PMA Final Decisions for November 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
P100022 **[1] 11/14/12**	Zilver PTX Drug-Eluting Peripheral Stent (6- 8 mm diameter; 20- 80 mm length)	Cook Incorporated Bloomington, IN 47402	Approval for the Zilver PTX Drug-Eluting Peripheral Stent. This device is indicated for improving luminal diameter for the treatment of *de novo* or restenotic symptomatic lesions in native vascular disease of the above-the-knee femoropopliteal arteries having reference vessel diameters from 4 mm to 9 mm and total lesion lengths up to 140 mm per limb and 280 mm per patient.
P100047 **[2] 11/20/12**	HeartWare® Ventricular Assist System	HeartWare, Inc. Miami Lakes, FL 33014	Approval for the HeartWare® Ventricular Assist System (VAS). This device is indicated for use as a bridge to cardiac

			transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The Heart Ware® VAS is designed for in-hospital and out-of-hospital settings, including transportation via fixed wing aircraft or helicopter.
P120002 **[3]** **11/7/12**	S.M.A.R.T.® CONTROL® and S.M.A.R.T.® Vascular Stent Systems	Cordis Corporation Miami Lakes, FL 33014	Approval for the S.M.A.R.T.® CONTROL® and S.M.A.R.T.® Vascular Stent Systems. This device is indicated for use to improve luminal diameter in the treatment of patients with de novo or restenotic native lesion(s) of the superficial femoral artery and/or proximal popliteal artery with total length up to 150 mm and with a reference vessel diameter ranging from 4 mm to 7 mm.
P120008 **[4]** **11/28/12**	ARCHITECT AFP Assay, ARCHITECT AFP Calibrators and ARCHITECT AFP Controls	Abbott Laboratories Abbott Park, IL 60064	Approval for the ARCHITECT AFP Assay, ARCHITECT AFP Calibrators and ARCHITECT AFP Controls. This device is indicated for: The ARCHITECT AFP assay is a

			chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of alpha-fetoprotein (AFP) in: 1) Human serum or plasma to aid in monitoring disease progression during the course of disease and treatment of patients with nonseminomatous testicular cancer; and 2) Human serum, plasma, and amniotic fluid at 15 to 21 weeks gestation to aid in the detection of fetal open neural tube defects (NTD). Test results when used in conjunction with ultrasonography or amniography are a safe and effective aid in the detection of fetal open NTD. The ARCHITECT AFP Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of alpha-fetoprotein (AFP) in human serum, plasma, and amniotic fluid. The performance of the ARCHITECT AFP Calibrators has not

			been established with any other AFP assays. The ARCHITECT AFP Controls are for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT *i* System when used for the quantitative determination of alpha-fetoprotein (AFP) in human serum, plasma, and amniotic fluid. The performance of the ARCHITECT AFP controls has not been established with any other AFP assays.

PMA Supplemental Approvals

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
P810002/S078 11/1/12 Real-Time	SJM Regent Mechanical Heart Valve, Mechanical Heart Valve SJM Masters Series (PTFE), Mechanical Heart Valve SJM Masters Series (Polyester) Mechanical HV SJM Masters Series Coated Aortic Valve Graft, SJM Masters HP Valved Graft w/Gelweave Valsalva Tech	St. Jude Medical St. Paul, MN 55117	Approval to update the Instructions for Use (IFU), St. Jude Medical (SJM) internet, and any other applicable device labeling to include the new magnetic resonance imaging (MRI) testing information to enhance the safe use of the device when undergoing MRI.
P830055/S127	LCS® Total Knee	DePuy	Approval for the

11/19/12 Real-Time	System	Orthopaedics, Inc. Warsaw, IN 46581	addition of mobile bearing Attune PS RP tibial inserts that are modifications to the previously approved LCS Complete/PFC Sigma RP/Attune RP tibial inserts, and are intended to be used with the cleared Attune Total Knee System femoral, patella, and components. The supplement also requests the addition of a 9mm tibial insert thickness for all sizes (I - I 0) of Attune CR RP tibial inserts. The new inserts are manufactured from the antioxidant polyethylene material (AOX™). The device, as modified, will be marketed under the trade name Attune™ and is indicated for use in total knee replacement in patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, or a failed previous implant.
P830055/S128 11/19/12 Special	LCS® Total Knee System	DePuy Orthopaedics, Inc. Warsaw, IN	Approval for an additional rinse step being implemented

		46581	in the manufacturing process for the MBT Cemented and Porous Trays and the Attune RP Tibial Base.
P850048/S028 **11/19/12** **Special**	Access Hybritech PSA reagents on the Access Immunoassay Systems	Beckman Coulter, Inc. Chaska, MN 55318	Approval for the addition of information to the Manufacturing procedures of the instrument (specifically, the instructions for application of the adhesive to the mixer pulley assembly and the implementation of a verification test to ensure the mixer pulley assemblies pass the torque specification.)
P860003/S066 **11/9/12** **Real-Time**	THERAKOS® UVAR XTS® Photopheresis System Procedural Kit	THERAKOS, Inc. Raritan, NJ 08869	Approval for the addition of 8 ribs to the neck of the centrifuge bowls used in the device and for the accompanying packaging changes.
P860003/S067 **11/19/12** **Real-Time**	THERAKOS® CELLEX® Photopheresis System	THERAKOS, Inc. Raritan, NJ 08869	Approval for some minor changes intended to reduce specular reflection of the KT8L sensor's laser beam and improve its optic path (e.g., removal of glass port, removal of resistor, and addition of gasket).
P880006/S082 **11/7/12** **Real-Time**	Sensolog, Dialog and Regency Family of Pacemakers	St. Jude Medical Sylmar, CA 91342	Approval for software changes to the Merlin PCS

			Programmer.
P880086/S223 **11/7/12** **Real-Time**	Affinity, Integrity, Victory, Zephyr, and Accent Family of Pacemakers	St. Jude Medical Sylmar, CA 91342	Approval for software changes to the Merlin PCS Programmer.
P900060/S050 **11/5/12** **135-Day**	Carbomedics Prosthetic Heart Valve	Sorin Group USA, Inc. Arvada, CO 80004	Approval for addition of an alternate supplier for manufacturing of the graphite substrate of valve leaflets.
P910023/S302 **11/7/12** **Real-Time**	Cadence and Current Family of ICDs	St. Jude Medical Sylmar, CA 91342	Approval for software changes to the Merlin PCS Programmer.
P930027/S015 **11/8/12** **135-Day**	IMMULITE PSA Assay	Siemens Medical Solutions Diagnostics East Walpole, MA 02032	Approval for eliminating the test redundancy by using only the BioRad Lyphocheck Immunoassay Plus controls in in-process component testing, post-fill testing and final kit combination testing for the assessment of IMMULITE AFP, Free PSA, and PSA/3 rd Generation PSA assay performance.
P950024/S040 **11/27/12** **180-Day**	CapSure Epi Epicardial Lead	Medtronic, Inc. Mounds View, MN 55112	Approval to add Model 4965 post-approval study results to the device labeling.
P950024/S044 **11/27/12** **180-Day**	CapSure Epi Epicardial Lead	Medtronic, Inc. Mounds View, MN 55112	Approval to add Model 4968 post-approval study results to the device labeling.
P950032/S069 **11/20/12** **Real-Time**	Apligraf (Graftskin)	Organogenesis, Incorporated Canton, MA 02021	Approval for the introduction of Human Epidermal Keratinocyte cell strain 200 (HEP

