PMA Final Decisions for July 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
N18033/S047 7/22/10	VISTAKON® (etafilcon A) Contact Lenses, Clear and Visibility Tinted with UV Blocker	Johnson & Johnson Vision Care, Inc. Jacksonville, FL 32256	Alternate method for visual inspection of raw materials.
P790007/S026 7/28/10	Hancock® I Low Porosity and Modified Orifice Valved Conduit	Medtronic, Inc. Santa Ana, CA 92705	Addition of a component manufacturer.
P790017/S108 7/1/10	Gruntzig Dilaca Balloon Dilatation Catheters	Medtronic Vascular Santa Rosa, CA 95403	Change to introduce the MicroVu measurement system for the dimensional measurements of extruded tubing.
P840001/S156 7/20/10	Restore Family of Implantable Neurostimulators	Medtronic Neuromodulation Minneapolis, MN 55432	Changes to the traceability software.
P840001/S157 7/29/10	Restor Implantable Neurostimulators	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of an alternate supplier for the gold plating process.
P860004/S134 7/20/10	Synchromed II Implantable Infusion Pumps	Medtronic Neuromodulation Minneapolis, MN 55432	Changes to the traceability software.
P860004/S135	Pump, Infusion,	Medtronic	Addition of an

7/29/10	Implanted, Programmable	Neuromodulation Minneapolis, MN 55432	alternate supplier for the gold plating process.
P860019/S258 7/28/10	Boston Scientific Corporation® Apex™ Monorail™ and Over-the-Wire PTA Dilatation Catheters	Boston Scientific Cardiovascular Maple Grove, MN 55311	Update of software used with a camera for inspecting the inner component at the Apex Distal Load manufacturing process.
P860057/S069 7/9/10	Carpentier-Edwards® Perimount® Pericardial Bioprostheses	Edwards Lifesciences, LLC Irvine, CA 92614	Addition of a new supplier for bovine pericardial tissue.
P870076/S011 7/8/10	Falope-Rings® Band and Applicator Systems	Gyrus ACMI, Inc. Southborough, MA 01772	Change in supplier of three components of the device.
P870078/S010 7/28/10	Hancock® Porcine Bioprosthesis	Medtronic, Inc. Santa Ana, CA 92705	Addition of a component manufacturer.
P880086/S190 7/15/10	Affinity/Integrity/ Victory Family of Pacemakers	St. Jude Medical, Inc. Sylmar, CA 91342	Addition of alternate suppliers for discrete components used on St. Jude Medical’s devices.
P880086/S191 7/16/10	Verity, Identity, Victory, and Zephyr Families of Implantable Pacemakers	St. Jude Medical, Inc. Sylmar, CA 91342	Change to the resistance weld process electrode.
P900061/S090 7/23/10	Transvene Defibrillation Lead	Medtronic, Inc. Mounds View, MN 55112	Changes at the final package assembly.
P910023/S237 7/15/10	Cadence Family of ICDs	St. Jude Medical, Inc. Sylmar, CA 91342	Addition of alternate suppliers for discrete components used on St. Jude Medical’s devices.
P910077/S105 7/22/10	Latitude™ Inductive Communicator and	Boston Scientific Corporation	Change in the bond line thickness and

	Latitude™ RF Communicator	St. Paul, MN 55112	lead frame plating for the digital potentiometer.
P930038/S062 7/15/10	Angio-Seal™ Vascular Closure Device	St. Jude Medical Cardiovascular Division St. Paul, MN 55128	Alternate seal strength specification assurance method.
P950022/S071 7/15/10	Durata Family of Leads	St. Jude Medical Cardiac Rhythm Management Division Sylmar, CA 91342	Change in the medical Adhesive cleaning process.
P960009/S087 7/20/10	Activa Family of Implantable Neurostimulators	Medtronic Neuromodulation Minneapolis, MN 55432	Changes to the traceability software.
P960009/S088 7/29/10	Stimulator, Implanted, for Parkinsons	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of an alternate supplier for the gold plating process.
P960042/S017 7/15/10	SLS II Laser Sheath	Spectranetics Corporation Colorado Springs, CO 80921	Change to the vacuum oven.
P970004/S088 7/14/10	InterStim II® Neurostimulator	Medtronic Neuromodulation Minneapolis, MN 55432	Change to the test specification limits of an existing manufacturing test related to the final functional test.
P970004/S089 7/20/10	Interstim Family of Implantable Neurostimulators	Medtronic Neuromodulation Minneapolis, MN 55432	Changes to the traceability software.
P970004/S090 7/29/10	Restor Implantable Neurostimulators	Medtronic Neuromodulation Minneapolis, MN 55432	Addition of an alternate supplier for the gold plating process.
P970008/S051 7/16/10	Urologix Targis® System for the Treatment of BPH	Urologix, Inc. Minneapolis, MN 55447	Change in the supplier of solder used in the manufacture of the

