PMA Final Decisions for April 2010

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.

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
P080032 [1] **4/27/10**	Alair Bronchial Thermoplasty System	Asthmatx, Inc. Sunnyvale, CA 94089	Approval for the Alair Bronchial Thermoplasty System. The device is indicated for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long acting beta agonists.
P080029 [2] **4/8/10**	Quick-CloseÃ,® Vascular Suturing System	Interventional Therapies, LLC Westport, CT 06880	Approval for the Quick-CloseÃ,® Vascular Suturing System. This device is indicated as follows: The Quick-CloseÃ,® Vascular Suturing System is indicated to close femoral artery access sites and to reduce time-to-hemostasis and time-to-ambulation in patients who have undergone diagnostic or

			interventional endovascular procedures utilizing a 5, 6, 7, or 8 French procedural sheath. Additionally, the Quick-CloseÃ,® Vascular Suturing System is indicated to reduce time-to-hemostasis in patients who have undergone interventional endovascular procedures utilizing a 5, 6, 7, or 8 French procedural sheath, who have received intraprocedural glycoprotein IIb/IIIa inhibitor therapy.
P090007 4/29/10	ElecsysÃ,® Anti-HCV Immunoassay ElecsysÃ,® PreciControl Anti-HCV for use on the Cobas e 411 Immunoassay Analyzer	Roche Diagnostics Corporation Indianapolis, IN 46256	Approval for the ElecsysÃ,® Anti-HCV Immunoassay & ElecsysÃ,® PreciControl Anti-HCV Assay for use on cobas e 411 Immunoassay Analyzer. This device is indicated for: **ElecsysÃ,® Anti-HCV Immunoassay** The Roche Elecsys Anti-HCV assay is an *in vitro* diagnostic test for the qualitative detection of total antibodies to hepatitis C virus (anti-HCV) in human serum or

			plasma (potassium EDTA, lithium heparin and sodium heparin). Assay results, in conjunction with other laboratory results and clinical information, may be used to aid in the presumptive diagnosis of HCV infection in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis C infection. The test does not determine the state of infection or associated disease. The electrochemilu mi-nescence immunoassay "ECLIA" is intended for use on the cobas e 411 immunoassay analyzer. **ElecsysÃ,® PreciControl Anti-HCV** Elecsys PreciControl Anti-HCV is used for quality control of the Elecsys Anti-HCV Immunoassay on the cobas e 411 immunoassay analyzer.
P090008 4/29/10	ElecsysÃ,® Anti-HCV Immunoassay ElecsysÃ,® PreciControl Anti-HCV for use on the Cobas e 601	Roche Diagnostics Corporation Indianapolis, IN 46256	Approval for the ElecsysÃ,® Anti-HCV Immunoassay & ElecsysÃ,® PreciControl Anti-

	Immunoassay Analyzer		HCV Assay for use on cobas e 601 Immunoassay Analyzer. This device is indicated for: **ElecsysÃ,® Anti-HCV Immunoassay** The Roche Elecsys Anti-HCV assay is an *in vitro* diagnostic test for the qualitative detection of total antibodies to hepatitis C virus (anti-HCV) in human serum or plasma (potassium EDTA, lithium heparin and sodium heparin). Assay results, in conjunction with other laboratory results and clinical information, may be used to aid in the presumptive diagnosis of HCV infection in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis C infection. The test does not determine the state of infection or associated disease. The electrochemilu mi-nescence immunoassay "ECLIA" is intended for use on the cobas e 601 immunoassay

			analyzer. **ElecsysÃ,® PreciControl Anti-HCV** Elecsys PreciControl Anti-HCV is used for quality control of the Elecsys Anti-HCV Immunoassay on the cobas e 601 immunoassay analyzer.
P090009 **4/29/10**	ElecsysÃ,® Anti-HCV Immunoassay ElecsysÃ,® PreciControl Anti-HCV for use on the MODULAR ANALYTICS E170 Analyzer	Roche Diagnostics Corporation Indianapolis, IN 46256	Approval for the ElecsysÃ,® Anti-HCV Immunoassay & ElecsysÃ,® PreciControl Anti-HCV Assay for use on MODULAR ANALYTICS E170 Analyzer. This device is indicated for: **ElecsysÃ,® Anti-HCV Immunoassay** The Roche Elecsys Anti-HCV assay is an *in vitro* diagnostic test for the qualitative detection of total antibodies to hepatitis C virus (anti-HCV) in human serum or plasma (potassium EDTA, lithium heparin and sodium heparin). Assay results, in conjunction with other laboratory results and clinical information, may be used to aid in the presumptive

			diagnosis of HCV infection in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis C infection. The test does not determine the state of infection or associated disease. The electrochemilu mi-nescence immunoassay "ECLIA" is intended for use on the MODULAR ANALYTICS E170 immunoassay analyzer. **ElecsysÃ,® PreciControl Anti-HCV** Elecsys PreciControl Anti-HCV is used for quality control of the Elecsys Anti-HCV Immunoassay on the MODULAR ANALYTICS E170 immunoassay analyzer.
P090022 [3] **4/12/10**	Softec HD Posterior Chamber Intraocular Lens (PCIOL)	Lenstec, Inc. St. Petersburg, FL 33716	Approval for the Softec HD Posterior Chamber Intraocular Lens (PCIOL). The device is indicated for the replacement of the human crystalline lens following phacoemulsification cataract removal in adults over the age of 21. The lens is indicated for capsular bag

