PMA Final Decisions for October 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
P100012 **[1] 10/26/12**	PCM® Cervical Disc System	NuVasive, Incorporated San Diego, CA 92121	Approval for the PCM Cervical Disc System. This device is indicated for use in skeletally mature patients for reconstruction of a degenerated cervical disc at one level from C3-C4 to C6-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 manifested by 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 PCM Cervical Disc is implanted using an anterior approach. Patients should have failed at least 6 weeks of conservative treatment prior to implantation of the PCM Cervical Disc.
P110008 **[2]** **10/17/12**	coflex® Interlaminar Technology	Paradigm Spine, LLC New York, NY 10022	Approval for the coflex ® Interlaminar Technology. This device is indicated for use in one- or two-level lumbar stenosis from L1- L5 in skeletally mature patients with at least moderate impairment in function, who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least 6 month of non-operative treatment. The coflex is intended to be implanted midline between adjacent lamina of 1 or 2 contiguous lumbar motion

			segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s).
P110021 **[3] 10/19/12**	Edwards SAPIEN™ Transcatheter Heart Valve (Model 9000TFX, sizes 23mm and 26mm) with RetroFlex 3 Delivery System (Models 9120FS23 and 9120FS26), Edwards SAPIEN™ Transcatheter Heart Valve with Ascendra Delivery System (Models 9100BCL23 and 9100BCL26), and accessories (RetroFlex™ Balloon Catheter, Models 9120BC20 and 9120BC23; Ascendra™ Balloon Aortic Valvuloplasty Catheter, Model 9100BAVC; AscendraTM Introducer Sheath Set Model 9100IS; and Crimper, Models 9100CR23 and 9100CR26)	Edwards Lifesciences LLC Irvine, CA 92614	Approval for Edwards SAPIEN™ Transcatheter Heart Valve Model 9000TFX, sizes 23mm and 26mm, and Transapical and Transfemoral Accessories listed above. This device is indicated for the following: Transapical - The Edwards SAPIEN transcatheter heart valve, model 9000TFX, sizes 23 mm and 26 mm, is indicated for transapical delivery in patients with severe symptomatic calcified native aortic valve stenosis without severe aortic insufficiency and with ejection fraction > 20% who have been examined by a heart team including an experienced cardiac surgeon and a cardiologist and found to be operative candidates for aortic valve replacement but who have a Society

			of Thoracic Surgeons operative risk score ≥ 8% or are judged by the heart team to be at a ≥15% risk of mortality for surgical aortic valve replacement. The Ascendra Balloon Catheter is indicated for the transapica1 delivery of the Edwards SAPIEN transcatheter heart valve. Transfemoral The Edwards SAPIEN Transcatheter Heart Valve, model 9000TFX, sizes 23 mm and 26 mm, is indicated for transfemoral delivery in patients with severe symptomatic calcified native aortic valve stenosis without severe aortic insufficiency and with ejection fraction >20% who have been examined by a heart team including an experienced cardiac surgeon and a cardiologist and found to either be: 1) inoperable and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis;

			or 2) be operative candidates for aortic valve replacement but who have a Society of Thoracic Surgeons predicted operative risk score ≥ 8% or are judged by the heart team to be at a ≥15% risk of mortality for surgical aortic valve replacement. The RetroFlex 3 Delivery System is indicated for the transfemoral delivery of the Edwards SAPIEN transcatheter heart valve.
P110039 **[4]** **10/18/12**	InSightec ExAblate® System, Model 2000/2100/ 2100 VI	InSightec, Incorporation Dallas, TX 75244	Approval for the ExAblate System, Model 2000/2100/ 2100 VI. This device is indicated for pain palliation of Metastatic Bone Cancer in patients 18 years of age or older who are suffering from bone pain due to metastatic disease and who arc failures of standard radiation therapy, or not candidates for, or refused radiation therapy. The bone tumor to be treated must be visible on non-contrast MR and device accessible.
P120005 **[5]** **10/5/12**	Dexcom G4 PLATINUM Continuous Glucose	Dexcom, Inc. San Diego, CA 92121	Approval for the Dexcom G4 PLATINUM

	Monitoring System		Continuous Glucose Monitoring System. This device is indicated for: The Dexcom G4 PLATINUM Continuous Glucose Monitoring System is a glucose monitoring device indicated for detecting trends and tracking patterns in persons (age 18 and older) with diabetes. The system is intended for single patient use and requires a prescription. The Dexcom G4 PLATINUM System is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices. The Dexcom G4 PLATINUM System aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of the Dexcom G4 PLATINUM System results should be based on the trends and patterns seen

			with several sequential readings over time.
P120006 **[6]** **10/5/12**	Ovation Abdominal Stent Graft System	TriVascular, Inc. Santa Rosa, CA 95403	Approval for the Ovation Abdominal Stent Graft System. This device is indicated for treatment of patients with abdominal aortic aneurysms having vascular morphology suitable for endovascular repair, including: 1) Adequate iliac/femoral access compatible with vascular access techniques, devices, and/or accessories; 2) Non-aneurysmal proximal aortic neck: a) with a length of at least 7 mm proximal to the aneurysm; b) with an inner wall diameter of no less than 16 mm and no greater than 30 mm; and c) with an aortic angle of ≤ 60 degrees if proximal neck is ≥ 10 mm and ≤ 45 degrees if proximal neck is ≤10 mm. 3) Adequate distal iliac landing zone: a) with a length of at least 10 mm; and with an inner wall diameter of no less than 8 mm and no greater than 20 mm.

P120007 **[7]** **10/12/12**	APTIMA® HPV 16 18/45 Genotype Assay	Gen-Probe Incorporated San Diego, CA 92121	Approval for the APTIMA HPV 16 18/45 Genotype Assay. APTIMA HPV 16 18/45 Genotype Assay Indications for Use: The APTIMA HPV 16 18/45 Genotype Assay is an in vitro nucleic acid amplification test for the qualitative detection of E6/E7 viral messenger RNA (mRNA) of human papillomavirus (HPV) types 16, 18, and 45 in cervical specimens from women with APTIMA HPV Assay positive results. The APTIMA HPV 16 18/45 Genotype Assay can differentiate HPV 16 from HPV 18 and/or HPV 45, but does not differentiate between HPV 18 and HPV 45. Cervical specimens in ThinPrep Pap Test vials containing PreservCyt Solution and collected with broom-type or cytobrush/spatula collection devices* may be tested with the APTIMA HPV 16 18/45 Genotype Assay. The assay is used with the TIGRIS DTS System. The use of the test is indicated:

			1) In patients 21 years and older with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results, the APTIMA HPV 16 18/45 Genotype Assay can be used to test samples from women with APTIMA HPV Assay positive results to assess the presence or absence of high-risk HPV genotypes 16, 18, and/or 45. This information, together with the physician's assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management. The results of this test are not intended to prevent women from proceeding to colposcopy; and 2) In women 30 years and older, the APTIMA HPV 16 18/45 Genotype Assay can be used to test samples from women with APTIMA HPV Assay positive results. The assay results wi11 be used in combination with cervical cytology to assess the presence

			or absence of high-risk HPV genotypes 16, 18, and/or 45. This information, together with the physician's assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management. * Broom-type device (e.g., Wallach Pipette), or endocervical brush/spatula.

