PMA Final Decisions for August 2012

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.

PMA Original Approvals

None.

PMA Supplemental Approvals

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
P910023/S290 8/9/12 135-Day	Current and Fortify Families of ICDs	St. Jude Medical Sylmar, CA 91342	Approval for the removal of a plasma cleaning step for hybrid surface preparation.
P910023/S295 8/9/12 180-Day	Version 6.1 Software for Merlin.net System	St. Jude Medical Sunnyvale, CA 94086	Approval of Model MN5000 version 6.1 software to be used with the Merlin.net System and for the Model EX2000 version 6.1 software to be used on Merlin@home devices.
P910066/S026 8/10/12 180-Day	OL1000 SM, OL1000 MED, Spinalogic, and Spinalogic, E-coil Bone Growth Stimulators	DJO, LLC Vista, CA 92081	Approval for a manufacturing site and acceptance activities located in Vista, California.
P910071/S014 8/31/12 Special	ADATO® SIL-OL 5000 Silicone Oil	Bausch & Lomb, Inc. Aliso Viejo, CA	Approval for the labeling changes to the Directions for

		92656	Use (DFU). The DFU was revised to include safety information regarding the use of CO 2 lasers in instances where silicone oil may have migrated out of the eye and formed lesions in the conjunctiva or eyelid.
P930036/S004 **8/14/12** **135-Day**	ADVIA Centaur/XP and Centaur CP AFP Reagents and Calibrators	Siemens Healthcare Diagnostics, Inc. East Walpole, MA 02032	Approval for the implementation of a Lot Specific Master Curve in the quality control testing of the anti-AFP antibody.
P950009/S016 **8/30/12** **Real-Time**	BD FocalPoint™ Slide Profiler	BD Diagnostics Durham, NC 27703	Approval for change of the Scan Controller Board for the device.
P950037/S109 **8/28/12** **Real-Time**	Reliaty Pacing System Analyzer	Biotronik, Inc. Lake Oswego, OR 97035	Approval for firmware modifications and labeling updates to the devices.
P950037/S110 **8/8/12** **Real-Time**	PSW 1202.U for Renamic & ICS 3000	Biotronik, Inc. Lake Oswego, OR 97035	Approval for updated software version PSW 1202.U.
P960004/S053 **8/2/12** **Real-Time**	FINELINE II and ThinLine II Pacing Leads	Boston Scientific St. Paul, MN 55112	Approval for an alternate primer material.
P960009/S149 **8/24/12** **Real-Time**	Activa Implantable Neurostimulators	Medtronic Neuromodulation Minneapolis, MN 55432	Approval for eliminating the external parylene coating from the following Implantable Neurostimulators: Activa RC Model 37612, Activa PC Model 37601, Activa SC Model

			37602 and Activa SC Model 37603.
P960058/S096 **8/20/12** **135-Day**	Harmony HiResolution Bionic Ear System, HiRes 90K	Advanced Bionics Sylmar, CA 91342	Approval for the change in fabrication line for the Analog Integrated Circuit (AIC).
D970003/S138 **8/29/12** **Real-Time**	ZOOMVIEW Programmer Software Application v1.08	Boston Scientific St. Paul, MN 55112	Approval for Model 2869 ZOOMVIEW Programmer Software Application v1.08
P990020/S047 **8/16/12** **135-Day**	Aneurx Advantage Stent Graft with Xcelerant Hydro Delivery System	Medtronic Vascular, Inc. Santa Rosa, CA 95403	Approval for a change to automate the information management system.
P990046/S026 **8/13/12** **180-Day**	Open Pivot Heart Valve	Medtronic, Inc. Minneapolis, MN 55432	Approval for a manufacturing site located at Biotest Laboratories in Brooklyn Park, Minnesota.
P990081/S012 **8/21/12** **Real-Time**	PATHWAY anti-HER-2/*neu* (4B5) Rabbit Monoclonal Primary Antibody	Ventana Medical Systems, Inc. Tucson, AZ 85755	Approval for an extension of shelf life of the iView DAB detection kit and the ultraView DAB detection kit for the device.
P000009/S050 **8/8/12** **Real-Time**	PSW 1202.U for Renamic & ICS 3000	Biotronik, Inc. Lake Oswego, OR 97035	Approval for updated software version PSW 1202.U.
P000053/S041 **8/21/12** **180-Day**	AMS Sphincter 800® Urinary Prosthesis with InhibiZone® Antibiotic Surface Treatment	American Medical Systems Minnetonka, MN 55343	Approval for revision of the amount of rifampin and minocycline specified in the Instruction for use and the Operating Room Manual.
P000054/S028 **8/3/12** **135-Day**	Infuse Bone Graft/LT-Cage Lumbar Tapered Fusion, Infuse Bone	Medtronic Sofamor Danek Memphis, TN 38132	Approval for changes to tests performed as part of the ongoing drug

	Graft		product stability program for rhBMP-2 (dibotermin alfa).
P000054/S030 **8/3/12** **135-Day**	INFUSE® Bone Graft	Medtronic Sofamor Danek Memphis, TN 38132	Approval for the substitution of a quality control test.
P000058/S041 **8/3/12** **135-Day**	Infuse Bone Graft/LT-Cage Lumbar Tapered Fusion, Infuse Bone Graft	Medtronic Sofamor Danek Memphis, TN 38132	Approval for changes to tests performed as part of the ongoing drug product stability program for rhBMP-2 (dibotermin alfa).
P000058/S043 **8/3/12** **135-Day**	INFUSE® Bone Graft/LT-Cage Lumbar Tapered Fusion	Medtronic Sofamor Danek Memphis, TN 38132	Approval for the substitution of a quality control test.
P010014/S036 **8/2/12** **Special**	Oxford® Partial Knee System	Biomet Manufacturing Corporation Warsaw, IN 46581	Approval for updates to the package insert which included the following: strengthening and clarification of the importance of following the surgical technique, additional wording to clarify a precaution to the end user, expanded language for a possible adverse event about foreign material sensitivity and reformatting of the Magnetic Resonance (MR) section.
P010030/S035 **8/15/12** **Real-Time**	LifeVest Wearable Defibrillator	ZOLL Lifecor Corporation Pittsburgh, PA 15238	Approval for minor hardware updates to lead-free components for the device.