			200) into the manufacture of the device.
P960040/S266 **11/14/12** **135-Day**	Incepta, Energen, Punctua, Teligen, Confient ICDs	Boston Scientific Corporation St. Paul, MN 55112	Approval for the addition of an automated vision system during seal plug inspection.
P960040/S270 **11/30/12** **180-Day**	Incepta, Energen, Punctua and Teligen Implantable Cardioverter Defibrillator	Boston Scientific Corporation St. Paul, MN 55112	Approval for software, firmware, and hardware enhancements and modifications to the INCEPTA, ENERGEN, PUNCTUA, COGNIS, and TELIGEN devices.
D970003/S137 **11/14/12** **135-Day**	Advantio, Ingenio, Altrua Pacemakers	Boston Scientific Corporation St. Paul, MN 55112	Approval for the addition of an automated vision system during seal plug inspection.
P970004/S141 **11/1/12** **180-Day**	Interstim Therapy	Medtronic Vascular Minneapolis, MN 55432	Approval for the post-approval study protocol.
P970013/S051 **11/7/12** **Real-Time**	Microny Family of Pacemakers	St. Jude Medical Sylmar, CA 91342	Approval for software changes to the Merlin PCS Programmer.
P970018/S025 **11/8/12** **135-Day**	BD PrepStain System	TriPath Imaging Durham, NC 27703	Approval for a supplier change to the raw microsope slide, a critical component in the device.
P970038/S017 **11/19/12** **Special**	Access Hybritech Free reagents on the Access Immunoassay Systems	Beckman Coulter, Inc. Chaska, MN 55318	Approval for the addition of information to the Manufacturing procedures of the instrument (specifically, the instructions for application of the adhesive to the mixer pulley assembly and the

			implementation of a verification test to ensure the mixer pulley assemblies pass the torque specification.)
P970051/S097 11/9/12 Real-Time	Nucleus® Cochlear™ Implant System	Cochlear Americas Centennial, CO 80111	Approval to introduce a remote control (CR120) for use with the Nucleus 5 (model CP810) sound processor for intraoperative use to conduct impedance and AutoNRT, measurements that are commonly used during cochlear implant surgery to indicate that the electrodes are functioning and are stimulating nerve tissue.
P980016/S384 11/2/12 Real-Time	Entrust, Intrinsic, Marquis, Onyx, Secura, Gem, Maximo, Protecta and Virtuoso	Medtronic, Inc. Mounds View, MN 55112	Approval for an update to the raw material of the capacitors used in the high voltage delivery circuitry.
P980022/S124 11/16/12 Real-Time	iPro2 Continuous Glucose Monitoring (COM) System	Medtronic MiniMed Northridge, CA 91325	Approval for software modifications to the CareLink iPro Therapy Management Software (MMT-7340) from version 1.4 to version 1.5A. The CareLink iPro Therapy Management Software (MMT-7340) is a component of the

			iPro2 Professional CGM System (MMT-7745).
P980041/S018 11/19/12 Special	Access Hybritech AFP reagents on the Access Immunoassay Systems	Beckman Coulter, Inc. Chaska, MN 55318	Approval for the addition of information to the Manufacturing procedures of the instrument (specifically, the instructions for application of the adhesive to the mixer pulley assembly and the implementation of a verification test to ensure the mixer pulley assemblies pass the torque specification.)
P990038/S017 11/30/12 Special	ETI-MAK-2 PLUS Assay	DiaSorin, Inc. Stillwater, MN 55082	Approval for a change to improve the sampling plan in the Quality Control Method for the incoming raw material microwell plates.
P990041/S016 11/30/12 Special	ETI-AB-EBK Assay	DiaSorin, Inc. Stillwater, MN 55082	Approval for a change to improve the sampling plan in the Quality Control Method for the incoming raw material microwell plates.
P990042/S013 11/30/12 Special	ETI-AB-AUK Plus Assay	DiaSorin, Inc. Stillwater, MN 55082	Approval for a change to improve the sampling plan in the Quality Control Method for the incoming raw material microwell plates.
P990043/S017 11/30/12 Special	ETI-EBK PLUS Assay	DiaSorin, Inc. Stillwater, MN 55082	Approval for a change to improve the sampling plan in

			the Quality Control Method for the incoming raw material microwell plates.
P990044/S014 11/30/12 Special	ETI-CORE-IGMK PLUS Assay	DiaSorin, Inc. Stillwater, MN 55082	Approval for a change to improve the sampling plan in the Quality Control Method for the incoming raw material microwell plates.
P990045/S014 11/30/12 Special	ETI-AB-COREK PLUS Assay	DiaSorin, Inc. Stillwater, MN 55082	Approval for a change to improve the sampling plan in the Quality Control Method for the incoming raw material microwell plates.
P990071/S020 11/20/12 Real-Time	CoolFlow Irrigation Pump	Biosense Webster, Inc. Diamond Bar, CA 91765	Approval for software and hardware modifications implemented to make the device compliant to IEC 60601-1 3 rd Edition.
P990081/S014 11/14/12 Real-Time	PATHWAY Anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody	Ventana Medical Systems, Inc. Tucson, AZ 85755	Approval for implementing a change to the Ventana regent dispenser seal for the Benchmark automated staining instruments.
P000008/S029 11/9/12 180-Day	LAP-BAND Adjustable Gastric Banding (LAGB) System	Allergan, Inc. Goleta, CA 93117	Approval of the post-approval study protocol.
P000013/S011 11/2/12 180-Day	Trident Ceramic-on-Ceramic Acetabular System	Howmedica Osteonics Corporation Mahwah, NJ 07430	Approval for labeling updates incorporating results of the completed post-

			approval study.
P000025/S058 11/21/12 180-Day	MED-EL COMBI 40+ Cochlear Implant System and Mi1000 MED-EL CONCERT PIN Cochlear Implant.	MED-EL Corporation Durham, NC 27713	Approval for the Mi1000 MED-EL CONCERT PIN cochlear implant.
P000025/S064 11/1/12 Real-Time	MED-EL COMBI 40+ Cochlear Implant System, MED-EL CONCERT Implant	MED-EL Corporation Durham, NC 27713	Approval for a minor design change to the stimulator housing component of the Mi1000 MED-EL CONCERT implant that is intended to correct an error of dimensional tolerance of the housing components used in the manufacturing of the devices.
P000053/S046 11/13/12 Real-Time	AMS 800™ Urinary Control System	American Medical Systems, Inc. Minnetonka, MN 55343	Approval for minor design change to the Pump Shell Interface tolerances.
P010007/S009 11/8/12 135-Day	IMMULITE AFP Assay	Siemens Medical Solutions Diagnostics East Walpole, MA 02032	Approval for eliminating the test redundancy by using only the BioRad Lyphocheck Immunoassay Plus controls in in-process component testing, post-fill testing and final kit combination testing for the assessment of IMMULITE AFP, Free PSA, and PSA/3rd Generation PSA assay performance.
P010012/S296 11/14/12 135-Day	Incepta, Energen, Punctua, Cognis, Livian CRT-Ds	Boston Scientific Corporation St. Paul, MN 55112	Approval for the addition of an automated vision system during seal plug inspection.

