

PMA Final Decisions for October 2011

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
D970012/S089 10/26/11	AMS Model 700 Inflatable Penile Prosthesis	American Medical Systems Minnetonka, MN 55343	Change in the packaging process for the devices.
P780007/S046 10/21/11	Biomedics 38 (Polymacon) Soft (Hydrophilic) Contract Lenses	CooperVision Incorporated Pleasanton, CA 94588	Addition of sterilization cycle runs for single blisters, CVI blisters and six pack blisters to sterilizer Fedegari.
P840001/S196 10/21/11	Restore Family of Implantable Neurostimulators	Medtronic, Inc. Minneapolis, MN 55432	Implement software updates to the Self Test application of the Next Generation Tester.
P850068/S009 10/14/11	Bausch & Lomb Silsoft (elastofilcon A) Contact Lenses	Bausch & Lomb Incorporated Rochester, NY 14609	Change the manufacturing process of the optical tools used to manufacture the device.
P870025/S010 10/12/11	Fetal Acoustic Stimulator (FAST)	Wipro GE Healthcare Laurel, MD 20723	Changes to the suppliers for components of the FAST device.
P890003/S236 10/21/11	Prodigy	Medtronic, Inc. Mounds View, MN 55112	Change to upgrade the software version from 1.5.1 to 1.5.2 on a laser welder at a supplier.
P910023/S274	Fortify ICDs	St. Jude Medical	Changes to the

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10/7/11		Sylmar, CA 91392	limits for a device level manufacturing test as well as the addition of in-process verification tests.
P910023/S275 10/12/11	Fortify ICDs	St. Jude Medical Sylmar, CA 91392	Use of an alternate supplier for back-up bands.
P940015/S022 10/7/11	Synvisc® and Synvisc-One®	Genzyme Corporation Cambridge, MA 02142	Addition of a syringe assembly machine to the packaging department.
P940015/S023 10/7/11	Synvisc® and Synvisc-One®	Genzyme Corporation Cambridge, MA 02142	Addition of a raw material identification system and an automated filter integrity test instrument.
P950005/S035 10/7/11	Celsius, Celsius RMT, EZ Steer, EZ Steer DS, Non-Temperature Sensing Ablation Catheters and Interface Cables	Biosense Webster, Inc. Diamond Bar, CA 91765	Parametric release of sterilized product using ethylene oxide.
P960009/S127 10/21/11	Activa Family of Implantable Neurostimulators	Medtronic, Inc. Minneapolis, MN 55432	Implement software updates to the Self Test application of the Next Generation Tester.
P960013/S067 10/6/11	Tendril Family of Leads	St Jude Medical, Inc. Sylmar, CA 91342	Increase the length of the ring electrode masking.
P960040/S246 10/26/11	Cognis CRT-Ds	Boston Scientific Corporation St. Paul, MN 55112	Alternate supplier of ceramic capacitor used for pulse generator (PG) manufacturing.
P960058/S092 10/26/11	Harmony HiResolution Bionic Ear System	Advanced Bionics Corporation Sylmar, CA 91342	Change in the manufacturing process to improve an insertion tool and to document a change in the tool

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			suppliers.
P970003/S136 10/18/11	VNS Therapy® Pulse Generators	Cyberonics, Inc. Houston, TX 77058	Change to inventory control and traceability of components and subassemblies.
P970003/S137 10/21/11	VNS Therapy® System	Cyberonics, Inc. Houston, TX 77058	Change in the acceptance criteria for the Model 102/102R Pulse Generators.
P970003/S138 10/27/11	VNS Therapy® System	Cyberonics, Inc. Houston, TX 77058	Implementation of Statistical Process Control (SPC) software.
P970008/S059 10/26/11	Urologix Targis System for the Treatment of BPH	Urologix, Inc. Minneapolis, MN 55447	Change in adhesive in the manufacturing of the Urologix Targis System control units.
P970020/S069 10/28/11	Multi-Link Zeta and Ultra Coronary Stent Systems	Abbott Vascular, Inc. Temecula, CA 92591	Automated process for preparation of the adaption cup.
P970027/S016 10/19/11	AxSYM Anti HCV	Abbott Laboratories Abbott Park, IL 60064	Relocation of a formulation room for the lyophilization of alkaline-treated casein used in the device.
P980016/S322 10/13/11	EnTrust, Intrinsic, Marquis, Maximo, Maximo II, Protecta, Protecta XT, Secura, Virtuoso, and Virtuoso II ICDs	Medtronic, Inc. Mounds View, MN 55112	Software updates for a testing application.
P980035/S241 10/13/11	Adapta, Advisa, EnRhythm, Relia, Sensia, and Versa IPGs	Medtronic, Inc. Mounds View, MN 55112	Software updates for a testing application.
P980035/S243 10/21/11	350 Series, Adapta, EnPulse, EnRhythm, Relia, Sensia, Sigma and Versa	Medtronic, Inc. Mounds View, MN 55112	Change to upgrade the software version from 1.5.1 to 1.5.2 on a laser welder at a supplier.