PMA Supplemental Approvals

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
P830060/S072 10/5/12 Real-Time	VENTAK Automatic Implantable Cardioverter Defibrillator (AICD) System Family	Boston Scientific Corporation, CRM St. Paul, MN 55112	Approval for the use of a longer sterile barrier Tyvek pouch as primary packaging for the BSC CRV leads accessory products.
P830061/S064 10/4/12 180-Day	CapSure Sense Bipolar Lead	Medtronic, Inc. Mounds View, MN 55112	Approval for a manufacturing site located at Medtronic Singapore Pte. Ltd., in Singapore.
P870025/S011 10/10/12 Special	Corometrics Fetal Acoustic Stimulator (FAST)	Wipro GE Healthcare Laurel, MD 20723	Approval for changes made to the labeling to comply with IEC 60601-1:2005, 3 rd Edition.
P870076/S013 10/26/12 Special	Falope-Ring Band and Applicator Systems	Gyrus ACMI, Inc. Southborough, MA 01772	Approval for labeling changes including adding/

			modifying warnings in the instruction for use, updating company branding, and separating the Quick Reference Guides for the reusable and disposable applicators.
P890055/S043 **10/16/12** **Real-Time**	MedStream Programmable Infusion System	Codman & Shurtleff, Incorporated Raynham, MA 02767	Approval for a modification to the Programmable Infusion System. This modification consisted of removal of the epoxy used on the wires of the actuator component of the Pump.
P890055/S045 **10/12/12** **Real-Time**	MedStream Programmable Infusion System	Codman & Shurtleff, Incorporated Raynham, MA 02767	Approval to add Gablofen intrathecal to the list of approved drugs in the instructions for use. The device, as modified, will be marketed under the trade name MedStream Programmable Infusion System and is indicated for chronic intrathecal infusion of baclofen injection sterile solution in the treatment of severe spasticity.
P890055/S046 **10/26/12** **Real-Time**	MedStream Implantable Infusion System	Codman & Shurtfleff, Incorporated Raynham, MA 02767	Approval for a packaging modification to the device.
P910056/S013 **10/19/12** **Real-Time**	enVista® Hydrophobic Acrylic Intraocular Lens	Bausch & Lomb, Incorporated Aliso Viejo, CA	Approval for changes to the directions for use

		92656	(DFU) to specify that the enVista® MX60 Lens is approved for use with the Medicel Accuject 2.2 (Rev. 1) injector set,or other injector sets that specifically identify the enVista® MX60 lens in the cleared labeling.
P910073/S105 **10/5/12** **Real-Time**	Transvenous Defibrillation Lead; Accessory Stylets	Boston Scientific Corporation, CRM St. Paul, MN 55112	Approval for the use of a longer sterile barrier Tyvek pouch as primary packaging for the BSC CRV leads accessory products.
P910077/S122 **10/5/12** **Real-Time**	VENTAK PRx and VENTAK MINI AICD Families	Boston Scientific Corporation, CRM St. Paul, MN 55112	Approval for the use of a longer sterile barrier Tyvek pouch as primary packaging for the BSC CRV leads accessory products.
P930035/S022 **10/5/12** **Real-Time**	VENTAK P/P2 AICD System Families	Boston Scientific Corporation, CRM St. Paul, MN 55112	Approval for the use of a longer sterile barrier Tyvek pouch as primary packaging for the BSC CRV leads accessory products.
P930036/S005 **10/15/12** **180-Day**	ADVIA Centaur® AFP Assay	Siemens Healthcare Diagnostics, Inc. Walpole, MA 02032	Approval for a manufacturing site located at STRATEC Biomedical Switzerland AG in Beringen, Switzerland.
P930039/S072 **10/4/12** **180-Day**	CapSureFix Novus Leads	Medtronic, Inc. Mounds View, MN 55112	Approval for a manufacturing site located at Medtronic Singapore Operation Pte, in Singapore.

P950021/S013 **10/15/12** **180-Day**	ADVIA Centaur® PSA Assay	Siemens Healthcare Diagnostics, Inc. Walpole, MA 02032	Approval for a manufacturing site located at STRATEC Biomedical Switzerland AG in Beringen, Switzerland.
P950022/S083 **10/16/12** **Real-Time**	Durata Lead Models	St. Jude Medical Sylmar, CA 91342	Approval for changes to the packaging of the Quartet IS4 and Durata DF4 leads.
P950037/S105 **10/3/12** **180-Day**	Programmer Software PSW	Biotronik, Inc. Lake Oswego, OR 97035	Approval for the Evia HF/HF-T family of CRT-Ps and new programmer software identified as 1203.U/1.
P960004/S054 **10/5/12** **Real-Time**	Active Fixation Transvenous Bipolar Pacing Lead	Boston Scientific Corporation, CRM St. Paul, MN 55112	Approval for the use of a longer sterile barrier Tyvek pouch as primary packaging for the BSC CRV leads accessory products.
P960040/S265 **10/5/12** **Real-Time**	VENTAK AV and PRIZM DR/VR, VITALITY, CONFIENT and Teligen AICD	Boston Scientific Corporation, CRM St. Paul, MN 55112	Approval for the use of a longer sterile barrier Tyvek pouch as primary packaging for the BSC CRV leads accessory products.
P960042/S042 **10/31/12** **Special**	Spectranetics Laser Sheath (SLS) II and Glidelight Laser Sheath	Spectranetics Corporation Colorado Springs, CO 80921	Approval for modifying the SLS II and GlideLight Instruction for Use Manuals to include a warning and precaution statement and strengthen a warning.
P980016/S376 **10/26/12** **180-Day**	EnTrust ICD; GEM II DR ICD; GEM II VR ICD; GEM III DR ICD; GEM III VR ICD; Intrinsic 30 ICD;	Medtronic, Inc. Mounds View, MN 55112	Approval for the Medtronic ICD Longevity Estimation Tool (MILET) to be used

	Intrinsic ICD; Marquis DR ICD; Marquis VR ICD; Maximo II ICD; Protecta ICD; Protecta XT ICD; Secura ICD; Virtuoso ICD; and Virtuoso II DR/VR ICD		by Medtronic personnel for the devices.
P980022/S123 10/26/12 Real-Time	Guardian® REAL-Time System	Medtronic, Inc. Northridge, CA 91325	Approval for minor software modifications in Guardian® REAL-Time System to optimize the shutdown procedure for the Guardian Monitor and to correct an anomaly that allowed access of out-of-bounds pointer errors.
P980035/S223 10/4/12 180-Day	Adapta/Versa/ Sensia Implantable Pulse Generator	Medtronic, Inc. Mounds View, MN 55112	Approval for a manufacturing site located at Medtronic Singapore Pte Ltd., in Singapore.
P980035/S252 10/3/12 135-Day	Adapta, Relia, Sensia and Versa IPGs	Medtronic, Inc. Mounds View, MN 55112	Approval for revisions to a test program used in the manufacture of integrated circuits.
P980037/S040 10/16/12 Real-Time	AngioJet® Rheolytic Thrombectomy System	MEDRAD Interventional Minneapolis, MN 55433	Approval for changing the packaging tray material for the AngioJet Ultra XMI, Ultra Spiroflex, and Ultra Spiroflex VG Thrombectomy Sets from PETG to PETG Denest, as well as changing the manufacturing of these packaging