			placement.
APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
N18286/S019 **4/8/10** **Special**	Gelfoam Plus Hemostatis Kit	Pfizer, Inc. New York, New York 10017	Approval to add a statement in the contraindications section of the labeling to address the potential risk in patients with known allergies to porcine collagen.
P860019/S241 **4/16/10** **Real-Time**	NC Quantum Apex Monorail and Over-the-Wire PTCA Catheters	Boston Scientific Corporation Maple Grove, MN 55311	Approval for: 1) a new balloon and markerband materials; 2) extension of the product matrix to include a 6mm length; 3) an alternate bond for Monorail models; and 4) a change in the hydrophilic coating length on Over-the-Wire models.
P870025/S009 **4/23/10** **135-Day**	Fetal Acoustic Stimulator (FAST)	GE Healthcare Laurel, MD 20723	Approval for a change in supplier of a coil assembly.
P900052/S017 **4/21/10** **Real-Time**	PORT-A-CATH II Low Profile Epidural Implantable Access System	Smiths Medical MD, Inc. St. Paul, MN 55112	Approval for modifications to the post-housing material and the guidewire coating.
P910077/S102 **4/6/10** **Real-Time**	Latitude Patient Management System	Boston Scientific CRM St. Paul, MN 55112	Approval for changes to the Latitude Regulated Application Software on Latitude System Server (Model 6488, v6.0).
P940013/S010 **4/13/10**	CIBA VISIONÃ,® (vasurfilcon A) Soft	CIBA VISION Corporation	Approval for a manufacturing site

180-Day	Contact Lenses	Duluth, GA 30097	located at P.T. CIBA VISION Batam, Batam Island, Indonesia for Front-end processing of the device.
P950032/S056 4/9/10 Real-Time	Apligraf (Graftskin)	Organogenesis, Inc. Canton, MA 02021	Approval for the introduction of keratinocyte cell strain (HEP072) into the manufacture of Apligraf.
P950037/S078 4/30/10 Real-Time	Lumax 540 VR-T DX Implantable Cardioverter Defibrillator	Biotronik, Inc. Lake Oswego, OR 97035	Approval for introduction of the Lumax 540 VR-T DX Implantable Cardioverter Defibrillator (ICD), a single lead ICD system used in conjunction with the currently approved Kainox A+ ICD lead. The device, as modified, will be marketed under the trade name Lumax 540 VR-T DX ICD and is indicated for providing ventricular antitachycardia pacing and ventricular defibrillation, for automated treatment of life threatening ventricular arrhythmias.
P960009/S049 4/16/10	Activa Tremor Control System	Medtronic Neuromodulation Minneapolis, MN 55432	Approval of the post-approval study protocol.
P960009/S080 4/30/10	Medtronic ActivaÃ,®	Medtronic Neuromodulation	Approval for adding a warning to both

Special	ParkinsonÃ¢??s Control Therapy	Minneapolis, MN 55432	the physician and patient manuals.
P960013/S054 **4/14/10** **180-Day**	Tendris STS Lead	St. Jude Medical, CRMD Sylmar, CA 91342	Approval for the Tendril STS Model 1988TC lead.
P960040/S214 **4/2/10** **Real-Time**	Teligen Pulse Generators	Boston Scientific St. Paul, MN 55112	Approval for 2 nd supplier (IXYS) to provide SCR/Anode gate Thyristors for the Super Output Module (SOM) of the Cognis/Teligen PGs.
P970003/S108 **4/14/10** **Special**	VNS Therapy System	CyberonicsÃ,®, Inc. Houston, TX 77058	Approval for labeling changes for End of Service (EOS) Warning and low Impedance Warning.
P970004/S079 **4/13/10** **Real-Time**	Medtronic InterStimÃ,® Therapy for Urinary Control	Medtronic Neuromodulation Minneapolis, MN 55432	Approval for a change to the hub material of the Foramen needle in the Medtronic InterStimÃ,® Accessory kits (Models 041828, 041829, and 3065U).
P970004/S082 **4/2/10** **180-Day**	InterStim Urinary Therapy	Medtronic Neuromodulation Minneapolis, MN 55432	Approval of the post-approval study protocol.
P970008/S048 **4/30/10** **Real-Time**	Urologix TargisÃ¢?¢ System for the Treatment of BPH	Urologix, Inc. Minneapolis, MN 55447	Approval for software changes to the Urologix Targis System CoolWaveÃ,® Control Unit Model 5000A.
D970012/S076 **4/30/10** **Special**	AMS 700Ã¢?¢ Series Product Line Inflatable Penile Prostheses	American Medical Systems, Inc. Minnetonka, MN 55343	Approval for modifications to the Operating Room Manual to improve the pre-operative

