint Quattro Lead, Sprint Quattro Secure Lead, Subcutaneous Defibrillation Lead, Transvene SVC Lead, Tunneling Tool, Sub-Q Lead, Sprint Quattro Single Coil	Medtronic, Inc. Mounds View, MN 55112	Approval for the change of the cleaning control area and the associated processes.
P930039/S049 **6/16/11** **135-Day**	CapSure Fix, CapSure Fix NovusSureFix Leads	Medtronic, Inc. Mounds View, MN 55112	Approval for an alternate supplier for the sterile barrier trays and change in orientation of tooling ID number on the tray.
P930039/S050 **6/27/11** **135-Day**	CapSureFix Novus Lead, SureFix Novus Lead, CapSureFix Lead, Vitatron Pirouet Lead, Vitatron Crystalline Actfix Lead	Medtronic, Inc. Mounds View, MN 55112	Approval for the change of the cleaning control area and the associated processes.
P950024/S029 **6/27/11** **135-Day**	CapSure EPI Unipolar Lead, CapSure EPI Bipolar Lead	Medtronic, Inc. Mounds View, MN 55112	Approval for the change of the cleaning control area and the associated processes.
P960007/S020 **6/13/11** **135-Day**	TransCyte Human Fibroblast-Derived Temporary Skin	Advanced BioHealing, Inc. La Jolla, CA	Approval for modification of the automated and

	Substitute	92037	manual cell expansion trypsinization processes for manufacturing TransCyte.
P960013/S065 **6/28/11** **180-day**	Tendril STS Lead	St. Jude Medical Sylmar, CA 91342	Approval for manufacturing site located at St. Jude Medical Puerto Rico LLC in Arecibo, Puerto Rico.
P970004/S087 **6/9/11** **180-Day**	Medtronic InterStim II Neurostimulator	Medtronic, Inc. Minneapolis, MN 55432	Approval for design and specification changes to the Model 3058 InterStim II battery.
P970004/S116 **6/8/11** **Special**	Medtronic InterStim® Therapy for Urinary Control	Medtronic, Inc. Minneapolis, MN 55432	Approval for the addition of two precaution statements to the labeling of the Model 3037 patient programmer.
P970021/S030 **6/13/11** **135-Day**	GYNECARE THERMACHOICE III Uterine Balloon Therapy System	ETHICON, Inc. Somerville, NJ 08876	Approval for changes to the catheter balloon measurement process.
P970051/S069 **6/3/11** **Real-Time**	Nucleus 24 Cochlear Implant System	Cochlear Americas Centennial, CO 80111	Approval for a modified version of the external CP810 sound processor main BTE module (approved under P970051/S049), called Build Standard D, which is primarily intended to allow for repair of the processor.
P980007/S016 **6/10/11** **180-Day**	AxSYM Free PSA	Abbott Laboratories Abbott Park, IL 60064	Approval for a manufacturing site located at Abbott Ireland Diagnostics Division in Sligo,

			Ireland.
P980007/S017 **6/22/11** **180-Day**	ARCHITECT Free PSA	Abbott Laboratories Abbott Park, IL 60064	Approval for a manufacturing site located at Abbott Ireland Diagnostics division in Sligo, Ireland.
P980016/S288 **6/27/11** **135-Day**	Marquis ICD Family, Maximo ICD Family, Intrinsic ICD Family, CapSure Lead, EnTrust ICD Family, Virtuoso ICD Family, Maximo II lCD, Secura lCD, Virtuoso ICD	Medtronic, Inc. Mounds View, MN 55112	Approval for the change of the cleaning control area and the associated processes.
P980035/S211 **6/27/11** **135-Day**	Sigma IPG Family, Medtronic 360 IPG Series, EnRhythm lPG, AT500 Systems, Adapta/ Versa/Sensia lPG, Relia IPG	Medtronic, Inc. Mounds View, MN 55112	Approval for the change of the cleaning control area and the associated processes.
P980035/S227 **6/2/11** **Real-Time**	Adapta, Versa, Sensia and Relia Implantable Pulse Generators	Medtronic, Inc. Mounds View, MN 55112	Approval for an increase in gold thickness on XE263 accelerometer.
P980050/S059 **6/27/11** **135-Day**	CS-SVC Transvene Lead	Medtronic, Inc. Mounds View, MN 55112	Approval for the change of the cleaning control area and the associated processes.
P990001/S086 **6/27/11** **135-Day**	C-Series IPG, T-Series IPG	Medtronic, Inc. Mounds View, MN 55112	Approval for the change of the cleaning control area and the associated processes.
P990056/S011 **6/20/11** **135-Day**	Elecsys *total PSA Immunoassay*	Roche Diagnostics Corporation Indianapolis, IN 46250	Approval for a change in the manufacturing site from buildings 341, 345 and 651 to building 761, all within the Roche Penzberg, Germany