P010012/S300 **11/30/12** **180-Day**	Incepta, Energen, Punctua and Cognis Cardiac Resynchronization Therapy-Defibrillator	Boston Scientific Corporation St. Paul, MN 55112	Approval for software, firmware, and hardware enhancements and modifications to the INCEPTA, ENERGEN, PUNCTUA, COGNIS, and TELIGEN devices.
P010013/S045 **11/15/12** **Real-Time**	NovaSure Impedance Controlled Endometrial Ablation System	Hologic, Inc. Malborough, MA 01752	Approval for a change to fittings in the suction and vacuum feedback lines and minor labeling changes.
P010030/S031 **11/2/12** **180-Day**	LifeVest Wearable Defibrillator	Zoll Lifecor Corporation Pittsburgh, PA 15238	Approval for several hardware design changes and a software driver upate.
P010031/S336 **11/2/12** **Real-Time**	Consulta, Maximo II, Concerto and Insync	Medtronic, Inc. Mounds View, MN 55112	Approval for an update to the raw material of the capacitors used in the high voltage delivery circuitry.
P010033/S020 **11/15/12** **180-Day**	QuantiFERON® Gold In-Tube	Cellestis Incorporated Valencia, CA 91355	Approval for a change in the formulation of the Wash Buffer 20X Concentrate.
P010038/S016 **11/9/12** **180-Day**	SecondLook DigitalV7.2 CAD	iCAD, Inc. Nashua, NH 03062	Approval for the SecondLook Digital V7.2 CAD for use with the Philips MicroDose full-field digital mammography (FFDM) system.
P020004/S072 **11/7/12** **135-Day**	GORE EXCLUDER AAA Endoprosthesis	W.L. Gore & Associates, Inc. Flagstaff, AZ 86001	Approval for use of an alternate PTFE resin.
P020004/S074 **11/20/12** **180-Day**	GORE® EXCLUDER® AAA Endoprosthesis	W.L. Gore & Associates, Inc. Phoenix, AZ 85085	Approval for the additions of the 35 mm Trunk-Ipsilateral Leg and

			36 mm Aortic Extender components to the GORE EXCLUDER AAA Endoprosthesis product portfolio.
P020004/S075 11/20/12 Real-Time	GORE® EXCLUDER® AAA Endoprosthesis	W.L. Gore & Associates, Inc. Phoenix, AZ 85085	Approval for the modification of the delivery system for the following device components of the GORE EXCLUDER AAA Endoprosthesis on the SIM-PULL (original) and C3 (EMDS) catheters in order to lower their delivery profiles as outlined below: 1) 16, 18 and 20 mm Contralateral Legs from 18 Fr to 12 Fr; 2) 23 mm Contralateral Leg from 18 Fr to 14 Fr; 3) 27 mm Colateral Leg from 18 Fr to 15 Fr; 4) 23, 26, 28.5 mm Aortic Extenders from 18 Fr to 16 Fr; 5) 32 mm Aortic Extender from 20 Fr to 17 Fr; 6) 31 mm Trunk-Ipsilateral Leg with SIM-PULL delivery system from 20 Fr to 18 Fr; and 7) 31 mm Trunk-Ipsilateral Leg with C3 delivery system from 20 Fr to 18 Fr.
P020055/S004 11/14/12 Real-Time	PATHWAY Anti-c-KIT (9.7) Rabbit Monoclonal Primary Antibody	Ventana Medical Systems, Inc. Tucson, AZ 85755	Approval for implementing a change to the Ventana regent dispenser seal for

			the Benchmark automated staining instruments.
P030005/S085 **11/14/12** **135-Day**	Invive CRT-Ps	Boston Scientific Corporation St. Paul, MN 55112	Approval for the addition of an automated vision system during seal plug inspection.
P030017/S144 **11/16/12** **Real-Time**	Implantable Pulse Generator (IPG)	Boston Scientific Neuromodulation (BSN) Valencia, CA 91355	Approval for a material change or the Implantable Pulse Generator (IPG) antenna coil from gold to copper.
P030017/S145 **11/19/12** **Real-Time**	Precision Spinal Cord Stimulator (SCS)	Boston Scientific Neuromodulation (BSN) Valencia, CA 91355	Approval for an update to the Clinician Programmer computer used with the device. A tablet computer from ASUS, model EEE Slate B121, will be used to replace the current Clinician Programmer (CP), a Toshiba model M400 laptop computer.
P030035/S101 **11/7/12** **Real-Time**	Frontier, Frontier II, and Anthem Family of CRT-Ps	St. Jude Medical Sylmar, CA 91342	Approval for software changes to the Merlin PCS Programmer.
P030036/S040 **11/2/12** **180-Day**	SelectSecure Lead	Medtronic CRDM Mounds View, MN 55112	Approval for improvements to the SelectSecure Model 3830 lead drug methods and specifications.
P030052/S010 **11/13/12** **Special**	UroVysion Bladder Cancer Kit	Abbott Molecular, Inc. Des Plaines, IL 60018	Approval for labeling changes to the UroVysion Bladder Cancer Kit package insert, kit and vial labeling.
P030054/S230 **11/7/12**	Epic HF, Atlas+ HF, and Promote Family	St. Jude Medical Sylmar, CA	Approval for software changes to

Real-Time	of CRT-Ds	91342	the Merlin PCS Programmer.
P040011/S002 **11/2/12** **180-Day**	c-Kit pharmDx™	Dako North America, Inc. Carpinteria, CA 93013	Approval for changing the company prefix to the device name (from Dako-Cytomation c-Kit pharmDx™ to c-Kit pharmDx™). The device, as modified, will be marketed under the trade name c-Kit pharmDx™.
P040016/S093 **11/5/12** **135-Day**	VeriFLEX(Liberte) Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Approval for use of an alternate cleaning procedure.
P040021/S020 **11/1/12** **Real-Time**	SJM Epic Valve SJM Biocor Valve	St. Jude Medical St. Paul, MN 55117	Approval to update the Instructions for Use (IFU), St. Jude Medical (SJM) internet, and any other applicable device labeling to include the new magnetic resonance imaging (MRI) testing information to enhance the safe use of the device when undergoing MRI.
P040043/S047 **11/7/12** **135-Day**	GORE TAG THORACIC Endoprosthesis	W.L. Gore & Associates, Inc. Flagstaff, AZ 86001	Approval for use of an alternate PTFE resin.
P050006/S029 **11/26/12** **135-Day**	GORE HELEX Septal Occluder	W. L. Gore & Associates, Inc. Flagstaff, AZ 86001	Approval for use of new testing equipment.
P050037/S023 **11/6/12** **135-Day**	Radiesse Injectable Implant	Merz Aesthetics, Inc. Franksville, WI 53126	Approval for addition of new clean suites to existing clean room facility.

P050037/S032 **11/8/12** **135-Day**	Radiesse Injectable Implant	Merz Aesthetics, Inc. Franksville, WI 53126	Approval for a change to syringe assembly.
P050048/S007 **11/13/12** **135-Day**	MONOLISA™ Anti-HBs EIA and MONOLISA™ Anti-HBs Calibrator Kit	Bio-Rad Laboratories, Inc. Redmond, WA 98052	Approval for the modification of the quality control testing specification for the 400 mIU/mL Calibrator in the device.
P050052/S026 **11/6/12** **135-Day**	Radiesse Injectable Implant	Merz Aesthetics, Inc. Franksville, WI 53126	Approval for addition of new clean suites to existing clean room facility.
P050052/S035 **11/8/12** **135-Day**	Radiesse Injectable Implant	Merz Aesthetics, Inc. Franksville, WI 53126	Approval for a change to syringe assembly.
P060005/S008 **11/8/12** **135-Day**	IMMULITE FPSA Assay	Siemens Medical Solutions Diagnostics East Walpole, MA 02032	Approval for eliminating the test redundancy by using only the BioRad Lyphocheck Immunoassay Plus controls in in-process component testing, post-fill testing and final kit combination testing for the assessment of IMMULITE AFP, Free PSA, and PSA/3rd Generation PSA assay performance.
P060006/S031 **11/5/12** **135-Day**	Express SD Monorail Premounted Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Approval for use of an alternate cleaning procedure.
P060008/S093 **11/5/12** **135-Day**	TAXUS Liberte Paciltaxel-eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Approval for use of an alternate cleaning procedure.
P060019/S023 **11/29/12** **135-Day**	Safire BLU and Therapy Cool Path Bi-Directional	St. Jude Medical Irvine, CA 92614	Approval for an alternate supplier of the catheter shaft