			trays from PerfecSeal To Brookdale.
P980050/S076 **10/26/12** **180-Day**	GEM III AT	Medtronic, Inc. Mounds View, MN 55112	Approval for the Medtronic ICD Longevity Estimation Tool (MILET) to be used by Medtronic personnel for the devices.
P990055/S014 **10/15/12** **180-Day**	ADVIA Centaur® cPSA Assay	Siemens Healthcare Diagnostics, Inc. Walpole, MA 02032	Approval for a manufacturing site located at STRATEC Biomedical Switzerland AG in Beringen, Switzerland.
P990071/S016 **10/31/12** **180-Day**	SmartAblate™ Irrigation Pump and SmartAblate™ Tubing Set	Biosense Webster, Inc. Diamond Bar, CA 91765	Approval for upgrading the existing accessory Coolflow™ Irrigation Pump for the STOCKERT 70 Radiofrequency (RF) Generator for Cardiac Ablation. The device, as modified, will be marketed under the trade name SmartAblate™ Irrigation Pump and SmartAblate™ Tubing Set. The indications are that the SmartAblate™ Irrigation Pump is a peristaltic pump designed to work in conjunction with the STOCKERT 70 Radiofrequency Generator to deliver irrigation solution at specified now rates to irrigated catheters (such as

			the Biosense Webster Celsius® ThermoCool® Catheters and NaviStar® ThermoCool® Catheters) for cooling purposes. The pump is used with the SmartAblate™ Irrigation Tubing Set that conducts the irrigation solution from an external source to the compatible irrigated catheters.
P000009/S049 **10/3/12** **180-Day**	Programmer Software PSW	Biotronik, Inc. Lake Oswego, OR 97035	Approval for the Evia HF/HF-T family of CRT-Ps and new programmer software identified as 1203.U/1.
P000025/S062 **10/26/12** **180-Day**	MED-EL COMBI 40+ Cochlear Implant System, RONDO Audio Processor	MED-EL Corporation Durham, NC 27713	Approval for the RONDO audio processor.
P000054/S031 **10/17/12** **135-Day**	INFUSE Bone Graft	Medtronic Sofamor Danek Memphis, TN 38132	Approval for change in resin usage lifetime.
P000054/S035 **10/25/12** **135-Day**	INFUSE® Bone Graft	Medtronic Sofamor Danek Memphis, TN 38132	Approval for the extension of the expiry of batch reference material.
P000058/S044 **10/17/12** **135-Day**	INFUSE Bone Graft/LT-Cage Lumbar Tapered Fusion	Medtronic Sofamor Danek Memphis, TN 38132	Approval for change in resin usage lifetime.
P000058/S050 **10/25/12** **135-Day**	INFUSE® Bone Graft/LT-Cage Lumbar Tapered Fusion	Medtronic Sofamor Danek Memphis, TN 38132	Approval for the extension of the expiry of batch reference material.
P010012/S295 **10/5/12** **Real-Time**	CONTAK CD, EASYTRAK, LIVIAN, COGNIS and ACUITY	Boston Scientific Corporation, CRM St. Paul, MN	Approval for the use of a longer sterile barrier Tyvek

	SPIRAL Families	55112	pouch as primary packaging for the BSC CRV leads accessory products.
P010031/S329 **10/26/12** **180-Day**	Concerto ICD; Concerto II CRT-D; Consulta DF4 ICD; InSync II Protect ICD; InSync III Marquis ICD; InSync Maximo ICD; InSync Sentry; InSync II Marquis; InSync Marquis; Maximo II CRT-D; Protecta CRT-D; and Protecta XT CRT-D	Medtronic, Inc. Mounds View, MN 55112	Approval for the Medtronic ICD Longevity Estimation Tool (MILET) to be used by Medtronic personnel for the devices.
P010032/S055 **10/25/12** **135-Day**	Eon Mini Neuromodulation System	St. Jude Medical Plano, TX 75024	Approval for the addition of stand-off tabs on the routed printed circuit board (PCB), to change the equipment used to route the PCBs, and to add Kapton Tape to the battery surface to prevent contact with copper traces from the PCB and the adjacent surface of the battery.
P020014/S038 **10/2/12** **180-Day**	Conceptus® Essure System for Permanent Birth Control	Conceptus, Inc. Mountain View, CA 94041	Approval for a material change and a minor process change. The use of new Carbothane materials in the delivery catheter with the new hydrophilic coating and a change in operating temperature.
P020018/S043 **10/1/12** **180-Day**	The Zenith Fenestrated AAA Endovascular Graft	Cook, Inc. Bloomington, IN 47402	Approval of the post-approval study protocol.
P020018/S046	Zenith® AAA	Cook Incorporated	Approval for

10/9/12 **180-Day**	Endovascular Graft System	Bloomington, IN 47402	modifications to the H & L-B One-Shot Introduction System.
P020056/S016 **10/1/12** **180-Day**	Natrelle (formerly named) Silicone-filled Breast Implant	Allergan Santa Barbara, CA 93111	Approval of the post-approval study protocol.
P030017/S140 **10/1/12** **Real-Time**	Precision Spinal Cord Stimulator (SCS) System	Boston Scientific Neuromodulation Valencia, CA 91355	Approval for minor packaging design changes to the inner tray and inner tray cover for the Precision Spinal Cord Stimulator (SCS) System Implantable Pulse Generator (IPG) kits.
P030029/S013 **10/15/12** **180-Day**	ADVIA Centaur® Anti-HBs Assay	Siemens Healthcare Diagnostics, Inc. Walpole, MA 02032	Approval for a manufacturing site located at STRATEC Biomedical Switzerland AG in Beringen, Switzerland.
P030031/S045 **10/2/12** **Real-Time**	ThermoCool SF Nav Uni-Directional Catheter	Biosense Webster, Inc. Diamond Bar, CA 91765	Approval for extending the Shelf Live for the catheter in the object of the current letter from one to three years.
P030040/S008 **10/15/12** **180-Day**	ADVIA Centaur® HBc IgM Assay	Siemens Healthcare Diagnostics, Inc. Walpole, MA 02032	Approval for a manufacturing site located at STRATEC Biomedical Switzerland AG in Beringen, Switzerland.
P030049/S010 **10/15/12** **180-Day**	ADVIA Centaur® HBsAg and HBsAg Confirmatory Assay	Siemens Healthcare Diagnostics, Inc. Walpole, MA 02032	Approval for a manufacturing site located at STRATEC Biomedical Switzerland AG in Beringen, Switzerland.
P030054/S232 **10/16/12** **Real-Time**	Quartet IS4 Lead Models	St. Jude Medical Sylmar, CA 91342	Approval for changes to the packaging of the

