PMA Final Decisions for September 2010

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.

None.

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
P840068/S047 **9/14/10** **Real-Time**	DELTA Pacemaker System	Boston Scientific Corporation St. Paul, MN 55112	Approval for changes to the Model 3120 Programmer System Software Model 2909 from Version 6.01 to version 7.01.
P870078/S008 **9/20/10** **180-Day**	Hancock® Apical Left Ventricle Connector	Medtronic Heart Valves Santa Ana, CA 92705	Approval for the Hancock® Apical Left Ventricle Connector, Model 174A. The device is indicated for providing an alternative method for relief of left ventricular hypertension in patients with severe left ventricular outflow tract obstruction due to hypoplasia of the aortic root, hypoplasia of the aortic annulus, or acquired problems secondary to aortic valve replacement

			which cannot be relieved through conventional techniques.
P880091/S032 **9/16/10** **Special**	Silicon UV-Absorbing Posterior Chamber Intraocular Lens (IOL)	STAAR Surgical Company Monrovia, CA 91016	Approval for a modification to the Directions for Use to comply with the latest Medical Device Directive (MDD) 93/42/EEC.
P900056/S098 **9/23/10** **135-Day**	Rotablator™ Rotational Angioplasty System	Boston Scientific Corporation Cardiovascular Maple Grove, MN 55311	Approval for a manufacturing production area move of the manufacture and service of the device Console and Dynaglide™ Foot Pedal assemblies.
P910023/S239 **9/23/10** **Real-Time**	Fortify VR/DR	St. Jude Medical Cardiac Rhythm Management Division Sunnyvale, CA 94086	Approval for changes to the labeling to include longevity information based on additional bench testing.
P910023/S243 **9/9/10** **180-Day**	Programmer Support for Atlas II+ HF and Promote	St. Jude Medical Sylmar, CA 91342	Approval of the post-approval study protocol.
P910023/S246 **9/23/10** **Real-Time**	Epic, Epic+, Epic II, Atlas, Atlas+, Atlas II, Current, Current+, Fortify VR/DR	St. Jude Medical Cardiac Rhythm Management Sunnyvale, CA 94086	Approval for modifications to the connector blocks including the use of metal injection molding (MIM) and the use of MP35N as the material.
P910073/S084 **9/28/10** **135-Day**	Reliance Family of Leads	Boston Scientific Cardiology, Rhythm and Vascular St. Paul, MN 55112	Modifications to inspection criteria for a specific lead component.
P910077/S108 **9/14/10** **Real-Time**	VENTAX PRx AICD System	Boston Scientific Corporation St. Paul, MN	Approval for changes to the Model 3120

		55112	Programmer System Software Model 2909 from Version 6.01 to version 7.01.
P920023/S028 **9/23/10** **Real-Time**	UroLume® Endoprosthesis	American Medical Systems Minnetonka, MN 55343	Approval for a modification of specifications of the radius and location of the bump on the end of the UroLume Endoprosthesis Outer Tube.
P940015/S019 **9/15/10** **135-Day**	Synvisc/Synvisc-One	Genzyme Biosurgery Cambridge, MA 02142	Approval for a manufacturing change involving installation of the Waters Empower 2 Chromatography Data System.
P940031/S069 **9/14/10** **Real-Time**	VIGOR DR/SR Pacemaker System	Boston Scientific Corporation St. Paul, MN 55112	Approval for changes to the Model 3120 Programmer System Software Model 2909 from Version 6.01 to version 7.01.
P950009/S012 **9/16/10** **Special**	BD FocalPoint GS Imaging System	Tripath Imaging, Inc. Durham, NC 27703	Approval for labeling revisions regarding workload calculation.
P950022/S073 **9/9/10** **180-Day**	Riata ST Optim and Riata STS Optim Leads	St. Jude Medical Sylmar, CA 91342	Approval of the post-approval study protocol.
P950037/S079 **9/2/10** **180-Day**	Reliaty/Model 3145 Pacing System Analyzer	Biotronik, Inc. Lake Oswego, OR 97035	Approval for a stand-alone version of the pacing system analyzer function found in the ICS 3000 Implant Control System. The device, as modified, will be marketed under the trade name Reliaty by

			Biotronik, Inc. and Model 3145 by Boston Scientific and is indicated for use in pacing lead system analysis during the implantation of pacemakers and defibrillators.
P960040/S218 **9/7/10** **135-Day**	Teligen Family of ICDs	Boston Scientific Corporation St. Paul, MN 55112	Approval for modifications to the cleaning process and moving a weld process from a supplier to Boston Scientific Corporation.
P960040/S234 **9/14/10** **Real-Time**	VENTAX AVAICD System	Boston Scientific Corporation St. Paul, MN 55112	Approval for changes to the Model 3120 Programmer System Software Model 2909 from Version 6.01 to version 7.01.
P960058/S076 **9/10/10** **180-Day**	Harmany HiResolution Bionic Ear System	Advanced Bionics, LLC Sylmar, CA 91342	Approval for the Off-The-EAR-Power (EOP) Accessories Designed to be used with the Behind-The-Ear (BTE) external sound processors Auria® or Harmony™.
P970003/S112 **9/17/10** **Real-Time**	VNS Therapy System	Cyberonics, Inc. Houston, TX 77058	Approval for upgrading the operating system of the Dell X5 handheld computer.
D970003/S124 **9/14/10** **Real-Time**	PULSAR, PULSAR MAX Pacemaker System	Boston Scientific Corporation St. Paul, MN 55112	Approval for changes to the Model 3120 Programmer System Software