	Ablation Catheters		subassembly.
P060023/S003 **11/30/12** **135-Day**	Bryan Cervical Disc	Medtronic Sofamor Danek Memphis, TN 38132	Approval for a revision to the bioburden enumeration test frequency for ethylene oxide.
P070016/S005 **11/5/12** **135-Day**	Zenith TX2 TAA Endovascular Graft	Cook Incorporated Bloomington, IN 47402	Approval for in-house manufacture of stent graft material.
P070026/S008 **11/21/12** **Real-Time**	DePuy Ceramax Ceramic Total Hip System	DePuy Orthopaedics, Incorporated Warsaw, IN 46581	Approval for addition of Summit Porocoat Stems as a compatible component to existing 28 mm ceramic head.
P070026/S009 **11/21/12** **Real-Time**	DePuy Ceramax Ceramic Total Hip System	DePuy Orthopaedics, Incorporated Warsaw, IN 46581	Approval for addition of Pinnacle 300, Multi-hole II and Sector II acetabular cup components.
P080011/S018 **11/1/12** **180-Day**	Biofinity (comfilcon A) Soft (Hydrophilic) Contact Lenses	CooperVision, Incorporated Pleasanton, CA 94588	Approval for a manufacturing site located at CooperVision Caribbean Corporation in Juana Diaz, Puerto Rico.
P080030/S001 **11/15/12** **135-Day**	Glaukos Corporation iStent Trabecular Micro-Bypass Stent System	Glaukos Corporation Laguna Hills, CA 92653	Approval of the shelf-life extension for two lots of Duraflo coating material used in the device.
P080030/S002 **11/8/12** **135-Day**	Glaukos Corporation iStent Trabecular Micro-Bypass Stent System	Glaukos Corporation Laguna Hills, CA 92653	Modifications to the design of the outer blister tray used for device packaging.
P080032/S010 **11/9/12** **Special**	Alair Bronchial Thermoplasty System	Boston Scientific Corporation Sunnyvale, CA 94089	Approval for labeling changes to the Alair Catheter Model ATS 2-5 Directions For Use

			(DFU), Alair Radiofrequency (RF) Controller Model ATS 200 Operator's Manual, and Alair Bronchial Thermoplasty System Patient Brochure.
P090003/S014 **11/5/12** **135-Day**	Express LD Monorail Iliac Premounted Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Approval for use of an alternate cleaning procedure.
P090018/S011 **11/13/12** **135-Day**	Esteem	Envoy Medical Corporation Saint Paul, MN 55110	Approval for the EO Sterilization load configuration change for the Esteem product family.
P090026/S001 **11/19/12** **Special**	Access Hybritech Free p2PSA reagents on the Access Immunoassay Systems	Beckman Coulter, Inc. Chaska, MN 55318	Approval for the addition of information to the Manufacturing procedures of the instrument (specifically, the instructions for application of the adhesive to the mixer pulley assembly and the implementation of a verification test to ensure the mixer pulley assemblies pass the torque specification.)
P100020/S005 **11/19/12** **Real-Time**	cobas® HPV Test	Roche Molecular Systems, Inc. Pleasanton, CA 94558	Approval for changes to the CPU component of the cobas® z480 Analyzer.
P100024/S003 **11/27/12** **Real-Time**	*HER2* CISH pharmDx™ Kit	Dako Denmark A/S Glostrup, Denmark DK-2600	Approval for a change in the mounting medium reagent supplied in the kit.

P100025/S003 **11/6/12** **Special**	BreathTek® UBT for *H. pylori* Kit	Otsuka Product Development & Commercialization, Inc. Rockville, MD 20850	Approval for a labeling change to enhance the safe use of the device.
P100027/S003 **11/14/12** **Real-Time**	INFORM HER-2 DUAL ISH DNA Probe Cocktail	Ventana Medical Systems, Inc. Tucson, AZ 85755	Approval for implementing a change to the Ventana regent dispenser seal for the Benchmark automated staining instruments.
P100027/S004 **11/21/12** **Real-Time**	INFORM HER-2 Dual ISH DNA Probe Cocktail	Ventana Medical Systems, Inc. Tucson, AZ 85755	Approval for the change of the two liter (2L) bottles for each of the aqueous-based reagents from fluorinated to non-fluorinated bottles.
P100029/S008 **11/1/12** **Real-Time**	Trifecta Heart Valve	St. Jude Medical St. Paul, MN 55117	Approval to update the Instructions for Use (IFU), St. Jude Medical (SJM) internet, and any other applicable device labeling to include the new magnetic resonance imaging (MRI) testing information to enhance the safe use of the device when undergoing MRI.
P100041/S011 **11/6/12** **180-Day**	Edwards Sapien Transcatheter Heart Valve	Edwards Lifesciences, LLC Irvine, CA 92614	Approval of the post-approval study protocol.
P100044/S003 **11/9/12** **Real-Time**	Propel™ Mini Sinus Implant	Intersect ENT Palo Alto, CA 94303	Approval for modifications to the stent crimper and delivery system accessory components of the device.

P110016/S005 11/29/12 135-Day	Safire BLU Duo Therapy Ablation Catheters	St. Jude Medical Irvine, CA 92614	Approval for an alternate supplier of the catheter shaft subassembly.
P110019/S031 11/20/12 180-Day	XIENCE PRIME® Everolimus Eluting Coronary Stent Systems (EECSS)	Abbott Vascular, Inc. Temecula, CA 92591	Approval to change the manufacturing and testing of the Active Pharmaceutical Ingredient (API) used in the manufacture of the device.
P110020/S004 11/19/12 Real-Time	cobas® 4800 BRAF V600 Mutation Test	Roche Molecular Systems, Inc. Pleasanton, CA 94558	Approval for changes to the CPU component of the cobas® z480 Analyzer.
P110043/S003 11/16/12 180-Day	Omnilink Elite Vascular Balloon-Expandable Stent System	Abbott Vascular Santa Clara, CA 94054	Approval for an e-beam sterilization site located at Synergy Health Ireland in Offaly, Ireland.

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
P830037/S054 11/8/12	FreshLook (phemfilcon A) Toric Soft Contact Lenses	CIBA Vision Corporation Duluth, GA 30097	Change to the production of casting cups.
P830060/S073 11/9/12	Ventak AICD System	Boston Scientific Corporation St. Paul, MN 55112	Software upgrade to the existing sterilizer system, a change in the existing sterilization process and addition of a new sterilization chamber.
P830061/S081 11/19/12	Capsure Sense Lead, Capsure Sense Unipolar Lead, Capsure	Medtronic, Inc. Mounds View, MN 55112	Addition of an alternative testing system for electrode

	Sense Bipolar Lead, Vitatron Crystalline Leads		components.
P840001/S229 11/2/12	Spinal Cord Stimulation, Implantable Neurostimulators, Itrel 4	Medtronic Neuromodulation Minneapolis, MN 55432	Change in the receiving inspection method used on the coated cathode current collector.
P840068/S051 11/9/12	Delta and Vista PGs	Boston Scientific Corporation St. Paul, MN 55112	Software upgrade to the existing sterilizer system, a change in the existing sterilization process and addition of a new sterilization chamber.
P850079/S058 11/8/12	Methafilcon A Soft Extended Wear Contact Lenses	CooperVision, Inc. Pleasanton, CA 94588	Change in the manufacturing remake process.
P850079/S059 11/8/12	Methafilcon A Soft (Hydrophilic) Extended Wear Contact Lenses	CooperVision, Inc. Pleasanton, CA 94588	Decrease in hydration time on Automated Wet Line (AWL) systems.
P850079/S060 11/20/12	Methafilcon A Soft (Hydrophilic) Extended Wear Contact Lenses	CooperVision, Inc. Pleasanton, CA 94588	Eliminate secondary repeat testing.
P850079/S061 11/20/12	Methafilcon A Soft (Hydrophilic) Extended Wear Contact Lenses	CooperVision, Inc. Pleasanton, CA 94588	Use of fully automated manufacturing equipment in the production of methafilcon A contact lenses.
P860004/S176 11/2/12	Drug Delivery Infusion Pumps SynchroMed Family, SynchroMed II	Medtronic Neuromodulation Minneapolis, MN 55432	Change in the receiving inspection method used on the coated cathode current collector.
P860057/S093 11/13/12	Carpentier-Edwards Perimount Pericardial Bioprosthesis	Edwards Lifesciences, LLC Irvine, CA 92614	Upgrades to the tissue treatment units.
P860057/S094 11/20/12	Carpentier-Edwards Perimount Pericardial Aortic	Edwards Lifesciences, LLC Irvine, CA	Addition of several ovens for terminal liquid sterilization.