			Quartet IS4 and Durata DF4 leads.
P030056/S007 **10/15/12** **180-Day**	ADVIA Centaur® HCV Assay	Siemens Healthcare Diagnostics, Inc. Walpole, MA 02032	Approval for a manufacturing site located at STRATEC Biomedical Switzerland AG in Beringen, Switzerland.
P040004/S009 **10/15/12** **180-Day**	ADVIA Centaur® HBc Total Assay	Siemens Healthcare Diagnostics, Inc. Walpole, MA 02032	Approval for a manufacturing site located at STRATEC Biomedical Switzerland AG in Beringen, Switzerland.
P040048/S017 **10/25/12** **135-Day**	Trilogy AB Acetabular System	Zimmer, Inc. Warsaw, Indiana 46581	Approval for the addition of a new cleanroom.
P050023/S053 **10/3/12** **180-Day**	Programmer Software PSW	Biotronik, Inc. Lake Oswego, OR 97035	Approval for the Evia HF/HF-T family of CRT-Ps and new programmer software identified as 1203.U/1.
P050033/S015 **10/22/12** **135-Day**	Hydrelle, Dermal Filler	Anika Therapeutics, Inc. Bedford, MA 01730	Approval for a change in the sample preparation procedure for HPLC testing.
P050053/S022 **10/17/12** **135-Day**	INFUSE Bone Graft	Medtronic Sofamor Danek Memphis, TN 38132	Approval for change in resin usage lifetime.
P050053/S026 **10/25/12** **135-Day**	INFUSE® Bone Graft	Medtronic Sofamor Danek Memphis, TN 38132	Approval for the extension of the expiry of batch reference material.
P060002/S028 **10/4/12** **Special**	Flair Endovascular Stent Graft	C.R. Bard, Inc. Tempe, AZ 85281	Approval for the incorporation of a new Leica DM2500M microscope and DFC295 digital camera to increase image resolution in order to measure

			material porosity in accordance with ISO 7198.
P060025/S009 **10/26/12** **180-Day**	3f Aortic Bioprosthesis	Medtronic ATS Medical, Inc. Lake Forest, CA 92630	Approval of the post-approval study protocol.
P060037/S017 **10/25/12** **135-Day**	Nexgen LPS/LPS Flex Mobile Knee	Zimmer, Inc. Warsaw, Indiana 46581	Approval for the addition of a new cleanroom.
P060038/S012 **10/9/12** **180-Day**	Mitroflow Aortic Pericardial Heart Valve (MAPHV)	Sorin Group USA, Inc. Arvada, CO 80004	Approval for the Mitroflow Valsalva Conduit (MVC).
P060040/S024 **10/5/12** **Real-Time**	Thoratec HeartMate II Left Ventricular Assist System (LVAS)	Thoratec Corporation Pleasanton, CA 94588	Approval to extend the shelf-life of both the HeartMate II (HM II) Sealed Outflow Graft and the Sealed Inflow Conduit from the current labeling of three years to five years.
P070008/S031 **10/3/12** **180-Day**	Evia HF/HF-T, Entovis HF/HF-T, Programmer Software PSW	Biotronik, Inc. Lake Oswego, OR 97035	Approval for the Evia HF/HF-T family of CRT-Ps and new programmer software identified as 1203.U/1.
P070015/S077 **10/23/12** **180-Day**	XIENCE V® Everolimus Eluting Coronary Stent System and PROMUS® Everolimus Eluting Coronary Stent System	Abbott Vascular Temecula, CA 92589	Approval to use everolimus, the active pharmaceutical ingredient (API) in the devices, following a change in the manufacturing process implement by Novartis, the API manufacturer.
P080006/S006 **10/4/12** **180-Day**	Attain Ability Left Ventricular Leads	Medtronic, Inc. Mounds View, MN 55113	Approval for component level analytical testing for release of the Model 4196, 4296

			and 4396.
P080020/S002 **10/10/12** **135-Day**	Gel-One®	Seikagaku Corporation Toyko, Japan 100-0005	Approval for the use of dedicated manufacturing equipment for additional purposes.
P090012/S002 **10/2/12** **180-Day**	MelaFind	Mela Sciences, Inc. Irvington, NY 10533	Approval of the post-approval study protocol.
P090013/S073 **10/4/12** **180-Day**	CapSureFix MRI SureScan Lead	Medtronic, Inc. Mounds View, MN 55112	Approval for a manufacturing site located at Medtronic Singapore Operation Pte, in Singapore.
P100005/S001 **10/1/12** **180-Day**	M-Vu Algorithm Engine	VuCOMP, Inc. Plano, TX 75093	Approval for algorithm updates and the expansion to multiple mammography systems.
P100020/S002 **10/18/12** **135-Day**	cobas® HPV Test	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Approval for a change in the DNA synthesizer instrument platform.
P100040/S008 **10/26/12** **Panel-Track**	Valiant® Thoracic Stent Graft with the Captivia Delivery System	Medtronic Vascular Santa Rosa, CA 95403	Approval for the Valiant Thoracic Stent Graft with the Captivia Delivery System. This device is indicated for the endovascular repair of isolated lesions (excluding dissections) of the descending thoracic aorta in patients having appropriate anatomy, including: iliac or femoral artery access vessel morphology that is compatible with vascular access techniques, devices,

			or accessories; nonaneurysmal aortic diameter in the range of 18 to 42 mm (fusiform and saccular aneurysms/ penetrating ulcers) or 18 mm to 44 mm (blunt traumatic aortic injuries); and nonaneurysmal aortic proximal and distal neck lengths > 20 mm.
P110001/S009 **10/9/12** **180-Day**	RX Herculink Elite Renal Stent System	Abbott Vascular Temecula, CA 92591	Approval for a manufacturing site located at Abbott Vascular Cardiac Therapies in Clonmel, Ireland.
P110019/S018 **10/5/12** **180-Day**	XIENCE PRIME and XIENCE PRIME LL Everolimus Eluting Coronary Stent System	Abbott Vascular, Inc. Temecula, CA 92591	Approval to allow the corresponding drug content values to be centered around 100% label claim and provide increased probability that individual units will have a drug content of greater than 90% of the labeled claim to meet the condition of approval that "within 12 months of PMA approval, you should submit a PMA supplement requesting approval to tighten the in-process coating weight gain specification or implement procedures to re-coat stents with less

			than 95% coating weight gain upon in-process inspection. The company has provided the alternative solution.

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
P810032/S062 10/31/12	Anterior and Posterior Chamber Intraocular Lenses	Alcon Laboratories, Inc. Fort Worth, TX 76134	Change to add a new sterilization vendor.
P830061/S078 10/3/12	CapSure, Vitatron Crystalline, Vitatron Excellence PS+	Medtronic, Inc. Mounds View, MN 55112	New annealing vacuum oven.
P830061/S079 10/25/12	CapSure. CapSure Sense, CapSure SP Novus, Vitatron Crystalline, and Vitatron Excellence PS+ Leads	Medtronic, Inc. Mounds View, MN 55112	Transfer of incoming inspection location for various components.
P830061/S080 10/26/12	Vitatron Excellence PS+	Medtronic, Inc. Mounds View, MN 55112	New annealing vacuum oven.
P840001/S227 10/10/12	External Neurostimulator, Intrel 4, Restore Prime, Prime Advanced, Restore, Restore Ultra, Restore Advanced and Restore Sensor	Medtronic Neuromodulation Minneapolis, MN 55432	Use of the new Automated Assembly Equipment Controller software release, interfacing with the Manufacturing Execution System at the hybrid component supplier.
P840001/S228 10/24/12	Itrel 3, Synergy, Syngery Versitrel, Itrel 4, Pocket Adaptors, Soletra, Kinetra, Activa SC, InterStim, and	Medtronic Neuromodulation Minneapolis, MN 55432	Manufacture of one inner seal silicone component at the alternate supplier, Flexan located in Suzhou Industrial