P010032/S057 **8/24/12** **Real-Time**	Eon Mini Implantable Pulse Generators (IPG) Neurostimulation System	St. Jude Medical Plano, TX 75024	Approval for a change to the internal battery housing material from titanium to 304L stainless steel.
P010047/S019 **8/23/12** **Real-Time**	NeoMend ProGEL Pleural Air Leak Sealant	NeoMend, Incorporated Irvine, CA 92618	Approval for an extension of the refrigerated shelf life of the device.
P020045/S044 **8/24/12** **Real-Time**	Cryoconsole	Medtronic CryoCath LP Quebec, Canada H9R 5Z8	Approval for changes related to updating for compliance to IEC 60601-1 3rd Edition standards, removal of the floppy disk drive, and related labeling updates.
P020047/S046 **8/20/12** **180-Day**	Multi-Link 8 and Multi-Link 8 LL Coronary Stent Systems (CSS)	Abbott Vascular Temecula, CA 92591	Approval for a sterilization site located in Tipperary, Ireland .
P030005/S086 **8/29/12** **Real-Time**	ZOOMVIEW Programmer Software Application v1.08	Boston Scientific St. Paul, MN 55112	Approval for Model 2869 ZOOMVIEW Programmer Software Application v1.08
P030009/S061 **8/16/12** **135-Day**	Driver, Micro-Driver and Integrity Coronary Stent Systems	Medtronic Vascular, Inc. Santa Rosa, CA 95403	Approval for a change to automate the information management system.
P030011/S015 **8/10/12** **Real-Time**	SynCardia Companion 2 Driver System	SynCardia Systems, Inc. Tucson, AZ 85713	Approval for a change in the pressure limit range for the external air pressure regulator of the device.
P030011/S016 **8/20/12** **180-Day**	SynCardia Companion 2 Driver System	SynCardia Systems, Inc. Tucson, AZ 85713	Approval of the post-approval study protocol.
P030054/S217 **8/9/12** **135-Day**	Promote and Unify Families of CRT-Ds	St. Jude Medical Sylmar, CA 91342	Approval for the removal of a plasma cleaning step for

			hybrid surface preparation.
P030054/S223 **8/9/12** **180-Day**	Version 6.1 Software for Merlin.net and Version 6.1 Software for Merlin@home	St. Jude Medical Sunnyvale, CA 94086	Approval of Model MN5000 version 6.1 software to be used with the Merlin.net System and for the Model EX2000 version 6.1 software to be used on Merlin@home devices.
P040002/S038 **8/22/12** **Real-Time**	AFX AAA Endovascular System	Endologix, Inc. Irvine, CA 92618	Approval for stand-alone delivery systems for the straight and tapered limb extension stent grafts and for the flared limb extensions grafts. The device, as modified, will be marketed under the trade name AFX Stand-Alone Limb Extension Delivery System as an accessory to the AFX AAA Endovascular System which is indicated for endovascular treatment in patients with AAA.
P040012/S044 **8/24/12** **180-Day**	RX Acculink Carotid Stent System	Abbott Vascular Santa Clara, CA 95054	Approval to update the labeling with long term CREST study results.
P040012/S046 **8/2/12** **180-Day**	Standard Risk Indication RX Acculink® Carotid Stent System CANOPY Trial	Abbott Vascular Inc. Santa Clara, CA 95054	Approval of the post-approval study for the device.
P040014/S019 **8/22/12** **135-Day**	Therapy Cardiac Ablation System	St. Jude Medical Irvine, CA 92614	Approval for an additional vendor of a generator

			component.
P040021/S022 **180-Day** **8/30/12**	Biocor and Biocor Supra Valves	St. Jude Medical St. Paul, MN 55117	Approval of the post-approval study protocol.
P040024/S056 **8/30/12** **Panel-Track**	Restylane L Injectable Gel	Medicis Aesthetics Holding Incorporated Scottsdale, AZ 85256	Approval for Restylane L Injectable Gel. This device is indicated for: 1) mid-to-deep dermal implantation for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds; and 2) submucosal implantation for lip augmentation in patients over the age of 21.
P040024/S062 **8/6/12** **Real-Time**	Restylane L and Perlane L Injectable Gel	Medicis Global Services Corporation Scottsdale, AZ 85256	Approval for an extension to the expiration date of the Restylane L and Perlane L Injectable Gels (0.5 and 1.0 mL) from 24 months to 36 months.
P040042/S024 **8/22/12** **135-Day**	Therapy Dual 8 Cardiac Ablation System	St. Jude Medical Irvine, CA 92614	Approval for an additional vendor of a generator component.
P050012/S045 **8/17/12** **180-Day**	Dexcom Color Continuous Glucose Monitoring System	Dexcom, Inc. San Diego, CA 92121	Approval for: 1) the addition of new components to the Global Transmitter/ Global Receiver system allowing communication at 2.4 GHz; 2) minor modifications to the Applicator bail and safety card; and 3) updates to the optional Data Manager software that is provided with the Seven Plus