			preparation instructions for the Momentary Squeeze (MS) Pump.
P970018/S018 **4/2/10** **180-Day**	BD Prepstain System	BD Diagnostic Systems Durham, NC 27703	Approval for a manufacturing site located at TriPath Imaging, Inc., Mebane, North Carolina.
P970029/S017 **4/15/10** **Special**	TMR2000 Holmium Laser System	Cariogenesis Corporation Irvine, CA 92618	Approval for modification of an existing warning statement to state: Ã¢??Each Handpiece Delivery System is supplied sterile for single use only. Do not reuse or resterilize. Any attempt to clean and resterilize can damage the fiberoptic.Ã¢?□
P970051/S060 **4/23/10** **135-Day**	Nucleus 24 Cochlear Implant System	Cochlear Americas Centennial, CO 80111	Approval for modification of the methodology used for the final electrode testing of te CI500 series implant.
P980022/S068 **4/5/10** **Real-Time**	Paradigm Real-Time Insulin Pump	Medtronic, Inc. Diabetes Northridge, CA 91325	Approval for modification to the Paradigm Real-Time Insulin Pump to add an insulation pad to the pump motor flex cable and is indicated for continuous delivery of insulin at set and variable rates, for the management of diabetes mellitus in persons requiring

			insulin. In addition to delivery of insulin, the Paradigm Insulin Pump is designed to receive and display real-time glucose values received via a compatible transmitting device.
P980049/S050 **4/7/10** **180-Day**	Paradym VR/DR	ELA Medical, Inc. Plymouth, MN 55441	Approval for the Paradym VR Model 8250 and DR Model 8550 with Smartview 2.18UG1 Programmer Software and the Paradym CRT-D Model 8750 with Hardware and Manufacturing Changes and Labeling and Programmer Software Changes to the Ovatio VR Model 6250, DR Model 6550 and CRT-D Model 6750. The device, as modified, will be marketed under the trade name Paradym VR Model 8250 and Paradym DR Model 8550 with Smartview 2.18UG1 and is indicated for use in patients who are at high risk of sudden cardiac death due to ventricular tachyarrhythmias and who have experienced one of the following situations: Survival

			of at least one episode of cardiac arrest manifested by the loss of consciousness) due to ventricular tachyarrhythmia, recurrent poorly tolerated sustained ventricular tachycardia.
P980049/S053 **4/27/10** **135-Day**	Ovatio VR ICD and Ovatio DR ICD	ELA Medical, Inc. Plymouth, MN 55441	Approval for a change to the soldering and cleaning processes for the Shock 6 hybrid modules.
P990071/S011 **4/7/10** **Special**	Stocked 70 Radiofrequency Ablation Generator with CoolFlow Irrigation Pump; Cool Flow Tubing Set	Biosense Webster, Inc. Diamond Bar, CA 91765	Approval for changes in the labeling made to the CoolFlow Irrigation PumpÃ¢??s Tubing set.
P000040/S014 **4/23/10** **180-Day**	GeneSys HTAÃ¢?¢ System	Boston Scientific Corporation Urology & WomenÃ¢??s Health Marlborough, MA 01752	Approval for the Ã¢??next generationÃ¢?□ HTA System with a redesigned operational unit (control unit, power cord, pedestal, IV pole) and a modified sterile procedure set. The device, as modified, will be marketed under the trade name GeneSys HTA System and is indicated for ablation of the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive uterine

			bleeding) due to benign causes for whom childbearing is complete.
P010012/S234 **4/2/10** **Real-Time**	Cognis Pulse Generators	Boston Scientific St. Paul, MN 55112	Approval for 2 nd supplier (IXYS) to provide SCR/Anode gate Thyristors for the Super Output Module (SOM) of the Cognis/Teligen PGs.
P010032/S032 **4/8/10** **Real-Time**	Eon mini Implantable Pulse Generator (IPG) Neurostimulation System	Advanced Neuromodulation Systems Plano, TX 75024	Approval for the incorporation of a color additive to change the color of the pocket sizer to yellow, so that it would be more easily visible to the physician.
P020014/S029 **4/6/10** **180-Day**	Conceptus EssureÃ,® System for Permanent Birth Control	Conceptus, Inc. Mountain View, CA 94041	Approval for updated micro-insert placement rates in the physician labeling resulting from the ESS305 post-approval study.
P030002/S022 **4/30/10** **Real-Time**	CrystalensÃ,® Model AT-45 Accommodating Intraocular Lens (IOL)	Bausch & Lomb, Inc. Aliso Viejo, CA 92656	Approval to modify the PhysicianÃ¢??s Labeling to include the addition of 0.25 diopter increments for the Crystalens Model AT50AO lenses in the +17 to +27 dioptric power range and for Model AT52AO lenses in the +16 to +16.75 dioptric power range.
P030011/S007 **4/28/10** **180-Day**	SynCardia temporary Total Artificial Heart (TAH-t)	SynCardia Systems, Inc. Tucson, AZ 85713	Approval for the trade name change of the subject device. The device

			will be marketed under the trade name SynCardia temporary Total Artificial Heart and is indicated for use in transplant-eligible candidates in imminent danger of death from irreversible biventricular failure.
P030025/S069 **4/27/10** **135-Day**	TAXUSÃ,® Express 2Ã,® Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Approval for a change in the stent coating process.
P030039/S015 **4/5/10** **Special**	CoSeal Surgical Sealant and Accessories	Baxter Healthcare Corporation McGaw Park, IL 60085	Approval for changes to the labeling to address safety-related information.
P040001/S016 **4/30/10** **180-Day**	X-STOPÃ,® Interspinous Process Spacer System	Medtronic Spine LLC Sunnyvale, CA 94089	Approval for additional surgical instruments, changes to existing instruments and a new sterilization tray. These new components include the Sizing Distractor, the Spacer Insertion Instrument with tri-lobe connectors, the Bi-directional Sizing Distractor, the Horizontal Handle, the Trial Spacers, and the Two-level Sterilization Tray.
P040003/S007 **4/19/10** **180-Day**	Exablate 2100 Magnetic Resonance (MR) Guided Focused Ultrasound	Insightec, Inc. Dallas, TX 75244	Approval of the post-approval study protocol.