	Enterra		Park, China.
P840060/S038 10/31/12	Anterior and Posterior Chamber Intraocular Lenses	Alcon Laboratories. Inc. Fort Worth, TX 76134	Change to add a new sterilization vendor.
P850079/S057 10/17/12	Methafilcon A Soft Extended Wear Contact Lenses	CooperVision, Inc. Pleasanton, CA 94588	Modify the inspection process.
P850089/S090 10/25/12	CapSure SP Novus, CapSure SP Z, CapSure Z Novus, and Vitatron Impulse II Leads	Medtronic, Inc. Mounds View, MN 55112	Transfer of incoming inspection location for various components.
P860057/S092 10/4/12	Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis	Edward Lifesciences Irvine, CA 92614	Manufacturing software change to automate in-process labeling.
P870077/S047 10/4/12	Carpentier-Edwards S.A.V. Bioprosthesis	Edward Lifesciences Irvine, CA 92614	Manufacturing software change to automate in-process labeling.
P870056/S052 10/4/12	Carpentier-Edwards Porcine Bioprosthesis	Edward Lifesciences Irvine, CA 92614	Manufacturing software change to automate in-process labeling.
P880006/S083 10/10/12	Regency	St. Jude Medical Sylmar, CA 91342	Changes to the bioburden action level and bioburden action limit.
P880086/S226 10/10/12	Identity, Integrity, Affinity, Verity, Victory, Zephyr, Sustain, Accent	St. Jude Medical Sylmar, CA 91342	Changes to the bioburden action level and bioburden action limit.
P880086/S227 10/31/12	Identify, Verify, Victory, Zephyr, Accent Family of Pacemaker Devices	St. Jude Medical, Inc. Sylmar, CA 91342	Alternate supplier of the septum component.
P880087/S020 10/31/12	Anterior and Posterior Chamber Intraocular Lenses	Alcon Laboratories, Inc. Fort Worth, TX 76134	Change to add a new sterilization vendor.
P890003/S261 10/25/12	CapSure VDD-2 and Vitatron Brilliant S+ Leads	Medtronic, Inc. Mounds View, MN 55112	Transfer of incoming inspection location for various components.
P910023/S304	Current, Current	St. Jude Medical	Changes to the

10/10/12	Accel, Current+, Current RF, Fortify, Epic/Epic+, Atlas/II/+	Sylmar, CA 91342	bioburden action level and bioburden action limit.
P910023/S306 10/31/12	Atlas/Atlas+, Atlas II/Atlas II+, Current, Current Accel, Current+, Epic/ Epic+, Epic II/Epic II+, Fortify, Fortify Assura, Ellipse Family of ICD Devices	St. Jude Medical, Inc. Sylmar, CA 91342	Alternate supplier of the septum component.
P910073/S106 10/3/12	Endotak Reliance EZ IS-1 and Endotak Reliance 4-Site Ez Quadripolar (DF4) Active Fixation Leads Active Fixation Leads	Boston Scientific Corporation St. Paul, MN 55112	Changes to the dexamethasone acetate drug substance specification and testing.
P910077/S124 10/24/12	Zoom LATITUDE Programming System	Boston Scientific Corporation St. Paul, MN 55112	Alternate component suppliers.
P910077/S125 10/24/12	LATITUDE RF Communicator	Boston Scientific Corporation St. Paul, MN 55112	Change to the main control board manufacturing line.
P920015/S095 10/3/12	Sprint Quattro, Sprint Quattro Lead	Medtronic, Inc. Mounds View, MN 55112	New annealing vacuum oven.
P920015/S096 10/15/12	“Y” adaptor/ extender kit, Spring Quattro Lead	Medtronic, Inc. Mounds View, MN 55112	Alternate suppliers for molded components.
P920015/S097 10/25/12	Sprint Quattro, Spring Quattro Secure, and Spring Quattro Secure S Leads	Medtronic, Inc. Mounds View, MN 55112	Transfer of incoming inspection location for various components.
P930014/S064 10/31/12	Anterior and Posterior Chamber Intraocular Lenses	Alcon Laboratories, Inc. Fort Worth, TX 76134	Change to add a new sterilization vendor.
P930031/S036 10/24/12	Wallstent Tips Endoprosthesis with Unistep Plus	Boston Scientific Corporation Maple Grove, MN	Change to the aeration cycle time for an ethylene

	Delivery System	55311	oxide sterilization cycle.
P930031/S037 10/31/12	Wallstent Endo (TIPS) Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Alternate inspection equipment for the extruded tubing component.
P930039/S073 10/3/12	CapSureFix Novus Lead, Vitatron Crystalline Leads	Medtronic, Inc. Mounds View, MN 55112	New annealing vacuum oven.
P930039/S074 10/15/12	CapSureFix Novus Lead, Vitatron Crystalline Leads	Medtronic, Inc. Mounds View, MN 55112	Alternate suppliers for molded components.
P930039/S075 10/25/12	CapSureFix DXAC/DSP, CapSureFix Novus, SureFix, and Vitatron Crystalline Lcuds	Medtronic, Inc. Mounds View, MN 55112	Transfer of incoming inspection location for various components.
P940019/S031 10/24/12	Wallstent Iliac Endoprosthesis with Unistep Plus Delivery System	Boston Scientific Corporation Maple Grove, MN 55311	Change to the aeration cycle time for an ethylene oxide sterilization cycle.
P940019/S032 10/31/12	Wallstent Reduced Profile Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Alternate inspection equipment for the extruded tubing component.
P950005/S040 10/24/12	Celsius RF Ablation Catheters	Biosense Webster, Inc. Diamond Bar, CA 91765	Addition of an alternate supplier for the extruding and braiding process.
P950020/S056 10/31/12	Flextome Cutting Balloon	Boston Scientific Corporation Maple Grove, MN 55311	A second proximal bond laser and several process changes to the Automatic Torch Box.
P950022/S084 10/10/12	Durata, Durata DF4	St. Jude Medical Sylmar, CA 91342	Changes to the bioburden action level and bioburden action limit.
P950024/S043 10/3/12	CapSure Epicardial Pacing Lead	Medtronic, Inc. Mounds View, MN	New annealing vacuum oven.

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P950024/S045 10/25/12	CapSure Epicardial Pacing Lead	Medtronic, Inc. Mounds View, MN 55112	Transfer of incoming inspection location for various components.
P950037/S112 10/10/12	Philos DR/DR-B/ SR/SR-B/DR-T/II DR/II DR-T/II SR, Cylos DR/DR-T/VR, Selox JT/ST, Setrox S, SLX BP, and Evia DR/DR-T/SR/SR-T	Biotronik, Inc. Lake Oswego, OR 97035	Addition of suppliers for components used in the devices.
P960004/S055 10/3/12	Thinline II Sterox Leads	Boston Scientific Corporation St. Paul, MN 55112	Changes to the dexamethasone acetate drug substance specification and testing.
P960004/S056 10/10/12	Fineline II and Thinline II Leads	Boston Scientific Corporation St. Paul, MN 55112	Addition of an alternate supplier for the distal tip electrodes.
P960006/S035 10/3/12	Flextend Bipolar Pacing Leads	Boston Scientific Corporation St. Paul, MN 55112	Changes to the dexamethasone acetate drug substance specification and testing.
P960009/S157 10/10/12	External Neurostimulator, Activa PC, Activa SC and Activa RC	Medtronic Neuromodulation Minneapolis, MN 55432	Use of the new Automated Assembly Equipment Controller software release, interfacing with the Manufacturing Execution System at the hybrid component supplier.
P960009/S158 10/24/12	Itrel 3, Synergy, Syngery Versitrel, Itrel 4, Pocket Adaptors, Soletra, Kinetra, Activa SC, InterStim, and Enterra	Medtronic Neuromodulation Minneapolis, MN 55432	Manufacture of one inner seal silicone component at the alternate supplier, Flexan located in Suzhou Industrial Park, China.