			facility.
P000012/S027 **6/27/11** **135-Day**	COBAS AMPLICOR HCV Test, COBAS Ampliprep/COBAS AMPLICOR HCV Test	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Approval for changes to the test methods 1) magnetic susceptibility; and 2) surface area of the Tosylated magnetic beads used by the vendor.
P000027/S009 **6/20/11** **135-Day**	Elecsys *free PSA Immunoassay*	Roche Diagnostics Corporation Indianapolis, IN 46250	Approval for a change in the manufacturing site from buildings 341, 345 and 651 to building 761, all within the Roche Penzberg, Germany facility.
P000053/S036 **6/13/11** **135-Day**	AMS 800 Artificial Urinary Sphincter	American Medical Systems, Inc. Minnetonka, MN 55343	Approval for a new component mold.
P000053/S037 **6/24/11** **180-Day**	AMS Sphincter 800® Urinary Prosthesis	American Medical Systems, Inc. Minnetonka, MN 55343	Approval for modifications to the design specifications and manufacturing process of the AMS 800 Control Pump, a component of the AMS Sphincter 800® Urinary Prosthesis.
P010015/S111 **6/16/11** **135-Day**	Attain Lead	Medtronic, Inc. Mounds View, MN 55112	Approval for an alternate supplier for the sterile barrier trays and change in orientation of tooling ID number on the tray.
P010015/S112 **6/27/11** **135-Day**	InSync III CRT-P, Attain OTW Lead, Attain Bipolar OTW Lead, Attain LV Lead	Medtronic, Inc. Mounds View, MN 55112	Approval for the change of the cleaning control area and the associated

			processes.
P010031/S242 **6/27/11** **135-Day**	InSync II Marquis lCD, InSync III Marquis lCD, InSync Marquis lCD, InSync Sentry ICD family, InSync Maximo ICD family, Concerto CRT-D, Maximo II CRT-D, Consulta CRT-D, Concerto II CRT-D	Medtronic, Inc. Mounds View, MN 55112	Approval for the change of the cleaning control area and the associated processes.
P010050/S011 **6/24/11** **180-Day**	IMMULITE® 2000 HBsAG Confirmatory Kit	Siemens Healthcare Diagnostics Norwood, MA 02062	Approval for an automated means of confirmation testing on-board the IMMULITE® 2000 immunoassay analyzer. The device, as modified, will be marketed under the trade name IMMULITE® 2000 HBsAg Confirmatory Kit and is indicated for: IMMULITE 2000 HBsAg Confirmatory is intended for *in vitro* diagnostic use with IMMULITE 2000 analyzers in conjunction with the IMMULITE 2000 HBsAg assay - for the confirmation of the presence of hepatitis B surface antigen (HBsAg) in human serum or plasma (EDTA, heparinized, citrate) that were repeatedly reactive when tested by the IMMULITE/

			IMMULITE 1000 HBsAg assay or by the IMMULITE 2000 HBsAg assay.
P020018/S037 **6/7/11** **180-Day**	Zenith Flex® AAA Endovascular Graft	Cook, Inc. Bloomington, IN 47402	Approval to add the Zenith Spiral-Z® AAA Endovascular Graft Iliac Leg to the existing Zenith Flex® AAA Endovascular Graft product line. The device, as modified, will be marketed under the trade name Zenith Spiral-Z® AAA Endovascular Graft Iliac Leg and is indicated for use with the Zenith AAA Endovascular Graft family of products, including the Zenith Flex AAA Endovascular Graft, Zenith Renu Ancillary Graft, Zenith Fenestrated AAA Endovascular Graft, or Zenith Branch Iliac Endovascular Graft, during either a primary or secondary procedure in patients who have adequate iliac/femoral access compatible with the required introduction systems. The graft is used in combination with these products for the endovascular treatment of

			abdominal aortic and aorto-iliac aneurysms.
P020047/S029 **6/16/11** **135-Day**	Multi-Link Vision, Multi-Link Mini-Vision OTW and RX, Multi-Link 8, Multi-Link 8LL, Multi-Link 8 SV Coronary Stent Systems	Abbott Vascular, Inc. Temecula, CA 92590	Approval to remove a redundant receiving inspection test.
P030009/S054 **6/9/11** **Real-Time**	Integrity Coronary Stent System	Medtronic Vascular Santa Rosa, CA 95403	Approval for addition of labeling regarding simultaneous use of the Integrity RX stent system with either another Integrity RX stent system, or with a Sprinter Legend RX balloon dilation catheter. In addition, approval to revise the MRI compatibility information in the labeling.
P030035/S084 **6/28/11** **180-Day**	Promote Accel CRT-D	St. Jude Medical Sylmar, CA 91342	Approval for manufacturing site located at St. Jude Medical Puerto Rico LLC in Arecibo, Puerto Rico.
P030036/S027 **6/27/11** **135-Day**	SelectSecure Lead, Sleeve Kit	Medtronic, Inc. Mounds View, MN 55112	Approval for the change of the cleaning control area and the associated processes.
P030054/S181 **6/21/11** **180-Day**	Epic HF/Atlas+HF/ Promote/Unify Family of CRT-Ds	St. Jude Medical Sunnyvale, CA 94086	Approval for Software Model MN5000 V.5.0 for use on the Merlin.net System and Model EX2000 V.5.0 for use on Merlin@ home Devices.