			CGM System. The device, as modified, will be marketed under the trade name Dexcom Color Continuous Glucose Monitoring (CGM) System, and is a glucose-monitoring device indicated for detecting and tracking glucose trends and patterns to aid in the detection of episodes of hyperglycemia and hypoglycemia in adults with diabetes. The system is intended for single patient use and requires a prescription.
P050023/S054 **8/8/12** **Real-Time**	PSW 1202.U for Renamic & ICS 3000	Biotronik, Inc. Lake Oswego, OR 97035	Approval for updated software version PSW 1202.U.
P050027/S003 **8/27/12** **Real-Time**	Karl Storz Photodynamic D-Light C (PDD) System	Karl Storz Endoscopy-America, Inc. El Segundo, CA 90245	Approval for an alternate sterilization method, STERRAD NX, for the fluid light cable device component within the device.
P050039/S008 **8/17/12** **135-Day**	Novation Ceramic Articulation Hip System	Exactech, Inc. Gainesville, FL 32653	Approval for requested changes to the Blend/Polish Work Instruction for the Novation Splined Stems.
P050053/S019 **8/3/12** **135-Day**	Infuse Bone Graft/LT-Cage Lumbar Tapered Fusion, Infuse Bone Graft	Medtronic Sofamor Danek Memphis, TN 38132	Approval for changes to tests performed as part of the ongoing drug product stability program for

			rhBMP-2 (dibotermin alfa).
P050053/S021 **8/3/12** **135-Day**	INFUSE® Bone Graft	Medtronic Sofamor Danek Memphis, TN 38132	Approval for the substitution of a quality control test.
P060019/S020 **8/22/12** **135-Day**	Therapy Cool Path Ablation Catheter and IBI RF Ablation Generator	St. Jude Medical Irvine, CA 92614	Approval for an additional vendor of a generator component.
P060033/S070 **8/16/12** **135-Day**	Endeavor Sprint Zotarolimus-Eluting Coronary Stent System	Medtronic Vascular, Inc. Santa Rosa, CA 95403	Approval for a change to automate the information management system.
P060039/S033 **8/16/12** **180-Day**	Attain StarFix Lead	Medtronic, Inc. Mounds View, CA 55112	Approval of the post-approval study protocol.
P070007/S035 **8/16/12** **135-Day**	Talent Thoracic Stent Graft System with the Xcelerant and Captivia Delivery System	Medtronic Vascular, Inc. Santa Rosa, CA 95403	Approval for a change to automate the information management system.
P070008/S033 **8/8/12** **Real-Time**	PSW 1202.U for Renamic & ICS 3000	Biotronik, Inc. Lake Oswego, OR 97035	Approval for updated software version PSW 1202.U.
P070027/S034 **8/16/12** **135-Day**	Talent Abdominal Stent Graft with Xcelerant Hydro Delivery System	Medtronic Vascular, Inc. Santa Rosa, CA 95403	Approval for a change to automate the information management system.
P090006/S008 **8/16/12** **135-Day**	Complete SE Vascular Stent System	Medtronic Vascular, Inc. Santa Rosa, CA 95403	Approval for a change to automate the information management system.
P090012/S001 **8/8/12** **180-Day**	MelaFind	Mela Sciences, Inc. Irvington, NY 10533	Approval of the post-approval study protocol.
P090016/S002 **8/10/12** **Real-Time**	Belotero Balance	Merz Aesthetics, Inc. Franksville, WI 53126	Approval for a modification to the Belotero Balance Instructions for Use to include 27 gauge needles as an

			option for injection.
P090022/S013 **8/16/12** **Special**	Softec HD Posterior Chamber Intraocular Lens (IOL)	Lenstec, Inc. St. Petersburg, FL 33716	Approval for a modification to the directions for use to include a warning that enhances the safety in the use of the device.
P100010/S017 **8/24/12** **Real-Time**	Cryoconsole	Medtronic CryoCath LP Quebec, Canada H9R 5Z8	Approval for changes related to updating for compliance to IEC 60601-1 3rd Edition standards, removal of the floppy disk drive, and related labeling updates.
P100021/S015 **8/16/12** **135-Day**	Endurant Stent Graft System	Medtronic Vascular, Inc. Santa Rosa, CA 95403	Approval for a change to automate the information management system.
P100023/S033 **8/20/12** **180-Day**	ION Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Approval of the post-approval study protocol.
P100023/S038 **8/16/12** **135-Day**	ION Paclitaxel-Eluting Platinum Chromium Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Approval for hardware and software changes to the catheter port manufacturing process.
P100029/S014 **8/8/12** **Special**	Trifecta ™ Valve	St. Jude Medical St. Paul, MN 55117	Approval for adding an inspection for the maximum length for certain flaws where the depth cannot be accurately assessed.
P100040/S007 **8/16/12** **135-Day**	Valiant Thoracic Stent Graft with the Captivia Delivery System	Medtronic Vascular, Inc. Santa Rosa, CA 95403	Approval for a change to automate the information management system.
P100041/S008	Edwards SAPIEN™	Edwards	Approval to add the

8/20/12 **180-Day**	Transcatheter Heart Valve and Accessories, RetroFlex™ Balloon Catheter and Crimper	Lifesciences, LLC Irvine, CA 92614	Edwards Transcatheter Balloon Catheters, Models 9350BC20 and 9350BC23 with a working balloon length of 4 cm, and to add some new control environments at the Draper facility in Draper, Utah to accommodate the manufacture of these catheters at that facility.
P100046/S001 **8/15/12** **180-Day**	AtriCure Synergy Ablation System	AtriCure, Inc. Northborough, MA 01532	Approval of the post-approval study protocol.
P110010/S010 **8/16/12** **135-Day**	PROMUS Element Plus Everolimus-Eluting Platinum Chromium Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Approval for hardware and software changes to the catheter port manufacturing process.
P110010/S020 **8/24/12**	Promus Element Plus Everolimus-Eluting Chromium Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Approval of the post-approval study protocol.
P110010/S021 **8/23/12** **180-Day**	PROMUS Element Plus Everolimus-Eluting Platinum Chromium Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Approval of the post-approval study protocol.
P110011/S002 **8/16/12** **135-Day**	Assurant Cobalt Iliac Balloon-Expandable Stent	Medtronic Vascular, Inc. Santa Rosa, CA 95403	Approval for a change to automate the information management system.
P110013/S001 **8/16/12** **135-Day**	Resolute Integrity and Resolute Microtrac Coronary Stent System	Medtronic Vascular, Inc. Santa Rosa, CA 95403	Approval for a change to automate the information management system.
P110019/S014 **8/20/12**	Xience Prime and Xience Prime LL	Abbott Vascular Temecula, CA	Approval for a sterilization site

180-Day	Everolimus Eluting Coronary Stent Systems	92590	located in Tipperary . Ireland.
P110019/S023 8/6/12 Real-Time	Xience Prime and Xience Prime LL Everolimus Eluting Coronary Stent System	Abbott Vascular Temecula, CA 92590	Approval for updating labeling for the Xience Prime Everolimus Eluting Coronary Stent System to reflect a 24 month shelf life.