			Model 2909 from Version 6.01 to version 7.01.
P980016/S252 **9/29/10** **Real-Time**	Concerto, Concerto II, Consulta, Maximo II, Virtuoso, Secura and Virtuoso II	Medtronic, Inc. Mounds View, MN 55112	Approval for the design changes to NPO-0402 Multilayer Ceramic Capacitors (XC269 and XC313).
P980023/S038 **9/17/10** **180-Day**	Linox Smart Steroid-Eluting Dual Coil ICD Leads	Biotronik, Inc. Lake Oswego, OR 97035	Approval for Linox Smart Steroid-Eluting Dual Coil ICD Leads with Silglide Coating.
P980049/S059 **9/9/10** **180-Day**	Paradym DR and Paradym VR	ELA Medical, Inc. Plymouth, MN 55441	Approval for revised embedded implant software (version W2.8.4) and revised Smartview programmer softwear (version 2.22 UG2).
P980049/S060 **9/8/10** **Real-Time**	Paradym VR/DR and CRT-D	ELA Medical, Inc. / Sorin Group Plymouth, MN 55441	Approval for the design changes for low voltage electronic hybrid module and interconnection flex circuit for Paradym VR/DR and CRT-D, Models 8250, 8550, and 8750.
P990013/S029 **9/16/10** **Special**	Collamer UV-Absorbing Posterior Chamber Intraocular Lens (IOL)	STAAR Surgical Company Monrovia, CA 91016	Approval for modification to the Directions for use to comply with the latest Medical Device Directive (MDD) 93/42/EEC.
P990037/S031 **9/15/10** **180-Day**	Vascular Solutions Diagnostic Duett Pro Sealing Device	Vascular Solutions, Inc. Minneapolis, MN 55369	Approval for a manufacturing site located at Steris Isomedix Services, Inc., Minneapolis, Minnesota to perform the

			ethylene oxide pre-treatment step of the bulk collagen component of the subject device.
P990040/S012 **9/27/10** **Real-Time**	TRUFILL n-Butyl Cyanoacrylate (n-BCA) Liquid Embolic System	Codman & Shurtleff, Inc. Raynham, MA 02767	Approval for relabeling and repackaging the ethiodized oil component to meet the current Codman specification.
P000021/S017 **9/2/10** **Real-Time**	Dimension® TPSA Flex® Reagent Cartridge	Siemens Healthcare Diagnostic, Inc. Newark, DE 19714	Approval for the addition of a clot check device to the Dimension® EXL™ with LM system when used with the Dimension® TPSA Flex® Reagent Cartridge.
P000025/S046 **9/3/10** **135-Day**	COMBI 40+ Cochlear Implant System	MED-EL Corporation Durham, NC 27713	Approval for a change in MED-EL's supplier of a critical component.
P000025/S047 **9/3/10** **135-Day**	COMBI 40+ Cochlear Implant System	MED-EL Corporation Durham, NC 27713	Approval for a change in the production of the thermoforming foil used to produce the blisters of the sterile package for the cochlear implants.
P000029/S066 **9/3/10** **135-Day**	Deflux® Injectable Gel	Oceana Therapeutics, Inc. Edison, NJ 08817	Approval for changes to the sampling for testing endotoxins and bioburden and changes to the manufacturing process.
P000032/S032 **9/2/10** **135-Day**	Her Option® Office Cryoablation Therapy System	Cooper Surgical, Inc. Trumbull, CT 06611	Approval for a change to the console testing method.

P000032/S033 **9/22/10** **135-Day**	Her Option® Office Cryoablation Therapy System	Cooper Surgical, Inc. Trumbull, CT 06611	Approval for a change to the incoming measurement method.
P000037/S019 **9/23/10** **180-Day**	On-X Prosthetic Heart Valve	On-X Life Technologies, Inc. Austin, TX 78754	Approval for a manufacturing site located in Austin, Texas.
P010001/S006 **9/15/10** **135-Day**	Transcend Hip Articulation System	CeramTec AG Memphis, TN 38119	Approval for the addition of a second identical line of grinding, polishing, and cleaning processes at the Plochingen, Germany facility.
P010001/S007 **9/15/10** **135-Day**	Transcend Hip Articulation System	CeramTec AG Memphis, TN 38119	Approval for the replacement of two grinding machines and addition of one piece of proof testing equipment at the Plochingen, Germany facility and addition of a grinding machine and piece of proof testing equipment at the Marktredwitz, Germany facility.
P010012/S230 **9/16/10** **Panel**	Cognis CRT-D, Livian CRT-D and Contak Renewal 3 RF HE CRT-D	Boston Scientific Corporation St. Paul, MN 55112	Approval for a modification to the indications for use for the Cognis CRT-D Models N118, N119; Livian CRT-D Models H220, H225, H227 and H229; and Contak Renewal 3 RF HE CRT-D Models H210, H215, H217, H219 Cardiac Resynchronization

			Therapy Defibrillators (CRT-Ds) as follows: These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications: 1) Moderate to severe heart failure (NYHA Class III-IV) with EF ? 35% and QRS duration ? 120 ms; or 2) Left bundle branch block (LBBB) with QRS ? 130 ms, EF ? 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure.
P010012/S237 9/7/10 135-Day	Cognis Family of CRT-Ds	Boston Scientific Corporation St. Paul, MN 55112	Approval for modifications to the cleaning process and moving a weld process from a supplier to Boston Scientific Corporation.
P010012/S254 9/14/10 Real-Time	CONTAK CD/EASYTRAK CRT-D System	Boston Scientific Corporation St. Paul, MN	Approval for changes to the Model 3120

		55112	Programmer System Software Model 2909 from Version 6.01 to version 7.01.
P010023/S003 **9/30/10** **135-Day**	MAXUM System Semi-Implantable Middle Ear Hearing Device	Ototronix LLC Houston, TX 77386	Approval for a change in the Magnet Canister Manufacturing process/inspection, and the re-qualification of the magnetization vendor at the vendor's new facility location.
P010023/S005 **9/10/10** **180-Day**	MAXUM System Semi-Implantable Middle Ear Hearing Device	Ototronix LLC Houston, TX 77386	Approval for a manufacturing site change to Biotest Laboratories, Inc. in Minneapolis, Minnesota.
P010025/S020 **9/7/10** **180-Day**	Selenia Dimensions 2D Full Field Digital Mammography System	Hologic, Inc. Bedford, MA 01730	Approval for the Selenia Dimensions 2D Full Field Digital Mammography System.
P010031/S208 **9/29/10** **Real-Time**	Concerto, Concerto II, Consulta, Maximo II, Virtuoso, Secura and Virtuoso II	Medtronic, Inc. Mounds View, MN 55112	Approval for the design changes to NPO-0402 Multilayer Ceramic Capacitors (XC269 and XC313).
P020002/S005 **9/16/10** **Special**	ThinPrep Imaging System	Hologic, Inc. Marlborough, MA 011752	Approval for labeling revisions regarding workload calculation.
P020011/S002 **9/17/10** **135-Day**	Versant HCV RNA Qualitative Assay/ Aptima HCV RNA Qualitative Assay	Gen-Probe, Inc. San Diego, CA 92121	Approval for a change in quality control specifications for the HCV calibrators.
P020026/S078 **9/2/10** **135-Day**	CYPHER® Sirolimus-Eluting Coronary Stent on RAPTOR™ Over-the-Wire	Cordis Corporation Miami Lakes, FL 33013	Approval for a change in sampling plan from lot-to-lot to a skip-lot testing