	Bioprosthesis; Carpentier-Edwards Perimount Theon Pericardial Aortic Bioprosthesis with ThermaFix tissue process; Carpentier-Edwards Perimount RSR Pericardial Aortic Bioprosthesis; Carpentier-Edwards Perimount Theon RSR Pericardial Aortic Bioprosthesis with ThermaFix tissue process; Carpentier-Edwards Perimount Magna Pericardial Aortic Bioprosthesis; Carpentier-Edwards Perimount Magna Pericardial Aortic Bioprosthesis with ThermaFix tissue process; Carpentier-Edwards Perimount Magna Ease Pericardial Aortic Bioprosthesis with ThermaFix tissue process; Carpentier-Edwards Perimount Plus Pericardial Mitral Bioprosthesis; Carpentier-Edwards Perimount Theon Pericardial Mitral Bioprosthesis with ThermaFix tissue process; Carpentier-	92614	

	Edwards Perimount Magna Mitral Pericardial Bioprosthesis; Carpentier-Edwards Perimount Magna Mitral Pericardial Bioprosthesis with ThermaFix tissue process; Carpentier-Edwards Perimount Magna Mitral Ease Pericardial Bioprosthesis; Carpentier-Edwards Perimount Magna Mitral Ease Pericardial Bioprosthesis with ThermaFix tissue process; Carpentier-Edwards Perimount Magna Mitral Ease Pericardial Bioprosthesis with ThermaFix tissue process; Carpentier-Edwards Perimount Magna Mitral Ease Pericardial Bioprosthesis; and Carpentier-Edwards Perimount Magna Mitral Ease Pericardial Bioprosthesis with ThermaFix tissue process		
P860057/S095 11/26/12	Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis	Edward Lifesciences, LLC Irvine, CA 92614	Changes to clean rooms #1, 2 and 3 in the Changi, Singapore facility.
P870072/S051 11/29/12	Thoratec Ventricular Assist	Thoratec Corporation	Addition of automated

	Devices	Pleasanton, CA 94588	equipment for the annealing process of the device.
P890003/S264 11/16/12	Prodigy IPG	Medtronic, Inc. Mounds View, MN 55112	Implementation of a new cleaning process and a curing oven.
P890061/S021 11/9/12	Ventak P AICD System	Boston Scientific Corporation St. Paul, MN 55112	Software upgrade to the existing sterilizer system, a change in the existing sterilization process and addition of a new sterilization chamber.
P910073/S108 11/5/12	Endotak Lead System	Boston Scientific Corporation St. Paul, MN 55112	Modification of the lead test software.
P910073/S109 11/9/12	Endotak ICD Leads	Boston Scientific Corporation St. Paul, MN 55112	Software upgrade to the existing sterilizer system, a change in the existing sterilization process and addition of a new sterilization chamber.
P910073/S110 11/7/12	Reliance/S/G/SG IS-1 (Passive) Defibrillation Leads	Boston Scientific CRM St. Paul, MN 55112	Updates to test methods for steroid eluting leads.
P910073/S111 11/14/12	RELIANCE IS-4 Defibrillator Lead	Boston Scientific Corporation St. Paul, MN 55112	Change in the rework process to the lead terminal assembly process.
P910077/S126 11/9/12	Ventak PRx and Ventak Mini ICDs	Boston Scientific Corporation St. Paul, MN 55112	Software upgrade to the existing sterilizer system, a change in the existing sterilization process and addition of a new sterilization chamber.
P910077/S127	LATITUDE G2	Boston Scientific	Alternate Surface

11/7/12	Communicator	Corporation St. Paul, MN 55112	Mount Technology manufacturing line at the contract manufacturer.
P910077/S128 11/14/12	Latitude PRM	Boston Scientific Corporation St. Paul, MN 55112	Moving production of various printed circuit board assemblies to new manufacturing lines and an alternate water wash system at a supplier location.
P930035/S023 11/9/12	Ventak P2 AICD System	Boston Scientific Corporation St. Paul, MN 55112	Software upgrade to the existing sterilizer system, a change in the existing sterilization process and addition of a new sterilization chamber.
P930039/S076 11/19/12	CapSure Fix Novus Lead, Vitatron Crystalline Leads	Medtronic, Inc. Mounds View, MN 55112	Addition of an alternative testing system for electrode components.
P930039/S077 11/28/12	CapSureFix Novus Lead	Medtronic, Inc. Mounds View, MN 55112	Replacement laser welding equipment.
P940008/S030 11/9/12	RES-Q and RES-Q Micron ICDs and RES-Q ICD Leads	Boston Scientific Corporation St. Paul, MN 55112	Software upgrade to the existing sterilizer system, a change in the existing sterilization process and addition of a new sterilization chamber.
P940031/S073 11/9/12	Vigor SR/DR, Discovery and Meridian PGs	Boston Scientific Corporation St. Paul, MN 55112	Software upgrade to the existing sterilizer system, a change in the existing sterilization process and addition of a new sterilization

			chamber.
P950001/S024 11/9/12	Selute Pacing Lead	Boston Scientific Corporation St. Paul, MN 55112	Software upgrade to the existing sterilizer system, a change in the existing sterilization process and addition of a new sterilization chamber.
P960004/S057 11/9/12	Thinline and Fineline Pacing Leads	Boston Scientific Corporation St. Paul, MN 55112	Software upgrade to the existing sterilizer system, a change in the existing sterilization process and addition of a new sterilization chamber.
P960006/S036 11/9/12	Sweet Tip Rx, Sweet Picotip Rx and Flextend Pacing Leads	Boston Scientific Corporation St. Paul, MN 55112	Software upgrade to the existing sterilizer system, a change in the existing sterilization process and addition of a new sterilization chamber.
P960009/S159 11/2/12	DBS Implantable Neurostimulators, Activa SC	Medtronic Neuromodulation Minneapolis, MN 55432	Change in the receiving inspection method used on the coated cathode current collector.
P960040/S275 11/7/12	Prizm HE, Vitality/AVT/2, Confient, Punctua, Teligen, Energen and Incepta ICDs	Boston Scientific Corporation St. Paul, MN 55112	Additional process inspection equipment with software and fixture modifications.
P960040/S276 11/9/12	Ventak AV, Ventak Prizm DR/VR, Vitality, Confient, Livian, and Teligen ICDs	Boston Scientific Corporation St. Paul, MN 55112	Software upgrade to the existing sterilizer system, a change in the existing sterilization process and addition of a new sterilization chamber.