P040012/S031 **4/30/10** **180-Day**	RX ACCULINK Carotid Stent System	Abbott Vascular Santa Clara, CA 95054	Approval for modifications to the indication statement and Instructions for Use to incorporate use with the Emboshield Embolic Protection System. The device, as modified, will be marketed under the trade name RX ACCULINK Carotid Stem System and is indicated for use in conjunction with Abbott Vascular's Accunet or Emboshield family of Embolic Protection Systems, for the treatment of patients at high risk for adverse events from carotid endarterectomy who require carotid revascularization and meet the criteria as previously approved.
P040023/S014 **4/20/10** **180-Day**	Duraloc Option Ceramic Hip System	Depuy Orthopaedics, Inc. Warsaw, IN 46581	Approval of the post-approval study protocol.
P040024/S045 **4/7/10** **135-Day**	RestylaneÃ,® Injectable Gel	Medicis Pharmaceutical Corporation Scottsdale, AZ 85256	Approval for changes in microbiological and environmental testing at the manufacturing sites in Sweden.
P050007/S024 **4/22/10** **Real-Time**	StarCloseÃ,® and StarCloseÃ,® SE Vascular Closure	Abbott Vascular, Inc. Redwood City, CA	Approval for changes to the pouch design and

	Systems	94063	packaging methods.
P050017/S005 **4/12/10** **Real-Time**	ZilverÃ,® Vascular Stent and ZilverÃ,® Vascular Stent with Rapid Exchange Delivery System	Cook, Inc. Bloomington, IN 47402	Approval for revised product labeling.
P050023/S029 **4/30/10** **Real-Time**	Lumax 540 VR-T DX Implantable Cardioverter Defibrillators	Biotronik, Inc. Lake Oswego, OR 97035	Approval for introduction of the Lumax 540 VR-T DX Implantable Cardioverter Defibrillator (ICD), a single lead ICD system used in conjunction with the currently approved Kainox A+ ICD lead. The device, as modified, will be marketed under the trade name Lumax 540 VR-T DX ICD and is indicated for providing ventricular antitachycardia pacing and ventricular defibrillation, for automated treatment of life threatening ventricular arrhythmias.
P060001/S008 **4/28/10** **Special**	PROTÃƒ?GÃƒ? GPS and RX Carotid Stent Systems	ev3 Endovascular, Inc. Plymouth, MN 55441	Approval for the addition of a new material specification and an incoming inspection step for the annealed tantalum sphere components of the device.
P060002/S011 **4/16/10**	FLAIR Endovascular Stent Graft	Bard Peripheral Vascular, Inc.	Approval for modifications to the

Special		Tempe, AZ 85280	device Instructions for Use to include language to improve the safety in use of the device, predominantly with respect to the potential for device migrations.
P060008/S024 **4/27/10** **135-Day**	TAXUSÃ,® LibertÃƒ©Ã,® Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Approval for a change in the stent coating process.
P060022/S006 **4/1/10** **Real-Time**	Akreos Advance Optics Aspheric Lens and Akreos AO Micro Incision Lens	Bausch & Lomb Rochester, NY 14609	Approval for design modifications to Model MI60L and use of Medicel VISCOJECT 2.2 LP60430 inserter with Model AO60 and is indicated for the replacement of the human crystalline lens in the visual correction of aphakia.
P060027/S015 **4/7/10** **180-Day**	Paradym CRT-D and Ovatio VR/DR	ELA Medical, Inc. Plymouth, MN 55441	Approval for the Paradym VR Model 8250 and DR Model 8550 with Smartview 2.18UG1 Programmer Software and the Paradym CRT-D Model 8750 with Hardware and Manufacturing Changes and Labeling and Programmer Software Changes to the Ovatio VR Model 6250, DR Model 6550 and CRT-D Model 6750.

			The device, as modified, will be marketed under the trade name Paradym VR Model 8250 and Paradym DR Model 8550 with Smartview 2.18UG1 and is indicated for use in patients who are at high risk of sudden cardiac death due to ventricular tachyarrhythmias and who have experienced one of the following situations: Survival of at least one episode of cardiac arrest manifested by the loss of consciousness) due to ventricular tachyarrhythmia, recurrent poorly tolerated sustained ventricular tachycardia.
P060027/S019 **4/27/10** **135-Day**	Ovatio CRT-D	ELA Medical, Inc. Plymouth, MN 55441	Approval for a change to the soldering and cleaning processes for the Shock 6 hybrid modules.
P060033/S049 **4/28/10** **180-Day**	Endeavor Zotarolimus-Eluting Coronary Stent	Medtronic Vascular Santa Rosa, CA 95403	Approval of the post-approval study protocol.
P060040/S006 **4/19/10** **180-Day**	Thoratec HeartMate II Left Ventricular Assist System (LVAS)	Thoratec Corporation Pleasanton, CA 94588	Approval for a design change to the pump end bend relief (PEBR) region of the HeartMate II percutaneous lead.
P060040/S007 **4/6/10**	Thoratec HeartMate II Left Ventricular	Thoratec Corporation	Approval for a repair kit (HM II