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
P810031/S045 8/9/12	Sodium Hyaluronate Ophthalmic Viscoelastic Devices (OVD), Healon, Healon GV and Healon5 Products	Abbott Medical Optics, Inc. Santa Ana, CA 92705	Replacement of an autoclave.
P830061/S077 8/30/12	CapSure Leads, Vitatron Crystalline Leads, and Vitatron Excellence PS+ Leads	Medtronic, Inc. Mounds View, MN 55112	Modifications to a controlled environment.
P840001/S218 8/1/12	Restore Family of Implantable of Neurostimulators	Medtronic Neuromodulation Minneapolis, MN 55432	A change to the final functional test.
P840001/S220 8/10/12	SCS Extensions, SCS Temporary Leads (for Screening), SCS Leads 1x8 Family, SCS Leads Pisces Family and SCS Leads Specify Family	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of a duplicate EtO Sterilization System.
P840001/S222 8/1/12	RestoreSensor Implantable Neurostimulator (INS)	Medtronic Neuromodulation Minneapolis, MN 55432	Design change to the post sterilization test software.
P840001/S224	Itrel 3, Synergy,	Medtronic	Addition of another

8/22/12	Synergy Versitrel, Itrel 4, and Pocket Adaptors	Neuromodulation Minneapolis, MN 55432	supplier for the Inner Seal Silicone Component 117988-001.
P850089/S089 8/30/12	CapSure SP Novus Leads, CapSure SP Z Leads, CapSure Z Novus Leads and Impulse II Leads	Medtronic, Inc. Mounds View, MN 55112	Modifications to a controlled environment.
P860004/S173 8/21/12	Synchromed II Infusion Pump	Medtronic Neuromodulation Minneapolis, MN 55432	Implementation of new package of sealing equipment.
P860004/S174 8/21/12	Synchromed II Infusion Pump	Medtronic Neuromodulation Minneapolis, MN 55432	Implementation of a new mold for a kit component.
P890003/S255 8/30/12	CapSure Leads and Prodigy IPG	Medtronic, Inc. Mounds View, MN 55112	Modifications to a controlled environment.
P900033/S022 8/22/12	Integra Dermal Regeneration Template	Integra LifeSciences Corporation Plainsboro, NJ 08536	Changes to the cleaning processes associated with the production equipment.
P900033/S023 8/14/12	Integra Dermal Regeneration Template	Integra LifeSciences, Corporation Plainsboro, NJ 08536	Improvements to the Water for Injection system associated with the production of the device.
P900033/S024 8/24/12	Integra Dermal Regeneration Template	Integra LifeSciences, Corporation Plainsboro, NJ 08536	Change in the inspection process for the manufacturing equipment.
P900033/S025 8/24/12	Integra Dermal Regeneration Template	Integra LifeSciences, Corporation Plainsboro, NJ 08536	Replacement of the air handling unit within a manufacturing suite.
P900061/S115 8/30/12	End Cap, Epicardial Patch Lead, Sizing Sleeve and Upsizing Sleeve	Medtronic, Inc. Mounds View, MN 55112	Modifications to a controlled environment.
P910007/S035	ARCHITECT TOTAL	Abbott Laboratories	Change to the

8/29/12	PSA	Abbott Park, IL 60064	manufacturing material used to filter the common accessories.
P910023/S299 8/22/12	Fortify VR DF-4 ICD's	St. Jude Medical Sylmar, CA 91342	Change to the tooling used during the routing step of the manufacturing process for the feedthru.
P910023/S300 8/30/12	Current, Fortify, Ellipse, Fortify Assura Family of ICD Devices	St. Jude Medical Sylmar, CA 91342	Addition of an alternate supplier for a seal component.
P910056/S012 8/31/12	enVista One Piece Hydrophobic Acrylic Lens	Bausch & Lomb Aliso Viejo, CA 92656	Alternate milling site and an alternate source for a material used for the manufacturing of the lenses.
P920015/S094 8/30/12	"Y" adaptor/ extender kit, DF-1 connector port pin plug, IS-1 connector port pin plug kit, Lead adaptor, Sprint Quattro Lead, Subcutaneous Lead and Transvene SVC Lead	Medtronic, Inc. Mounds View, MN 55112	Modifications to a controlled environment.
P920023/S031 8/2/12	AMS UroLume Endoprosthesis	American Medical Systems, Inc. Minnetonka, MN 55343	Change in the label database server and a labeling software revision to the NiceLabel System.
P930014/S063 8/9/12	AcrySof Posterior Chamber Intraocular Lenses	Alcon Laboratories, Inc. Fort Worth, TX 76134	Implementation of a modified validated curing cycle.
P930039/S069 8/6/12	CapSureFix Novus Lead, Vitatron Crystalline Leads	Medtronic, Inc. Mounds View, MN 55112	Alternate suppliers of molded silicone components.
P930039/S070 8/15/12	CapSureFix Lead	Medtronic, Inc. Mounds View, MN 55112	Changes to the laser weld parameters used for the connector pin to