P030054/S191 **6/28/11** **180-Day**	Quickflex µ Leads, Unify CRT-Ds	St. Jude Medical Sylmar, CA 91342	Approval for manufacturing site located at St. Jude Medical Puerto Rico LLC in Arecibo, Puerto Rico.
P040020/S029 **6/30/11** **180-Day**	AcrySof IQ ReSTOR IOL	Alcon Research, Ltd. Fort Worth, TX 76134	Approval for a manufacturing site located at Alcon Laboratories Ireland Ltd. in Cork, Ireland.
P040048/S014 **6/2/11** **Special**	*Trilogy AB*® Acetabular System	Zimmer, Inc. Warsaw, IN 46581	Approval for adding information about MRI safety to the package insert and patient labeling.
P050011/S002 **6/17/11** **135-Day**	ADEPT Adhesion Reduction Solution (4% Icodextrin)	Baxter Healthcare Corporation McGaw Park, IL 60085	Approval to implement the assay for detecting the amount of peptidoglycan (PG) in the Icodextrin Active Pharmaceutical Ingredient (API).
P050012/S037 **6/3/11** **Real-Time**	DexCom Seven and Seven Plus Continuous Glucose Monitoring Systems	DexCom, Inc. San Diego, CA 92121	Approval for replacement of an obsolete LCD in the receiver assembly with a similar component and minor modifications to the receiver firmware to accommodate the new hardware.
P050028/S011 **6/24/11** **135-Day**	COBAS AmpliPrep/ COBAS TaqMan HBV Test	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Approval for an addition of a second sintering oven for the manufacture of the bulk Magnetic Glass Particle (MGP) raw material used in the production of the MPG reagent.
P050042/S012 **6/1/11**	ARCHITECT Anti-HCV	Abbott Laboratories Irving, TX	Approval for a manufacturing site

180-Day		75038	located at Flextronics Manufacturing (S) Pte Ltd. in Singapore.
P050046/S009 **6/29/11** **135-Day**	ACUITY™ Steerable Stylet Accessory	Boston Scientific Corporation St. Paul, MN 55112	Approval for acceptance of a change to relocate a sensor on wire grinding equipment and formalize inspections as acceptance activities.
P050051/S012 **6/1/11** **180-Day**	ARCHITECT AUSAB	Abbott Laboratories Irving, TX 75038	Approval for a manufacturing site located at Flextronics Manufacturing (S) Pte Ltd. in Singapore.
P060003/S005 **6/9/11** **Real-Time**	Abbott AxSYM AUSAB	Abbott Laboratories Abbott Park, IL 60064	Approval for changes to the manufacturing and quality control testing for AxSYM AUSAB Calibrators, Controls, and Reagents.
P060007/S014 **6/1/11** **180-Day**	ARCHITECT HBsAg/ Confirmatory	Abbott Laboratories Irving, TX 75038	Approval for a manufacturing site located at Flextronics Manufacturing (S) Pte Ltd. in Singapore.
P060033/S064 **6/2/11** **180-Day**	Endeavor Sprint Zotarolimus-Eluting Coronary Stent Systems	Medtronic Vascular Santa Rosa, CA 95403	Approval for changes to the instructions for use (with the latest available follow-up clinical data from the Endeavor clinical trial programs).
P060035/S008 **6/1/11**	ARCHITECT CORE-M	Abbott Laboratories Irving, TX	Approval for a manufacturing site

180-Day		75038	located at Flextronics Manufacturing (S) Pte Ltd. in Singapore.
P060039/S023 **6/16/11** **135-Day**	Attain StarFix Lead	Medtronic, Inc. Mounds View, MN 55112	Approval for an alternate supplier for the sterile barrier trays and change in orientation of tooling ID number on the tray.
P060039/S024 **6/27/11** **135-Day**	Attain StarFix Lead	Medtronic, Inc. Mounds View, MN 55112	Approval for the change of the cleaning control area and the associated processes.
P070015/S058 **6/16/11** **135-Day**	XIENCE V and Promus Everolimus Eluting Coronary Stent Systems	Abbott Vascular, Inc. Temecula, CA 92590	Approval to remove a redundant receiving inspection test.
P070026/S001 **6/7/11** **180-Day**	Ceramax Ceramic Total Hip System	DePuy, Inc. Warsaw, IN 46581	Approval of post-approval study protocol.
P080004/S007 **6/15/11** **Real-Time**	iSert®	Hoya Surgical Optics, Inc. Chino Hills, CA 91709	Approval for packaging changes to the Model PY-60AD. The device, as modified, will be marketed under the trade name iSert® Model PY-60ADC and is indicated for primary implantation in the capsular bag of the eye for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed.
P080006/S021 **6/27/11**	Attain Ability Lead	Medtronic, Inc. Mounds View, MN	Approval for the change of the

135-Day		55112	cleaning control area and the associated processes.
P080023/S008 **6/1/11** **180-Day**	ARCHITECT CORE	Abbott Laboratories Irving, TX 75038	Approval for a manufacturing site located at Flextronics Manufacturing (S) Pte Ltd. in Singapore.
P080025/S008 **6/10/11** **Special**	Medtronic® InterStim® Therapy System	Medtronic, Inc. Minneapolis, MN 55432	Approval for changes to the labeling for the 3037 Patient Programmer to add new precautions relating to modification of the device and the effect of electromagnetic interference (EMI) on the patient programmer's ability to communicate with the neurostimulator.
P080032/S005 **6/10/11** **180-Day**	Alair® Bronchial Thermoplasty System	Asthmatx, Inc. Sunnyvale, CA 94089	Approval for a manufacturing site located at Asthmatx, Inc. in Sunnyvale, California.
P080032/S007 **6/21/11** **180-Day**	Alair® Bronchial Thermoplasty System	Boston Scientific Corporation Sunnyvale, CA 94089	Approval of the post approval study protocol.
P090013/S010 **6/16/11** **135-Day**	CapSure Fix MRI Lead	Medtronic, Inc. Mounds View, MN 55112	Approval for an alternate supplier for the sterile barrier trays and change in orientation of tooling ID number on the tray.
P090013/S011	Revo IPG, Revo MRI	Medtronic, Inc.	Approval for the

6/27/11 **135-Day**	Lead	Mounds View, MN 55112	change of the cleaning control area and the associated processes.
P100010/S010 **6/28/11** **Real-Time**	Arctic Front® Cardiac Cryoablation Catheter	Medtronic CryoCath, LP Eagan, MN 55123	Approval for changes to the labeling to include compatibility for use with the Medtronic Achieve Mapping Catheter.
P100018/S001 **6/27/11** **180-Day**	Pipeline Embolic Device	Chestnut Medical Technologies, Inc. Meno Park, CA 94025	Approval of post-approval study protocol.

