PMA Final Decisions for September 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

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
P100003 **[1]** **9/28/12**	Secure-C Artificial Cervical Disc	Globus Medical, Inc. Audubon, PA 19403	Approval for the Secure-C Artificial Cervical Disc. This device is indicated in skeletally mature patients for reconstruction of the disc at one level from C3-C7 following single-level discectomy for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to a single-level abnormality localized to the disc space and at least one of the following conditions confirmed by radiographic imaging (CT, MRI, X-rays): herniated nucleus pulposus, spondylosis (defined by the

			presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels. The SECURE®-C Cervical Artificial Disc is implanted using an anterior approach. Patients should have failed at least 6 weeks of conservative treatment prior to implantation of the SECURE®-C Cervical Artificial Disc.
P110006 **[2]** **9/18/12**	somo-v® Automated Breast Ultrasound System (ABUS)	U-Systems, Inc. Sunnyvale, CA 94085	Approval for the somo-v®: Automated Breast Ultrasound System (ABUS). This device is indicated as an adjunct to mammography for breast cancer screening in asymptomatic women for whom screening mammography findings are normal or benign (BI-RADS Assessment Category 1 or 2), with dense breast parenchyma (BI-RADS Composition/ Density 3 or 4) and have not had previous clinical breast intervention. The device is intended to increase breast cancer detection in the described

			patient population.
P110038 **[3]** **9/21/12**	Relay® Thoracic Stent-Graft with Plus Delivery System	Bolton Medical, Inc. Sunrise, FL 33325	Approval for the Relay® Thoracic Stent-Graft with Plus Delivery System. This device is indicated for the endovascular repair of fusiform aneurysms and saccular aneurysms/ penetrating atherosclerotic ulcers in the descending thoracic aorta in patients having appropriate anatomy, including: 1) Iliac or femoral access vessel morphology that is compatible with vascular access techniques, devices and/or accessories; 2) Non-aneurysmal aortic neck diameter in the range of 19 - 42 mm; and 3) Non-aneurysmal proximal aortic neck lengths between 15 and 25 nun and distal aortic neck lengths between 25 and 30 mm depending on the diameter stent-graft required
P110042 **[4]** **9/28/12**	Subcutaneous Implantable Defibrillator (S-ICD®) System	Cameron Health, Inc. San Clemente, CA 92673	Approval for the Subcutaneous Implantable Defibrillator (S-ICD®) System. This device is indicated to provide

			defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with antitachycardia pacing.

PMA Supplemental Approvals

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
P840001/S199 9/6/12 180-Day	Medtronic Implantable Neurostimulators for Spinal Cord Stimulation	Medtronic Neuromodulation Minneapolis, MN 55432	Approval for a manufacturing site located at Medtronic Neuromodulation in Minneapolis, Minnesota.
P840001/S221 9/14/12 Real-Time	Spinal Cord Stimulation Extension	Medtronic Neuromodulation Minneapolis, MN 55432	Approval for minor modifications to the package dimensions, the inner tray and the retainer lid. Also requested was a package material change from Polyvinyl Chloride (PVC) to Polyethylene Terephthalate Glycol (PETG) for the outer tray, the inner tray and the

			retainer lid.
P880086/S221 **9/6/12** **Real-Time**	Affinity/Integrity/ Victory/Zephyr/ Accent Family of Pacemakers	St. Jude Medical, Inc. Sunnyvale, CA 94086	Approval for an update to the pace and sense integrated circuit.
P890003/S251 **9/12/12** **180-Day**	DDMA Software	Medtronic, Inc. Mounds View, MN 55112	Approval for the use of recently approved software 9995 version 7.4 and associated DDMA software 2491 with recently approved device models D264VRM and D204VRM.
P890003/S258 **9/25/12** **Real-Time**	CareLink Monitor, CardioSight Reader Monitor, CareLink Express Monitor	Medtronic, Inc. Mounds View, MN 55112	Approval for firmware updates to the Model 2490C Medtronic CareLink Remote Home Monitor, the Model 2020A Medtronic CardioSight Reader, and the Model 2020B CareLink Express Monitor.
P900060/S049 **9/10/12** **135-Day**	Carbomedics Prosthetic Heart Valve	Sorin Group USA, Inc. Arvada, CO 80004	Approval to add equipment to the Pyrolytic Carbon Coating Process.
P910023/S298 **9/6/12** **180-Day**	Ellipse DR, Ellipse VR, Fortify Assura DR and Fortify Assura VR ICDs	St. Jude Medical Sylmar, CA 91342	Approval for a manufacturing site located at St. Jude Medical Operations Malaysia (SJM-MYPE) in Penang, Malaysia.
P910056/S011 **9/4/12** **Real-Time**	enVista® Hydrophobic Acrylic Intraocular Lens	Bausch & Lomb, Inc. Aliso Viejo, VA 92656	Approval for changes to the directions for use (DFU) to specify that the enVista MX60 lens is approved for use with the Medicel Accuject 2.6 injector set, or other injector

			sets that specifically identify the enVista MX60 lens in the cleared labeling.
P910077/S123 **9/25/12** **Real-Time**	LATITUDE PATIENT MANAGEMENT SYSTEM Application Server Software v7.03.0 1 on LATITUDE System Server	Boston Scientific Corporation St. Paul, MN 55112	Approval for the LATITUDE PATIENT MANAGEMENT SYSTEM Application Server Software v7.03.0 1 on LATITUDE System Server (Model 6488).
P950022/S079 **9/13/12** **180-Day**	Durata Leads	St. Jude Medical, CRMD Sylmar, CA 91342	Approval for design changes to the helix-shaft subassembly of market approved Tendril Models 1882, 1888, 1988, 2088 and Durata Models 7120Q, 7121Q, 7122Q, 7120, 7121, 7122, 7130, and 7131 leads for improved manufacturability and cost.
P950037/S111 **9/24/12** **Real-Time**	Reocor S/D External Pacemaker	Biotronik, Inc. Lake Oswego, OR 97035	Approval for a change to the low impedance alarm and other minor changes.
P960013/S068 **9/13/12** **180-Day**	Tendril Leads	St. Jude Medical, CRMD Sylmar, CA 91342	Approval for design changes to the helix-shaft subassembly of market approved Tendril Models 1882, 1888, 1988, 2088 and Durata Models 7120Q, 7121Q, 7122Q, 7120, 7121, 7122, 7130, and 7131 leads for improved manufacturability and cost.
P960016/S039 **9/10/12**	Safire™ Cardiac Ablation System	St. Jude Medical Minnetonka, MN	Approval for minor design