			coil laser weld process.
P930039/S071 8/30/12	CapSurefix Lead, CapSureFix Novus Lead, Surefix Lead and Torque Clip Device and Vitatron Crystalline Leads	Medtronic, Inc. Mounds View, MN 55112	Modifications to a controlled environment.
P950024/S042 8/30/12	CapSure Epicardial Pacing Lead	Medtronic, Inc. Mounds View, MN 55112	Modifications to a controlled environment.
P950029/S071 8/23/12	Reply SR and DR, Esprit SR and DR	Sorin CRM Plymouth, MN 55441	Addition of a cleaning step and new electrical test equipment.
P960009/S150 8/1/12	Activa Family of Implantable of Neurostimulators	Medtronic Neuromodulation Minneapolis, MN 55432	Requested a change to the final functional test.
P960009/S151 8/10/12	DBS Extensions and DBS Leads	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of a duplicate EtO Sterilization System.
P960009/S153 8/22/12	Soletra, Kinetra, Activa SC. and Pocket Adaptors	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of another supplier for the Inner Seal Silicone Component 117988-001.
P960040/S267 8/22/12	Teligen, Incepta, Energen and Punctua ICDs	Boston Scientific Corporation St. Paul, MN 55112	Add an Automatic Optical Inspection (AOI) system used to inspect component placed on the printed circuit board.
P960058/S097 8/24/12	HiResolution Bionic Ear Systems	Advanced Bionics Sylmar, CA 91342	Change in the biological indicator used in the firm’s Ethylene Oxide sterilization process.
P970004/S137 8/10/12	SNS Urinary Extensions and SNS Urinary Leads	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of a duplicate EtO Sterilization System.
P970004/S139	InterStim	Medtronic	Addition of another

8/22/12		Neuromodulation Minneapolis, MN 55432	supplier for the Inner Seal Silicone Component 117988-001.
D970012/S092 8/2/12	AMS Ambicor Penile Prosthesis and AMS 700 Inflatable Penile Prosthesis	American Medical Systems, Inc. Minnetonka, MN 55343	Change in the label database server and a labeling software revision to the NiceLabel System.
P970020/S074 8/14/12	Multi-link 8 Coronary Stent System (CSS)	Abbott Vascular Temecula, CA 92591	Addition of a new test to inspect tubing used in the manufacturing of stents for the devices.
P970051/S092 8/24/12	Nucleus 24 Cochlear Implant System	Cochlear Americas Centennial, CO 80111	Implementation of a new cleaning system for the implant electronic assemblies for the C124RE(CA), C124RE(ST), and C1422 Nucleus Cochlear Implants.
P980007/S026 8/29/12	ARCHITECT FREE PSA	Abbott Laboratories Abbott Park, IL 60064	Change to the manufacturing material used to filter the common accessories.
P980016/S365 8/1/12	Maximo II, Maximo II DF4, Protecta, Protecta DF4, Protecta XT, Protecta XT DF4, Secura, Secura DF4, Virtuoso, Virtuoso II DR/VR, and EnTrust ICDs	Medtronic, Inc. Mounds View, MN 55112	Changes to the Radio Frequency Device Test application.
P980016/S367 8/10/12	Maximo II DF4 CRT-D, Maximo II DF4 ICD, Maximo II ICD, Secura DF4 ICD Secura ICD, Virtuoso II DR/VR ICD	Medtronic, Inc. Mounds View, MN 55112	Updates to the next generation hybrid tester software.
P980016/S368	Maximo II DF4 CRT-	Medtronic, Inc.	Updates to the

8/14/12	D, Maximo II DF4 ICD, Maximo II ICD, Secura DF4 ICD, Secura ICD, and Virtuoso II DR/VR ICD	Mounds View, MN 55112	hybrid testing process.
P980016/S369 8/20/12	EnTrust lCD, Intrinsic lCD, Marquis DR lCD, Marquis VR ICD, Maximo DR lCD, Maximo II DR4 ICD, Maximo II lCD, Maximo VR lCD, Protecta DF4 lCD, Protecta lCD, Protecta XT DF4 ICD, Protecta XT lCD, Secura DF4 lCD, Secura ICD, Virtuso lCD, Virtuoso II DR/VR lCD	Medtronic, Inc. Mounds View, MN 55112	Manufacturing lines in a new extension of a controlled environment area.
P980016/S370 8/17/12	EnTrust ICD, Intrinsic ICD, Marquis DR ICD, Marquis VR ICD, Maximo DR ICD, Maximo II DF4 ICD, Maximo II ICD, Maximo VR ICD, Protecta DF4 ICD, Protecta ICD, Protecta XT DF4 ICD, Protecta XT ICD, Secura DF4 ICD, Secura ICD, Virtuoso ICD, Virtuoso II DR/VR ICD	Medtronic, Inc. Mounds View, MN 55112	New pressure test equipment used to verify hermeticity.
P980016/S371 8/22/12	Maximo II ICD, Protecta ICD, Protecta XT ICD, Secura ICD, and Virtuoso II DR/VR ICD	Medtronic, Inc. Mounds View, MN 55112	CMOS process flow changes at the supplier.
P980016/S372 8/27/12	Maximo II, Protecta, Protecta	Medtronic, Inc. Mounds View, MN	Update test software and

	XT, Secura and Virtuoso II DR/VR ICDs	55112	hardware on the Teradyne Test Platform for M019 and M017 integrated circuits.
P980016/S373 8/30/12	EnTrust ICD, Intrinsic ICD, Marquis DR ICD, Marquis VR ICD. Maximo DR ICD, Maximo II ICD, Maximo VR ICD, Protecta ICD. Protecta XT ICD, Secura ICD, Virtuoso ICD and Virtuoso II DR/VR ICD	Medtronic, Inc. Mounds View, MN 55112	Modifications to a controlled environment.
P980016/S375 8/31/12	Maximo II, Secura and Virtuoso II DR/VR ICDs	Medtronic, Inc. Mounds View, MN 55112	Update test software for the CD Surge Tester.
P980022/S120 8/17/12	Paradigm REAL-Time System, Paradigm REAL-Time Revel System and Guardian REAL-Time System	Medtronic MiniMed, Inc. Northridge, CA 91325	Transfer of the sub-assembly manufacturing processes of the MiniLink Real-Time Transmitter (MMT-7703) from IntriCon Corporation in Arden Hills, Minnesota to an alternate manufacturing facility at IntriCon in Admirax, Singapore. The MiniLink Real-Time Transmitter is a component of the devices.
P980035/S278 8/10/12	Adapta, Versa, Sensia and Relia IPGs	Medtronic, Inc. Mounds View, MN 55112	Updates to the Proteus Device Test System software.
P980035/S279 8/6/12	Adapta, Adapta L, Adapta S, Sensia L, Sensia, Versa IPG, Sigma DR IPG, Sigma S IPG	Medtronic, Inc. Mounds View, MN 55112	Alternate suppliers of molded silicone components.