30-Day Notices (135 Day Supplement was not required)

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
N18033/S056 **6/10/11**	VISTAKON (etafilcon A) and (senofilcon) Brand Contact Lenses	Vision Care, Inc. Jacksonville, FL 32256	Replacement of a Differential Scanning Calorimeter (DSC) for a previous model that is no longer supported by the same manufacturer.
N18033/S057 **6/8/11**	VISTAKON (etafilcon A) Brand Contact Lenses	Johnson & Johnson Vision Care, Inc. Jacksonville, FL 32256	Evaluation of the automation of the repackaging activities conducted by a qualified supplier.
N18033/S058 **6/16/11**	VISTAKON (etafilcon A) Brand Contact Lenses	Johnson & Johnson Vision Care, Inc. Jacksonville, FL 32256	Change in the software for processing laboratory data related to the VISTAKON® (etafilcon A) Brand and VISTAKON® (senofilcon A) Brand Contact Lenses.

N18033/S059 6/22/11	VISTAKON (etafilcon A) Brand Contact Lenses	Johnson & Johnson Vision Care, Inc. Jacksonville, FL 32256	Use an electronic Raw Material Tracking System.
P820003/S106 6/10/11	Disposable Cover	Medtronic, Inc. Mounds View, MN 55112	Change the cleaning area of the devices.
P820021/S033 6/8/11	Vifilcon A Soft Contact Lenses for Extended Wear	CIBA VISION Corporation Duluth, GA 30097	Change the Alternate Raw Material Sourcing for (Vifilcon A formulation) Soft Contact Lens Materials.
P830060/S069 6/17/11	Tachy Adapter	Boston Scientific Corporation St. Paul, MN 55112	Alternate ingredient for the adhesive used in sterile packaging.
P830061/S065 6/10/11	CapSure and Vitatron Excellence+	Medtronic, Inc. Mounds View, MN 55112	Change the cleaning area of the devices.
P840001/S186 6/16/11	Restore Family of Implantable Neurostimulators, Itrel 3 Implantable Neurostimulator, Synergy Family of Implantable Neurostimulators, Specify Surgical Leads, Hinged 2X4 Surgical Leads, Resume Surgical Leads, SymMix Surgical Leads, 1X8 Lead Family, Pisces Lead Family, Quadripolar Extensions, 1X8 Extensions, 1X8 Synergy Extensions, Low Profile Quadripolar, Extensions, Accessories and	Medtronic, Inc. Minneapolis, MN 55432	Implement or change software used for manufacturing of several devices.

	Accessory Kits for use with Spinal Cord Stimulation Devices, Adaptors and Control Magnet		
P840001/S187 6/17/11	7425 Itrel 3 IPG, 7427 Synergy IPG, 7427V Synergy Versitrel IPG, 37701 RestorePrime INS, 37702 PrimeAdvanced INS, 37711 Restore INS, 37712 RestoreUltra INS, and 37713 RestoreAdvanced INS	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of an ethylene oxide sterilizer system.
P840001/S188 6/22/11	Intrel 3, Synergy Family	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of an alternate qualified supplier for components used in the feedthrough assembly.
P850089/S077 6/10/11	CapSure SP Z Leads, Vitatron Impulse, Vitatron Excellence S+, Vitratron Excellence SS+ and Vitatron Impulse II	Medtronic, Inc. Mounds View, MN 55112	Change the cleaning area of the devices.
P860004/S152 6/16/11	Synchromed II Implantable Infusion Pumps, Intra-arterial Vascular Catheters, InDura IP Intrathecal Catheters, Intrathecal Catheters, Refill Kits, Sutureless Pump Connector Revision Kits, Proximal Catheter Revision Kits, Distal Catheter Revision Kits, Accessories and Accessory Kits	Medtronic, Inc. Minneapolis, MN 55432	Implement or change software used for manufacturing of several devices.

	for use with Programmable Infusion Pumps, Intraspinal Trial Kits and Programmer Power Adaptor		
P860022/S058 6/22/11	Boston Equalens/Equalens II	Bausch & Lomb Incorporated Rochester, NY 14609	Alternate supplier of 0.2 micron formulation filter.
P880047/S016 6/30/11	GYNECARE INTERCEED Absorbable Adhesion Barrier	Ethicon, Inc. Somerville, NJ 08876	Alternative cycle parameters for the manufacturing process.
P890003/S223 6/8/11	Prodigy IPG	Medtronic, Inc. Mounds View, MN 55112	Changes to the NeliPak Sealer manufacturing process; including addition of new equipment, a change to the process recipe specification, and the implementation of a monitoring test.
P890003/S224 6/9/11	Prodigy IPG	Medtronic, Inc. Mounds View, MN 55112	Addition of an ethylene oxide (EtO) sterilizer system.
P890003/S225 6/10/11	CapSure (Drug Eluting), ECG Cable	Medtronic, Inc. Mounds View, MN 55112	Change the cleaning area of the devices.
P900060/S042 6/30/11	Carbomedics Prosthetic Heart Valve (CPHV), Carbo-Seal Ascending Aortic Prosthesis (AAP), Carbo-Seal Valsalva Ascending Aortic Prosthesis, Orbits Prosthetic Heart Valve, OptiFoam Prosthetic Mitral Heart Valve	Sorin Group USA, Inc. Arvada, CO 80004	Change of a supplier for lock wire components.
P900060/S043 6/30/11	Carbomedics Prosthetic Heart	Sorin Group USA, Inc.	Analytical services supplier change.