	Delivery System and RAPTORRAIL® Rapid Exchange Delivery System		plan.
P020027/S012 **9/2/10** **Real-Time**	Dimension® FPSA Flex® Reagent Cartridge	Siemens Healthcare Diagnostic, Inc. Newark, DE 19714	Approval for the addition of a clot check device to the Dimension® EXL™ with LM system when used with the Dimension® FPSA Flex® Reagent Cartridge.
P030005/S070 **9/14/10** **Real-Time**	CONTAK RENEWAL TR CRT-P System	Boston Scientific Corporation St. Paul, MN 55112	Approval for changes to the Model 3120 Programmer System Software Model 2909 from Version 6.01 to version 7.01.
P030009/S039 **9/14/10** **180-Day**	Integrity Coronary Stent System	Medtronic Vascular Santa Rose, CA 95403	Approval for the Integrity Coronary Stent System. The device is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete de novo or restenotic lesions, with reference vessel diameters of 2.25-4.0 mm and ?30 mm in length, using direct stenting or predilatation.
P030016/S017 **9/15/10** **Special**	Visian Implantable Collamer Lens for Myopia	STAAR Surgical Company Monrovia, CA 91016	Approval for a modification to the Directions for Use to include a warning statement and a modification

			to a contraindication.
P030029/S009 **9/1/10** **180-Day**	ADVIA® Centaur Anti-HBs (aHBs) Assay on Centaur CP	Siemens Healthcare Diagnostics Tarrytown, NY 10591	Approval for adding quantitative determination of total antibodies to hepatitis B surface antigen in human adult, adolescent, and pediatric serum or plasma to the intended use. The device, as modified, will be marketed under the trade name ADVIA® Centaur Anti-HBs (aHBs) Assay on Centaur CP and is indicated for: **ADVIA® Centaur Anti-HBs (aHBs) Assay on the Centaur CP Analyzer:** The ADVIA Centaur Anti-HBs assay is an *in vitro* diagnostic immunoassay for the qualitative and quantitative determination of total antibodies to hepatitis B surface antigen in human adult, adolescent, and pediatric serum or plasma (EDTA or heparinized) using the ADVIA Centaur CP System. The assay results may be used as an aid in the determination of susceptibility to hepatitis B virus

			(HBV) infection in individuals prior to or following HBV vaccination or where vaccination status is unknown. Assay results may be used with other HBV serological markers for the laboratory diagnosis of HBV disease associated with HBV infection. A reactive assay result will allow a differential diagnosis in individuals displaying signs and symptoms of hepatitis in whom etiology is unknown.
P030032/S010 **9/15/10** **135-Day**	PREVELLE Silk	Genzyme Biosurgery Cambridge, MA 02142	Approval for a manufacturing change involving installation of the Waters Empower 2 Chromatography Data System.
P030050/S008 **9/9/10** **180-Day**	Sculptra Aesthetic	Sanofi Aventis U.S. Bridgewater, NJ 08807	Approval of the post-approval study protocol.
P030053/S009 **9/14/10** **180-Day**	Mentor MemoryGel™ Silicone-filled Breast Implant	Mentor Corporation Santa Barbara, CA 93111	Approval of the post-approval study protocol.
P030054/S157 **9/23/10** **Real-Time**	Unify CRT-D	St. Jude Medical Cardiac Rhythm Management Division Sunnyvale, CA 94086	Approval for changes to the labeling to include longevity information based on additional bench testing.
P030054/S162	Atlas II+ HF and	St. Jude Medical	Approval of the

9/9/10 **180-Day**	Promote CRT-Ds	Sylmar, CA 91342	post-approval study protocol.
P030054/S165 **9/23/10** **Real-Time**	Epic, Epic+, Epic II, Atlas, Atlas+, Atlas II, Promote, Promote+, Unify CRT-D	St. Jude Medical Cardiac Rhythm Management Sunnyvale, CA 94086	Approval for modifications to the connector blocks including the use of metal injection molding (MIM) and the use of MP35N as the material.
P030054/S170 **9/24/10** **Real-Time**	Quickflex LV Leads and Quickflex µ LV Leads	St. Jude Medical Sylmar, CA 91342	Approval for an increase in inner diameter of the stylet stop feature of the electrode component of the device.
P040023/S016 **9/2/10** **135-Day**	Duraloc Option Ceramic Hip System	DePuy Orthopedics, Inc. Warsaw, IN 46581	Approval for a change to an automated cleaning process and combination of that cleaning process with the final polish process on the firm's routers.
P040027/S019 **9/15/10** **135-Day**	Gore VIATORR® TIPS Endoprosthesis	W.L. Gore & Associates, Inc. Flagstaff, AZ 86001	Approval for automating the loading of the access sleeve and to use an alternate material vendor.
P050012/S030 **9/9/10** **Real-Time**	DexCom Seven and Seven Plus Continuous Glucose Monitoring System	DexCom, Inc. San Diego, CA 92121	Approval for modification to the sensor needle carrier to reduce force required to release snaps during cannula retraction.
P050012/S031 **9/9/10** **Real-Time**	DexCom Seven and Seven Plus Continuous Glucose Monitoring System	DexCom, Inc. San Diego, CA 92121	Approval for a change from a single to four-cavity production mold as well as the addition of an alternative gate location for