P980035/S281 8/20/12	Adapa, Adapta L, Adapta S, Sensia L, Sensia, Versa IPG, Advisa DR IPG, EnRyhthm IPG, Relia IPG	Medtronic, Inc. Mounds View, MN 55112	Manufacturing lines in a new extension of a controlled environment area.
P980035/S282 8/17/12	Adapta, Adapta L, Adapta S, Scnsia L, Sensia, Versa IPG, Advisa DR IPG, EnRhythm IPG, Relia IPG	Medtronic, Inc. Mounds View, MN 55112	New pressure test equipment used to verify hermeticity.
P980035/S283 8/22/12	Adapta, Adapta L, Adapta S, Sensia L, Sensia, Versa IPG, Advisa DR IPG, and Relia IPG	Medtronic, Inc. Mounds View, MN 55112	CMOS process flow changes at the supplier.
P980035/S284 8/27/12	Advisa DR IPG	Medtronic, Inc. Mounds View, MN 55112	Update test software and hardware on the Teradyne Test Platform for M019 and M017 integrated circuits.
P980035/S0285 8/30/12	Adapta, Adapta L, Adapta S, Sensia L, Sensia, Versa IPG, Advisa DR IPG, EnRhythm IPG, Relia IPG, Sigma DR IPG and Sigma S IPG	Medtronic, Inc. Mounds View, MN 55112	Modifications to a controlled environment.
P980049/S077 8/23/12	Paradym VR and DR, Paradym RF VR and DR	Sorin CRM Plymouth, MN 55441	Addition of a cleaning step and new electrical test equipment.
P980050/S075 8/30/12	Transvene Lead	Medtronic, Inc. Mounds View, MN 55112	Modifications to a controlled environment.
P990001/S106 8/20/12	Vitatron C20 SR IPG, Vitatron C60 DR IPG, Vitatron T20 SR IPG, Vitatron T60 DR IPG	Medtronic, Inc. Mounds View, MN 55112	Manufacturing lines in a new extension of a controlled environment area.
P990001/S107 8/17/12	Vitatron C20 SR IPG, Vitatron C60	Medtronic, Inc. Mounds View, MN	New pressure test equipment used to

	DR IPG, Vitatron T20 SR IPG, VitatronT60 DR IPG	55112	verify hermeticity.
P990001/S108 8/30/12	Vitatron C20 SR IPG, Vitatron C60 DR IPG, Vitatron T20 SR IPG and Vitatron T60 DR IPG	Medtronic, Inc. Mounds View, MN 55112	Modifications to a controlled environment.
P990064/S043 8/23/12	Mosaic Porcine Bioprosthesis	Medtronic, Inc. Santa Ana, CA 92705	Addition of an in-process tissue quality control test to measure muscle bar.
P990081/S013 8/9/12	PATHWAY HER2/NEU (4B5) Rabbit Monoclonal Primary Antibody	Ventana Medical Systems, Inc. Tucson, AZ 85755	Addition of a supplier of raw materials for the iView Detection kit, which is part of the device.
P000053/S044 8/2/12	AMS 800 Urinary Control System	American Medical Systems, Inc. Minnetonka, MN 55343	Change in the label database server and a labeling software revision to the NiceLabel System.
P010012/S297 8/22/12	Cognis, Incepta, Energen and Punctua CRT-Ds	Boston Scientific Corporation St. Paul, MN 55112	Add an Automatic Optical Inspection (AOI) system used to inspect component placed on the printed circuit board.
P010014/S037 8/15/12	Oxford Meniscal Unicompartmental Knee System	Biomet Manufacturing Corporation Warsaw, IN 46582	Changes to the device sterile packaging.
P010015/S167 8/20/12	Consulta CRT-P and Syncra CRT-P	Medtronic, Inc. Mounds View, MN 55112	Manufacturing lines in a new extension of a controlled environment area.
P010015/S168 8/17/12	Consulta CRT-P, Syncra CRT-P	Medtronic, Inc. Mounds View, MN 55112	New pressure test equipment used to verify hermeticity.
P010015/S169 8/22/12	Consulta CRT-P, Syncra CRT-P	Medtronic, Inc. Mounds View, MN 55112	CMOS process flow changes at the supplier.

P010015/S170 8/27/12	Consulta and Syncra CRT-Ps	Medtronic, Inc. Mounds View, MN 55112	Update test software and hardware on the Teradyne Test Platform for M019 and M017 integrated circuits.
P010015/S171 8/30/12	Attain Bipolar OTW Lead, Consulta CRT-P, Left Ventricular Pacing Lead, and Syncra CRT-P	Medtronic, Inc. Mounds View, MN 55112	Modifications to a controlled environment.
P010019/S033 8/9/12	Lotrafilcon Soft Contact Lenses for Extended Wear	CIBA Vision Corporation Duluth, GA 30097	Improved measurement on the particle size of a component.
P010020/S025 8/2/12	Acticon Neosphincter	American Medical Systems, Inc. Minnetonka, MN 55343	Change in the label database server and a labeling software revision to the NiceLabel System.
P010031/S317 8/1/12	Concerto, Concerto II, Consulta, Consulta DF4, Maximo II, Maximo II DF4, Protecta, Protecta DF4, Protecta XT, and Protecta XT DF4 CRT-Ds	Medtronic, Inc. Mounds View, MN 55112	Changes to the Radio Frequency Device Test application.
P010031/S320 8/10/12	Concerto II CRT-D, Consulta DF4 ICD, Consulta ICD, Maximo II CRT-D, Maximo II DF4 CRT-D	Medtronic, Inc. Mounds View, MN 55112	Updates to the next generation hybrid tester software.
P010031/S321 8/14/12	Concerto II CRT-D, Consulta DF4 ICD, Consulta ICD, Maximo II CRT-D, and Maximo II DF4 CRT-D	Medtronic, Inc. Mounds View, MN 55112	Updates to the hybrid testing process.
P010031/S322 8/20/12	Concerto ICD, Concerto II CRT-D, Consulta lCD, lnSync III Marquis	Medtronic, Inc. Mounds View, MN 55112	Manufacturing lines in a new extension of a controlled environment area.