P960013/S074 10/10/12	Tendril SDx, Tendril ST, Tendril STS, Optisense	St. Jude Medical Sylmar, CA 91342	Changes to the bioburden action level and bioburden action limit.
P960030/S037 10/10/12	Isoflex P, Isoflex Optim, Isoflex S	St. Jude Medical Sylmar, CA 91342	Changes to the bioburden action level and bioburden action limit.
P960040/S271 10/5/12	Punctua, Energen, Incepta, Teligen ICD	Boston Scientific Corporation St. Paul, MN 55112	Cleaning tool aid for the sealer heating plates.
P960040/S272 10/17/12	TELIGEN, INCEPTA, ENERGEN, and PUNCTUA Implantable Cardioverter High Energy Defibrillators	Boston Scientific Corporation St. Paul, MN 55112	Changes to the final hybrid component electrical test and the addition of new test equipment.
P960040/S273 10/24/12	Punctua, Teligen, Energen and Incepta Implantable Cardioverter Defibrillators	Boston Scientific Corporation St. Paul, MN 55112	Move a component coating processes in-house.
P960040/S274 10/24/12	Cognis CRT-D	Boston Scientific Corporation St. Paul, MN 55112	Software updates for the E2 and FP (Final Pack) tests.
D970003/S139 10/5/12	Advantio, Ingenio Pacemaker	Boston Scientific Corporation St. Paul, MN 55112	Cleaning tool aid for the sealer heating plates.
P970003/S153 10/30/12	VNS Therapy System	Cyberonics, Inc. Houston, Texas 77058	Change and the use of alternate components on the printed circuit board for the Programming Wand.
P970004/S142 10/10/12	InterStim II	Medtronic Neuromodulation Minneapolis, MN 55432	Use of the new Automated Assembly Equipment Controller software release, interfacing with the Manufacturing Execution System

			at the hybrid component supplier.
P970004/S143 10/24/12	Itrel 3, Synergy, Syngery Versitrel, Itrel 4, Pocket Adaptors, Soletra, Kinetra, Activa SC, InterStim, and Enterra	Medtronic Neuromodulation Minneapolis, MN 55432	Manufacture of one inner seal silicone component at the alternate supplier, Flexan located in Suzhou Industrial Park, China.
P970013/S052 10/10/12	Microny	St. Jude Medical Sylmar, CA 91342	Changes to the bioburden action level and bioburden action limit.
D970012/S093 10/5/12	AMS 700 Inflatable Penile Prosthesis, AMS Ambicor Penile Prosthesis	American Regulatory Systems, Inc. Minneotonka, MN 55343	The silicon receiving inspection and milling processes to be streamlined and to remove duplicate testing to provide consistency for the entire silicone processes.
P970020/S075 10/23/12	Ultra and Zeta RX Coronary Stent Systems	Abbott Vascular, Inc. Temecula, CA 92591	Modification to the pyrogen sampling frequency.
P980016/S383 10/4/12	Maximo II, Protecta, Protecta XT, Secura, Virtuoso II DR/VR ICDs	Medtronic, Inc. Mounds View, MN 55112	Update to the Automatic Assembly Equipment Controller (AAEC) System.
P980023/S048 10/10/12	Kainox VCS, Linox S/T/SD/TD	Biotronik, Inc. Lake Oswego, OR 97035	Addition of suppliers for components used in the devices.
P980033/S025 10/24/12	Wallstent Venous Endoprosthesis with Unistep Plus Delivery System	Boston Scientific Corporation Maple Grove, MN 55311	Change to the aeration cycle time for an ethylene oxide sterilization cycle.
P980033/S026 10/31/12	Wallstent Endo (Venous) Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Alternate inspection equipment for the extruded tubing component.

P980035/S291 10/1/12	Advisa DR IPG	Medtronic, Inc. Mounds View, MN 55112	Change to the hybrid burn-in time.
P980035/S292 10/4/12	Adapta, Adapta L, Adapta S, Sensia L, Sensia, Versa, Advisa DR and Relia IPGs	Medtronic, Inc. Mounds View, MN 55112	Update to the Automatic Assembly Equipment Controller (AAEC) System.
P980035/S293 10/15/12	Adapta, Adapta L, Adapta S, Sensia L, Sensia, Versa IPG, Sigma DR IPG, Sigma S IPG	Medtronic, Inc. Mounds View, MN 55112	Alternate suppliers for molded components.
P980035/S295 10/31/12	Advisa DR IPG	Medtronic, Inc. Minneapolis, MN 55112	Elimination of the incoming inspection of a battery component at an internal supplier location.
P980050/S077 10/3/12	Transvene Lead	Medtronic, Inc. Mounds View, MN 55112	New annealing vacuum oven.
P980050/S078 10/25/12	Transvene CS/SVC Lead	Medtronic, Inc. Mounds View, MN 55112	Transfer of incoming inspection location for various components.
P990025/S034 10/24/12	Navi-Star RF Ablation Catheters	Biosense Webster, Inc. Diamond Bar, CA 91765	Addition of an alternate supplier for the extruding and braiding process.
P000007/S034 10/4/12	Edwards Prima Plus Stentless Bioprosthesis	Edward Lifesciences Irvine, CA 92614	Manufacturing software change to automate in-process labeling.
P000012/S040 10/10/12	COBAS® AMPLICOR® Hepatitis C Virus Test and COBAS® AmpliPrep/ COBAS® AMPLICOR® HCV Test	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Scale up of a bulk enzyme used in the manufacture of kit components.
P000025/S065 10/15/12	MED-EL COMBI 40+ Cochlear Implant System	MED-EL Corporation Durham, NC 27713	Addition of a new laser welding system for the purposes of welding

			implant housings to implant headers for the Mi1000 MED-EL CONCERT model cochlear implants.
P000040/S025 10/24/12	Genesys HTA System	Boston Scientific Corporation Marlborough, MA 01752	Supplier site change.
P000053/S045 10/5/12	AMS 800 Urinary Control System	American Regulatory Systems, Inc. Minnetonka, MN 55343	The silicon receiving inspection and milling processes to be streamlined and to remove duplicate testing to provide consistency for the entire silicone processes.
P010012/S302 10/3/12	Easytrak 2 LV -1 and IS-1, Easytrak 3 LV -1 and IS-1 and Acuity Spiral Leads	Boston Scientific Corporation St. Paul, MN 55112	Changes to the dexamethasone acetate drug substance specification and testing.
P010012/S303 10/6/12	Punctua, Energen, Incepta, Cognis CRT-D	Boston Scientific Corporation St. Paul, MN 55112	Cleaning tool aid for the sealer heating plates.
P010012/S304 10/17/12	COGNIS, INCEPT A, ENERGEN, and PUNCTUA Cardiac Resynchronization High Energy Defibrillators	Boston Scientific Corporation St. Paul, MN 55112	Changes to the final hybrid component electric test and the addition of new test equipment.
P010012/S305 10/24/12	Punctua, Cognis, Energen and Incepta Cardiac Resynchronization Therapy Defibrillators	Boston Scientific Corporation St. Paul, MN 55112	Move a component coating processes in-house.
P010012/S306 10/24/12	Teligen ICD	Boston Scientific Corporation St. Paul, MN 55112	Software updates for the E2 and FP (Final Pack) tests.
P010015/S176 10/3/12	Attain Bipolar OTW Lead	Medtronic, Inc. Mounds View, MN	New annealing vacuum oven.