			Targis Short Catheter.
P970012/S070 7/23/10	Kappa 400 IPG	Medtronic, Inc. Mounds View, MN 55112	Addition of a new piece of equipment used in the battery burn-in process.
P970020/S056 7/20/10	Multi-Link OTW ZETA® Coronary Stent System and Multi-Link RX ZETA® Coronary Stent System	Abbott Vascular, Inc. Temecula, CA 92591	Increase in the minimum seal length requirement for the manufacturing of the stent delivery system.
P980016/S245 7/7/10	EnTrust, Virtuoso, Maximo II DR/VR, Virtuoso II DR/VR, and Secura DR/VR Families of ICDs	Medtronic, Inc. Mounds View, MN 55112	Alternate supplier of a component plating process.
P980016/S246 7/8/10	EnTrust ICDs	Medtronic, Inc. Mounds View, MN 55112	Adding new test equipment.
P980016/S247 7/16/10	Secura DR, Secura VR, Maximo II DR, Maximo II VR, Virtuoso II DR, Virtuoso II VR, and Virtuoso ICDs	Medtronic, Inc. Mounds View, MN 55112	Changes in platinum flow on Complementary Metal Oxide Semiconductor (CMOS) at the supplier location.
P980016/S248 7/23/10	Secura DR, Secura VR, Maximo II DR, Maximo II VR, Virtuoso II DR, Virtuoso II VR Family of ICDs	Medtronic, Inc. Mounds View, MN 55112	Changes to L409 Integrated Circuit test.
P980016/S249 7/23/10	Maximo II, Secura, Virtuoso, Virtuoso II Family of ICDs	Medtronic, Inc. Mounds View, MN 55112	Update to the laser weld process.
P980016/S251 7/28/10	Secura DR/VR, Maximo II DR/VR, Entrust and Virtuoso ICDs	Medtronic, Inc. Mounds View, MN 55112	Implementation of a software revision for a laser bonder.
P980022/S078 7/15/10	MiniLink Transmitter and iPro Digital Recorder	Medtronic MiniMed Northridge, CA 91325	Change to a new component supplier for the capacitor used in the device.

P980022/S079 7/15/10	MMT-7002 and MMT-7003 Glucose Sensors	Medtronic MiniMed Northridge, CA 91325	Modification of the GLM onto 8 plates at a time with 48 sensors per plate from 24 sensors per plate.
P980035/S172 7/8/10	EnRhythm IPGs	Medtronic, Inc. Mounds View, MN 55112	Adding new test equipment.
P980035/S174 7/16/10	Adapta/Versa/ Sensia, Relia, and EnRythm IPGs	Medtronic, Inc. Mounds View, MN 55112	Changes in platinum flow on Complementary Metal Oxide Semiconductor (CMOS) at the supplier location.
P980035/S175 7/23/10	Kappa 600/700, 650, 800/900 IPG, Relia IPG, EnPulse IPG, Adapta/Versa/ Sensia IPG	Medtronic, Inc. Mounds View, MN 55112	Addition of a new piece of equipment used in the battery burn-in process.
P980035/S176 7/28/10	EnRhythm, Relia and Adapta/Versa/ Sensia Families of IPGs	Medtronic, Inc. Mounds View, MN 55112	Additional supplier for the performance of a plating process.
P980035/S178 7/28/10	EnRhythm, Adapta/ Versa/Sensia and Relia IPGs	Medtronic, Inc. Mounds View, MN 55112	Implementation of a software revision for a laser bonder.
P980040/S034 7/8/10	TECNIS® One-Piece Acrylic Soft Intraocular Lens (IOL) and TECNIS® Multifocal One-Piece IOL	Abbott Medical Optics, Inc. Santa Ana, CA 92705	Addition of a cosmetic inspection step to the manufacturing process of one-piece intraocular lenses.
P980043/S027 7/28/10	Hancock® II Porcine Bioprosthesis	Medtronic, Inc. Santa Ana, CA 92705	Addition of a component manufacturer.
P980049/S058 7/9/10	Paradym VR/DR ICD	ELA Medical, Inc. Plymouth, MN 55441	Change to in-source the micro-electronic assembly of electronic hybrid modules.
P990001/S071 7/28/10	DA+C Series and DA+T Series of	Medtronic, Inc. Mounds View, MN	Additional supplier for the performance