Real-Time	Catheter	55345	modifications to the pinion gear component.
P970029/S021 **9/13/12** **Special**	TMR2000 Holmium Laser System	Cardiogenesis Kennesaw, GA 30144	Approval for changes to the instructions for use to clarify the device description, warnings, adverse effects and device operating instructions.
P970054/S009 **9/5/12** **180-Day**	Biotrin International's Parvovirus B19 IgG Enzyme Immunoassay	Biotrin International, Ltd. Dublin, Ireland	Approval for a manufacturing site located at Biotrin International LTD in Dublin, Ireland.
P970055/S010 **9/5/12** **180-Day**	Biotrin International's Parvovirus B19 IgM Enzyme Immunoassay	Biotrin International, Ltd. Dublin, Ireland	Approval for a manufacturing site located at Biotrin International LTD in Dublin, Ireland.
P970058/S025 **9/21/12** **180-Day**	ImageChecker M5000D	Hologic, Inc. Santa Clara, CA 95054	Approval for improvements in the CAD algorithm, updated digital test database and support for GE Senographe Essential FFDM.
P980016/S361 **9/10/12** **180-Day**	Protecta ICD; Protecta DF4 ICD; Protecta XT ICD; and Protecta XT DF4 ICD	Medtronic, Inc. Mounds View, MN 55112	Approval for the Protecta ICD Models D334DRG, D334VRG; Protecta DF4 ICD Models D334DRM, D334VRM; Protecta XT ICD Models D314DRG, D314VRG; Protecta XT DF4 ICD; Models D314DRM; and D314VRM.
P980016/S362 **9/12/12** **180-Day**	Application Software, Maximo II DF4 ICD, Secura DF4 ICD	Medtronic, Inc. Mounds View, MN 55112	Approval for the use of recently approved software 9995 version 7.4

			and associated DDMA software 2491 with recently approved device models D264VRM and D204VRM.
P980016/S381 **9/25/12** **Real-Time**	Entrust/Virtuoso/ Protecta, CareLink Monitor, Cardiosight Reader Monitor, CareLink Express Monitor	Medtronic, Inc. Mounds View, MN 55112	Approval for firmware updates to the Model 2490C Medtronic CareLink Remote Home Monitor, the Model 2020A Medtronic CardioSight Reader, and the Model 2020B CareLink Express Monitor.
P980035/S290 **9/25/12** **Real-Time**	Enrythm, CardioSight Reader Monitor, CareLink Express Monitor	Medtronic, Inc. Mounds View, MN 55112	Approval for firmware updates to the Model 2490C Medtronic CareLink Remote Home Monitor, the Model 2020A Medtronic CardioSight Reader, and the Model 2020B CareLink Express Monitor.
P980040/S035 **9/12/12** **180-Day**	TECNIS OptiBlue Intraocular Lens (IOL), and TECNIS OptiBlue 1-Piece IOL	Abbott Medical Optics, Inc. Santa Ana, CA 92705	Approval for the addition of two additives (i.e., 2-(3’-*t* -butyl-2’-hydroxy-5’ -vinyl-phenyl)-5-chl orobenzotriazole) (UVAM) and yellow dye) to the SENSAR soft acrylic IOLs (Models ZA9003 and ZCB00).
P000012/S036 **9/18/12** **135-Day**	COBAS® AMPLICOR® Hepatitis C Virus Test version 2.0 and COBAS® AmpliPrep/ COBAS® AMPLICOR® HCV Test Version 2.0	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Approval for the manufacturing changes to the DNA synthesizer instrument platform for the vialed master mix and probe reagent

			components.
P000023/S008 **9/6/12** **135-Day**	TMJ Fossa-Eminence and Condylar Prosthesis System	TMJ Medical Golden, CO 80401	Approval for changes in degreasing solvent, cutting/machine lubricants and packaging equipment.
P000035/S008 **9/6/12** **135-Day**	TMJ Fossa-Eminence Prosthesis System	TMJ Medical Golden, CO 80401	Approval for changes in degreasing solvent, cutting/machine lubricants and packaging equipment.
P000036/S011 **9/5/12** **135-Day**	Dermagraft	Advanced BioHealing, Inc. San Diego, CA 92121	Approval for the qualification of an alternate supplier for a critical device component.
P010015/S175 **9/25/12** **Real-Time**	InSync, Consulta and Syncra Family of IPGs, CardioSight Reader Monitor, CareLink Express Monitor	Medtronic, Inc. Mounds View, MN 55112	Approval for firmware updates to the Model 2490C Medtronic CareLink Remote Home Monitor, the Model 2020A Medtronic CardioSight Reader, and the Model 2020B CareLink Express Monitor.
P010020/S024 **9/4/12** **180-Day**	AMS Acticon™ Neosphincter	American Medical Systems, Inc. Minnetonka, MN 55343	Approval for modifications to the design specifications and manufacturing process of the AMS Acticon™ Control Pump, a component of the device.
P010031/S305 **9/17/12** **180-Day**	Cardiac Resynchronization Therapy Defibrillator (CRT-D)	Medtronic, Inc. Mounds View, MN 55112	Approval of the post-approval study protocol.
P010031/S314 **9/10/12**	Protecta CRT-D; Protecta DF4 CRT-D;	Medtronic, Inc. Mounds View, MN	Approval for Protecta CRT-D

180-Day	Protecta XT CRT-D; Protecta XT DF4 CRT-D	55112	Model D334TRG; Protecta DF4 CRT-D; Model 334TRM: Protecta XT CRT-D Model D314TRG; and Protecta XT DF4 CRT-D Model D314TRM.
P010031/S334 9/25/12 Real-Time	Concerto/Protecta, CareLink Monitor, CardioSight Reader Monitor, CareLink Express Monitor	Medtronic, Inc. Mounds View, MN 55112	Approval for firmware updates to the Model 2490C Medtronic CareLink Remote Home Monitor, the Model 2020A Medtronic CardioSight Reader, and the Model 2020B CareLink Express Monitor.
P010032/S058 9/14/12 Real-Time	Eon Mini LE Charger and Eon Mini LE Charging System	St. Jude Medical Plano, TX 75024	Approval for the modification to the Model 3721 Eon Mini Charging System. The device, as modified, will be marketed under the trade name Model 3720 Eon mini LE Charger and Model 3722 Eon mini LE Charging System and is indicated as an aid in the management of chronic pain of the trunk and/or limbs, including unilateral pain associated with any of the following: failed back surgery syndrome, and chronic low back/leg pain.
P010047/S021 9/5/12 Real-Time	NeoMend ProGel Pleural Air Leak Sealant	NeoMend, Incorporated Irvine, CA 92618	Approval for modifications to the Push Rod (C-00286), End Cap (C-00280) and

			Outer Housing (C-00279) components of the Applicator Kit and associated minor labeling changes.
P020009/S088 **9/27/12** **135-Day**	Express 2 Monorail and OTW Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Approval for a modified configuration of the carrier coil used in product packaging.
P020045/S045 **9/21/12** **Real-Time**	7F Freezor Cardiac CryoAblation Catheter, Cryoconsole, 7F Freezor Xtra Surgical Device and Cryoconsole and 9F Freezor MAX Surgical Catheter and Cryoconsole	Medtronic CryoCath, LP Kirkland, Quebec Canada H9H 5H3	Approval for modifications to the firmware and software which is upgraded from version 4.03 to 4.04.080 for the devices.
P020050/S008 **9/7/12** **Real-Time**	ALLEGRETTO WAVE® EYE-Q Excimer Laser System	Alcon Laboratories, Inc. Fort Worth, TX 76134	Approval for introduction of a new notebook computer model (Toshiba Tecra A11) to replace the current notebook model (Toshiba Tecra M10) which is being phased out by the manufacturer. This will require a change in the operating system from Windows 2000 to Windows XP Service Pack 2 as the new notebook computer will not be supported by the old system.
P030008/S008 **9/7/12** **Real-Time**	ALLEGRETTO WAVE® EYE-Q Excimer Laser System	Alcon Laboratories, Inc. Fort Worth, TX 76134	Approval for introduction of a new notebook computer model (Toshiba Tecra A11) to replace the