Real-Time	Assist System (LVAS)	Pleasanton, CA 94588	PLRK) for the external portion of the HeartMate II percutaneous lead and a repair kit (Clam Shell) for the external bend relief.
P060040/S009 **4/30/10** **Special**	Thoratec HeartMate II Left Ventricular Assist System (LVAS)	Thoratec Corporation Pleasanton, CA 94588	Approval for providing additional information in the labeling regarding the proper procedure for making connections between the electrical power cables of the device.
P070007/S016 **4/1/10** **Real-Time**	Talent Thoracic Stent Graft System	Medtronic Vascular Santa Rosa, CA 95403	Approval for a change to the stent graft spring attachment tensile strength specification.
P070007/S017 **4/30/10** **Special**	Talent Thoracic Stent Graft System	Medtronic Vascular Santa Rosa, CA 95403	Approval for labeling changes regarding over sizing beyond current recommendations and the placement of bare springs inside of covered stent grafts.
P070015/S028 **4/1/10** **Real-Time**	XIENCE VÃ,® Everolimus Eluting Coronary Stent System	Abbott Vascular Temecula, CA 92591	Approval for *the In vivo In vitro* Correlation (IVIVC) method for the device.
P070022/S002 **4/15/10** **180-Day**	AdianaÃ,® Permanent Contraception System	Hologic, Inc. Marlborough, MA 01652	Approval for a manufacturing site located at Biotest Laboratories, Inc. Minneapolis, Minnesota .
P070027/S015	Talent Abdominal	Medtronic Vascular	Approval of the

4/29/10 180-Day	Stent Graft System	Santa Rosa, CA 95403	post-approval study protocol.
P070027/S016 4/1/10 Real-Time	Talent Abdominal Stent Graft System	Medtronic Vascular Santa Rosa, CA 95403	Approval for a change to the stent graft spring attachment tensile strength specification.
APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
N18033/S046 4/30/10	VISTAKONÃ,® (etafilcon A) Contact Lens	Johnson & Johnson Vision Care, Inc. Jacksonville, FL 32256	Alternate suppler for the foil lidstock material.
P790017/S107 4/21/10	Sprinter Legend Rapid Exchange Balloon Dilatation Catheters	Medtronic Vascular Santa Rose, CA 95403	Additional vendor for a component of the device.
P810046/S236 4/23/10	Simpson-RobertÃ,® Coronary Balloon Dilatation Catheters (VOYAGERÃ,® and VOYAGER NC)	Abbott Vascular Temecula, CA 92591	Requested a change in manufacturing equipment used to coat the stent delivery system and balloon dilatation catheters.
P830061/S050 4/28/10	CapSure, CapSure Z Novus, STERx Tip Pacing Lead (ventricular), Vitatron Excellence S+, Vitatron Excellence SS+, Vitatron Impulse, and Vitatron Impulse II Families	Medtronic, Inc. Mounds View, MN 55112	Addition of a business rule to the Manufacturing Execution System.
P840001/S149 4/16/10	Restore Family of Implantable Neurostimulators	Medtronic Neuromodulation Minneapolis, MN 55432	Implementation of the QualityHold Business Rule within the FACTORY works manufacturing traceability system.
P840001/S150	RestoreÃ,®	Medtronic, Inc.	Addition of a

4/30/10	Implantable Neurostimulators	Minneapolis, MN 55432	supplier for the planting process.
P850089/S065 4/28/10	CapSure, CapSure Z Novus, STERx Tip Pacing Lead (ventricular), Vitatron Excellence S+, Vitatron Excellence SS+, Vitatron Impulse, and Vitatron Impulse II Families	Medtronic, Inc. Mounds View, MN 55112	Addition of a business rule to the Manufacturing Execution System.
P860004/S124 4/16/10	Synchromed Family of Implantable Infusion Pumps	Medtronic Neuromodulation Minneapolis, MN 55432	Implementation of the QualityHold Business Rule within the FACTORY works manufacturing traceability system.
P860019/S251 4/6/10	Maverick XL PTCA Dilatation Catheter	Boston Scientific Corporation Maple Grove, MN 55311	Change to the method used to create the proximal marks on the shaft of the stent delivery system.
P860019/S253 4/22/10	Maverick 2Ã¢?¢ Monorail Percutaneous Transluminal Coronary Angioplasty (PTCA Catheters)	Boston Scientific Corporation Maple Grove, MN 55311	Alternate manufacturing process flow for the device.
P880086/S186 4/23/10	Frontier/Frontier II Family of CRT-Ps	St. Jude Medical Sunnyvale, CA 94086	Change in automated manufacturing tests.
P890003/S187 4/28/10	CapSure, CapSure Model, Prodigy, Service Kit-Pacemaker Repair Kit, Thera-I, Vitatron Legacy, Vitatron Legacy II, and Vitatron Visa Families	Medtronic, Inc. Mounds View, MN 55112	Addition of a business rule to the Manufacturing Execution System.
P900061/S088	Gem, PCD Tachy	Medtronic, Inc.	Addition of a