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P010015/S177 10/1/12	Consulta and Syncra CRT-Ps	Medtronic, Inc. Mounds View, MN 55112	Change to the hybrid burn-in time.
P010015/S178 10/4/12	Consulta, Syncra CRT-Ps	Medtronic, Inc. Mounds View, MN 55112	Update to the Automatic Assembly Equipment Controller (AAEC) System.
P010015/S179 10/15/12	Attain Bipolar OTW Lead, Left Ventricular Pacing Lead	Medtronic, Inc. Mounds View, MN 55112	Alternate suppliers for molded components.
P010015/S180 10/25/12	Attain OTW Bipolar and Attain OTW Unipolar Lead	Medtronic, Inc. Mounds View, MN 55112	Transfer of incoming inspection location for various components.
P010015/S181 10/31/12	Consulta and Syncra CRT-Ps	Medtronic, Inc. Minneapolis, MN 55112	Elimination of the incoming inspection of a battery component at an internal supplier location.
P010019/S034 10/25/12	Lotrafilcon Contact Lenses for Extended Wear	CIBA Vision Corporation Duluth, GA 30097	Minor manufacturing change to the method for the monitoring and data processing for all production modules of various lenses.
P010020/S026 10/5/12	AMS Acticon Neosphincter	American Regulatory Systems, Inc. Minnetonka, MN 55343	The silicon receiving inspection and milling processes to be streamlined and to remove duplicate testing to provide consistency for the entire silicone processes.
P010030/S036 10/18/12	LifeVest Wearable Cardioverter Defibrillator	Zoll Lifecor Corporation Pittsburg, PA 15238	Changes to the battery manufacturing process at the supplier location.
P010031/S335	Concerto II CRT-D,	Medtronic, Inc.	Update to the

10/4/12	Consulta DF4 ICD, Consulta ICD, Maximo II CRT-D, Protecta CRT-D and Protecta XT CRT-D	Mounds View, MN 55112	Automatic Assembly Equipment Controller (AAEC) System.
P010041/S036 10/4/12	Carpentier-Edwards S.A.V. Bioprosthesis	Edward Lifesciences Irvine, CA 92614	Manufacturing software change to automate in-process labeling.
P010047/S023 10/23/12	ProGel™ Pleural Air Leak Sealant	Neomend, Inc. Irvine, CA 92618	Addition of a second supplier for the materials comprising the outer pouch, which maintains the sterile barrier and holds the applicator accessories.
P010068/S030 10/24/12	Celsius DS and Navi-Star DS RF Ablation Catheters	Biosense Webster, Inc. Diamond Bar, CA 91765	Addition of an alternate supplier for the extruding and braiding process.
P020009/S094 10/31/12	Express 2 Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Alternate inspection equipment for the extruded tubing component.
P020022/S011 10/24/12	VERSANT® HCV RNA 3.0 Assay (bDNA)	Siemens Healthcare Diagnostics, Inc. E. Walpole, MA 02032	Change in microplate coating equipment for a component, and a change to add an incoming functional test for a supplier component.
P020047/S051 10/23/12	Vision and ML8 Coronary Stent Systems	Abbott Vascular, Inc. Temecula, CA 92591	Modification to the pyrogen sampling frequency.
P030005/S087 10/5/12	Invive CRT-P	Boston Scientific Corporation St. Paul, MN 55112	Cleaning tool aid for the sealer heating plates.
P030017/S143 10/11/12	Precision® Spinal Cord Stimulator System	Boston Scientific Corporation Valencia, CA	Procurement of a fuse subassembly from a qualified

		91355	supplier.
P030031/S048 10/24/12	Celsius Thermocool Catheters	Biosense Webster, Inc. Diamond Bar, CA 91765	Addition of an alternate supplier for the extruding and braiding process.
P030035/S104 10/10/12	Anthem. Frontier II	St. Jude Medical Sylmar, CA 91342	Changes to the bioburden action level and bioburden action limit.
P030035/S105 10/31/12	Frontier, Frontier II, Anthem Family of CRT-P Devices	St. Jude Medical, Inc. Sylmar, CA 91342	Alternate supplier of the septum component.
P030036/S047 10/3/12	SelectSecure Lead	Medtronic, Inc. Mounds View, MN 55112	New annealing vacuum oven.
P030036/S048 10/15/12	Anchoring Sleeve Kit, SelectSecure Lead	Medtronic, Inc. Mounds View, MN 55112	Alternate suppliers for molded components.
P030036/S049 10/25/12	SelectSecure 4 French Lead	Medtronic, Inc. Mounds View, MN 55112	Transfer of incoming inspection location for various components.
P030054/S233 10/10/12	QuickFlex micro, Quartet, Promote, Promote+, Promote RF, Promote Accel, Promote Q, Promote Quadra, Unify, Unify Quadra, Epic, Atlas	St. Jude Medical Sylmar, CA 91342	Changes to the bioburden action level and bioburden action limit.
P030054/S235 10/31/12	Atlas+ HF/Atlas II HF, Atlas II+ HF, Epic+, Epic HF, Epic II HF, Epic II+ HF, Promote, Promote+, Promote RF, Promote Accel, Unify, Unify Quadra, Quadra Assura Family of CRT-D Devices	St. Jude Medical, Inc. Sylmar, CA 91342	Alternate supplier of the septum component.
P040016/S099 10/31/12	VeriFLEX (Libertè) Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Alternate inspection equipment for the extruded tubing component.

P040020/S043 10/31/12`	Anterior and Posterior Chamber Intraocular Lenses	Alcon Laboratories, Inc. Fort Worth, TX 76134	Change to add a new sterilization vendor.
P040047/S024 10/18/12	Coaptite Injectable Implant	Merz Aesthetics, Inc. Franksville, WI 53126	Addition of defect categories to an existing incoming inspection procedure.
P050012/S049 10/23/12	Dexcom SEVEN® PLUS Continuous Glucose Monitoring System	Dexcom, Inc. San Diego, CA 92121	Change to a torque driver used in the receiver component assembly process of the device.
P050023/S055 10/10/12	Corox OTW UP Steriod, and Lumax 300 DR-T/340 DR-T/300 VR-T/340 VR-T/500 DT-T/540 DR -T/500 VR-T/540 VR-T/540 VRT-DX/300 HFT/340 HF-T/500 HF-T/540 HF-T	Biotronik, Inc. Lake Oswego, OR 97035	Addition of suppliers for components used in the devices.
P050028/S027 10/10/12	COBAS® TaqMan HBV Test For Use With The High Pure System and COBAS® AmpliPrep/ COBAS® TaqMan® HBV Test	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Scale up of a bulk enzyme used in the manufacture of kit components.
P050037/S034 10/17/12	Radiesse Injectable Implant	Merz Aesthetics, Inc. Franksville, WI 53126	Addition of defect categories to the incoming inspection procedures based on risk and commensurate with severity.
P050039/S012 10/17/12	Exactech Novation Ceramic Articulation Hip System	Exactech, Inc. Gainesville, FL 32653	Addition of a new sealer.
P050044/S024 10/4/12	Vitagel Surgical Hemostat	Stryker Orthobiologics Malvern, PA 19355	Relocate certain Vitagel Surgical Hemostat assembly and packaging manufacturing equipment within the current