	lCD, lnSync Maximo lCD, Maximo II CRT-D, Maximo II DF4 CRT-D, Protecta CRT-D, Protecta DF4 CRT-D, Protecta XT CRT-D, and Protecta XT DF4 CRT-D		
P010031/S323 8/17/12	Concerto ICD, Concerto II CRT-D, Consulta DF4 ICD, Consulta, lnSync III Marquis ICD, InSync Maximo ICD, Maximo II CRT-D, Maximo II DF4 CRT-D, Protecta CRT-D, Protecta DF4 CRT-D, Protecta XT CRT-D, Protecta XT DF4 CRT-D	Medtronic, Inc. Mounds View, MN 55112	New pressure test equipment used to verify hermeticity.
P010031/S324 8/22/12	Concerto II CRT-D, Consulta DF4 1CD, Consults ICD, Maximo II CRT-D. Protecta CRT-D, and Protecta XT CRT-D	Medtronic, Inc. Mounds View, MN 55112	CMOS process flow changes at the supplier.
P010031/S325 8/27/12	Consulta and Consulta DF4 ICDs and Concerto II, Maximo II, Protecta and Protecta XT CRT-Ds	Medtronic, Inc. Mounds View, MN 55112	Update test software and hardware on the Teradyne Test Platform for M019 and M017 integrated circuits.
P010031/S326 8/30/12	Concerto ICD, Concerto II CRT-D, Consulta DF4 ICD, Consulta ICD, InSync III Marquis ICD, lnSync Maximo ICD, Maximo II CRT-D, Protecta CRT-D, and Protecta XT CRT-D	Medtronic, Inc. Mounds View, MN 55112	Modifications to a controlled environment.
P010031/S328 8/31/12	Consulta, Consulta DF4 ICDs, Concerto II and Maximo II CRT-	Medtronic, Inc. Mounds View, MN 55112	Update test software for the CD Surge Tester.

	Ds		
P010032/S056 8/1/12	EonMini IPG System	St. Jude Medical Plano, TX 75024	Change to the in-process and final inspection impedance test.
P010032/S060 8/10/12	Eon, EonC™ & Econ Mini™ Neurostimulation IPG Systems	St. Jude Medical Plano, TX 75024	Software revision to an in-process inspection step.
P010032/S062 8/31/12	Penta™ Lead Series	St. Jude Medical Plano, TX 75024	Change the in-process dimensional inspection for the devices.
P020009/S090 8/31/12	Express 2 Coronary Stent Systems	Boston Scientific Corporation Maple Grove, MN 55311	Removal of in-process monitoring for seal burst testing.
P020047/S049 8/14/12	VISION and MINI-VISION Coronary Stent System (CSS)	Abbott Vascular Temecula, CA 92591	Addition of a new test to inspect tubing used in the manufacturing of stents for the devices.
P020047/S050 8/24/12	MULTI-LINK 8 Coronary Stent System	Abbott Vascular Temecular, CA 92591	Irradiation equipment change for the manufacturing of the devices.
P030017/S139 8/15/12	Precision® Spinal Cord Stimulator System	Boston Scientific Neuromodulation Valencia, CA 91355	Allow cable ablation to be processed in-house.
P030036/S045 8/6/12	SelectSecure Lead	Medtronic, Inc. Mounds View, MN 55112	Alternate suppliers of molded silicone components.
P030036/S046 8/30/12	Anchoring Sleeve Kit and SelectSecure Lead	Medtronic, Inc. Mounds View, MN 55112	Modifications to a controlled environment.
P030052/S009 8/10/12	UroVysion Bladder Cancer Kit	Abbott Molecular, Inc. Des Plaines, IL 60018	Eliminate a second clone identity testing procedure at the fermentation stage for LSI 9p21, qualify the GENEPREP instrument, qualify

			the overhead mixing system and validation of mixing process in the manufacture of hybridization buffer, implement the optical density reading as an additional in process quality control, validate an existing mixing process for the UroVysion bulk solution, and transfer an existing in-process testing of labeled DNA.
P030054/S225 8/8/12	Merlin Patient Care System Accessories	St. Jude Medical Sylmar, CA 91342	Alternate supplier for ECG Cables.
P030054/S228 8/30/12	Epic, Atlas, Promote, Unify, Unify Assura, Unify Quadra, Quadra Assura Family of CRT-D Devices	St. Jude Medical Sylmar, CA 91342	Addition of an alternate supplier for a seal component.
P040016/S094 8/31/12	VeriFLEX (Libertè) Bare-Metal Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Removal of in-process monitoring for seal burst testing.
P040024/S061 8/10/12	Restylane Injectable Gel	Medicis Pharmaceutical Corporation Scottsdale, AZ 85256	Transfer of laboratory testing equipment to the newly constructed quality control laboratory testing site within the Q-Med facility.
P050012/S048 8/3/12	SEVEN® and SEVEN® PLUS Continuous Glucose Monitoring Systems	Dexcom, Inc. San Diego, CA 92121	Addition of an alternative component supplier. Actimed, for the pushrod and cannula components of the Sensor applicator of