4/28/10	Control System, Jewel, Micro Jewel, Micro Jewel II, Oval Patch Lead, Epicardial Patch Lead Families	Mounds View, MN 55112	business rule to the Manufacturing Execution System.
P910023/S231 4/23/10	Cadence Family of ICDs	St. Jude Medical Sunnyvale, CA 94086	Change in automated manufacturing tests.
P910077/S103 4/1/10	LatitudeÃ¢?¢ Communicator RF	Boston Scientific Corporation St. Paul, MN 55112	Use of new test management system at device final test.
P920015/S059 4/28/10	Sprint, Sprint Fidelis, Sprint Quattro, Subcutaneous Lead, Sub-Q Defibrillation Lead, Transvene CS/SVC Lead, Transvene DF1 Lead, Transvene RV Lead, Transvene SubQ Lead, Transvene SVC Lead Families	Medtronic, Inc. Mounds View, MN 55112	Addition of a business rule to the Manufacturing Execution System.
P930039/S036 4/28/10	CapSure, SureFix, Vitatron Crystalline ActFix, Vitatron Pirouet S+ Families	Medtronic, Inc. Mounds View, MN 55112	Addition of a business rule to the Manufacturing Execution System.
P940034/S018 4/23/10	AMPLIFIEDÃ,® MTD (Mycobacterium Tuberculosis Direct) Test	Gen-Probe, Inc. San Diego, CA 92121	Change of location for a QC lab to segregate the pre- and post-amplification steps into separate rooms.
P950018/S013 4/2/10	PerfluoronÃ,®	Alcon Research, Ltd. Fort Worth, TX 76134	Room changes, mechanical changes and an oven replacement.
P950020/S039 4/6/10	Coronary FlextomeÃ,® Cutting BalloonÃ,®	Boston Scientific Corporation Maple Grove, MN 55311	Implementation of a new coating process for mandrels.

P950024/S020 4/28/10	CapSure Epicardial Pacing Lead Families	Medtronic, Inc. Mounds View, MN 55112	Addition of a business rule to the Manufacturing Execution System.
P950032/S057 4/9/10	ApligrafÃ,®	Organogenesis, Inc. Canton, MA 02021	Change in an alternate in-process tray assembly.
P960009/S079 4/30/10	ActivaÃ,® Implantable Neurostimulators	Medtronic, Inc. Minneapolis, MN 55432	Addition of a supplier for the planting process.
P960016/S028 4/6/10	Livewire TCÃ¢?¢ Cardiac Ablation System	St. Jude Medical Minnetonka, MN 55345	Replacement of the custom thermometer equipment used in the Sensor Test with off-the-shelf thermometer equipment.
P960040/S219 4/15/10	TELIGEN Family of ICDs	Boston Scientific St. Paul, MN 55112	Second source supplier for connector blocks.
P960040/S220 4/15/10	TELIGEN, CONFIENT and VITALITY Families of ICDs	Boston Scientific St. Paul, MN 55112	Changes to the hybrid cleaning process to align with other product lines.
P970004/S083 4/16/10	Interstim Family of Implantable Neurostimulators	Medtronic Neuromodulation Minneapolis, MN 55432	Implementation of the QualityHold Business Rule within the FACTORY works manufacturing traceability system.
P970004/S084 4/30/10	InterStimÃ,® Implantable Neurostimulator	Medtronic, Inc. Minneapolis, MN 55432	Addition of a supplier for the planting process.
P970008/S050 4/15/10	Urologix Targis System for the Treatment of BPH	Urologix, Inc. Minneapolis, MN 55447	Change in the cooling balloon bonding process.
P970012/S066 4/28/10	Kappa 400 Family	Medtronic, Inc. Mounds View, MN 55112	Addition of a business rule to the Manufacturing Execution System.
D970012/S075 4/22/10	AMS AmbicorÃ,® Penile Prosthesis	American Medical Systems, Inc.	Implementation of an additional,

		Minnetonka, MN 55343	duplicate mold for a component of the assembly.
P970020/S055 4/23/10	MULTI-LINK ZETAÃ,® Coronary Stent System (CSS)	Abbott Vascular Temecula, CA 92591	Requested a change in manufacturing equipment used to coat the stent delivery system and balloon dilatation catheters.
P980016/S233 4/28/10	CapSure, Entrust, Gem, Gem II, Gem III, Intrinsic, Marquis, Maximo, Maximo II, Onyx, Secura, Virtuoso, and Virtuoso II Families	Medtronic, Inc. Mounds View, MN 55112	Addition of a business rule to the Manufacturing Execution System.
P980016/S235 4/30/10	EnTrust ICD, Secura DR ICD, Secura VR ICD, Maximo II DR Maximo II VR, Virtuoso II DR ICD, Virtuoso ICD, Virtuoso II VR ICD	Medtronic, Inc. Mounds View, MN 55112	Addition of an alternate supplier for the gold planting process.
P980035/S163 4/28/10	350 Series, Adapta, AT500, EnPulse, EnRhythm, Kappa 600, Kappa 700, Kappa 800, Kappa 900, Relia, Sensia, Versa, and Sigma Families	Medtronic, Inc. Mounds View, MN 55112	Addition of a business rule to the Manufacturing Execution System.
P980035/S164 4/30/10	EnRhythm IPG, Adapta, Versa, Sensia IPG, Relia IPG	Medtronic, Inc. Mounds View, MN 55112	Addition of an alternate supplier for the gold planting process.
P980049/S055 4/22/10	Isoline 2CR and Isoline 2CT Leads	ELA Medical, Inc. Plymouth, MN 55442	Change in incoming inspection procedure.
P980050/S048 4/28/10	Jewel AF, Gem III AT, and CS-SVD Transvene Lead Families	Medtronic, Inc. Mounds View, MN 55112	Addition of a business rule to the Manufacturing Execution System.