P960040/S277 11/5/12	Incepta, Energen, Punctua ICDs	Boston Scientific Corporation St. Paul, MN 55112	Change to the spot-weld process.
P960040/S278 11/5/12	Incepta, Energen, Punctua Implantable Cardioverter High Energy Defibrillators	Boston Scientific Corporation St. Paul, MN 55112	New rework process for components in the header.
P960040/S279 11/7/12	Teligen, Incepta ICD, Energen ICD and Punctua ICD	Boston Scientific Corporation St. Paul, MN 55112	Addition of plasma cleaning steps at a supplier.
P960040/S280 11/29/12	Cognis, Incepta, Energen and Punctua Cardiac Resynchronization Therapy Defibrillators	Boston Scientific Corporation St. Paul, MN 55112	Alternate supplier for a modified welding component.
D970003/S141 11/9/12	Pulsar, Pulsar Max, Insignia and Altrua PGs	Boston Scientific Corporation St. Paul, MN 55112	Software upgrade to the existing sterilizer system, a change in the existing sterilization process and addition of a new sterilization chamber.
D970003/S142 11/7/12	Insignia, Advantio, Ingenio and Altrua Pacemakers	Boston Scientific Corporation St. Paul, MN 55112	Additional process inspection equipment with software and fixture modifications.
D970003/S144 11/28/12	INGENIO, ANVANTIO Pacemakers	Boston Scientific Corporation St. Paul, MN 55112	Alternate supplier for header components.
P970004/S144 11/2/12	Sacral Nerve Stimulation, Urinary, Implantable Neurostimulators, Interstim II	Medtronic Neuromodulation Minneapolis, MN 55432	Change in the receiving inspection method used on the coated cathode current collector.
P970020/S076 11/2/12	ULTRA and ZETA RX Coronary Stent Systems	Abbott Vascular Temecula, CA 92589	Change to sampling for pyrogen testing.
P970051/S098 11/20/12	Nucleus 24 Cochlear Implant	Cochlear Americas Centennial, CO	Re-installation of a laser welder

	System	80111	system.
P980016/S386 11/7/12	Maximo II CRT-D and Maximo II, Protecta and Protecta XT ICDs	Medtronic, Inc. Mounds View, MN 55112	Change to the burn-in testing process for tantalum capacitors.
P980016/S387 11/16/12	EnTrust, Intrinsic, Marquis DR/VR, Maximo DR/VR, Maximo II, Protecta, Protecta XT, Secura, Virtuoso, and Virtuoso II DR/VR ICDs	Medtronic, Inc. Mounds View, MN 55112	Implementation of a new cleaning process and a curing oven.
P980035/S297 11/16/12	Adapta, Adapta L, Adapta S, Sensia L, Sensia, Versa, Advisa DR, EnRhythm, Relia, and Sigma DR IPGs	Medtronic, Inc. Mounds View, MN 55112	Implementation of a new cleaning process and a curing oven.
P990012/S017 11/2/12	Elecsys® HBsAg Immunoassay, Elecsys® PreciControl HBsAg, and Elecsys® HBsAg Confirmatory Test	Roche Diagnostics Indianapolis, IN 46250	Change to the lyophilization process for components of the assay.
P990012/S018 11/2/12	Elecsys® HBsAg Immunoassay, Elecsys® PreciControl HBsAg, and Elecsys® HBsAg Confirmatory Test	Roche Diagnostics Indianapolis, IN 46250	Change to the functional test procedure of an assay component.
P990046/S030 11/20/12	Open Pivot Heart Valve	Medtronic, Inc. Minneapolis, MN 55432	Addition of a dual chamber coater.
P000014/S026 11/13/12	VITROS® Immunodiagnostic Products Anti-HBs Reagent Pack and Calibrator	Ortho-Clinical Diagnostics, Inc. Rochester, NY 14626	Modifications to the component parts of the Luminometer Signal Processor Board (LSPB). The LSPB is used on the VITROS® ECi/ECiQ Immunodiagnostic System, the VITROS® 3600 Immunodiagnostic

			System and the VITROS® 5600 Integrated System.
P000020/S016 11/13/12	Bard Ablation System	C.R. Bard, Inc. Lowell, MA 01851	Changes to the electrical tester and barcode scanner.
P000021/S024 11/20/12	Dimension TPSA Flex Reagent Cartridge	Siemens Healthcare Diagnostics, Inc. Newark, DE 19714	New supplier of Nylon/Surlyn canister film.
P000044/S030 11/13/12	VITROS® Immunodiagnostic Products HBsAg Reagent Pack and Calibrator	Ortho-Clinical Diagnostics, Inc. Rochester, NY 14626	Modifications to the component parts of the Luminometer Signal Processor Board (LSPB). The LSPB is used on the VITROS® ECi/ECiQ Immunodiagnostic System, the VITROS® 3600 Immunodiagnostic System and the VITROS® 5600 Integrated System.
P010012/S307 11/7/12	Contak Renewal 3/3 HE, Livian, Punctua, Cognis, Energen and Incepta CRT-Ds	Boston Scientific Corporation St. Paul, MN 55112	Additional process inspection equipment with software and fixture modifications.
P010012/S308 11/9/12	Contak CD, Livian, and Cognis CRT-Ds; and, Easytrak, Acuity, and Spiral LV Pacing Lead	Boston Scientific Corporation St. Paul, MN 55112	Software upgrade to the existing sterilizer system, a change in the existing sterilization process and addition of a new sterilization chamber.
P010012/S309 11/7/12	Acuity Spiral Heart Failure Leads	Boston Scientific CRM St. Paul, MN 55112	Updates to test methods for steroid eluting leads.
P010012/S310 11/5/12	Incepta, Energen, Punctua CRT-Ds	Boston Scientific Corporation St. Paul, MN 55112	Change to the spot-weld process.

P010012/S311 11/5/12	Incepta, Energen, Punctua Cardiac Resynchronization Therapy High Energy Defibrillators	Boston Scientific Corporation St. Paul, MN 55112	New rework process for components in the header.
P010012/S312 11/7/12	Cognis, Incepta CRT-D, Energen CRT-D and Punctua CRT-D	Boston Scientific Corporation St. Paul, MN 55112	Addition of plasma cleaning steps at a supplier.
P010012/S313 11/29/12	Teligen, Incepta, Energen and Punctua Implantable Cardioverter Defibrillators	Boston Scientific Corporation St. Paul, MN 55112	Alternate supplier for a modified welding component.
P010021/S023 11/13/12	VITROS® Immunodiagnostic Products Anti-HCV Reagent Pack and Calibrator	Ortho-Clinical Diagnostics, Inc. Rochester, NY 14626	Modifications to the component parts of the Luminometer Signal Processor Board (LSPB). The LSPB is used on the VITROS® ECi/ECiQ Immunodiagnostic System, the VITROS® 3600 Immunodiagnostic System and the VITROS® 5600 Integrated System.
P010030/S038 11/20/12	LifeVest Wearable Defibrillator	Zoll Lifecor Corporation Pittsburgh, PA 15238	Modifications to a fixture and a change in the backup battery charging process during the thermal cycling.
P010031/S338 11/7/12	Consulta ICD and Maximo II, Protecta and Protecta XT CRT-Ds	Medtronic, Inc. Mounds View, MN 55112	Change to the burn-in testing process for tantalum capacitors.
P010031/S339 11/16/12	Concerto, Consulta, Consulta DF4, InSync III Marquis, and InSync Maximo ICDs; and, Concerto II, Maximo II, Protecta, and	Medtronic, Inc. Mounds View, MN 55112	Implementation of a new cleaning process and a curing oven.