			current notebook model (Toshiba Tecra M10) which is being phased out by the manufacturer. This will require a change in the operating system from Windows 2000 to Windows XP Service Pack 2 as the new notebook computer will not be supported by the old system.
P030035/S099 **9/6/12** **Real-Time**	Frontier/Frontier II/ Anthem Family of CRT-Ps	St. Jude Medical, Inc. Sunnyvale, CA 94086	Approval for an update to the pace and sense integrated circuit.
P030054/S227 **9/6/12** **180-Day**	Quadra Assura and Unify Assura CRT-Ds	St. Jude Medical Sylmar, CA 91342	Approval for a manufacturing site located at St. Jude Medical Operations Malaysia (SJM-MYPE) in Penang, Malaysia.
P040016/S091 **9/27/12** **135-Day**	VeriFLEX (Liberté) Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Approval for a modified configuration of the carrier coil used in product packaging.
P040023/S024 **9/6/12** **Special**	Duraloc Option Ceramic Hip System	DePuy Orthopaedics, Incorporated Warsaw, IN 46581	Approval for the addition of an independent inspector to perform visual check of the S-ROM femoral stem component sterile packaging.
P040033/S018 **9/11/12** **180-Day**	Birmingham Hip Resurfacing (BHR) System	Smith & Nephew, Inc. Memphis, TN 38116	Approval for a manufacturing site located in Warwick, United Kingdom.
P050027/S004 **9/10/12** **Special**	Karl Storz Photodynamic D-Light C (PDD)	Karl Storz Endoscopy-America, Inc.	Approval of corrections to the Ethylene Oxide

	System	El Segundo, CA 90245	(EtO) sterilization instructions contained in the PDD Camera Heads instruction card, Hopkins II PDD Telescopes instruction manual and Tricam SL II Camera Control Unit instruction manual.
P050028/S023 **9/18/12** **135-Day**	COBAS® TaqMan HBV Test For Use With The High Pure System and COBAS® AmpliPrep/ COBAS® TaqMan® HBV Test version 2.0	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Approval for the manufacturing changes to the DNA synthesizer instrument platform for the vialed master mix and probe reagent components.
P050037/S033 **9/25/12** **Real-Time**	Radiesse®	Merz Aesthetics, Incorporation Franksville, WI 53126	Approval to extend the labeled shelf life of the 3.0cc product fill volume Radiesse from 6 months to 24 months.
P050044/S023 **9/25/12** **Special**	Vitagel	Stryker Orthobiologics Malvern, PA 19355	Approval for the following two changes to the labeling instructions for use for the VitaPrep Plasma Separator: 1) inclusion of warning statement: "Always wear well fitting gloves when handling VitaPrep" and 2) inclusion of instructions: "Assure there is no blood in the Luer connection. If blood is present, carefully clear the area of residual blood."
P050052/S036 **9/25/12**	Radiesse®	Merz Aesthetics, Incorporated	Approval to extend the labeled shel f

Real-Time		Franksville, WI 53126	life of the 3.0cc product fill volume Radiesse from 6 months to 24 months.
P060002/S024 **9/27/12** **135-Day**	Bard FLAIR Endovascular Stent Graft	Bard Peripheral Vascular, Inc. Tempe, AZ 85281	Approval for automation of an inspection step.
P060006/S030 **9/27/12** **135-Day**	Express SD Renal Monorail Premounted Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Approval for a modified configuration of the carrier coil used in product packaging.
P060019/S022 **9/7/12** **Real-Time**	Therapy Cool Path Ablation Catheters	St. Jude Medical Irvine, CA 92614	Approval for a design modification to the bond between that catheter shaft and the extension tubing. Specifically, to change the adhesive from loctite to urethane and to modify the contact hole from a circular to an octagonal shape.
P060023/S002 **9/13/12** **135-Day**	BRYAN Cervical Disc	Medtronic Sofamor Danek USA, Inc. Memphis, TN 38132	Approval for a change to the injection molding process.
P060030/S024 **9/18/12** **135-Day**	COBAS® AmpliPrep/ COBAS® TaqMan® HCV Test and COBAS® TaqMan HCV Test version 2.0 For Use With The High Pure System	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Approval for the manufacturing changes to the DNA synthesizer instrument platform for the vialed master mix and probe reagent components.
P070006/S008 **9/5/12** **Real-Time**	T-SPOT® .*TB* Test	Oxford Immunotec, Ltd. Toms River, NJ 08754	Approval for a design change, for a larger reagent volume format for the T-Cell *Xtend*® reagent, an

			accessory to the *T-SPOT® .TB* Test, to increase the volume from 3 X 2mL vials in a pack to a 50mL bottle.
P070014/S030 **9/27/12** **135-Day**	LifeStent Vascular Stent Systems	Bard Peripheral Vascular, Inc. Tempe, AZ 85281	Approval for automation of an inspection step.
P070014/S033 **9/12/12** **Special**	LifeStent Vascular Stent System	C.R. Bard, Inc. Tempe, AZ 85281	Approval for the separation of the manufacturing and inspection responsibilities for the manual press process.
P070015/S070 **9/7/12** **180-Day**	Xience V Everolimus-Eluting Coronary Stent System	Abbott Vascular Temecula, CA 92591	Approval for a manufacturing site located at Abbott Nutrition in Sligo, Ireland.
P070015/S087 **9/14/12** **180-Day**	XIENCE V and XIENCE nano Everolimus Eluting Coronary Stent System	Abbott Vascular, Inc. Santa Clara, CA 95054	Approval to update the product labeling contained in the Instructions for Use (IFU) and patient guide for the XIENCE V and XIENCE nano Everolimus Eluting Coronary Stent System and for the XIENCE PRIME and XIENCE PRIME LL Everolimus Eluting Coronary Stent System. These updates specifically included longer term follow-up data to all applicable clinical trials for the devices.
P070015/S088 **9/10/12** **135-Day**	XIENCE V/ XIENCE Everolimus-Eluting Coronary Stent System	Abbott Vascular Temecula, CA 92591	Approval for transferring the testing of Total Organic Carbon