			the sensor safety lock.
P050028/S004 **9/9/10** **180-Day**	COBAS® AmpliPrep/COBAS® TaqMan® HBV Test, v2.0	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Approval for a device design modification that includes reagents, disposables, and instrumentation, to automate the manual sample preparation process currently used by the COBAS® TaqMan® HBV Test For Use With The High Pure System. The device, as modified, will be marketed under the trade name COBAS® AmpliPrep/ COBAS® TaqMan® HBV Test, v2.0 and is indicated for: The COBAS® AmpliPrep/COBAS® TaqMan® HBV Test, v2.0 is an *in vitro* nucleic acid amplification lest for the quantitation of hepatitis B virus (HBV) DNA in human serum or plasma (EDTA), using the COBAS® AmpliPrep Instrument for automated specimen processing and the COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer for automated

			amplification and detection. This test is intended for use as an aid in the management of patients with chronic HBV infection undergoing antiviral therapy. The test can be used to measure HBV DNA levels at baseline and during treatment to aid in assessing response to treatment. The results from the COBAS® AmpliPrep/ COBAS® TaqMan1® HBV Test, v2.0 must be interpreted within the context of all relevant clinical and laboratory findings. Assay performance characteristics have been established for individuals treated with adefovir dipivoxil. Assay performance for determining the slate of HBV infection has not been established. The COBAS® AmpliPrep/ COBAS®TaqMan® HBV Test, v2.0 is not intended for use as a screening test for the presence of HBV in

			blood or blood products or as a diagnostic test to confirm the presence of HBV infection.
P050048/S006 **9/27/10** **135-Day**	Bio-Rad Monolisa Anti-HBs EIA	Bio-Rad Laboratories Redmond, WA 98052	Approval for a change in supplier for the hepatitis B antigens used in the manufacture of the device.
P060002/S010 **9/15/10** **135-Day**	Bard® FLAIR® Endovascular Stent Graft	Bard Peripheral Vascular, Inc. Tempe, AZ 85280	Approval for a modification to the procedures for implementing shelf lives of raw materials.
P060027/S026 **9/9/10** **180-Day**	Paradym CRT-D	ELA Medical, Inc. / Sorin Group Plymouth, MN 55441	Approval for revised embedded implant software (version W2.8.4) and revised Smartview programmer softwear (version 2.22 UG2).
P060027/S027 **9/14/10** **180-Day**	Ovatio CRT-D and Situs OTW LV Lead	ELA Medical, Inc. / Sorin Group Plymouth, MN 55441	Approval of the post-approval study protocol.
P060027/S028 **9/8/10** **Real-Time**	Paradym VR/DR and CRT-D	ELA Medical, Inc. / Sorin Group Plymouth, MN 55441	Approval for the design changes for low voltage electronic hybrid module and interconnection flex circuit for Paradym VR/DR and CRT-D, Models 8250, 8550, and 8750.
P060029/S001 **9/7/10** **Real-Time**	Ethicon™ Omnex™ Surgical Sealant (250µl)	Ethicon, Inc. Somerville, NJ 08876	Approval for changes to the applicator and packaging.
P060030/S006	COBAS® AmpliPrep	Roche Molecular	Approval for a

9/1/10 **180-Day**	/ COBAS TaqMan® HCV Test and COBAS® TaqMan® HCV Test, v2.0 for use with the High Pure System	Systems, Inc. Pleasanton, CA 94588	manual specimen preparation option to the currently approved automated sample preparation method. The device, as modified, will be marketed under the trade name COBAS® TaqMan® HCV Test, v2.0 For Use With The High Pure System and is indicated for: The COBAS® TaqMan® HCV Test, v2.0 For Use With The High Pure System is an *in vitro* nucleic acid amplification test for the quantitation of hepatitis C virus (HCV) RNA in human plasma or serum of HCV-infected individuals using the High Pure System Viral Nucleic Acid Kit for manual specimen preparation and the COBAS05® TaqMan® 48 Analyzer for automated amplification and detection. Specimens containing HCV genotypes 1 through 6 have been validated for

			quantitation in the assay. The COBAS® TaqMan® HCV Test, v2.0 For Use With The High Pure System is intended for use as an aid in the management of HCV-infected individuals undergoing anti-viral therapy. The assay measures HCV RNA levels at baseline and during treatment and can be used to predict sustained and non-sustained virological response to HCV therapy. The results from the COBAS® TaqMan HCV Test, v2.0 For Use With The High Pure System must be interpreted within the context of all relevant clinical and laboratory findings. Assay performance characteristics have been established for individuals treated with peginterferon alfa-2a plus ribavirin. No information is available on the assay's predictive value when other therapies are used. Assay performance for determining the

			state of HCV infection has not been established.
P060040/S008 **9/30/10** **180-Day**	Thoratec HeartMate® II Left Ventricular Assist System (LVAS)	Thoratec Corporation Pleasanton, CA 94588	Approval for a sealed inflow conduit.
P060040/S011 **9/13/10** **180-Day**	HeartMate II® Left Ventricular Assist System (LVAS)	Thoratec Corporation Pleasanton, CA 94588	Approval for updated Instructions for Use (IFU) including post-approval study results.
P070014/S012 **9/15/10** **135-Day**	Bard® Lifestent® Vascular Stent Systems	Bard Peripheral Vascular, Inc. Tempe, Az 85280	Approval for modification to the procedures for implementing shelf lives of raw materials.
P070014/S013 **9/14/10** **135-Day**	Bard® Lifestent® Vascular Stent Systems	Bard Peripheral Vascular, Inc. Tempe, Az 85280	Approval for a modification to a step in the handle assembly process.
P070015/S038 **9/15/10** **135-Day**	XIENCE V™ Everolimus-Eluting Coronary Stent System and PROMUS™ Everolimus-Eluting Coronary Stent System	Abbott Vascular Temecula, CA 92591	Approval for a change to the in-process sampling and testing plan for the primer and drug coating solutions.
P080007/S003 **9/15/10** **135-Day**	E-LUMINEXX® Vascular Stent	Bard Peripheral Vascular, Inc. Tempe, AZ 85280	Approval for modification to the procedures for implementing shelf lives of raw materials.
P080032/S001 **9/14/10** **180-Day**	Alair Bronchial Thermoplasty System	Asthmatx, Inc. Sunnyvale, CA 94089	Approval of the post-approval study protocol.
P090007/S001 **9/23/10** **180-Day**	Elecsys® Anti-HCV Immunoassay & Elecsys ® PreciControl Anti-HCV for use on the Roche cobas e 411	Roche Diagnostics Corp. Indianapolis, IN 46250	Approval for a modification to the device labeling to define the immunoassay cutoff-index above