	Valve (CPHV), Carbo-Seal Ascending Aortic Prosthesis (AAP), Carbo-Seal Valsalva Ascending Aortic Prosthesis, Orbits Prosthetic Heart Valve, OptiFoam Prosthetic Mitral Heart Valve	Arvada, CO 80004	
P900060/S044 6/30/11	Carbomedics Prosthetic Heart Valve (CPHV), Carbo-Seal Ascending Aortic Prosthesis (AAP), Carbo-Seal Valsalva Ascending Aortic Prosthesis, Orbits Prosthetic Heart Valve, OptiFoam Prosthetic Mitral Heart Valve	Sorin Group USA, Inc. Arvada, CO 80004	Addition of a new Optical OGP SmartScope System to an existing component inspection.
P900061/S103 6/10/11	Upsizing Sleeve for HV Lead DF-1, Upsizing Sleeve, Epicardial Patch Leads	Medtronic, Inc. Mounds View, MN 55112	Change the cleaning area of the devices.
P910001/S048 6/8/11	ELCA Coronary Artherectomy Catheters	Spectranetics Corporation Colorado Springs, CO 80921	Addition of an alternate supplier for a device component.
P910007/S030 6/24/11	ARCHITECT Total PSA	Abbott Laboratories Abbott Park, IL 60064	Change in the quality control testing used on an incoming raw material and a finished accessory used in ARCHITECT Total PSA and ARCHITECT Free PSA Assays.
P910073/S097 6/2/11	Endotak Reliance EZ, Endotak Reliance RX, Endotak Reliance 4-site EZ and Endotak Reliance	Boston Scientific Corporation St. Paul, MN 55112	Reduction in sample size.

	4-site RX Leads		
P910073/S098 6/17/11	ENDOTAK Lead, ENDOTAK RELIANCE Lead, ENDOTAK Endurance Lead Brady Adapter, and Tachy Adapter	Boston Scientific Corporation St. Paul, MN 55112	Alternate ingredient for the adhesive used in sterile packaging.
P910077/S116 6/17/11	ENDOTAK Lead, Tachy Adapter	Boston Scientific Corporation St. Paul, MN 55112	Alternate ingredient for the adhesive used in sterile packaging.
P920015/S077 6/10/11	Transvene SVC Lead	Medtronic, Inc. Mounds View, MN 55112	Change the cleaning area of the devices.
P930029/S030 6/10/11	RF Marinr, RF Marinr NTC, 5F RF Marinr, RF Conductr, RF Enhancr II, RF Conactr	Medtronic, Inc. Mounds View, MN 55112	Change the cleaning area of the devices.
P930039/S053 6/10/11	Vitatron Pirouet/S+, Vitatron Crystalline ActFix, CapSure	Medtronic, Inc. Mounds View, MN 55112	Change the cleaning area of the devices.
P930039/S055 6/29/11	CapSureFix and Crystalline Act Fix	Medtronic, Inc. Mounds View, MN 55112	A lead assembly crimping process improvement.
P950020/S044 6/30/11	Flextome® Cutting Balloon® Dilation Device	Boston Scientific Corporation Maple Grove, MN 55311	Implementation of the use of a closed-loop control (feedback), in the extrusion of the tie layer of the tri-layer component.
P960006/S031 6/17/11	FLEXTEND Lead	Boston Scientific Corporation St. Paul, MN 55112	Alternate ingredient for the adhesive used in sterile packaging.
P960009/S116 6/16/11	Activa Family of Implantable Neurostimulators, Soletra Implantable Neurostimulator, Kinetra Implantable Neurostimulator, Leads, Stereotactic Frame Lead Kit Extensions,	Medtronic, Inc. Minneapolis, MN 55432	Implement or change software used for manufacturing of several devices.

	Adaptors, Accessory Kits used with Deep Brain Stimulation, Control Magnet		
P960009/S117 6/17/11	7426 Soletra INS, 7428 Kinetra INS, 37601 Activa PC INS, 37602 Activa SC INS, 37603 Activa SC INS, and 37612 Activa RC INS	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of an ethylene oxide sterilizer system.
P960009/S118 6/22/11	Activa SC, Soletra, Kinetra	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of an alternate qualified supplier for components used in the feedthrough assembly.
P960040/S244 6/17/11	CONFIENT PG, VENTAK PRIZM PG, VITALITY PG, TELIGEN PG	Boston Scientific Corporation St. Paul, MN 55112	Alternate ingredient for the adhesive used in sterile packaging.
P960042/S030 6/8/11	SLS Spectranetics Laser Sheaths	Spectranetics Corporation Colorado Springs, CO 80921	Addition of an alternate supplier for a device component.
P970003/S127 6/3/11	VNS Therapy System Pulse Generator	Cyberonics Houston, TX 77058	Make changes to software used in an electrical testing system.
D970003/S129 6/17/11	INSIGNIA PG, ALTRUA PG	Boston Scientific Corporation St. Paul, MN 55112	Alternate ingredient for the adhesive used in sterile packaging.
P970004/S113 6/16/11	Interstim Family of Implantable Neurostimulators Leads, Extension, Test Stimulation Lead, Test Stimulation Kit, Accessories and Accessory Kits for use with Interstim therapy and Control Magnet	Medtronic, Inc. Minneapolis, MN 55432	Implement or change software used for manufacturing of several devices.