			(TOC) from a contract laboratory to Abbott Vascular in Temecula, California.
P070015/S094 **9/19/12** **180-Day**	XIENCE V®/ XIENCE nano™ Everolimus-Eluting Coronary Stent System	Abbott Vascular Temecula, CA 92591	Approval to change the coating integrity specification for the 28 mm length stents to align with that of the 33 mm and 38 mm stents for the XIENCE family of products.
P070026/S007 **9/6/12** **Special**	DePuy Ceramax Ceramic Total Hip System	DePuy Orthopaedics, Incorporated Warsaw, IN 46581	Approval for the addition of an independent inspector to perform visual check of the S-ROM femoral stem component sterile packaging.
P080007/S011 **9/27/12** **135-Day**	E-LUMINEXX Vascular Stent	Bard Peripheral Vascular, Inc. Tempe, AZ 85281	Approval for automation of an inspection step.
P080026/S003 **9/26/12** **135-Day**	RealTime HBV Assay	Abbott Molecular, Inc. Des Plaines, IL 60018	Approval for a change from a manual assembly system to an automated process for kit packaging.
P100010/S018 **9/21/12** **Real-Time**	Arctic Front Cardiac CryoAblation Catheters, Freezor MAX CryoAblation Catheter, Cryoconsole, Manual Retraction Kit and Accessories	Medtronic CryoCath, LP Kirkland, Quebec Canada H9H 5H3	Approval for modifications to the firmware and software which is upgraded from version 4.03 to 4.04.080 for the device.
P090002/S005 **9/6/12** **Special**	Pinnacle CoMplete Acetabular Hip System	DePuy Orthopaedics, Incorporated Warsaw, IN 46581	Approval for the addition of an independent inspector to perform visual check of the S-ROM

			femoral stem component sterile packaging.
P090013/S072 **9/25/12** **Real-Time**	Revo MRI, CardioSight Reader Monitor, CareLink Express Monitor	Medtronic, Inc. Mounds View, MN 55112	Approval for firmware updates to the Model 2490C Medtronic CareLink Remote Home Monitor, the Model 2020A Medtronic CardioSight Reader, and the Model 2020B CareLink Express Monitor.
P100010/S018 **9/21/12** **Real-Time**	Arctic Front Cardiac CryoAblation Catheters; Freezor MAX CryoAblation Catheter; Cryoconsole; Manual Retraction Kit; and Accessories	Medtronic CryoCath, LP Kirkland, Quebec Canada H9H 5H3	Approval for modifications to the firmware and software which is upgraded from version 4.03 to 4.04.080 for the device.
P100013/S003 **9/19/12** **Real-Time**	EXOSEAL™ Vascular Closure Device	Cordis Corporation Miami Lakes, FL 33014	Approval for the patient brochure.
P100017/S002 **9/27/12** **135-Day**	RealTime HCV Assay	Abbott Molecular, Inc. Des Plaines, IL 60018	Approval for a change from a manual assembly system to an automated process for kit packaging.
P100023/S053 **9/27/12** **Real-Time**	ION™ Paclitaxel-Eluting Platinum Chromium Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Approval for removal of the ball from the tip of the corewire which is located between the inner and outer lumen of the Stent Delivery System. The device, as modified, will be marketed under the trade PROMUS Element™ Plus Everolimus-Eluting Platinum Chromium Coronary Stent System and ION™

			Paclitaxel-Eluting Platinum Chromium Coronary Stent System and are indicated for improving luminal diameter in patients with symptomatic heart disease or documented silent ischemia due to *de novo* lesions in native coronary arteries >2.25 mm to <4.00 mm in diameter in lesions <34 mm in length, and for improving luminal diameter for the treatment of *de novo* lesions in native coronary arteries >2.25 mm to < 4.00 mm in diameter in lesions < 3 4 mm in length, respectively
P100025/S001 **9/5/12** **180-Day**	BreathTek® UBT for *H. pylori* Kit (BreathTek UBT Kit) and Pediatric Urea Hydrolysis Rate Calculation Application (*p*UHR-CA), Version 1.0	Otsuka America Pharmaceutical, Inc. Rockville, MD 20850	Approval for packaging changes for the BreathTek® UBT for *H. pylori* Kit (BreathTek UBT Kit) and Pediatric Urea Hydrolysis Rate Calculation Application (*p*UHR-CA), Version 1.0. The packaging changes consist of new kit and shipper cartons along with new labeling on each of these cartons.
P100044/S001 **9/21/12** **180-Day**	Propel™ Mini Sinus Implant	Intersect ENT Palo Alto, CA 94303	Approval for a shortened version of the drug-eluting sinus stent. The

			device, as modified, will be marketed under the trade name Propel™ Mini Sinus Implant and is indicated for use in patients ≥ 18 years of age following ethmoid sinus surgery to maintain patency, thereby reducing the need for post-operative intervention such as surgical adhesion lysis and/or use of oral steroids. The Propel Mini Sinus Implant separates mucosal tissues, provides stabilization of the middle turbinate, prevents obstruction by adhesions, and reduces edema.
P110010/S028 **9/27/12** **Real-Time**	PROMUS Element™ Plus Everolimus-Eluting Platinum Chromium Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Approval for removal of the ball from the tip of the corewire which is located between the inner and outer lumen of the Stent Delivery System. The device, as modified, will be marketed under the trade PROMUS Element™ Plus Everolimus-Eluting Platinum Chromium Coronary Stent System and ION™ Paclitaxel-Eluting Platinum Chromium Coronary Stent System and are indicated for

			improving luminal diameter in patients with symptomatic heart disease or documented silent ischemia due to *de novo* lesions in native coronary arteries >2.25 mm to <4.00 mm in diameter in lesions <34 mm in length, and for improving luminal diameter for the treatment of *de novo* lesions in native coronary arteries >2.25 mm to < 4.00 mm in diameter in lesions < 3 4 mm in length, respectively
P110016/S001 **9/13/12** **135-Day**	Therapy Cool Path Duo Ablation Catheter, Safire BLU Duo Ablation Catheter, and Cardiac Ablation Generator	St. Jude Medical – Irvine Biomedical Irvine, CA 92614	Approval for an alternate vendor to supply printed circuit boards for the 1500T9-CP v1.6 generator.
P110016/S004 **9/7/12** **Real-Time**	Therapy Cool Path Duo Ablation Catheters	St. Jude Medical Irvine, CA 92614	Approval for a design modification to the bond between that catheter shaft and the extension tubing. Specifically, to change the adhesive from loctite to urethane and to modify the contact hole from a circular to an octagonal shape.
P110019/S009 **9/14/12** **180-Day**	XIENCE PRIME and XIENCE PRIME LL Everolimus Eluting Coronary Stent System	Abbott Vascular, Inc. Santa Clara, CA 95054	Approval to update the product labeling contained in the Instructions for Use (IFU) and patient

			guide for the XIENCE V and XIENCE nano Everolimus Eluting Coronary Stent System and for the XIENCE PRIME and XIENCE PRIME LL Everolimus Eluting Coronary Stent System. These updates specifically included longer term follow-up data to all applicable clinical trials for the devices.
P110019/S011 **9/10/12** **135-Day**	XIENCE Prime LL Everolimus-Eluting Coronary Stent System	Abbott Vascular Temecula, CA 92591	Approval for transferring the testing of Total Organic Carbon (TOC) from a contract laboratory to Abbott Vascular in Temecula, California.
P110019/S020 **9/19/12** **180-Day**	XIENCE PRIME™/ XIENCE PRIME LL™ Everolimus-Eluting Coronary Stent System	Abbott Vascular Temecula, CA 92591	Approval to change the coating integrity specification for the 28 mm length stents to align with that of the 33 mm and 38 mm stents for the XIENCE family of products.
P110020/S003 **9/4/12** **135-Day**	cobas® 4800 BRAF V600 Mutation Test	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Approval for a change in the DNA synthesizer instrument platform for certain vialed master mix and probe reagent components.
P110037/S001 **9/5/12** **Real-Time**	COBAS® AmpliPrep/ COBAS® TaqMan® CMV Test	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Approval for a change to the Test Definition File (TDF). The device, as modified, will be

			marketed under the trade name COBAS AmpliPrep/COBAS TaqMan CMV Test and is indicated for: COBAS AmpliPrep/COBAS TaqMan CMV Test: The COBAS AmpliPrep/ COBAS TaqMan CMV Test is an *in vitro* nucleic acid amplification test for the quantitative measurement of cytomegalovirus (CMV) DNA in human EDTA plasma using the COBAS AmpliPrcp Instrument for automated specimen processing and the COBAS TaqMan Analyzer or the COBAS TaqMan 48 Analyzer for automated amplification and detection. The COBAS AmpliPrcp/ COBAS TaqMan CMV Test is intended for usc as an aid in the management of solid-organ transplant patients who arc undergoing anti-CMV therapy. In this population serial DNA measurements can be used to assess virological response to antiviral treatment. The

			results from the COBAS AmpliPrep/COBAS TaqMan CMV Test must be interpreted within the context of all relevant clinical and laboratory findings. The COBAS AmpliPrep/ COBAS TaqMan CMV Test is not intended for use as a screening test for the presence of CMV DNA in blood or blood products.