	Protecta XT CRT-Ds		
P020009/S093 11/7/12	Express Monorail and OTW Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Replace the component verification system.
P020009/S095 11/23/12	Express 2 Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Elimination of several redundant testing requirements from the balloon component manufacturing process.
P020009/S096 11/23/12	Express 2 Coronary Stent System (Monorail & OTW)	Boston Scientific Corporation Maple Grove, MN 55311	Removal of several redundant inspections at the Finished Device Inspection step.
P020027/S019 11/20/12	Dimension FPSA Flex Reagent Cartridge	Siemens Healthcare Diagnostics, Inc. Newark, DE 19714	New supplier of Nylon/Surlyn canister film.
P020047/S052 11/2/12	VISION and ML8 Coronary Stent Systems	Abbott Vascular Temecula, CA 92589	Change to sampling for pyrogen testing.
P030005/S089 11/7/12	Contak Renewal TR/TR 2, and Ivive ICDs	Boston Scientific Corporation St. Paul, MN 55112	Additional process inspection equipment with software and fixture modifications.
P030005/S090 11/9/12	Contak Renewal TR CRT-P	Boston Scientific Corporation St. Paul, MN 55112	Software upgrade to the existing sterilizer system, a change in the existing sterilization process and addition of a new sterilization chamber.
P030024/S020 11/13/12	VITROS® Immunodiagnostic Products Anti-HBc Reagent Pack and Calibrator	Ortho-Clinical Diagnostics, Inc. Rochester, NY 14626	Modifications to the component parts of the Luminometer Signal Processor Board (LSPB). The LSPB is used on the

			VITROS® ECi/ECiQ Immunodiagnostic System, the VITROS® 3600 Immunodiagnostic System and the VITROS® 5600 Integrated System.
P030026/S026 11/13/12	VITROS® Immunodiagnostic Products Anti-HBc IgM Reagent Pack and Calibrator	Ortho-Clinical Diagnostics, Inc. Rochester, NY 14626	Modifications to the component parts of the Luminometer Signal Processor Board (LSPB). The LSPB is used on the VITROS® ECi/ECiQ Immunodiagnostic System, the VITROS® 3600 Immunodiagnostic System and the VITROS® 5600 Integrated System.
P030036/S050 11/19/12	SelectSecure 4 French Lead	Medtronic, Inc. Mounds View, MN 55112	Addition of an alternative testing system for electrode components.
P040016/S098 11/7/12	VeriFLEX (Liberté) Coronary Stent Systems	Boston Scientific Corporation Maple Grove, MN 55311	Replace the component verification system.
P040016/S100 11/23/12	VeriFlex (Liberté) Bare Metal Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Elimination of several redundant testing requirements from the balloon component manufacturing process.
P040016/S101 11/23/12	VeriFlex Coronary Stent System (Monorail & OTW)	Boston Scientific Corporation Maple Grove, MN 55311	Removal of several redundant inspections at the Finished Device Inspection step.
P040023/S025 11/20/12	Duraloc Option Ceramic Hip System	DePuy Orthopaedics, Inc. Warsaw, IN	Changes to the sealing parameters for two pouch

		46581	sealers used for SROM Sleeves Blister Packs.
P040024/S064 11/29/12	Restylane Injectable Gel	Medicis Pharmaceutical Corporation Scottsdale, AZ 85256	Change to a new vision system for the verification of lot number and expiration date for the assembly machine in Factory 1.
P050006/S032 11/7/12	HELEX Septal Occluder	W.L. Gore & Associates, Inc. Flagstaff, AZ 86001	Addition of a supplier for polyvinyl alcohol (PVA).
P050019/S011 11/27/12	Carotid WALLSTENT Monorail Endoprosthesis	Boston Scientific Corporation Maple Grove, MN 55311	Addition of alternate extrusion lines for components.
P050039/S013 11/1/12	Exactech Novation Ceramic Articulation Hip System	Exactech, Inc. Gainesville, FL 32653	Addition of a new blast cabinet.
P050046/S017 11/9/12	Acuity Steerable LV Pacing Lead	Boston Scientific Corporation St. Paul, MN 55112	Software upgrade to the existing sterilizer system, a change in the existing sterilization process and addition of a new sterilization chamber.
P050048/S008 11/13/12	MONOLISA™ Anti-HBs EIA	Bio-Rad Laboratories, Inc. Redmond, WA 98052	Change to automate the filling and capping process for components in the devices.
P050051/S016 11/27/12	ARCHITECT AUSAB	Abbott Laboratories, Inc. Abbott Park, IL 60064	Change to the quality control testing used on an incoming raw material.
P060001/S018 11/7/12	Protégé GPS and Protégé RX Carotid Stent System	Ev3, Inc. Plymouth, MN 55441	Alternate microblaster.
P060006/S034 11/7/12	Express SD Renal Monorail	Boston Scientific Corporation	Replace the component

	Premounted Stent System	Maple Grove, MN 55311	verification system.
P060006/S036 11/23/12	Express SD Renal Monorail Premounted Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Removal of several redundant inspections at the Finished Device Inspection step.
P060007/S022 11/27/12	ARCHITECT HBsAg/ Confirmatory	Abbott Laboratories, Inc. Abbott Park, IL 60064	Change to the quality control testing used on an incoming raw material.
P060031/S006 11/13/12	MONOLISA™ Anti-HBc EIA	Bio-Rad Laboratories, Inc. Redmond, WA 98052	Change to automate the filling and capping process for components in the devices.
P060033/S072 11/20/12	Endeavor Sprint Zotarolimus-Eluting Coronary Stent Systems	Medtronic Vascular Santa Rosa, CA 95403	Changes to the orientation of the sterilization cartons, location of the internal process challenge devices, and modifications to the external process challenge devices used during sterilization.
P060034/S006 11/13/12	MONOLISA™ Anti-HBc IgM EIA	Bio-Rad Laboratories, Inc. Redmond, WA 98052	Change to automate the filling and capping process for components in the devices.
P060035/S015 11/27/12	ARCHITECT CORE-M	Abbott Laboratories, Inc. Abbott Park, IL 60064	Change to the quality control testing used on an incoming raw material.
P060038/S015 11/20/12	Mitroflow Aortic Pericardial Heart Valve	Sorin Group USA, Inc. Arvada, CO 80004	Transfer of component secondary operations from supplier to in-house.
P070014/S035 11/21/12	LifeStent Vascular Stent System	Bard Peripheral Vascular, Inc.	Addition of an alternate supplier to

		Tempe, AZ 85281	manufacture larger stent sizes.
P070015/S102 11/2/12	XIENCE V and XIENCE nano Everolimus Eluting Coronary Stent Systems	Abbott Vascular Temecula, CA 92589	Change to sampling for pyrogen testing.
P070026/S010 11/20/12	DePuy Ceramax Ceramic Total Hip System	DePuy Orthopaedics, Inc. Warsaw, IN 46581	Changes to the sealing parameters for two pouch sealers used for SROM Sleeves Blister Packs.
P080006/S046 11/19/12	Attain Ability LV Lead, Attain Ability Plus LV Lead, Attain Ability Straight LV Lead	Medtronic, Inc. Mounds View, MN 55112	Addition of an alternative testing system for electrode components.
P080012/S009 11/6/12	Prometra Programmable Infusion Pump System	Flowonix Medical, Inc. Mt. Olive, NJ 07828	Use of an alternate solder paste during the manufacture of the device.
P080020/S003 11/1/12	Gel-One®	Seikagaku Corporation Toyko, Japan 100-0005	Replacement of an existing cold storage unit.
P080020/S004 11/30/12	Gel-One®	Seikagaku Corporation Tokyo, Japan	Increase in production capacity.
P080023/S016 11/27/12	ARCHITECT CORE	Abbott Laboratories, Inc. Abbott Park, IL 60064	Change to the quality control testing used on an incoming raw material.
P080025/S040 11/2/12	Sacral Nerve Stimulation, Bowel, Implantable Neurostimulators, InterStim II	Medtronic Neuromodulation Minneapolis, MN 55432	Change in the receiving inspection method used on the coated cathode current collector.
P080026/S004 11/1/12	RealTi*me* HBV Assay	Abbott Molecular, Inc. Des Plaines, IL 60018	Change to the equipment utilized for identity testing of oligonucleotides.
P090002/S006 11/20/12	Pinnacle CoMplete Acetabular Hip System	DePuy Orthopaedics, Inc. Warsaw, IN	Changes to the sealing parameters for two pouch