	Immunoassay Analyzer		which supplemental recombinant immunoblot assay testing is not required.
P090008/S001 9/23/10 180-Day	Elecsys® Anti-HCV Immunoassay & Elecsys ® PreciControl Anti-HCV for use on the Roche cobas e 601 Immunoassay Analyzer	Roche Diagnostics Corp. Indianapolis, IN 46250	Approval for a modification to the device labeling to define the immunoassay cutoff-index above which supplemental recombinant immunoblot assay testing is not required.
P090009/S001 9/23/10 180-Day	Elecsys® Anti-HCV Immunoassay & Elecsys ® PreciControl Anti-HCV for use on the Modular Analytics E170 Immunoassay Analyzer	Roche Diagnostics Corp. Indianapolis, IN 46250	Approval for a modification to the device labeling to define the immunoassay cutoff-index above which supplemental recombinant immunoblot assay testing is not required.

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
P790017/S109 9/14/10	Gruntzig Dilaca Balloon Dilatation Catheters	Medtronic Vascular Santa Rosa, CA 95403	Alternate system for measuring extruded tubing.
P810032/S058 9/9/10	PMMA Multi-Piece Posterior Chamber IOLs	Alcon Research Ltd. Fort Worth, TX 76134	Modifications to the sterilant gas distribution and delivery systems.
P810032/S059 9/22/10	PMMA Intraocular Lenses	Alcon Research, Ltd. Fort Worth, TX 76134	Change in the Packaging System.
P840001/S161 9/10/10	Restore® Ultra	Medtronic Neuromodulation	Changes to the brazed and

		Minneapolis, MN 55432	sputtered filtered feedthrough inspection process.
P840001/S162 9/10/10	Itrel® EZ Patient Programmer and Synergy® EZ Patient Programmer	Medtronic Neuromodulation Minneapolis, MN 55432	Change to remove a conditioning procedure from the Patient Programmers' manufacturing processes.
P840001/S163 9/16/10	Restore ULTRA Implantable Neurostimulator	Medtronic Neuromodulation Minneapolis, MN 55432	Update of the software for the Laser Ribbon Bonding (ORB) processing equipment located at Medtronic's Puerto Rico Operations Company (MPROC) in Juncos, Puerto Rico.
P840060/S035 9/9/10	PMMA Single-Piece Posterior Chamber IOLs	Alcon Research Ltd. Fort Worth, TX 76134	Modifications to the sterilant gas distribution and delivery systems.
P840060/S036 9/22/10	PMMA Intraocular Lenses	Alcon Research, Ltd. Fort Worth, TX 76134	Change in the Packaging System.
P860004/S137 9/1/10	SynchroMed Infusion Systems - Alarm Test Software	Medtronic Neuromodulation Minneapolis, MN 44532	Change to lengthen the time for measuring the alarm output of the "Alarm Test" of the device.
P860019/S260 9/1/10	PTCA Catheters (Maverick 2, Maverick®, Maverick® XL, Quantum™ Maverick®, and APEX®)	Boston Scientific Corporation Maple Grove, MN 55311	Reduction of in-process destructive testing and associated measurements performed on the balloon components of the devices during the balloon molding operation.

P860019/S261 9/8/10	Maverick 2™ Monorail® PTCA Dilation Catheters	Boston Scientific Corporation Maple Grove, MN 55311	Alternate sterilization cycle to be used at Isotron, Tullamore, Ireland.
P860019/S263 9/8/10	Apex PTCA and NC Quantum Apex PTCA Catheters	Boston Scientific Corporation Maple Grove, MN 55311	Changes to the in-process monitoring requirements.
P880087/S017 9/9/10	PMMA Single-Piece Anterior Chamber IOLs	Alcon Research Ltd. Fort Worth, TX 76134	Modifications to the sterilant gas distribution and delivery systems.
P880087/S018 9/22/10	PMMA Single-Piece Anterior Chamber IOLs	Alcon Research, Ltd. Fort Worth, TX 76134	Change in the Packaging System.
P910073/S086 9/8/10	Endotak Reliance Family of Leads	Boston Scientific Corporation St. Paul, MN 55112	Change in the Manufacturing Automated Traceability Tracking (MATT) system used during the manufacturing of leads.
P910077/S107 9/29/10	6481 Latitude Inductive Communicator, 6482 Lattitude RF Communicator, 3120 Programmer/ Recorder/Monitor (PRM)	Boston Scientific Corp. St. Paul, MN 55112	New soldering equipment and site relocation for printed circuit boards supplier.
P920023/S027 9/30/10	AMS UroLume Endoprosthesis	American Medical Systems, Inc. Minnetonka, MN 55343	Change in a measurement method used during receiving/ inspection.
P930014/S042 9/9/10	AcrySof® Monofocal and AcrySof® Toric Posterior Chamber IOLs and AcrySert® Delivery System	Alcon Research Ltd. Fort Worth, TX 76134	Modifications to the sterilant gas distribution and delivery systems.
P930014/S043 9/17/10	AcrySof® and AcrySof IQ Toric Intraocular Lenses	Alcon Research, Ltd. Fort Worth, TX	Use of a new Toric Lens Bench Gauge (Renishaw).