P990001/S065 4/28/10	Clarity, DA+ C-Series, DA+ T-Series, Diamond 3, Diamond II, Jade 3, Jade II, Ruby 3, Ruby II, Selection AFm, Topaz 3, Topaz II, Vita, and Vita 2 Families	Medtronic, Inc. Mounds View, MN 55112	Addition of a business rule to the Manufacturing Execution System.
P990034/S017 4/16/10	IsoMed Infusion Pumps	Medtronic Neuromodulation Minneapolis, MN 55432	Implementation of the QualityHold Business Rule within the FACTORY works manufacturing traceability system.
P000010/S015 4/8/10	Amplicor HCV Test, version 2.0	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Room changes for the manufacture of Quantitation Standard and Internal Control Reagents.
P000010/S016 4/7/10	Amplicor HCV Test	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Changes to the CIP process for the bulk formulation tanks and their associated filling transfer lines, and minor modifications to the hopper equipment used in the formulation of bulk reagents for the device.
P000012/S022 4/8/10	Cobas Amplicor HCV Test, version 2.0 and Cobas AmpliPrep/Cobas Amplicor HCB Test, version 2.0	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Room changes for the manufacture of Quantitation Standard and Internal Control Reagents.
P000021/S016 4/26/10	DimensionÃ,® TPSA FlexÃ,® Reagent Cartridge	Siemens Healthcare Diagnostics, Inc. Newark, DE 19714	Replacement of the insulin supply used in the antibody growth media production process

			to compensate for a shortage.
P000039/S035 4/22/10	AMPLATZERÃ,® Septal Occluder and AMPLATZERÃ,® Exchange System	AGA Medical Corporation Plymouth, MN 55442	Addition of an alternate component supplier.
P000053/S028 4/23/10	AMS 800 Artificial Urinary Sphincter	American Medical Systems Minnetonka, MN 55343	Modification of a parameter in a receiving inspection test for silicone used in the coating process.
P010012/S238 4/15/10	COGNIS Family of CRT-Ds	Boston Scientific St. Paul, MN 55112	Second source supplier for connector blocks.
P010012/S239 4/15/10	COGNIS, LIVIAN and RENEWAL 3 Families of CRT-Ds	Boston Scientific St. Paul, MN 55112	Changes to the hybrid cleaning process to align with other product lines.
P010015/S083 4/28/10	Attain, InSync, and InSync III Families	Medtronic, Inc. Mounds View, MN 55112	Addition of a business rule to the Manufacturing Execution System.
P010019/S013 4/1/10	Lotrafilcon Soft Contact lenses for Extended Wear	CIBA Vision Corporation Duluth, CA 30097	Change to the use of an automated vision inspection systems.
P010020/S015 4/23/10	Acticon Neosphincter Artificial Bowel Sphincter	American Medical Systems Minnetonka, MN 55343	Modification of a parameter in a receiving inspection test for silicone used in the coating process.
P010031/S192 4/28/10	Concerto, Concerto II, Consulta, InSync ICD, InSync Marquis, InSync Maximo, InSync II Marquis, Maximo II, InSync II Protect, InSync III Marquis, and InSync Sentry Families	Medtronic, Inc. Mounds View, MN 55112	Addition of a business rule to the Manufacturing Execution System.

P010031/S194 4/30/10	Concerto II ICD, Consulta CRT-D, Maximo II CRT-D, Concerto CRT-D	Medtronic, Inc. Mounds View, MN 55112	Addition of an alternate supplier for the gold planting process.
P010047/S002 4/15/10	Neomend Progel Pleural Air Leak Sealant	Neomend, Inc. Irvine, CA 926178	Change from a manual manufacturing process to automated process for filling a component.
P020004/S051 4/14/10	Gore ExcluderÃ,® AAA Endoprosthesis	W.L. Gore & Associates Flagstaff, AZ 86003	Modification to deployment force and tensile strength specifications for the device components.
P020011/S003 4/23/10	VERSANTÃ,® HCV RNA Qualitative Assay and APTIMAÃ,® HCV RNA Qualitative Assay	Gen-Probe, Inc. San Diego, CA 92121	Change of location for a QC lab to segregate the pre- and post-amplification steps into separate rooms.
P020024/S028 4/22/10	AMPLATZERÃ,® Duct Occluder and 180 Degree Delivery System	AGA Medical Corporation Plymouth, MN 55442	Addition of an alternate component supplier.
P020027/S011 4/26/10	DimensionÃ,® FPSA FlexÃ,® Reagent Cartridge	Siemens Healthcare Diagnostics, Inc. Newark, DE 19714	Replacement of the insulin supply used in the antibody growth media production process to compensate for a shortage.
P020030/S006 4/29/10	Situs OTW UW28D Leads	ELA Medical, Inc. Plymouth, MN 55441	Change in laser welding energy monitoring.
P020047/S018 4/23/10	MULTI-LINK VISIONÃ,® Family of Coronary Stent Systems (VISIONÃ,® and MINI-VISIONÃ,®)	Abbott Vascular Temecula, CA 92591	Requested a change in manufacturing equipment used to coat the stent delivery system and balloon dilatation