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
P810006/S034 9/14/12	COLLASTAT Absorbable Collagen Hemostatic Sponge, COLLASTAT Absorbable Collagen Hemostatic Agent-Microfibrillar Form	Integra LifeSciences Corporation Plainsboro, NJ 08536	Change in Chart Recording System.
P810006/S035 9/28/12	CollaStat Absorbable Collagen Hemostatic Sponge CollaStat Absorbable Collagen Hemostatic Agent-Microfibrillar Form	Integra LifeSciences Corporation Plainsboro, NJ 08536	Upgrades to the Medical Products Manufacturing Suite.
P840001/S225 9/12/12	Restore Rechargeable/ Restore Prime/Restore Advanced/Prime Advanced/Restore	Medtronic, Inc. Minneapolis, MN 55432	Change the acceptance criteria for titanium content in the cables and to add an alternate supplier for the

	Ultra/Itrel 4/ Synergy/Synergy Verstirel/Restore Sensor		cable braiding and micro-extrusion processes.
P840001/S226 9/13/12	Itrel®, Synergy®, Restore®, Soletra®, Kinetra®, Interstim® & Enterra® Neurostimulators	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of manufacturing equipment at the MPROC-Juncos facility germane to the devices.
P840062/S023 9/14/12	CollaCote, CollaTape and CollaPlug Absorbable Collagen Wound Dressings for Dental Surgery	Integra LifeSciences Corporation Plainsboro, NJ 08536	Change in Chart Recording System.
P840062/S024 9/28/12	CollaCote, CollaTape, CollaPlug Absorbable Collagen Wound Dressing for Dental Surgery	Integra LifeSciences Corporation Plainsboro, NJ 08536	Upgrades to the Medical Products Manufacturing Suite.
P850010/S031 9/14/12	HELISTAT and HELITENE Absorbable Collagen Hemostatic Agent	Integra LifeSciences Corporation Plainsboro, NJ 08536	Change in Chart Recording System.
P850010/S032 9/28/12	HeliStat, Helitene Absorbable Collagen Hemostatic Agents	Integra LifeSciences Corporation Plainsboro, NJ 08536	Upgrades to the Medical Products Manufacturing Suite.
P850079/S054 9/11/12	Methafilcon A and B Soft Extended Wear Contact Lenses	CooperVision, Inc. Pleasanton, CA 94588	Relocation of a manufacturing line and installation of supporting parts.
P850079/S055 9/18/12	Methafilcon A and B Soft Extended Wear Contact Lenses	CooperVision, Inc. Pleasanton, CA 94588	Temporary change to the inspection process.
P850079/S056 9/18/12	Methafilcon A and B Soft Extended Wear Contact Lenses	CooperVision, Inc. Pleasanton, CA 94588	New manufacturing line.
P860057/S091 9/19/12	Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis	Edward Lifesciences, LLC Irvine, CA 92614	Modify the layout of an isolation clean room.

P870056/S051 9/19/12	Carpentier-Edwards Porcine Bioprosthesis	Edward Lifesciences, LLC Irvine, CA 92614	Modify the layout of an isolation clean room.
P870077/S046 9/19/12	Carpentier-Edwards S.A.V. Bioprosthesis	Edward Lifesciences, LLC Irvine, CA 92614	Modify the layout of an isolation clean room.
P880086/S222 9/14/12	Accent Family of Pacemakers	St. Jude Medical Sylmar, CA 91342	Clarification of the visual inspection criteria for low voltage pulse generators.
P880086/S224 9/12/12	Accent Family of Pacemakers	St. Jude Medical, Inc. Sylmar, CA 91342`	Alternate supplier for the electromagnetic coil receiver used in the voice coil assembly.
P880086/S225 9/24/12	Family of Pacemakers	St. Jude Medical, Inc. Sylmar, CA 91342	Reduction in the cure time for the room temperature vulcanized adhesive.
P890003/S256 9/10/12	Prodigy IPG	Medtronic, Inc. Mounds View, MN 55112	Update to the battery burn-in process and inspection methods.
P890003/S257 9/19/12	Prodigy	Medtronic, Inc. Mounds View, MN 55112	Addition of a new supplier for packaging materials, and a change to the orientation of an identification number on the packaging
P910001/S061 9/5/12	ELCA Coronary Artherectomy Catheter	Spectranetics Corporation Colorado Springs, CO 80921	Use of additional sterilization chambers at the contract sterilizer.
P910023/S303 9/24/12	Family of ICDs	St. Jude Medical, Inc. Sylmar, CA 91342	Reduction in the cure time for the room temperature vulcanized adhesive.
P920047/S053	Blazer Prime HTD	Boston Scientific	Use of new

9/21/12	Temperature Ablation Catheter	Corporation Maple Grove, MN 55311	Statistical Process Control software.
P930031/S034 9/6/12	Wallstent Transjugular Portosystemic Shunt (TIPS) Endoprosthesis with Unistep Plus Delivery System	Boston Scientific Corporation Maple Grove, MN 55311	Use of new Statistical Process Control software.
P930031/S035 9/21/12	Wallstent Transjugular Portosystemic Shunt (TIPS) Endoprosthesis with Unistep Plus Delivery System	Boston Scientific Corporation Maple Grove, MN 55311	Use of new Statistical Process Control software.
P940019/S029 9/6/12	Wallstent Iliac Endoprosthesis with Unistep Plus Delivery System	Boston Scientific Corporation Maple Grove, MN 55311	Use of new Statistical Process Control software.
P940019/S030 9/21/12	Wallstent Iliac Endoprosthesis with Unistep Plus Delivery System	Boston Scientific Corporation Maple Grove, MN 55311	Use of new Statistical Process Control software.
P950020/S052 9/6/12	Flextome Cutting Balloon Dilation Device	Boston Scientific Corporation Maple Grove, MN 55311	Use of new Statistical Process Control software.
P950020/S053 9/7/12	Flextome Cutting Balloon	Boston Scientific Corporation Maple Grove, MN 55311	An alternate supplier for the balloon protector cap component; and minor dimensional changes for the balloon protector cap component.
P950020/S054 9/21/12	Flextome Cutting Balloon Dilation Device (Monorail & Over-the-Wire)	Boston Scientific Corporation Maple Grove, MN 55311	Use of new Statistical Process Control software.
P960009/S115 9/13/12	Itrel®, Synergy®, Restore®, Soletra®, Kinetra®, Interstim® & Enterra®	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of manufacturing equipment at the MPROC-Juncos facility germane to