		46581	sealers used for SROM Sleeves Blister Packs.
P090003/S018 11/9/12	Express LD Iliac Premounted Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Addition of an alternate resin compounder.
P090013/S077 11/16/12	Revo MRI IPG	Medtronic, Inc. Mounds View, MN 55112	Implementation of a new cleaning process and a curing oven.
P090013/S078 11/19/12	CapSureFix MRI Lead	Medtronic, Inc. Mounds View, MN 55112	Addition of an alternative testing system for electrode components.
P090013/S079 11/28/12	CapSureFix MRI Lead	Medtronic, Inc. Mounds View, MN 55112	Replacement laser welding equipment.
P090028/S004 11/13/12	VITROS® Immunodiag-nostic Products HBeAg Reagent Pack and Calibrator	Ortho-Clinical Diagnostics, Inc. Rochester, NY 14626	Modifications to the component parts of the Luminometer Signal Processor Board (LSPB). The LSPB is used on the VITROS® ECi/ECiQ Immunodiagnostic System, the VITROS® 3600 Immunodiagnostic System and the VITROS® 5600 Integrated System.
P090028/S005 11/26/12	VITROS® Immunodiag-nostic Products Anti-HBeAg Reagent Pack and Calibrator	Ortho-Clinical Diagnostics, Inc. Rochester, NY 14626	Addition of a supplier for negative human plasma.
P100001/S003 11/13/12	VITROS® Immuno-diagnostic Products Anti-HBe Reagent Pack and Calibrator	Ortho-Clinical Diagnostics, Inc. Rochester, NY 14626	Modifications to the component parts of the Luminometer Signal Processor Board (LSPB). The LSPB is used on the VITROS® ECi/ECiQ Immunodiagnostic System, the

			VITROS® 3600 Immunodiagnostic System and the VITROS® 5600 Integrated System.
P100001/S004 11/19/12	VITROS® Immuno-diagnostic Products Anti-HBe Reagent Pack and Calibrator	Ortho-Clinical Diagnostics, Inc. Rochester, NY 14626	Addition of a supplier for negative human plasma.
P100010/S020 11/7/12	Arctic Front & Arctic Front Advance Cardiac CryoAblation Catheters	Medtronic CryoCath LP Quebec, Canada H9R 5Z8	Use of an automatic pull wire crimper.
P100010/S021 11/20/12	Arctic Front Advance Cardiac CryoAblation Catheters	Medtronic, Inc. Mounds View, MN 55112	Change to a semi-automated sanding method at a component supplier.
P100017/S003 11/1/12	RealTi*me* HCV Assay	Abbott Molecular, Inc. Des Plaines, IL 60018	Change to the equipment utilized for identity testing of oligonucleotides.
P100020/S007 11/6/12	cobas® HPV Test	Roche Molecular Systems, Inc Pleasanton, CA 94588	Change of resin for closures, and an addition of new filling and capping equipment.
P100021/S022 11/20/12	Endurant Stent Graft System	Medtronic Vascular Santa Rosa, CA 95403	Reduction to the incoming inspection for a component assembly.
P100023/S056 11/5/12	ION Paclitaxel-Eluting Platinum Chromium Coronary	Boston Scientific Corporation Maple Grove, MN 55311	Manufacturing software changes pertaining to the catheters.
P100023/S057 11/20/12	ION Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Changes to proximal balloon bond manufacturing software.
P100023/S058 11/23/12	ION (Taxus Element) Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Elimination of several redundant testing requirements from the balloon component manufacturing

			process.
P100023/S059 11/23/12	ION (Taxus Element) Paclitaxel-Eluting Platinum Chromium Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Addition of a second injection molding line for manifold-hypotube assemblies.
P100023/S060 11/29/12	ION (Taxus Element) Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Modification of the distal heat shrink alignment software.
P100023/S061 11/23/12	ION (Taxus Element) Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Updates to the visual standard inspection criteria for gouges.
P100023/S062 11/23/12	ION Paclitaxel-Eluting Platinum Chromium Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Software upgrade to the Visicon Inspection System.
P100041/S015 11/13/12	Carpentier-Edwards P erimount, Edwards SAPIEN Transcatheter Heart Valve	Edwards Lifesciences, LLC Irvine, CA 92614	Upgrades to the tissue treatment units.
P110003/S002 11/13/12	LeGoo Endovascular Occlusion Gel	Pluromed, Inc. Woburn, MA 01801	Changes to the packaging configurations of the device.
P110003/S003 11/13/12	LeGoo Endovascular Occlusion Gel	Pluromed, Inc. Woburn, MA 01801	Changes to the packaging configurations by reducing the number of Tyvek pouched cannulae per sales carton.
P110010/S031 11/5/12	Promus Element Plus Everolimus-Eluting Platinum	Boston Scientific Corporation Maple Grove, MN 55311	Manufacturing software changes pertaining to the catheters.
P110010/S032 11/20/12	PROMUS Element Plus Everolimus-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Changes to proximal balloon bond manufacturing software.
P110010/S033 11/23/12	PROMUS Element Plus Everolimus-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Addition of a second injection molding line for manifold-hypotube

			assemblies.
P110010/S034 11/29/12	PROMUS Element Plus Everolimus-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Modification of the distal heat shrink alignment software.
P110010/S036 11/23/12	PROMUS Element Plus Everolimus-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Updates to the visual standard inspection criteria for gouges.
P110010/S037 11/23/12	PROMUS Element Plus Everolimus-Eluting Platinum Chromium Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Software upgrade to the Visicon Inspection System.
P110019/S035 11/2/12	XIENCE PRIME and XIENCE PRIME LL Everlimus Eluting Coronary Stent Systems	Abbott Vascular Temecula, CA 92589	Change to sampling for pyrogen testing.
P110023/S004 11/7/12	Everflex Self-Expanding Peripheral Stent System	Ev3, Inc. Plymouth, MN 55441	Alternate microblaster.
P110028/S005 11/14/12	Absolute Pro Vascular Self-Expanding Stent System	Abbott Vascular, Inc. Temecula, CA 92591	Modify the stent subassembly expansion process.
P110029/S006 11/19/12	ARCHITECT HBsAg Qualitative and ARCHITECT HBsAg Qualitative Confirmatory	Abbott Laboratories Abbott Park, IL 60064	Change to a quality control test method for purified antibodies used in the manufacture of the ARCHITECT HBsAg Qualitative and ARCHITECT HBsAg Qualitative Confirmatory assays.
P110029/S007 11/27/12	ARCHITECT HBsAg Qualitative/ Confirmatory	Abbott Laboratories, Inc. Abbott Park, IL 60064	Change to the quality control testing used on an incoming raw material.
P110035/S004 11/7/12	Epic Vascular Self-Expanding Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Replace the component verification system.

Summary of PMA Originals & Supplements Approved
Originals: 4
Supplements: 92

Summary of PMA Originals Under Review
Total Under Review: 49
Total Active: 18
Total On Hold: 31

Summary of PMA Supplements Under Review
Total Under Review: 640
Total Active: 480
Total On Hold: 160

Summary of All PMA Submissions Received
Originals: 3
Supplements: 82

Summary of PMA Supplement PMA Approval/Denial Decision Times
Number of Approvals: 92
Number of Denials: 0
Average Days Fr Receipt to Decision (Total Time): 140
FDA Time: 98.7 Days MFR Time: 41.3 Days

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