			catheters.
P030017/S101 4/6/10	PrecisionÃ,® Spinal Cord Stimulator (SCS) System	Boston Scientific Neuromodulation Corporation Valencia, CA 91355	Consolidation to a single component supplier for the Artisan 2X8 Surgical Lead Disc Electrode.
P030017/S103 4/28/10	Precision Spinal Cord Stimulator (SCS) System Artisan 2x8 Surgical Lead	Boston Scientific Neuromodulation Corporation Valencia, CA 91355	Use of a rework process within the production process to increase product yield.
P030035/S067 4/23/10	Affinity/Integrity/ Victory Family of Pacemakers	St. Jude Medical Sunnyvale, CA 94086	Change in automated manufacturing tests.
P030036/S016 4/28/10	SelectSecure Families	Medtronic, Inc. Mounds View, MN 55112	Addition of a business rule to the Manufacturing Execution System.
P030049/S008 4/20/10	ADVIA Centaur HBsAg Assay	Siemens Healthcare Diagnostics East Walpole, MA 02032	Change of raw material used in the production of the Lite Reagent buffer.
P030054/S147 4/23/10	Epic HF/Atlas+ HF Family of CTR-Ds	St. Jude Medical Sunnyvale, CA 94086	Change in automated manufacturing tests.
P040040/S012 4/22/10	AMPLATZERÃ,® Muscular VSD Occluder	AGA Medical Corporation Plymouth, MN 55442	Addition of an alternate component supplier.
P040044/S029 4/28/10	MynxÃ,® Vascular Closure Device	Access Closure, Inc. Mountain View, CA 94043	Adding a manufacturing process for the advancer tube component in-house.
P040044/S030 4/30/10	MynxÃ,® Vascular Closure Device	Access Closure, Inc. Mountain View, CA 94043	Moving post-sterile activities associated with product handling, storage and shipping from one facility to another

			facility on the same street.
P040045/S013 4/30/10	VISTAKONÃ,® (senofilcon A) Contact Lenses	Vistakon, Division of Johnson & Johnson Vision Care Jacksonville, FL]32256	Addition of a new supplier for soil lidding material.
P050028/S006 4/8/10	Cobas TaqMan HBV Test	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Room changes for the manufacture of Quantitation Standard and Internal Control Reagents.
P050044/S013 4/2/10	Vitagel Surgical Hemostatic Agent and Dressing	Orthovita, Inc. Malven, PA 19335	Alternate supplier for a component of the device.
P060006/S009 4/6/10	ExpressÃ¢?¢ SD Renal MonorailÃ¢?¢ Premounted Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Change to the method used to create the proximal marks on the shaft of the stent delivery system.
P060027/S022 4/29/10	Situs OTW UW28D Leads	ELA Medical, Inc. Plymouth, MN 55441	Change in laser welding energy monitoring.
P060030/S007 4/8/10	Cobas AmpliPrep/ Cobas TaqMan HCV Test	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Room changes for the manufacture of Quantitation Standard and Internal Control Reagents.
P060039/S011 4/28/10	Attain StarFix Families	Medtronic, Inc. Mounds View, MN 55112	Addition of a business rule to the Manufacturing Execution System.
P070014/S011 4/13/10	BardÃ,® LifestentÃ,® Vascular Stent Systems	Bard Peripheral Vascular, Inc. Tempe, Az 85280	Addition of alternate tensile strength testing equipment.
P070015/S033 4/23/10	XIENCE VÃ,® Everolimus-Eluting Coronary Stent System (EECSS) and PROMUSÃ,® Everolimus-Eluting	Abbott Vascular Temecula, CA 92591	Requested a change in manufacturing equipment used to coat the stent delivery system

	Coronary Stent System		and balloon dilatation catheters.
P080006/S007 4/28/10	Attain Families	Medtronic, Inc. Mounds View, MN 55112	Addition of a business rule to the Manufacturing Execution System.
P080010/S005 4/28/10	TECNISÃ,® Multifocal Foldable Posterior Chamber Intraocular Lens	Abbott Medical Optics, Inc. Santa Ana, CA 92705	Change from manual to automated rotation during the hole-drilling step.
P080011/S003 4/7/10	BiofinityÃ,® (Comfilcon A) soft contact lenses for extended wear	CooperVision, Inc. Pleasanton, CA 94588	Addition of a new qualified vendor of the raw material for the device.

Summary of PMA Originals & Supplements Approved
Originals: 6
Supplements: 55

Summary of PMA Originals Under Review
Total Under Review: 80
Total Active: 35
Total On Hold: 45
Number Greater Than 180 Days: 5

Summary of PMA Supplements Under Review
Total Under Review: 574
Total Active: 357
Total On Hold: 217
Number Greater Than 180 Days: 18

Summary of All PMA Submissions Received
Originals: 5
Supplements: 50

Summary of PMA Supplement PMA Approval/Denial Decision Times
Number of Approvals: 55
Number of Denials: 0
Average Days Fr Receipt to Decision (Total Time): 110.8
FDA Time: 84.0 Days MFR Time: 26.8 Days

SOURCE [4]

Source URL (retrieved on *06/19/2013 - 6:43am*):
http://www.mdtmag.com/news/2010/05/pma-final-decisions-april-2010

Links:
[1] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=P080032
[2] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=P080029
[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=P090022
[4] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm213621.htm