	Neurostimulators		the devices.
P960009/S154 9/12/12	Activa Tremor Control System	Medtronic, Inc. Minneapolis, MN 55432	Change the acceptance criteria for titanium content in the cables and to add an alternate supplier for the cable braiding and micro-extrusion processes.
P960040/S268 9/11/12	Punctua, Energen and Incepta ICDs	Boston Scientific Corporation St. Paul, MN 55112	Addition of an alternate supplier for the tantalum capacitors.
P960040/S269 9/24/12	Teligen. Cognis, Incepta, Energen and Punctua ICDs	Boston Scientific Corporation St. Paul, MN 55112	Update to the acceptance activities for tab length measurement inspection process.
P960042/S041 9/5/12	Spectranetics Laser Sheaths SLS	Spectranetics Corporation Colorado Springs, CO 80921	Use of additional sterilization chambers at the contract sterilizer.
P970003/S151 9/6/12	VNS Therapy® Pulse Generators	Cyberonics, Inc. Houston, TX 77058	Addition of a fixture for cleaning of a component.
P970003/S152 9/13/12	VNS Therapy System	Cyberonics, Inc. Houston, TX 77058	Use of alternate Schottky diodes for the VNS Therapy Implantable Pulse Generators and the Programming Wand.
P970004/S140 9/13/12	Itrel®, Synergy®, Restore®, Soletra®, Kinetra®, Interstim® & Enterra® Neurostimulators	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of manufacturing equipment at the MPROC-Juncos facility germane to the devices.
P970051/S095 9/5/12	Nucleus 24 Cochlear Implant System	Cochlear Americas Centennial, CO 80111	Re-commissioning of a clean room and establishment of a new manufacturing line.
P980016/S374 9/4/12	Protecta ICD, Protecta XT ICD	Medtronic, Inc. Mounds View, MN	Software update to a CD Surge test.

		55112	
P980016/S377 9/5/12	Maximo II, Protecta, Protecta XT, Secura, Virtuoso II DR/VR ICDs	Medtronic, Inc. Mounds View, MN 55112	Implementation of FACTORY works Release 8.0 and MES Web Services Release 2.1.
P980016/S378 9/19/12	Maximo II, Protecta, Protecta XT, Secura, Virtuosos II DR/VR ICDs	Medtronic, Inc. Mounds View, MN 55112	Updates to the IC wafer probe test specifications and test software.
P980016/S379 9/20/12	Maximo II DF4 CRT-D, Maximo II DF4 ICD, Maximo II ICD, Protecta DF4 ICD, Protecta ICD, Protecta XT DF4 ICD, Protccta XT ICD, Secura DF4, Secura and Virtuoso II DR/VR ICDs	Medtronic, Inc. Mounds View, MN 55112	Update acceptance criteria inspection process for all die locations on all hybrids.
P980016/S380 9/20/12	Protecta and Protecta XT ICDs	Medtronic, Inc. Mounds View, MN 55112	Update to the manufacturing test for an integrated circuit (IC) at the supplier location.
P980022/S121 9/13/12	Paradigm® REAL-Time System, Paradigm® REA L-Time REVEL System, and Guardian® REAL-Time System	Medtronic MiniMed Northridge, CA 91325	Reinstatement of the Ayutthaya, Thailand facility as an additional facility for the manufacture of printed circuit board assemblies and stack subassemblies used by Medtronic MiniMed in the production of the Paradigm® REAL-Time Insulin Pump (models MMT-522, MMT-522K, MMT-722, MMT-722K), Paradigm® REAL-Time REVEL Insulin Pump (models MMT-523, MMT-523K,

			MMT-723, and MMT-723K)) and Guardian® REAL-Time Monitor (CSS7100, CSS7 100K). The Paradigm® REAL-Time Insulin Pump, Paradigm® REAL-Time REVEL Insulin Pump, and Guardian® REAL-Time Monitor are components of the devices.
P980022/S122 9/18/12	Paradigm® REAL-Time System, Paradigm® REA L-Time REVEL System, and Guardian® REAL-Time System, CGMS IPro System and CGMS iPro2 System	Medtronic, Inc. Northridge, CA 91325	Manufacturing process change which will incorporate the addition of process water to a once-diluted batch of platinum plating solution for the Sof-Sensor Glucose Sensors (models MMT-7002 and MMT-7003) that are components of the devices.
P980023/S047 9/24/12	Linox Smart Drug-Eluting Pacing Lead	Biotronik, Inc. Lake Oswego, OR 97035	Adding new labeling software used to print the labels for various devices and accessories.
P980033/S023 9/6/12	Wallstent Venous Endoprosthesis with Unistep Plus Delivery System	Boston Scientific Corporation Maple Grove, MN 55311	Use of new Statistical Process Control software.
P980033/S024 9/21/12	Wallstent Venous Endoprosthesis with Unistep Plus Delivery System	Boston Scientific Corporation Maple Grove, MN 55311	Use of new Statistical Process Control software.
P980035/S286 9/5/12	Adapta, Adapta L, Adapta S, Sensia L, Sensia, Versa, Advisa DR, Relia IPGs	Medtronic, Inc. Mounds View, MN 55112	Implementation of FACTORY works Release 8.0 and MES Web Services Release 2.1.

P980035/S287 9/10/12	Adapta, Adapta L, Adapta S, Sensia L, Sensia, Versa, IPGs	Medtronic, Inc. Mounds View, MN 55112	Update to the battery burn-in process and inspection methods.
P980035/S288 9/19/12	Adapta, Relia and Sensia	Medtronic, Inc. Mounds View, MN 55112	Addition of a new supplier for packaging materials, and a change to the orientation of an identification number on the packaging.
P980035/S289 9/19/12	Advisa DR IPG	Medtronic, Inc. Mounds View, MN 55112	Updates to the IC wafer probe test specifications and test software.
P980044/S014 9/18/12	SUPARTZ®	Seikagaku Corporation Tokyo, Japan 100-0005	Modification of an existing water system.
P000007/S033 9/19/12	Edwards Prima Plus Stentless Bioprosthesis	Edward Lifesciences, LLC Irvine, CA 92614	Modify the layout of an isolation clean room.
P000012/S039 9/14/12	COBAS® AMPLICOR® Hepatitis C Virus Test version 2.0 and COBAS® AmpliPrep/ COBAS® AMPLICOR® HCV Test Version 2.0	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Change to adjust the environmental testing performed at the RMS Branchburg facility.
P000037/S029 9/19/12	On-X Prosthetic Heart Valve	On-X Technologies, Inc. Austin, TX 78752	Modification to the Limulus Amebocyte Lysate (LAL) test method and procedure.
P010012/S298 9/11/12	Punctua, Energen and Incepta CRT-Ds	Boston Scientific Corporation St. Paul, MN 55112	Addition of an alternate supplier for the tantalum capacitors.
P010012/S299 9/24/12	Teligen, Cognis, Incepta, Energen and Punctual CRT-Ds	Boston Scientific Corporation St. Paul, MN 55112	Update to the acceptance activities for tab length measurement