P970004/S114 6/17/11	3023 InterStim INS and 3058 InterStim II INS	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of an ethylene oxide sterilizer system.
P970004/S115 6/22/11	InterStim Family	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of an alternate qualified supplier for components used in the feedthrough assembly.
P970012/S085 6/10/11	Kappa 400 IPG	Medtronic, Inc. Mounds View, MN 55112	Change the cleaning area of the devices.
P970027/S014 6/22/11	AxSYM Anti-HCV	Abbott Laboratories Abbott Park, IL 60064	Modification to a supplier of the antifoam solution used in AxSYM Anti-HCV.
P970037/S006 6/24/11	AutoDELFIA/DELFIA Xpress hAFP Test System	PerkinElmer, Inc. Waltham, MA 02451	Change in the TOPO (Trioctylphosphine oxide) raw material type used in the manufacturing of the DELFIA Inducer.
P970051/S071 6/15/11	Nucleus 24 Cochlear Implant System	Cochlear Americas Centennial, CO 80111	Change from a manual assembly to an automated assembly of the case of the sound processor battery pack.
P970051/S076 6/15/11	Nucleus 24 Cochlear Implant System	Cochlear Americas Centennial, CO 80111	Extension of the cure time in the moulding process.
P970051/S077 6/15/11	Nucleus 24 Cochlear Implant System	Cochlear Americas Centennial, CO 80111	Changes to the production of the solid ball assembly electrode.
P980006/S019 6/10/11	Bausch & Lomb PureVision (balafilcon A) Soft Contact Lenses	Bausch & Lomb, Incorporated Rochester, NY 14609	Upgrade the Cognex software for the automated Wet Vision Automated Inspection System (AIS) to Version 4.4.
P980007/S021 6/24/11	ARCHITECT Free PSA	Abbott Laboratories Abbott Park, IL 60064	Change in the quality control testing used on an

			incoming raw material and a finished accessory used in ARCHITECT Total PSA and ARCHITECT Free PSA Assays.
P980016/S300 6/8/11	Secura DR/VR t Virtuoso II DR /VR, Maximo II DR/VR t EnTrust, Virtuoso, Maximo, Intrinsic, Protecta, and Protecta XT Families of ICDs	Medtronic, Inc. Mounds View, MN 55112	Changes to the NeliPak Sealer manufacturing process; including addition of new equipment, a change to the process recipe specification, and the implementation of a monitoring test.
P980016/S301 6/9/11	Entrust, Intrinsic, Marquis, Maximo, Maximo II, Maximo II M4, Protecta XT/ Protecta, Protecta XT M4, Protecta M4, Secura, Secura M4, Virtuoso, Virtuoso II ICDs	Medtronic, Inc. Mounds View, MN 55112	Addition of an ethylene oxide (EtO) sterilizer system.
P980016/S302 6/10/11	Protecta DR, Protecta VR, Protecta XT DR and Protecta XT VR ICDs	Medtronic, Inc. Mounds View, MN 55112	Change the cleaning area of the devices.
P980035/S224 6/8/11	Adpta/Versa/Sensia, Sigma, Relia, Advisa DR, EnRythm Families of IPGs	Medtronic, Inc. Mounds View, MN 55112	Changes to the NeliPak Sealer manufacturing process; including addition of new equipment, a change to the process recipe specification, and the implementation of a monitoring test.
P980035/S225 6/9/11	Adapta, Advisa, EnRhythm, Relia, Sensia, Versa IPGs	Medtronic, Inc. Mounds View, MN 55112	Addition of an ethylene oxide (EtO) sterilizer system.
P980035/S226	Advisa DR IPG	Medtronic, Inc.	Change the

6/10/11		Mounds View, MN 55112	cleaning area of the devices.
P980035/S229 6/22/11	Advisa IPG	Medtronic, Inc. Mounds View, MN 55112	Changes to testing software.
P980037/S037 6/8/11	AngioJet Rheolytic Thrombectomy System	Medrad, Inc. Minneapolis, MN 55433	Modification of a wiping procedure.
P990034/S022 6/16/11	Side Catheter Access Port Kits Side Catheter Access Port Kits, bulk, Refill Kits Refill Kits, bulk	Medtronic, Inc. Minneapolis, MN 55432	Implement or change software used for manufacturing of several devices.
P010012/S267 6/17/11	EASYTRAK Lead, ACUITY Lead, CONTAK RENEWAL PG, LIVIAN ICD, COGNIS, Left Ventricular Lead Adapter	Boston Scientific Corporation St. Paul, MN 55112	Alternate ingredient for the adhesive used in sterile packaging.
P010013/S036 6/29/11	NovaSure Impedance Controlled Endometrial	Hologic, Inc. Marlborough, MA 01752	Change in manufacturing materials.
P010015/S122 6/8/11	Syncra and Consulta CRT-Ps	Medtronic, Inc. Mounds View, MN 55112	Changes to the NeliPak Sealer manufacturing process; including addition of new equipment, a change to the process recipe specification, and the implementation of a monitoring test.
P010015/S123 6/9/11	Consulta/Syncra CRT-PS	Medtronic, Inc. Mounds View, MN 55112	Addition of an ethylene oxide (EtO) sterilizer system.
P010015/S124 6/10/11	Syncra and Consulta CRT-P	Medtronic, Inc. Mounds View, MN 55112	Change the cleaning area of the devices.
P010015/S127 6/22/11	Consulta CRT-P, Syncra CRT-P	Medtronic, Inc. Mounds View, MN 55112	Changes to testing software.