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P990001/S095 10/13/11	Vitatron DA+ C-Series and Vitatron DA+ T-Series IPGs	Medtronic, Inc. Mounds View, MN 55112	Software updates for a testing application.
P990001/S097 10/21/11	Vitatron DA+ C-Series IPG	Medtronic, Inc. Mounds View, MN 55112	Change to upgrade the software version from 1.5.1 to 1.5.2 on a laser welder at a supplier.
P990025/S029 10/7/11	NaviStar, NaviStar RMT, EZ Steer Nav, QwikStar Catheters and Interface Cables	Biosense Webster, Inc. Diamond Bar, CA 91765	Parametric release of sterilized product using ethylene oxide.
P990071/S015 10/7/11	Interface Cables	Biosense Webster, Inc. Diamond Bar, CA 91765	Parametric release of sterilized product using ethylene oxide.
P000010/S025 10/11/11	AMPLICOR HCV Test, v2.0	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Changes to the room location and equipment for filling and labeling of certain vial intermediate components.
P000012/S035 10/11/11	COBAS AMPLICOR HCV Test, v2.0 and COBAS AmpliPrep/COBAS AMPLICOR HCV Test, v2.0	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Changes to the room location and equipment for filling and labeling of certain vial intermediate components.
P000039/S042 10/21/11	AMPLATZER Septal Occluder AMPLATZER 45 Delivery and Exchange Systems	AGA Medical Corporation Plymouth, MN 55442	Change the current seal test method from manual to semiautomatic.
P000040/S019 10/3/11	HTA System ProCerva Procedure Set	Boston Scientific Corporation Marlborough, MA 01752	Addition of a new manufacturing fixture and the modifications of an existing manufacturing fixture.
P000053/S039 10/26/11	AMS 800 Urinary Control System	American Medical Systems Minnetonka, MN 55343	Change in the packaging process for the devices.

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P010012/S272 10/26/11	Teligen ICDs	Boston Scientific Corporation St. Paul, MN 55112	Alternate supplier of ceramic capacitor used for pulse generator (PG) manufacturing.
P010015/S138 10/13/11	Consulta and Syncra CRT-Ps	Medtronic, Inc. Mounds View, MN 55112	Software updates for a testing application.
P010015/S140 10/21/11	InSync III	Medtronic, Inc. Mounds View, MN 55112	Change to upgrade the software version from 1.5.1 to 1.5.2 on a laser welder at a supplier.
P010019/S026 10/28/11	Lotrafilcon A and Lotrafilcon B Soft Contact Lenses for Extended Wear	CIBA VISION Corporation Duluth, GA 30097	Addition of an alternate supplier for Isopropyl Alcohol (IPA).
P010020/S021 10/26/11	Acticon Neosphincter	American Medical Systems Minnetonka, MN 55343	Change in the packaging process for the devices.
P010030/S030 10/26/11	LifeVest Wearable Cardioverter Defibrillator	ZOLL Lifecor Corporation Pittsburgh, PA 15238	Alternate supplier for the holster and a change to the incoming inspection sampling plan.
P010031/S276 10/13/11	Concerto, Concerto II, Consulta, InSync II Marquis, InSync III Marquis, InSync Maximo, InSync Sentry, Maximo II, Protecta, and Protecta XT ICDs	Medtronic, Inc. Mounds View, MN 55112	Software updates for a testing application.
P010047/S013 10/19/11	ProGel™ Pleural Air Leak Sealant	Neomend, Inc. Irvine, CA 92618	Reduction in sample size of the current testing for the applicator kits.
P010068/S025 10/7/11	Celsius DS, NaviStar DS, NaviStar RMT DS, EZ Steer Nav DS, QwikStar DS Catheters and Interface Cables	Biosense Webster, Inc. Diamond Bar, CA 91765	Parametric release of sterilized product using ethylene oxide.
P020004/S065	GORE EXCLUDER	W.L. Gore &	Change to visual