			inspection process.
P010015/S172 9/5/12	Consulta and Syncra CRT-Ps	Medtronic, Inc. Mounds View, MN 55112	Increase in a test limit on the feed through assembly at the supplier location.
P010015/S173 9/5/12	Consulta, Syncra CRT-Ps	Medtronic, Inc. Mounds View, MN 55112	Implementation of FACTORY works Release 8.0 and MES Web Services Release 2.1.
P010015/S174 9/19/12	Consulta, Syncra CRT-P	Medtronic, Inc. Mounds View, MN 55112	Updates to the IC wafer probe test specifications and test software.
P010031/S327 9/4/12	Protecta CRT-D, Protecta XT CRT-D	Medtronic, Inc. Mounds View, MN 55112	Software update to a CD Surge test.
P010031/S330 9/5/12	Concerto II, Consulta DF4, Maximo II, Protecta, Protecta XT 1CDs and CRT-Ds	Medtronic, Inc. Mounds View, MN 55112	Implementation of FACTORY works Release 8.0 and MES Web Services Release 2.1.
P010031/S331 9/19/12	Concerto II CRT-D, Consulta DF4 ICD, Consulta ICD, Maximo II CRT-D, Protecta CRT-D and Protecta XT CRT-D	Medtronic, Inc. Mounds View, MN 55112	Updates to the IC wafer probe test specifications and test software.
P010031/S332 9/20/12	Concerto II CRT-D, Consulta DF4 ICD, Consulta 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	Update acceptance criteria inspection process for all die locations on all hybrids.
P010031/S333 9/20/12	Protecta and Protecta XT CRT-Ds	Medtronic, Inc. Mounds View, MN 55112	Update to the manufacturing test for an integrated circuit (IC) at the supplier location.
P010041/S035	Carpentier-Edwards	Edward	Modify the layout of

9/19/12	S.A.V. Bioprosthesis	Lifesciences, LLC Irvine, CA 92614	an isolation clean room.
P020009/S091 9/21/12	Express Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Alternate equipment for dispensing and mixing urethane adhesive.
P020009/S092 9/21/12	Express 2 Coronary Stent System (Monorail & Over-the-Wire)	Boston Scientific Corporation Maple Grove, MN 55311	Use of new Statistical Process Control software.
P020025/S035 9/21/12	Blazer Prime XP Temperature Ablation Catheter	Boston Scientific Corporation Maple Grove, MN 55311	Use of new Statistical Process Control software.
P030017/S141 9/14/12	Precision Spinal Cord Stimulator System	Boston Scientific Corporation Valencia, CA 91355	Addition of an alternate supplier for a component of the charger assembly.
P030017/S142 9/26/12	Precision Spinal Cord Stimulator (SCS) System	Boston Scientific Corporation Valencia, CA 91355	Update the test systems used for the testing of the Implantable Pulse Generator (IPG) of the device.
P030022/S022 9/6/12	Reflection Ceramic Acetabular Hip System	Smith & Nephew, Inc. Memphis, TN 38116	Addition of an alternate vendor for the Anthology Hip Stem porous coating process.
P030031/S047 9/20/12	ThermoCool SF Catheters	Biosense Webster, Inc. Diamond Bar, CA 91765	New test equipment for the devices.
P030035/S100 9/14/12	Anthem Family of Pacemakers	St. Jude Medical Sylmar, CA 91342	Clarification of the visual inspection criteria for low voltage pulse generators.
P030035/S102 9/12/12	Anthem Family of CRT-Ps	St. Jude Medical, Inc. Sylmar, CA 91342`	Alternate supplier for the electromagnetic coil receiver used in the voice coil assembly.

P030035/S103 9/24/12	Family of CRT-Ps	St. Jude Medical, Inc. Sylmar, CA 91342	Reduction in the cure time for the room temperature vulcanized adhesive.
P030054/S231 9/24/12	Family of CRT-Ds	St. Jude Medical, Inc. Sylmar, CA 91342	Reduction in the cure time for the room temperature vulcanized adhesive.
P040003/S012 9/7/12	ExAblate System	Insightec, Ltd. Dallas, TX 75244	Change in the manufacturing of the transducer for the ExAblate System from a contract manufacturer to the in-house facility.
P040012/S049 9/21/12	RX Acculink Carotid Stent System	Abbott Vascular Santa Clara, CA 95054	Change to the dispensing system for applying controlled amounts of assembly fluids during the manufacturing process.
P040016/S095 9/6/12	VeriFLEX Coronary Stent System (Monorail)	Boston Scientific Corporation Maple Grove, MN 55311	Use of new Statistical Process Control software.
P040016/S096 9/21/12	VeriFLEX (Libertè) Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Alternate equipment for dispensing and mixing urethane adhesive.
P040016/S097 9/21/12	VeriFLEX Coronary Stent System (Monorail & Over-the-Wire)	Boston Scientific Corporation Maple Grove, MN 55311	Use of new Statistical Process Control software.
P050006/S030 9/7/12	Gore Helex Septal Occluder	W.L. Gore & Associates, Inc. Flagstaff, AZ 86001	Redesigned flaring equipment and reduction of the sampling plans for the device lock release force.
P050006/S031 9/27/12	GORE HELEX Septal Occluder	W.L. Gore & Associates, Inc.	Use of alternate cutting equipment.

		Flagstaff, AZ 86001	
P050019/S010 9/6/12	Carotid WALLSTENT Monorail Endoprosthesis	Boston Scientific Corporation Maple Grove, MN 55311	Use of new Statistical Process Control software.
P050028/S026 9/14/12	COBAS® TaqMan HBV Test For Use With The High Pure System and COBAS® AmpliPrep/ COBAS® TaqMan® HBV Test version 2.0	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Change to adjust the environmental testing performed at the RMS Branchburg facility.
P050039/S011 9/27/12	Novation Ceramic Articulation Hip System	Exatech, Inc. Gainesville, FL 32653	Addition of laser marking systems for purposes of the product identification of the mating femoral stems used with the devices.
P060006/S033 9/21/12	Express SD Renal Monorail Premounted Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Use of new Statistical Process Control software.
P060007/S020 9/14/12	ARCHITECT HBsAg/HBsAg Confirmatory	Abbott Laboratories Abbott Park, IL 60064	Change to a test method used in the manufacture of the components of the ARCHITECT HBsAg and HBsAg Confirmatory assay, and the ARCHITECT HBsAg Qualitative and HBsAg Qualitative Confirmatory assay.
P060008/S094 9/6/12	TAXUS Libertè Paclitaxel-Eluting Platinum Chromium Coronary Stent System (Monorail)	Boston Scientific Corporation Maple Grove, MN 55311	Use of new Statistical Process Control software.
P060008/S095 9/21/12	TAXUS Libertè Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Alternate equipment for dispensing and mixing urethane