		76134	
P930014/S044 9/22/10	AcrySof® Intraocular Lenses	Alcon Research, Ltd. Fort Worth, TX 76134	Change in the Packaging System.
P950034/S033 9/14/10	Seprafilm Adhesion Barrier	Genzyme Corporation Cambridge, MA 02142	Addition of a new procedure for the Seprafilm labeling and packaging.
P950037/S085 9/10/10	Philos and Philos II Families of IPGs	Biotronik, Inc. Lake Oswego, OR 97035	Alternate joining process of pulse generator housings.
P950037/S086 9/17/10	Philos DR, Philos DR-B, Philos SR, Philos SR-B, Philos DR-T, Philos II DR, Philos II DR-T, Philos II SR, Cylos DR, Cylos DR-T, Cylos VR, Evia DR, Evia DR-T, Evia SR, Evia SR-T, Entovis DR-T, Entovis DR, Entovis SR, and Entovis SR-T PGs; Selox JT, Selox ST, Dextrus, Setrox S, SLS xxxx-BP, and Selox SR Electrodes; CardioMessenger LLT, ICS 3000, and EDP30	Biotronik, Inc. Lake Oswego, OR 97035	New labeling software used to print the labels for various devices and accessories.
P960004/S046 9/22/10	Thinline II ASterox, Thinline Sterox EZ, Fineline II Sterox, and Fineline II Sterox EZ	Boston Scientific Corporation St. Paul, MN 55112	Change to the shelf-life expiration of polyurethane tubing from 36 months to "indefinite".
P960009/S093 9/10/10	Activa® RC	Medtronic Neuromodulation Minneapolis, MN 55432	Changes to the brazed and sputtered filtered feedthrough inspection process.
P960009/S094 9/10/10	Access® Therapy Controller	Medtronic Neuromodulation	Change to remove a conditioning

		Minneapolis, MN 55432	procedure from the Patient Programmers' manufacturing processes.
P960009/S095 9/16/10	Activa RC Deep Brain Stimulator	Medtronic Neuromodulation Minneapolis, MN 55432	Update of the software for the Laser Ribbon Bonding (ORB) processing equipment located at Medtronic's Puerto Rico Operations Company (MPROC) in Juncos, Puerto Rico.
P960016/S032 9/10/10	Livewire TC Cardiac Ablation System	St. Jude Medical, Inc. Minnetonka, MN 55345	Changes to the Livewire TC steerable catheter subassembly process.
P960040/S228 9/3/10	Confient	Boston Scientific Corporation St. Paul, MN 55112	Changes to test software used to perform electrical testing of Integrated Circuits used in pulse generators.
P960040/S229 9/2/10	Vitality, Confient and Teligen	Boston Scientific Corporation St. Paul, MN 55112	Change to the supplied pin length and welding process used in the anode assembly manufacturing process.
P960040/S230 9/8/10	Teligen Implantable Cardioverter defibrillator (ICD)	Boston Scientific Corporation St. Paul, MN 55112	Addition of a 100% pass/fail inspection for capacitors during manufacturing.
P960040/S231 9/14/10	Confient ICDs	Boston Scientific Corporation St. Paul, MN 55112	Change to the thermode blade wing.
P960040/S232	Vitality, Prizm,	Boston Scientific	Addition of heptane

9/17/10	Confient, Teligen	Corporation St. Paul, MN 55112	as a solvent in the pulse generator cleaning step.
PP960040 **9/22/10**	Confient RF-1 HE IS-2 AV and Teligen HE VR DR-1	Boston Scientific Corporation St. Paul, MN 55112	Change to the shelf-life expiration of polyurethane tubing from 36 months to "indefinite".
P960042/S019 **9/1/10**	Spectranetics Laser Sheath II Products	Spectranetics Colorado Springs, CO 80921	Change to the polishing process for the SLS laser sheath distal tip.
P960042/S020 **9/15/10**	SLS II Laser Sheath	Spectranetics Corporation Colorado Springs, CO 80921	Removal of a QC step that verifies the fiber bundle alignment.
P960042/S021 **9/15/10**	Spectranetics SLS II Laser Sheath	Spectranetics Corporation Colorado Springs, CO 80921	Change in the labeling process.
P970003/S113 **9/10/10**	VNS Therapy® Systems	Cyberonics, Inc. Houston, TX 77058	Addition of a supplier in the sterilization process.
P970004/S091 **9/10/10**	InterStim® Patient Programmer	Medtronic Neuromodulation Minneapolis, MN 55432	Change to remove a conditioning procedure from the Patient Programmers' manufacturing processes.
P970027/S009 **9/20/10**	AxSYM Anti-HCV	Abbott Laboratories Abbott Park, IL 60064	Modifications to the quality control test method used to determine a specific attribute of the AxSYM Anti-HCV solution based components.
P980022/S082 **9/9/10**	Paradigm Real Time Insulin Pump	Medtronic, Inc. Northridge, CA 91325	Additional supplier of the molded plastic components used in the

			manufacture of the Paradigm Pump (MMT-522, MMT-522K, MMT-523, MMT-523K).
P980035/S186 9/9/10	Adapta/Versa/ Sensia, Relia IPGs	Medtronic, Inc. Mounds View, MN 55112	Additional supplier for the plating process.
P980035/S187 9/8/10	Sigma, Medtronic 350, EnRhythm and AT500 IPGs	Medtronic, Inc. Cardiac Rhythm and Disease Management Mounds View, MN 55112	Change to the Brazed and Sputtered Filtered Feedthrough inspection process.
P990001/S076 9/8/10	InSync III CRT-P	Medtronic, Inc. Cardiac Rhythm and Disease Management Mounds View, MN 55112	Change to the Brazed and Sputtered Filtered Feedthrough inspection process.
P990009/S030 9/3/10	Floseal Hemostatic Matrix	Baxter Healthcare Corporation McGaw Park, IL 60085	Modification of the thawing process for a component of the device.
P990064/S034 9/8/10	Mosaic Bioprosthesis	Medtronic, Inc. Santa Ana, CA 92705	Modification to the contour ring and sizing pressure.
P000009/S041 9/17/10	Lexos DR, Lexos DR-T, Lexos VR, Lexos VR-T, Lumos DR-T, and Lumos VR-T ICDs	Biotronik, Inc. Lake Oswego, OR 97035	New labeling software used to print the labels for various devices and accessories.
P000010/S017 9/23/10	AMPLICOR HCV Test	Roche Molecular Systems, Inc. Pleasanton, CA 94566	Changes to reduce the batch size for manufacture of Substrate A, Subatrate B, Stop Reagent and Wash Concentrate bulk solution.
P000012/S025 9/23/10	COBAS AMPLICOR HCV Test, Version 2.0 and COBAS AmpliPrep/COBAS AMPLICOR HCV	Roche Molecular Systems, Inc. Pleasanton, CA 94566	Changes to reduce the batch size for manufacture of Substrate A, Subatrate B, Stop