	IPGs	55112	of a plating process.
P990013/S027 7/29/10	STAAR Surgical Collamer® Intraocular Lenses	STAAR Surgical Company Monrovia, CA 91016	Change of the solvent used in the dewaxing process, and to implement redesigned sieves.
P990020/S040 7/1/10	AneuRx Stent Graft Systems	Medtronic Vascular Santa Rosa, CA 95403	Change to introduce the MicroVu measurement system for the dimensional measurements of extruded tubing.
P990033/S017 7/20/10	PepGen P-15 FLOW	Dentsply International York, PA 17405	Use of an alternate foil pouch supplier and alternate autoclave sterilizer.
P990034/S019 7/20/10	Side Catheter Access Port Kits	Medtronic Neuromodulation Minneapolis, MN 55432	Changes to the traceability software.
P000006/S021 7/14/10	Titan Inflatable Penile Prosthesis (IPP)	Coloplast Corp. Minneapolis, MN 55411	Use of a new mold by a new vendor and modification of the current engineering drawing.
P000040/S016 7/8/10	Genesys HTA™ System	Boston scientific Corporation Marlborough, MA 01752	Implementation of an inspection at the cassette manufacturer and an update to a subassembly drawing.
P010013/S030 7/21/10	NovaSure® Impedance Controlled Endometrial Ablation System	Hologic, Inc. Marlborough, MA 01752	Change in the coating of the individual conductive wires.
P010015/S090 7/8/10	Attain OTW and Attain Bipolar OTW Leads	Medtronic, Inc. Mounds View, MN 55112	Implementation of a new manufacturing traceability system.

P010019/S017 7/26/10	Lotrafilcon Soft Contact Lenses for Extended Wear	Ciba Vision Corporation Duluth, GA 30097	Changes to optical tool manufacturing.
P010031/S202 7/7/10	Concerto, Consulta, Concerto II, and Maximo II Families of CRT-Ds	Medtronic, Inc. Mounds View, MN 55112	Alternate supplier of a component plating process.
P010031/S203 7/16/10	Concerto II ICD, Consulta CRT-D, Maximo II CRT-D, and Concerto	Medtronic, Inc. Mounds View, MN 55112	Changes in platinum flow on Complementary Metal Oxide Semiconductor (CMOS) at the supplier location.
P010031/S204 7/23/10	Concerto II, Consulta, and Maximo II Family of CRT-Ds	Medtronic, Inc. Mounds View, MN 55112	Changes to L409 Integrated Circuit test.
P010031/S205 7/23/10	Concerto, Concerto II, Consulta, Maximo II Family of CRT-Ds	Medtronic, Inc. Mounds View, MN 55112	Update to the laser weld process.
P010031/S207 7/28/10	Concerto, Consulta, and Maximo II CRT-Ds	Medtronic, Inc. Mounds View, MN 55112	Implementation of a software revision for a laser bonder.
P020018/S036 7/15/10	Zenith Flex® AAA Endovascular Graft and Zenith Renu® AAA Ancillary Graft with the Z-trak® Introduction System	Cook, Inc. Bloomington, IN 47402	Addition of a Quality Control Test to the Captor hemostatic valve tubing subassembly process.
P020047/S021 7/20/10	Multi-Link Vision® RX Coronary Stent System, Multi-Link Vision® OTW Coronary Stent System,	Abbott Vascular, Inc. Temecula, CA 92591	Increase in the minimum seal length requirement for the manufacturing of the stent delivery system.
P030009/S043 7/1/10	Driver and Micro-Driver Coronary Stent Systems	Medtronic Vascular Santa Rosa, CA 95403	Change to introduce the MicroVu measurement system for the

			dimensional measurements of extruded tubing.
P030016/S015 7/29/10	STAAR Surgical Implantable Collamer® Lens	STAAR Surgical Company Monrovia, CA 91016	Change of the solvent used in the dewaxing process, and to implement redesigned sieves.
P030019/S015 7/15/10	Orthovisc High Molecular Weight Hyaluronan	Anika Therapeutics, Inc. Bedford, MA 01730	Increase in storage time for depyrogenated equipment from 48 hours to 5 days.
P030031/S030 7/15/10	Celsius Thermocool Diagnostic Ablation Deflectable Tip Catheter	Biosense Webster, Inc. Diamond Bar, CA 91765	Addition of a second source supplier for the tip dome electrode.
P030035/S071 7/15/10	Frontier/Frontier II Family of CRT-Ps	St. Jude Medical, Inc. Sylmar, CA 91342	Addition of alternate suppliers for discrete components used on St. Jude Medical’s devices.
P030036/S017 7/8/10	SelectSecure Lead	Medtronic, Inc. Mounds View, MN 55112	Implementation of a new manufacturing traceability system.
P030054/S154 7/15/10	Epic HF/Atlas+ HF Family of CRT-Ds	St. Jude Medical, Inc. Sylmar, CA 91342	Addition of alternate suppliers for discrete components used on St. Jude Medical’s devices.
P040016/S060 7/8/10	VeriFLEX™ (Liberté®) Monorail and Over-the-Wire Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Change to in-process stent inspection.
P040050/S005 7/2/10	Macroplastique® Implants	Uroplasty, Inc. Minnetonka, MN 55343	Alternate vendor for the inner and outer Macroplastique® Implants packaging.
P050020/S024	FreeStyle Navigator	Abbott Diabetes	Modification of the