			manufacturing facility.
P050046/S016 10/3/12	Acuity Steerable Leads	Boston Scientific Corporation St. Paul, MN 55112	Changes to the dexamethasone acetate drug substance specification and testing.
P050047/S028 10/25/12	JUVÉDERM Hyaluronate Gel Implants	Allergan	Change in the residual crosslinker analysis method for the device.
P050052/S037 10/17/12	Radiesse Injectable Implant	Merz Aesthetics, Inc. Franksville, WI 53126	Addition of defect categories to the incoming inspection procedures based on risk and commensurate with severity.
P060006/S035 10/31/12	Express SD Renal Monorail Premounted Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Alternate inspection equipment for the extruded tubing component.
P060007/S021 10/15/12	ARCHITECT HBsAg and HBsAg Confirmatory	Abbott Laboratories Abbott Park, IL 60064	Change in test method used for the determination of antibody activity during manufacture.
P060008/S098 10/31/12	TAXUS Liberté Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Alternate inspection equipment for the extruded tubing component.
P060022/S014 10/4/12	Akreos Intraocular Lenses	Bausch & Lomb, Inc. Aliso Viejo, CA 92656	New supplier for the 2-hydroxyl ethyl methacrylate (HEMA) monomer used in the manufacture of Akreos IOLs.
P060030/S029 10/10/12	COBAS® AmpliPrep/ COBAS® TaqMan® HCV Test and COBAS® TaqMan HCV Test For Use With The	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Scale up of a bulk enzyme used in the manufacture of kit components.

	High Pure System		
P060039/S036 10/3/12	Attain StarFix Lead	Medtronic, Inc. Mounds View, MN 55112	New annealing vacuum oven.
P060039/S037 10/15/12	Attain StarFix Lead	Medtronic, Inc. Mounds View, MN 55112	Alternate suppliers for molded components.
P060039/S038 10/25/12	Attain StarFix Lead	Medtronic, Inc. Mounds View, MN 55112	Transfer of incoming inspection location for various components.
P070008/S034 10/10/12	Corox OTW-S BP/OTW-L BP	Biotronik, Inc. Lake Oswego, OR 97035	Addition of suppliers for components used in the devices.
P070015/S101 10/23/12	XIENCE V and XIENCE nano Everolimus-Eluting Coronary Stent Systems	Abbott Vascular, Inc. Temecula, CA 92591	Modification the pyrogen sampling frequency.
P080006/S044 10/3/12	Attain Ability Leads	Medtronic, Inc. Mounds View, MN 55112	New annealing vacuum oven.
P080006/S045 10/25/12	Attain Ability Leads	Medtronic, Inc. Mounds View, MN 55112	Transfer of incoming inspection location for various components.
P080025/S038 10/10/12	InterStim II	Medtronic Neuromodulation Minneapolis, MN 55432	Use of the new Automated Assembly Equipment Controller software release, interfacing with the Manufacturing Execution System at the hybrid component supplier.
P080025/S039 10/24/12	Itrel 3, Synergy, Syngery Versitrel, Itrel 4, Pocket Adaptors, Soletra, Kinetra, Activa SC, InterStim, and Enterra	Medtronic Neuromodulation Minneapolis, MN 55432	Manufacture of one inner seal silicone component at the alternate supplier, Flexan located in Suzhou Industrial Park, China.

P090003/S016 10/12/12	Express LD Illiac Premounted Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Addition of an alternate electropolishing recipe.
P090003/S017 10/23/12	Express LD Iliac Premounted Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Use of a new extrusion die.
P090007/S010 10/4/12	Elecsys® Anti-HCV Immunoassay and Elecsys® PreciControl Anti-HCV for use on the cobas e 411 Immunoassay Analyzer	Roche Diagnostics Corporation Indianapolis, IN 46250	Harmonization of the lyophilization process for peptide manufacturing.
P090008/S011 10/4/12	Elecsys® Anti-HCV Immunoassay and Elecsys® PreciControl Anti-HCV for use on the cobas e 601 Immunoassay Analyzer	Roche Diagnostics Corporation Indianapolis, IN 46250	Harmonization of the lyophilization process for peptide manufacturing.
P090009/S010 10/4/10	Elecsys® Anti-HCV Immunoassay and Elecsys® PreciControl Anti-HCV for use on the MODULAR ANALYTICS E170 Analyzer	Roche Diagnostics Corporation Indianapolis, IN 46250	Harmonization of the lyophilization process for peptide manufacturing.
P090013/S074 10/15/12	CapSureFix MRI Lead	Medtronic, Inc. Mounds View, MN 55112	Alternate suppliers for molded components.
P090013/S075 10/25/12	CapSureFix MRI Lead	Medtronic, Inc. Mounds View, MN 55112	Transfer of incoming inspection location for various components.
P090013/S076 10/31/12	Revo MRI IPG	Medtronic, Inc. Minneapolis, MN 55112	Elimination of the incoming inspection of a battery component at an internal supplier location.
P090028/S003 10/17/12	VITROS® Immunodiagnostic	Ortho-Clinical Diagnostics, Inc.	Change to the manufacturing

	Products HBeAg Reagent Pack, Calibrator and Controls	Rochester, NY 14626	process and storage conditions of the antifoam solution.
P100001/S002 10/17/12	VITROS® Immunodiagnostic Products Anti-HBc Reagent Pack, Calibrator and Controls	Ortho-Clinical Diagnostics, Inc. Rochester, NY 14626	Change to the manufacturing process and storage conditions of the antifoam solution.
P100010/S019 10/10/12	Arctic Front Cardiac and Arctic Front Advance CryoAblation Catheters	Medtronic, Inc. Mounds View, MN 55112	Change in the outer balloon curing fixture and process changes.
P100013/S006 10/12/12	EXOSEAL Vascular Closure Device	Cordis Corporation Bridgewater, NJ 08807	An alternate tool for positioning a component and the addition of two optical sensors.
P100023/S055 10/24/12	ION Paclitaxel-Eluting Platinum Chromium Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Changes to weld and heat shrink removal process parameters.
P110007/S001 10/9/12	Abbott Medical Optics (AMO) Heaton EndoCoat Ophthalmic Viscosurgical Device (3% Sodium Hyaluronate Ophthalmic Viscosurgical Device)	Abbott Medical Optics, Incorporated Santa Ana, CA 92705	Change from a manual to an automated process for the syringe and carton assemblies.
P110010/S030 10/24/12	PROMUS Element Plus Everolimus-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Changes to weld and heat shrink removal process parameters.
P110019/S033 10/11/12	XIENCE PRIME and XIENCE PRIME LL Everolimus Eluting Coronary Stent Systems	Abbott Vascular Temecula, CA 92591	Add an alternate compressed gas in the manufacturing of the devices.
P110019/S034 10/23/12	XIENCE Prime and XIENCE Prime LL Everolimus-Eluting Coronary Stent	Abbott Vascular, Inc. Temecula, CA 92591	Modification to the pyrogen sampling frequency.

	Systems		
P110029/S005 10/15/12	ARCHITECT HBsAg Qualitative and HBsAg Qualitative Confirmatory	Abbott Laboratories Abbott Park, IL 60064	Change in test method used for the determination of antibody activity during manufacture.

Summary of PMA Originals & Supplements Approved
Originals: 7
Supplements: 69

Summary of PMA Originals Under Review
Total Under Review: 51
Total Active: 21
Total On Hold: 30

Summary of PMA Supplements Under Review
Total Under Review: 555
Total Active: 392
Total On Hold: 163

Summary of All PMA Submissions Received
Originals: 2
Supplements: 71

Summary of PMA Supplement PMA Approval/Denial Decision Times
Number of Approvals: 69
Number of Denials: 0
Average Days Fr Receipt to Decision (Total Time): 164
FDA Time: 123.6 Days MFR Time: 40.4 Days

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