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10/24/11	AAA Endoprosthesis	Associates, Inc. Flagstaff, AZ 86001	inspection criteria for the stent graft deployment line fiber.
P020004/S066 10/27/11	GORE EXCLUDER AAA Endoprosthesis	W.L. Gore & Associates, Inc. Flagstaff, AZ 86001	Update in bacterial endotoxin testing software.
P020009/S078 10/19/11	Express and Express 2 Coronary Stent Systems	Boston Scientific Corporation Maple Grove, MN 55311	Additional sterilization cycle for the device.
P020009/S079 10/31/11	Express Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Process settings to be optimized or defined for extrusion of the proximal outer component.
P020024/S034 10/21/11	AMAPLATZER Duct Occluder 180 Delivery and Exchange System	AGA Medical Corporation Plymouth, MN 55442	Change the current seal test method from manual to semiautomatic.
P020045/S040 10/7/11	Freezor Cardiac CryoAblation Catheter, Freezor Xtra Surgical and Freezor MAX Surgical CryoAblation Devices	Medtronic CryoCath LP Pointe Claire, Quebec H9R5Z8	Change to reduce adhesive curing time for ECG rings and the tip electrode.
P020047/S040 10/28/11	Multi-Link Vision, Multi-Link Mini Vision, ML8 Coronary Stent Systems	Abbott Vascular, Inc. Temecula, CA 92591	Automated process for preparation of the adaption cup.
P020052/S008 10/13/11	Response™ CV Cardioversion Electrophysiology Catheter and System Accessory Equipment	St. Jude Medical, Inc. Minnetonka, MN 55345	Eliminate the UV Post Trim process.
P030009/S060 10/19/11	Driver OTW Stent System	Medtronic, Inc. Santa Rosa, CA 95403	Changing the product print information from a manual process to an automated process.

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P030017/S123 10/12/11	Precision® Spinal Cord Stimulator System	Boston Scientific Neuromodulation Valencia, CA 91355	Add an alternative welder for the antenna welding process.
P030031/S035 10/7/11	Celsius ThermoCool, Celsius RMT ThermoCool, NaviStar ThermoCool, NaviStar RMT ThermoCool, EZ Steer ThermoCool and EZ Steer ThermoCool Nav Catheters	Biosense Webster, Inc. Diamond Bar, CA 91765	Parametric release of sterilized product using ethylene oxide.
P030032/S013 10/7/11	PREVELLE Silk	Genzyme Corporation Cambridge, MA 02142	Addition of a raw material identification system and an automated filter integrity test instrument.
P030054/S201 10/7/11	Unify CRT-Ds	St. Jude Medical Sylmar, CA 91392	Changes to the limits for a device level manufacturing test as well as the addition of in-process verification tests.
P030054/S203 10/12/11	Unify CRT-Ds	St. Jude Medical Sylmar, CA 91392	Use of an alternate supplier for back-up bands.
P040016/S078 10/14/11	VeriFLEX (Liberté) Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Implementation of a semi-automated kitting process of accessory kits at a contract supplier.
P040016/S079 10/19/11	VeriFLEX OTW Bare Metal Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Updates to the Hydrophilic Coating (HPC) equipment process.
P040016/S080 10/31/11	VeriFLEX Coronary Stent System (Formerly Liberté)	Boston Scientific Corporation Maple Grove, MN 55311	Process settings to be optimized or defined for extrusion of the proximal outer component.