7/9/10	Continuous Glucose Monitoring System	Care, Inc. Alameda, CA 94502	Injection Molded Tray which protects the Sensor Delivery Unit of the device during shipping.
P050044/S014 7/8/10	Vitagel Surgical Hemostat	Orthovita, Inc. Malvern, PA 19335	Use of new packaging material for the device.
P060008/S056 7/8/10	Taxus® Liberté® Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Change to in-process stent inspection.
P060027/S025 7/9/10	Paradym VR/DR ICD	ELA Medical, Inc. Plymouth, MN 55441	Change to in-source the micro-electronic assembly of electronic hybrid modules.
P060033/S053 7/1/10	Endeavor Sprint Zotarolimus-Eluting Coronary Stent Systems	Medtronic Vascular Santa Rosa, CA 95403	Change to the spray weigh system.
P060033/S056 7/1/10	Endeavor Sprint Zotarolimus-Eluting Coronary Stent Systems	Medtronic Vascular Santa Rosa, CA 95403	Change to introduce the MicroVu measurement system for the dimensional measurements of extruded tubing.
P060038/S007 7/8/10	Mitroflow Aortic Pericardial Heart Valve	Sorin Group USA, Inc. Arvada, CO 80004	Expanded use of an existing isolator.
P060039/S012 7/8/10	Attain StarFix Lead	Medtronic, Inc. Mounds View, MN 55112	Implementation of a new manufacturing traceability system.
P070001/S007 7/2/10	ProDisc-C™ Total Disc Replacement	Synthes Spine West Chester, PA 19380	Modified fixture used for inspection of the ProDisc-C endplates.
P070001/S008 7/2/10	ProDisc-C™ Total Disc Replacement	Synthes Spine West Chester, PA 19380	Update to an existing holding fixture.
P070007/S019	Talent Thoracic	Medtronic Vascular	Change to

7/1/10	Stent Graft Systems	Santa Rosa, CA 95403	introduce the MicroVu measurement system for the dimensional measurements of extruded tubing.
P070007/S020 7/8/10	Talent Thoracic Stent Graft System	Medtronic Vascular Santa Rosa, CA 95403	Addition of an in-process manufacturing stent loading aid.
P070009/S010 7/26/10	Realize® Adjustable Gastric Band-C	Ethicon Endo-Surgery, Inc. Cincinnati, OH 45242	Addition of an alternate sub-assembly supplier.
P070015/S039 7/23/10	XIENCE V® Everolimus-Eluting Coronary Stent System (EECSS)	Abbott Vascular Temecula, CA 92590	Modification of the stent crimp manufacturing process by eliminating the redundant inspection that occurs at the pre-crimp stage.
P070015/S040 7/20/10	XIENCE V® Everolimus-Eluting Coronary Stent System (EECSS)	Abbott Vascular, Inc. Temecula, CA 92591	Increase in the minimum seal length requirement for the manufacturing of the stent delivery system.
P070022/S005 7/21/10	Adiana Permanent Contraception System	Hologic, Inc. Marlborough, MA 01752	Addition of incoming inspection requirements to the plastic tubing used in the matrix molding process.
P070027/S019 7/1/10	Talent Abdominal Stent Graft Systems	Medtronic Vascular Santa Rosa, CA 95403	Change to introduce the MicroVu measurement system for the dimensional measurements of extruded tubing.
P070027/S020	Talent Abdominal	Medtronic Vascular	Addition of an in-

7/8/10	Stent Graft System	Santa Rosa, CA 95403	process manufacturing stent loading aid.
P080006/S009 7/8/10	Attain Ability Lead	Medtronic, Inc. Mounds View, MN 55112	Implementation of a new manufacturing traceability system.
P090003/S004 7/15/10	Express™ LD Iliac Premounted Stent System	Boston Scientific Maple Grove, MN 55311	Changes to the lap weld process and the addition of an in-process inspection specification.

Summary of PMA Originals & Supplements Approved
Originals: 1
Supplements: 63

Summary of PMA Originals Under Review
Total Under Review: 87
Total Active: 38
Total On Hold: 49
Number Greater Than 180 Days: 6

Summary of PMA Supplements Under Review
Total Under Review: 643
Total Active: 440
Total On Hold: 203
Number Greater Than 180 Days:18

Summary of All PMA Submissions Received
Originals: 7
Supplements: 71

Summary of PMA Supplement PMA Approval/Denial Decision Times
Number of Approvals: 63
Number of Denials: 0
Average Days Fr Receipt to Decision (Total Time): 121.6
FDA Time: 89.3 Days MFR Time: 32.3 Days

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