			adhesive.
P060008/S096 9/21/12	TAXUS Libertè Paclitaxel-Eluting Platinum Chromium Coronary Stent System (Monorail & Over-the-Wire)	Boston Scientific Corporation Maple Grove, MN 55311	Use of new Statistical Process Control software.
P060030/S028 9/14/12	COBAS® AmpliPrep/ COBAS® TaqMan® HCV Test and COBAS® TaqMan HCV Test version 2.0 For Use With The High Pure System	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Change to adjust the environmental testing performed at the RMS Branchburg facility.
P070007/S036 9/21/12	Talent Thoracic Stent Graft System	Medtronic Vascular Santa Rosa, CA 95403	Automation of a cutting/sealing step.
P070014/S034 9/21/12	LifeStent Vascular Stent System	Bard Peripheral Vascular, Inc. Tempe, AZ 85281	Addition of an alternate supplier for tantalum markers.
P070015/S099 9/7/12	XIENCE V and Nano Everolimus Eluting Coronary Stent System (EECSS)	Abbott Vascular Temecula, CA 92591	Change to the method used to test for drug release.
P070027/S035 9/21/12	Talent Abdominal Stent Graft with the Xcelerant Hydro Delivery System	Medtronic Vascular Santa Rosa, CA 95403	Automation of a cutting/sealing step.
P080006/S043 9/19/12	Attain Ability Leads	Medtronic, Inc. Mounds View, MN 55112	Addition of a new supplier for packaging materials, and a change to the orientation of an identification number on the packaging.
P080011/S017 9/27/12	Biofinity (Comfilcon A) Soft Extended Wear Contact Lenses	CooperVision, Inc. Pleasanton, CA 94588	Addition of an alternate supplier of raw material.
P080012/S006 9/13/12	Prometra Programmable Infusion Pump	Flowonix Medical, Inc. Mount Olive, NJ	New Alternate sub-tier supplier for a component of the

	System	07828	device.
P080012/S007 9/11/12	Prometra Programmable Implantable Infusion Pump System	Flowonix Medical, Inc. Mt. Olive, NJ 07828	Use of an alternate sub-tier supplier for a component of the device.
P080025/S037 9/13/12	Itrel®, Synergy®, Restore®, Soletra®, Kinetra®, Interstim® & Enterra® Neurostimulators	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of manufacturing equipment at the MPROC-Juncos facility germane to the devices.
P080030/S006 9/18/12	Glaukos Corporation iStent Trabecular Micro-Bypass Stent System	Glaukos Corporation Laguna Hills, CA 92653	Addition of a second clean room and to perform in house peel testing.
P090003/S015 9/6/12	Express LD Iliac Premounted Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Use of new Statistical Process Control software.
P090013/S070 9/5/12	Revo MRI IPG	Medtronic, Inc. Mounds View, MN 55112	Implementation of FACTORY works Release 8.0 and MES Web Services Release 2.1.
P090013/S071 9/10/12	Revo MRI IPG	Medtronic, Inc. Mounds View, MN 55112	Update to the battery burn-in process and inspection methods.
P090018/S018 9/28/12	Esteem	Envoy Medical Corporation Saint Paul, MN 55110	Change to the Ear Insert Tube cleaning process.
P090022/S014 9/20/12	Softec HD, Softec I, Softec HD PS and Softec HDO Intraocular Lenses (IOLs)	Lenstec Incorporated St. Petersburg, FL 33716	Inclusion of two additional steam sterilizer units for the sterilization of the firm's Softec series of IOLs.
P100020/S006 9/14/12	cobas® HPV Test	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Change to adjust the environmental testing performed at the RMS Branchburg facility.
P100021/S020 9/25/12	Endurant and Endurant II Stent Graft Systems	Medtronic Vascular Santa Rosa, CA 95403	Process change to the spindle hypotube assembly

			to improve its adhesive properties.
P100023/S049 9/17/12	ION Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Changes to the distal bond process for the stent delivery system.
P100023/S052 9/6/12	ION Paclitaxel-Eluting Platinum Chromium Coronary Stent System (Monorail)	Boston Scientific Corporation Maple Grove, MN 55311	Use of new Statistical Process Control software.
P100023/S054 9/21/12	ION Paclitaxel-Eluting Platinum Chromium Coronary Stent System (Monorail & Over-the-Wire)	Boston Scientific Corporation Maple Grove, MN 55311	Use of new Statistical Process Control software.
P100040/S009 9/21/12	Valiant Thoracic Stent Graft with the Captivia Delivery System	Medtronic Vascular Santa Rosa, CA 95403	Automation of a cutting/sealing step.
P100041/S014 9/19/12	Edwards SAPIEN Transcatheter Heart Valve	Edward Lifesciences, LLC Irvine, CA 92614	Modify the layout of an isolation clean room.
P110010/S024 9/17/12	PROMUS Element Plus Everolimus-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Changes to the distal bond process for the stent delivery system.
P110010/S027 9/6/12	PROMUS Element Plus Everolimus-Eluting Platinum Chromium Coronary Stent System (Monorail and OTW)	Boston Scientific Corporation Maple Grove, MN 55311	Use of new Statistical Process Control software.
P110010/S029 9/21/12	PROMUS Element Plus Everolimus-Eluting Platinum Chromium Coronary Stent System (Monorail & Over-the- Wire)	Boston Scientific Corporation Maple Grove, MN 55311	Use of new Statistical Process Control software.
P110019/S030 9/7/12	XIENCE PR1ME and PRIME LL Everolimus Eluting	Abbott Vascular Temecula, CA 92591	Change to the method used to test for drug release.

	Coronary stent System (EECSS)		
P110020/S005 9/14/12	COBAS 4800 BRAF V600 Mutation Test	Roche Molecular, Systems, Inc. Pleasanton, CA 94558	Change to adjust the environmental testing performed at the RMS Branchburg facility.
P110027/S027 9/6/12	PROMUS Element Plus Everolimus-Eluting Platinum Chromium Coronary Stent System (Monorail & OTW)	Boston Scientific Corporation Maple Grove, MN 55311	Use of new Statistical Process Control software.
P110029/S004 9/14/12	ARCHITECT HBsAg Qualitative/HBsAg Qualitative Confirmatory	Abbott Laboratories Abbott Park, IL 60064	Change to a test method used in the manufacture of the components of the ARCHITECT HBsAg and HBsAg Confirmatory assay, and the ARCHITECT HBsAg Qualitative and HBsAg Qualitative Confirmatory assay (P110029).
P110035/S003 9/21/12	Epic Vascular Self Expanding Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Use of new Statistical Process Control software.
P110037/S002 9/14/12	COBAS® AmpliPrep/ COBAS® TaqMan® CMV Test	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Change to adjust the environmental testing performed at the RMS Branchburg facility.
P110043/S001 9/7/12	Omnilink Elite Vascular Balloon Expandable Stent System	Abbott Vascular, Inc. Temecula, CA 92580	New straightness test for cobalt chromium stent tubing.
P110043/S002 9/24/12	Omnilink Elite Vascular Stent System	Abbott Vascular, Inc. Temecula, CA 92580	Changes to the extruded tubing process.

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

Summary of PMA Originals Under Review
Total Under Review: 57
Total Active: 30
Total On Hold: 27
Number Greater Than 180 Days: 1

Summary of PMA Supplements Under Review
Total Under Review: 581
Total Active: 443
Total On Hold: 138
Number Greater Than 180 Days: 5

Summary of All PMA Submissions Received
Originals: 0
Supplements: 57

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): 145.7
FDA Time: 104.9 Days MFR Time: 40.8 Days

Source URL (retrieved on *03/27/2015 - 8:04am*):
http://www.mdtmag.com/news/2012/11/pma-final-decisions-september-2012

Links:
[1] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=P100003
[2] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=P110006
[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=P110038
[4] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=P110042