			the device.
P050039/S010 8/24/12	Novation Ceramic Articulation Hip System	Exactech, Inc. Gainesville, FL 32653	Changes to the process for use of the burst test fixture, which is used to evaluate the seal strength of the packaging.
P050042/S018 8/30/12	ARCHITECT Anti-HCV	Abbott Laboratories Abbott Park, IL 60064	Change to the manufacturing material used to filter the common accessories.
P050046/S015 8/27/12	Acuity Steerable Implantable Leads	Boston Scientific St. Paul, MN 55112	Additional supplier for a lead component.
P050051/S015 8/30/12	ARCHITECT AUSAB	Abbott Laboratories Abbott Park, IL 60064	Change to the manufacturing material used to filter the common accessories.
P060006/S032 8/31/12	Express SD Monorail Premounted Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Removal of in-process monitoring for seal burst testing.
P060007/S019 8/30/12	ARCHITECT HBsAg and HBsAg Confirmatory	Abbott Laboratories Abbott Park, IL 60064	Change to the manufacturing material used to filter the common accessories.
P060027/S045 8/23/12	Paradym CRT-D, Paradym RF CRT-D	Sorin CRM Plymouth, MN 55441	Addition of a cleaning step and new electrical test equipment.
P060033/S071 8/31/12	Endeavor Sprint Zotarolimus-Eluting Coronary Stent Systems	Medtronic Vascular Santa Rosa, CA 95403	Manufacturing equipment change to the Initial Crimp Stent process.
P060035/S014 8/30/12	ARCHITECT CORE-M	Abbott Laboratories Abbott Park, IL 60064	Change to the manufacturing material used to filter the common accessories.
P060037/S018 8/10/12	NexGen® LPS Flex Mobile and LPS-Mobile Bearing	Zimmer, Inc. Warsaw, IN 46581	Change in package heat sealing process parameters

	Knee System		for the inner pouch.
P060039/S035 8/30/12	Attain StarFix Lead	Medtronic, Inc. Mounds View, MN 55112	Modifications to a controlled environment.
P070015/S097 8/14/12	XIENCE V and Nano Everolimus Eluting Coronary Stem System (EECSS)	Abbott Vascular Temecula, CA 92591	Addition of a new test to inspect tubing used in the manufacturing of stents for the devices.
P070015/S098 8/27/12	XIENCE V and Nano Everolimus Eluting Coronary Stem System (EECSS)	Abbott Vascular Temecula, CA 92591	Alternate storage conditions for the long-term of the everolimus drug substance.
P080006/S042 8/30/12	Attain Ability Leads	Medtronic, Inc. Mounds View, MN 55112	Modifications to a controlled environment.
P080023/S015 8/30/12	ARCHITECT CORE	Abbott Laboratories Abbott Park, IL 60064	Change to the manufacturing material used to filter the common accessories.
P080025/S034 8/10/12	SNS Bowel Extensions and SNS Bowel Leads	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of a duplicate EtO Sterilization System.
P080025/S036 8/22/12	InterStim	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of another supplier for the Inner Seal Silicone Component 117988-001.
P090003/S013 8/3/12	Express LD Iliac Premounted Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Change to the aeration cycle time for the 40C ethylene oxide sterilization cycle.
P090013/S066 8/14/12	CapSureFix MRI	Medtronic, Inc. Mounds View, MN 55112	Additional laser welder to perform the laser weld process of the connector pin to the coil.
P0900013/S067 8/20/12	Revo MRI IPG	Medtronic, Inc. Mounds View, MN 55112	Manufacturing lines in a new extension of a controlled

			environment area.
P090013/S068 8/17/12	Revo MRI IPG	Medtronic, Inc. Mounds View, MN 55112	New pressure test equipment used to verify hermeticity.
P090013/S069 8/30/12	CapSureFix MRI Lead and Revo MRI IPG	Medtronic, Inc. Mounds View, MN 55112	Modifications to a controlled environment.
P100013/S005 8/14/12	EXOSEAL Vascular Closure Device	Cordis Corporation Bridgewater, NJ 08807	Implementation changes to the pouch sealing process.
P100023/S050 8/14/12	ION (TAXUS Element) Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Changes to the inspection mandrel verification process.
P100023/S051 8/22/12	ION Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Pre-sterilization equipment change to the ethylene oxide sterilization process for the device.
P100041/S013 8/9/12	SAPIEN Transcatheter Heart Valve	Edwards Lifesciences, LLC Irvine, CA 92614	Upgrade to braiding equipment and removal of surfactant for a manufacturing process.
P100044/S002 8/10/12	Propel Sinus Implant	Intersect ENT Palo Alto, CA 94303	Modification to a quality control test used on an incoming component.
P110001/S008 8/14/12	Herculink Elite RX Stent System	Abbott Vascular Temecula, CA 92591	Addition of a new test to inspect tubing used in the manufacturing of stents for the devices.
P110010/S025 8/14/12	Promus Element Plus Everolimus-Eluting Chromium Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Changes to the inspection mandrel verification process.
P110019/S026 8/14/12	XIENCE PRIME and PRIME LL Everolimus Eluting	Abbott Vascular Temecula, CA 92591	Addition of a new test to inspect tubing used in the

	Coronary Stent System (EECSS)		manufacturing of stents for the devices.
P110019/S027 8/24/12	XIENCE PRIME Coronary Stent System	Abbott Vascular Temecula, CA 92591	Irradiation equipment change for the manufacturing of the devices.
P110019/S028 8/27/12	XIENCE Prime and XIENCE Prime LL Everolimus-Eluting Coronary Stent System	Abbott Vascular Temecula, CA 92591	Alternate storage conditions for the long-term storage of the everolimus drug substance.
P110029/S003 8/30/12	ARCHITECT HBsAg Qualitative and HBsAg Qualitative Confirmatory	Abbott Laboratories Abbott Park, IL 60064	Change to the manufacturing material used to filter the common accessories.

Summary of PMA Originals & Supplements Approved
Originals: 0
Supplements: 71

Summary of PMA Originals Under Review
Total Under Review: 65
Total Active: 34
Total On Hold: 31
Number Greater Than 180 Days: 1

Summary of PMA Supplements Under Review
Total Under Review: 601
Total Active: 449
Total On Hold: 152
Number Greater Than 180 Days: 5

Summary of All PMA Submissions Received
Originals: 2
Supplements: 88

Summary of PMA Supplement PMA Approval/Denial Decision Times
Number of Approvals: 71
Number of Denials: 0
Average Days Fr Receipt to Decision (Total Time): 157.3
FDA Time: 122.2 Days MFR Time: 35.1 Days

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