	Test		Reagent and Wash Concentrate bulk solution.
P000025/S049 9/17/10	COMBI 40+ Cochlear Implant System	MED-EL Corporation Durham, NC 27713	Implementation of a quality assurance inspection step for the incoming inspection of the liquid silicone rubber.
P010012/S248 9/3/10	Contak Renewal and Livian	Boston Scientific Corporation St. Paul, MN 55112	Changes to test software used to perform electrical testing of Integrated Circuits used in pulse generators.
P010012/S249 9/2/10	Contak Renewal, Livian and Cognis	Boston Scientific Corporation St. Paul, MN 55112	Change to the supplied pin length and welding process used in the anode assembly manufacturing process.
P010012/S250 9/8/10	Cognis Implantable Cardiac Resynchronization Therapy Defibrillator (CRT-D)	Boston Scientific Corporation St. Paul, MN 55112	Addition of a 100% pass/fail inspection for capacitors during manufacturing.
P010012/S251 9/14/10	Contak Renewal 3 and Livian CRT-Ds	Boston Scientific Corporation St. Paul, MN 55112	Change to the thermode blade wing.
P010012/S252 9/17/10	Livian, Renewal, Cognis	Boston Scientific Corporation St. Paul, MN 55112	Addition of heptane as a solvent in the pulse generator cleaning step.
P010012/S253 9/22/10	Easytrak 2, Easytrak 3, Easytrak 2 IS-1, Easytrak 3 IS-1, Acuity Spiral, Contak Renewal 3 RF, Contak Renewal 3 RF HE, Livian	Boston Scientific Corporation St. Paul, MN 55112	Change to the shelf-life expiration of polyurethane tubing from 36 months to "indefinite".

	RF-1 SE, Livian RF-1 HE, and Cognis.		
P010015/S099 9/8/10	Dema, C-series, and T-series IPGs	Medtronic, Inc. Cardiac Rhythm and Disease Management Mounds View, MN 55112	Change to the Brazed and Sputtered Filtered Feedthrough inspection process.
P010019/S018 9/2/10	Lotrafilcon Soft Contact Lenses for Extended Wear	Ciba Vision Corporation Duluth, GA 30097	Shelf life extension for contact lens material formulations.
P010019/S019 9/8/10	Ciba Vision® (lotrafilcon B) Soft Contact Lens	Ciba Vision Corporation Duluth, GA 30097	Change to eliminate the staging/hold time for the device.
P010030/S022 9/1/10	LifeVest® Wearable Defibrillator	Zoll Lifecor Corporation Pittsburgh, PA 15238	New test texture for the functional testing of the electrode belt.
P020004/S055 9/15/10	Gore® Excluder® AAA Endoprosthesis	W.L. Gore & Associated, Inc. Flagstaff, AZ 86001	Changes to the sterilization cycle process.
P020011/S004 9/17/10	VERSANT® HCV RNA Qualitative Assay/APTIMA® HCV RNA Qualitative Assay	Gen-Probe, Inc. San Diego, CA 92121	Modification to the purification and desalting processes for two classes of oligonucleotides (RXL Intermediates and PPOs), which are components of some reagents of the device.
P020036/S019 9/2/10	Smart® Nitinol Stent System and Smart® Control Nitinol Stent Systems	Cordis Corporation Miami Lakes, FL 33014	Discontinuance of a final packaging inspection.
P020045/S034 9/17/10	Freezor®, Freezor® Xtra Surgical and Freezor® MAX Surgical Catheters and CryoConsole	Medtronic AF Solutions Mounds View, MN 55112	Alternate components for the manufacturing of printed circuit board assemblies.

P030005/S068 9/3/10	Contak Renewal TR	Boston Scientific Corporation St. Paul, MN 55112	Changes to test software used to perform electrical testing of Integrated Circuits used in pulse generators.
P030005/S069 9/17/10	Renewal	Boston Scientific Corporation St. Paul, MN 55112	Addition of heptane as a solvent in the pulse generator cleaning step.
P030009/S044 9/14/10	Driver and Micro Driver Coronary Stent Systems	Medtronic Vascular Santa Rosa, CA 95403	Alternate system for measuring extruded tubing.
P030017/S107 9/3/10	Precision Spinal Cord Stimulator (SCS) System	Boston Scientific Neuromodulation Corp. Valencia, CA 91355	Addition of an alternate supplier for certain components.
P030047/S022 9/2/10	Precise®, Precise® RX, and Precise® PRO Rx Nitinol Stent Systems	Cordis Corporation Miami Lakes, FL 33014	Discontinuance of a final packaging inspection.
P040016/S062 9/1/10	VeriFLEX (Liberté®) Stent Delivery System	Boston Scientific Corporation Maple Grove, MN 55311	Reduction of in-process destructive testing and associated measurements performed on the balloon components of the devices during the balloon molding operation.
P040020/S026 9/9/10	AcrySof® Multifocal Posterior Chamber Intraocular Lenses (IOLs)	Alcon Research Ltd. Fort Worth, TX 76134	Modifications to the sterilant gas distribution and delivery systems.
P040020/S027 9/22/10	AcrySof® Intraocular Lenses	Alcon Research, Ltd. Fort Worth, TX 76134	Change in the Packaging System.
P040027/S021 9/1/10	Gore Viatorr® TIPS Endoprosthesis	W.L. Gore & Associates, Inc. Flagstaff, AZ 86001	Modification to the terminating wire attachment process.