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P040016/S081 10/31/11	VeriFLEX (Liberté) Bare Metal Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Hardware and software updates for the Plasma Treater.
P040020/S038 10/6/11	AcrySof Intraocular Lenses (IOLs)	Alcon Research, Ltd. Fort Worth, TX 76134	Modifications to the final cleaning process.
P040027/S025 10/27/11	GORE VIATORR TIPS Endoprosthesis	W.L. Gore & Associates, Inc. Flagstaff, AZ 86001	Final product assembly at the firm's Phoenix location.
P040027/S026 10/27/11	GORE VIATORR TIPS Endoprosthesis	W.L. Gore & Associates, Inc. Flagstaff, AZ 86001	Update in bacterial endotoxin testing software.
P040036/S026 10/7/11	NaviStar ThermoCool, NaviStar RMT ThermoCool, EZ Steer ThermoCool and EZ Steer ThermoCool Nav Catheters	Biosense Webster, Inc. Diamond Bar, CA 91765	Parametric release of sterilized product using ethylene oxide.
P040037/S038 10/27/11	GORE VIABAHN Endoprosthesis	W.L. Gore & Associates, Inc. Flagstaff, AZ 86001	Update in bacterial endotoxin testing software.
P040040/S019 10/21/11	AMPLATZER Muscular VSD Occluder	AGA Medical Corporation Plymouth, MN 55442	Change the current seal test method from manual to semiautomatic.
P040043/S042 10/24/11	GORE TAG Thoracic Endoprosthesis	W.L. Gore & Associates, Inc. Flagstaff, AZ 86001	Change to visual inspection criteria for the stent graft deployment line fiber.
P040043/S043 10/27/11	GORE TAG THORACIC Endoprosthesis	W.L. Gore & Associates, Inc. Flagstaff, AZ 86001	Update in bacterial endotoxin testing software.
P040045/S025 10/12/11	VISTAKON (senofilcon A) Brand Contact Lenses	Johnson & Johnson Vision Care, Inc. Jacksonville, FL 32256	Upgrade to the saline dose head during the manufacturing of the device.
P040045/S027	Vistakon (senofilcon	Johnson & Johnson	Update the current

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10/26/11	A) Contact Lenses, Clear & Visibly Tinted with UV Blocker	Vision Care, Inc. Jacksonville, FL 32256	test method for Vistakon (senofilcon A) Contact Lenses.
P050006/S021 10/21/11	GORE HELEX Septal Occluder	W.L. Gore & Associates, Inc. Flagstaff, AZ 86001	Replacement of sand paper with a lock loop polishing tool in the manufacture of the subject device.
P050006/S022 10/27/11	GORE HELEX Septal Occluder	W.L. Gore & Associates, Inc. Flagstaff, AZ 86001	Addition of a procedure for inventory processing.
P050006/S023 10/19/11	GORE HELEX Septal Occluder	W.L. Gore & Associates, Inc. Flagstaff, AZ 86001	Addition of Expiry Report requirement to the return product procedure.
P050006/S024 10/27/11	GORE HELEX Septal Occluder	W.L. Gore & Associates, Inc. Flagstaff, AZ 86001	Update in bacterial endotoxin testing software.
P050006/S026 10/28/11	GORE HELEX Septal Occluder	W.L. Gore & Associates, Inc. Flagstaff, AZ 86001	Adoption of an instruction for single piece flow in the boxing operation.
P050018/S015 10/27/11	AngioSculpt PTCA Scoring Balloon Catheter	Angioscore, Inc. Fremont, CA 94538	Remove redundant in-process inspection tests.
P050028/S022 10/11/11	COBAS TaqMan HBV Test For Use with The High Pure System and COBAS AmpliPrep/COBAS TaqMan HBV Test v2.0	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Changes to the room location and equipment for filling and labeling of certain vial intermediate components.
P060002/S021 10/31/11	Bard Flair Endovascular Stent Graft	C.R. Bard, Inc. Tempe, AZ 85281	Introduction of an automated labeling inspection system and introduction of a new barcode scan system.
P060003/S010 10/3/11	Abbott AxSYM AUSAB	Abbott Laboratories Abbott Park, IL 60064	Change to vendor for the incoming Non-Fat Dry Milk.