P010031/S254 6/8/11	Consulta, Concerto II**,** Maximo II and InSync II Protect Families of CRT-Ds; Concerto, InSync II, Marquis DR, InSync III Marquis, InSync Marquis, InSync Maximo, and InSync Sentry Families of ICDs	Medtronic, Inc. Mounds View, MN 55112	Changes to the NeliPak Sealer manufacturing process; including addition of new equipment, a change to the process recipe specification, and the implementation of a monitoring test.
P010031/S255 6/9/11	Concerto, Concerto II, Consulta, Consulta DF4, InSync II Marquis, InSync Marquis, InSync Maximo, InSync Sentry, Maximo II, Maximo II M4, Protecta XT/ Protecta CRT-D, Protecta XT M4/ Protecta M$ CRT-Ds	Medtronic, Inc. Mounds View, MN 55112	Addition of an ethylene oxide (EtO) sterilizer system.
P010031/S256 6/10/11	Protecta and Protecta XT CRT-D	Medtronic, Inc. Mounds View, MN 55112	Change the cleaning area of the devices.
P010062/S009 6/22/11	Boston Orthokeratology Shapring Lens for Overnight Wear	Bausch & Lomb Incorporated Rochester, NY 14609	Alternate supplier of 0.2 micron formulation filter.
P020004/S063 6/8/11	Gore Excluder AAA Endoprosthesis	W.L. Gore & Associates Inc. Flagstaff, AR 86003	Automation of a bonding process.
P020009/S074 6/30/11	Express 2® Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Implementation of the use of a closed-loop control (feedback), in the extrusion of the tie layer of the tri-layer component.
P030005/S076 6/2/11	Contak Renewal Models	Boston Scientific Corporation St. Paul, MN 55112	Various changes in hybrid level test.
P030005/S077	CONTAK RENEWAL	Boston Scientific	Alternate ingredient

6/17/11	TR PG	Corporation St. Paul, MN 55112	for the adhesive used in sterile packaging.
P030017/S120 6/16/11	Precision Spinal Cord Stimulator System, Implantable Pulse Generator Charge Coil	Boston Scientific Neuromodulation Valencia, CA 91355	Addition of an alternate qualified supplier for components used in assembly of the device.
P030026/S023 6/14/11	VITROS Immunodiagnostic Products Anti-HBc IgM Reagent Pack and Calibrator	Ortho-Clinical Diagnostic, Inc. Rochester, NY 14626	Manufacturing process change for the manufacture and storage of the antifoam solution used in the VITROS Anti-HBc IgM Conjugate Reagent.
P030050/S010 6/14/11	Sculptra and Sculptra Aesthetic (infectable poly-L-lactic acid)	Sanofi-Aventis U.S., Inc. Bridgewater, NJ 08807	Change the location of the Design Control Center for Sculptra and Sculptra Aethetic from Sanofi Aventis U.S. LLC, Bridgewater, New Jersey to Anagni Italy.
P030052/S007 6/1/11	UroVysion Bladder Cancer Kit Assay	Abbott Molecular, Inc. Des Plaines, IL 60018	Implementation of process change to the manufacture of the FISH DNA bulk probe solution, including a new fISH DNA extraction process, a new sonication equipment, a new amination/labeling procedure, and a supplemental DNA purification processing step to reduce RNA carry-over.
P040002/S032 6/30/11	Powerlink Stent with IntuiTrak Delivery System	Endologix, Inc. Irvine, CA 92618	Alternate supplier of suture material.

P040014/S017 6/6/11	Therapy, Therapy Bi-Directional and Therapy 4 mm Thermistor Cardiac Ablation Catheters	St. Jude Medical Irvine, CA 92614	Implement an additional manufacturing rework step.
P040016/S072 6/30/11	VeriFLEX™ Bare-Metal Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Implementation of the use of a closed-loop control (feedback), in the extrusion of the tie layer of the tri-layer component.
P040042/S022 6/6/11	Therapy Dual 8, Therapy 8mm Thermistor and Safire TX Ablation Catheters	St. Jude Medical Irvine, CA 92614	Implement an additional manufacturing rework step.
P040045/S019 6/10/11	VISTAKON® (etafilcon A) and (senofilcon) Brand Contact Lenses	Vision Care, Inc. Jacksonville, FL 32256	Replacement of a Differential Scanning Calorimeter (DSC) for a previous model that is no longer supported by the same manufacturer.
P040045/S020 6/8/11	VISTAKON® (senofilcon A) Brand Contact Lenses	Johnson & Johnson Vision Care, Inc. Jacksonville, FL 32256	Evaluation of the automation of the repackaging activities conducted by a qualified supplier.
P040045/S021 6/16/11	VISTAKON® (senofilcon A) Brand Contact Lenses	Johnson & Johnson Vision Care, Inc. Jacksonville, FL 32256	Change in the software for processing laboratory data related to the VISTAKON® (etafilcon A) Brand and VISTAKON® (senofilcon A) Brand Contact Lenses.
P040045/S022 6/15/11	VISTAKON (senofilcon A) Brand Contact Lenses	Johnson & Johnson Vision Care, Inc. Jacksonville, FL 32256	Addition of a cure tunnel lane.
P040045/S023	VISTAKON	Johnson & Johnson	Use an electronic