P040027/S022 9/1/10	Gore Viatorr® TIPS Endoprosthesis	W.L. Gore & Associates, Inc. Flagstaff, AZ 86001	Modification of the process parameters for one of the EO sterilization cycles.
P040034/S017 9/16/10	DuraSeal Dural Sealant system	Covidien Bedford, MA 01730	Addition of an alternate lab for testing certain raw materials.
P040037/S028 9/8/10	Gore® Viabahn® Endoprosthesis	W.L. Gore & Associated, Inc. Flagstaff, AZ 86001	Automation of a manufacturing process.
P040037/S029 9/15/10	Gore® Viabahn® Endoprosthesis	W.L. Gore & Associated, Inc. Flagstaff, AZ 86001	Changes to the sterilization cycle process.
P040043/S036 9/15/10	Gore® Tag® Thoracic Endoprosthesis	W.L. Gore & Associated, Inc. Flagstaff, AZ 86001	Changes to the sterilization cycle process.
P040045/S015 9/24/10	Vistakon® (senofilcon A) Contact Lenses, Clear and Visibility Tinted with UV Blocker	Johnson & Johnson Vision Care, Inc. Jacksonville, FL 32256	Change to the Oxygen Permeability Test Method TM-0534.
P050006/S018 9/15/10	Gore® Helex Septal Occluder	W.L. Gore & Associated, Inc. Flagstaff, AZ 86001	Changes to the sterilization cycle process.
P050018/S010 9/8/10	AngioSculpt® PTCA Scoring Balloon Catheters	AngioScore, Inc. Fremont, CA 94538	Alternate supplier for the nitinol scoring element.
P050023/S037 9/17/10	Lumax 300 DR-T, Lumax 340 DR-T, Lumax 300 VR-T, Lumax 340 VRT, Lumax 500 DR-T, Lumax 540 DR-T, Lumax 500 VR-T, Lumax 540 VR-T, Lumax 540 VR-T DX, Lumax 300 HF-T, Lumax 340 HF-T, Lumax 500 HF-T,	Biotronik, Inc. Lake Oswego, OR 97035	New labeling software used to print the labels for various devices and accessories.

	and Lumax 540 HF-T PGs; Corox OTW UP Steroid Electrode, CardioMessenger II, CardioMessenger II-LLT, CardioMessenger -Tline, CardioMessenger II-S, CardioMessenger II-S TLine, CardioMessenger S, and CardioMessenger S TLine		
P050046/S007 9/22/10	Acuity Steerable	Boston Scientific Corporation St. Paul, MN 55112	Change to the shelf-life expiration of polyurethane tubing from 36 months to "indefinite".
P050047/S012 9/14/10	Juvéderm Hyaluronate Gel Implants	Allergan Goleta, CA 93117	Change in the packaging process.
P050047/S013 9/24/10	Juvéderm Hyaluronate Gel Implants	Allergan Goleta, CA 93117	Change in fill volume for the device.
P060002/S015 9/8/10	Bard Flair® Endovascular Stent Graft	Bard Peripheral Vascular, Inc. Tempe, AZ 85280	Upgrade to the maintenance management software program used to track and schedule preventative maintenance talk, equipment, and supplies.
P060002/S016 9/8/10	Bard Flair® Endovascular Stent Graft	Bard Peripheral Vascular, Inc. Tempe, AZ 85280	Updates to the environmental storage specifications for the raw material used in manufacturing.
P060006/S015 9/1/10	Express® SD Premounted Stent	Boston Scientific Corporation	Reduction of in-process destructive

	System	Maple Grove, MN 55311	testing and associated measurements performed on the balloon components of the devices during the balloon molding operation.
P060008/S058 9/1/10	TAXUS® Liberté® Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Reduction of in-process destructive testing and associated measurements performed on the balloon components of the devices during the balloon molding operation.
P060030/S014 9/22/10	COBAS AmpliPrep/ COBAS TaqMan HCV Test	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Changes to release testing procedures used in the CAP/CTM HCV Test.
P060033/S057 9/1/10	Endeavor Zotarolimus-Eluting Coronary Stent Systems and Endeavor Sprint Zotarolimus-Eluting Coronary Stent Systems	Medtronic Vascular Santa Rosa, CA 95403	Change to sterilization load configuration.
P060033/S058 9/14/10	Endeavor Sprint Zotarolimus-Eluting Coronary Stent System	Medtronic Vascular Santa Rosa, CA 95403	Alternate system for measuring extruded tubing.
P070008/S018 9/17/10	Stratos LV and Stratos LV-T CRT-Ps; and Corox OTW(-S) BP Electrode	Biotronik, Inc. Lake Oswego, OR 97035	New labeling software used to print the labels for various devices and accessories.
P070015/S044 9/2/10	XIENCE V™ Everolimus Eluting Coronary Stent System and PROMUS™ Everolimus Eluting	Abbott Vascular Temecula, CA 92591	Change in the number of stents pooled for analytical release testing.

	Coronary Stent System		
P080007/S004 9/8/10	Bard® ELUMINEXX® Vascular Stent	Bard Peripheral Vascular, Inc. Tempe, AZ 85280	Revised formulation for the adhesive used during manufacturing.
P080032/S003 9/30/10	Alair Bronchial Thermoplasty System	Asthmatx, Inc. Sunnyvale, CA 94089	Addition of a new test method for impedance measurement accuracy.
P090018/S005 9/8/10	Esteem	Envoy Medical Corporation St. Paul, MN 55110	Change the manufacture of the Ear Insert Assembly and Microphone Assembly.
P090018/S007 9/21/10	Esteem	Envoy Medical Corporation St. Paul, MN 55110	Changes for the personal programmer.

Summary of PMA Originals & Supplements Approved
Originals: 0
Supplements: 79

Summary of PMA Originals Under Review
Total Under Review: 93
Total Active: 40
Total On Hold: 53
Number Greater Than 180 Days: 5

Summary of PMA Supplements Under Review
Total Under Review: 629
Total Active: 436
Total On Hold: 193
Number Greater Than 180 Days: 16

Summary of All PMA Submissions Received
Originals: 4
Supplements: 67

Summary of PMA Supplement PMA Approval/Denial Decision Times
Number of Approvals: 79
Number of Denials: 0
Average Days Fr Receipt to Decision (Total Time): 120.6
FDA Time: 87.9 Days MFR Time: 32.7 Days

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