6/22/11	(senofilcon A) Brand Contact Lenses	Vision Care, Inc. Jacksonville, FL 32256	Raw Material Tracking System.
P050042/S013 **6/24/11**	ARCHITECT ANTI-HCV	Abbott Laboratories Abbott Park, IL 60064	Change in the quality control testing used on an incoming raw material and a finished accessory used in the subject ARCHITECT Assays.
P050046/S011 **6/17/11**	ACUITY Lead	Boston Scientific Corporation St. Paul, MN 55112	Alternate ingredient for the adhesive used in sterile packaging.
P050051/S013 **6/24/11**	ARCHITECT AUSAB	Abbott Laboratories Abbott Park, IL 60064	Change in the quality control testing used on an incoming raw material and a finished accessory used in the subject ARCHITECT Assays.
P060001/S014 **6/27/11**	Protégé GPS & Protégé RX Carotid Stent System	Ev3 Endovascular Inc. Plymouth, MN 55441	Alternate etching process for sphere components.
P060007/S015 **6/24/11**	ARCHITECT HBsAg, ARCHITECT HBsAg Confirmatory	Abbott Laboratories Abbott Park, IL 60064	Change in the quality control testing used on an incoming raw material and a finished accessory used in the subject ARCHITECT Assays.
P060008/S071 **6/30/11**	TAXUS® Liberte® Paclitaxel-Eluting Coronary Stent Systems	Boston Scientific Corporation Maple Grove, MN 55311	Implementation of the use of a closed-loop control (feedback), in the extrusion of the tie layer of the tri-layer component.
P060010/S009 **6/14/11**	The Spanner Temporary Prostatic Stent	AbbeyMoor Medical, Inc. Parkers Prairie, MN 56351	Minor formulation change in a raw material.
P060022/S011	Akreos Posterior	Bausch & Lomb Inc.	Addition of an

6/8/11	Chamber Intraocular Lens	Aliso Viejo, CA 92656	alternate facility as a source or the Akreos lens button and an alternate supplier of methyl methacrylate.
P060035/S009 6/24/11	ARCHITECT CORE-M	Abbott Laboratories Abbott Park, IL 60064	Change in the quality control testing used on an incoming raw material and a finished accessory used in the subject ARCHITECT Assays.
P080006/S026 6/2/11	Attain Ability Family of Leads	Medtronic, Inc. Mounds View, MN 55112	Addition of an additional testing laboratory for sterilization.
P080006/S027 6/8/11	Attain Ability	Medtronic, Inc. Mounds View, MN 55112	Update to the sterile packaging operation process.
P080006/S028 6/10/11	Attain Ability Plus, Attain Ability Straight	Medtronic, Inc. Mounds View, MN 55112	Change the cleaning area of the devices.
P080014/S008 6/23/11	Cervista® Papilloma Virus (HPV) High Risk (HR)	Hologic LP Marlborough, MA 01752	Addition of a new supplier of Bovine Serum Albumin (BSA).
P080015/S004 6/23/11	Cervista® Human Papilloma Virus (HPV) 16/18	Hologic LP Marlborough, MA 01752	Addition of a new supplier of Bovine Serum Albumin (BSA).
P080023/S009 6/24/11	ARCHITECT CORE	Abbott Laboratories Abbott Park, IL 60064	Change in the quality control testing used on an incoming raw material and a finished accessory used in the subject ARCHITECT Assays.
P080025/S005 6/16/11	Interstim Family of Implantable Neurostimulators, Leads, Extension, Test Stimulation Lead, Test Stimulation Kit,	Medtronic, Inc. Minneapolis, MN 55432	Implement or change software used for manufacturing of several devices.

	Accessories and Accessory Kits for use with Interstim therapy and Control Magnet		
P080025/S006 6/17/11	InterStim INS and 3058 InterStim II INS	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of an ethylene oxide sterilizer system.
P080025/S007 6/22/11	InterStim Family	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of an alternate qualified supplier for components used in the feedthrough assembly.
P090013/S023 6/8/11	Revo MRI IPG	Medtronic, Inc. Mounds View, MN 55112	Changes to the NeliPak Sealer manufacturing process; including addition of new equipment, a change to the process recipe specification, and the implementation of a monitoring test.
P090013/S024 6/9/11	Revo MRI IPG	Medtronic, Inc. Mounds View, MN 55112	Addition of an ethylene oxide (EtO) sterilizer system.
P090013/S026 6/29/11	CapSureFix MRI	Medtronic, Inc. Mounds View, MN 55112	A lead assembly crimping process improvement.
P100023/S001 6/7/11	Ion (Taxus Element) Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Changes to your cut-to-length process during catheter assembly.
P100023/S004 6/29/11	Ion (Taxus Element) Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Changes to the proximal Heat Shrinking Removal Inspection Process.

Summary of PMA Originals & Supplements Approved
Originals: 4
Supplements: 78

Summary of PMA Originals Under Review

Total Under Review: 93
Total Active: 35
Total On Hold: 58
Number Greater Than 180 Days: 3

Summary of PMA Supplements Under Review
Total Under Review: 691
Total Active: 501
Total On Hold: 190
Number Greater Than 180 Days: 11

Summary of All PMA Submissions Received
Originals: 3
Supplements: 98

Summary of PMA Supplement PMA Approval/Denial Decision Times
Number of Approvals: 78
Number of Denials: 0
Average Days Fr Receipt to Decision (Total Time): 116.2
FDA Time: 93.3 Days MFR Time: 22.9 Days

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