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P060008/S077 10/14/11	TAXUS Liberté Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Implementation of a semi-automated kitting process of accessory kits at a contract supplier.
P060008/S078 10/14/11	TAXUS Liberté Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Change to the feedstock source for the manufacturing of a solvent.
P060008/S079 10/19/11	TAXUS Liberté OTW Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Updates to the Hydrophilic Coating (HPC) equipment process.
P060008/S080 10/31/11	TAXUS Liberté Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Process settings to be optimized or defined for extrusion of the proximal outer component.
P060008/S081 10/31/11	TAXUS Liberté Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Hardware and software updates for the Plasma Treater.
P060022/S009 10/7/11	Akreos Posterior Chamber Intraocular Lenses	Bausch & Lomb, Inc. Aliso Viejo, CA 92656	Transfer of bioburden testing of the Akreos Adapt AO Holder Folder, M160 Holder, and Parker Gasket from a contract vendor to Bausch & Lomb.
P060030/S023 10/11/11	COBAS AmpliPrep/ COBAS TaqMan HCV Test	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Changes to the room location and equipment for filling and labeling of certain vialled intermediate components.
P060033/S068 10/19/11	Endeavor Sprint Zotarolimus-Eluting Coronary Stent System	Medtronic, Inc. Santa Rosa, CA 95403	Changing the product print information from a manual process to an automated process.
P070007/S032 10/19/11	Talent Thoracic Stent Graft with Xcelerant Delivery	Medtronic Vascular Santa Rosa, CA 95403	Modification of a wiping procedure.

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	System		
P070014/S024 10/7/11	LifeStent Vascular Stent Systems	Bard Peripheral Vascular, Inc. Tempe, AZ 85281	Change to the tensile testing process.
P070014/S028 10/31/11	LifeStent Vascular Stent	C.R. Bard, Inc. Tempe, AZ 85281	Introduction of an automated labeling inspection system and introduction of a new barcode scan system.
P070015/S081 10/28/11	XIENCE V and PROMUS Everolimus-Eluting Coronary Stent	Abbott Vascular, Inc. Temecula, CA 92591	Automated process for preparation of the adaption cup.
P070027/S033 10/19/11	Abdominal Stent Graft with the Xcelerent System, Talent Converter Stent Graft with the Xcelerant System	Medtronic Vascular Santa Rosa, CA 95403	Modification of a wiping procedure.
P080004/S009 10/26/11	Hoya iSpheric	Hoya Surgical Optics, Inc. Chino Hills, CA 91709	Change to the endotoxin testing method.
P080007/S008 10/31/11	E-LUMINEXX Vascular Stent Graft	C.R. Bard, Inc. Tempe, AZ 85281	Introduction of an automated labeling inspection system and introduction of a new barcode scan system.
P090013/S039 10/13/11	Revo MRI IPG	Medtronic, Inc. Mounds View, MN 55112	Software updates for a testing application.
P090028/S001 10/21/11	VITROS Immunodiagnostic Products HBeAg Reagent Pack and VITROS Immunodiagnostic Products HBeAg Calibrator	Ortho-Clinical Diagnostics, Inc. Rochester, NY 14626	Conversion of the in-process limit for the process control of the selling calibrator from a signal ratio to a numerical test result.
P100010/S012 10/7/11	Freezor MAX Cardiac CryoAblation Catheter	Medtronic CryoCath LP Pointe Claire, Quebec H9R5Z8	Change to reduce adhesive curing time for ECG rings and the tip electrode.

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P100023/S020 10/6/11	ION (TAXUS Element) Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Addition of the ION Stent System to sterilization Chamber 6 at Coventry, Rhode Island.
P100023/S021 10/14/11	ION Paclitaxel-Eluting Platinum Chromium Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Change to the feedstock source for the manufacturing of a solvent.
P100023/S022 10/19/11	ION (TAXUS Element) Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Updates to the Hydrophilic Coating (HPC) equipment process.
P100023/S023 10/27/11	ION (Taxus Element) Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Change to the in-process monitoring plan for proximal and port welds.
P100023/S024 10/19/11	ION (TAXUS Element) Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Updates to the Marker Band and DVT equipment inspection software.
P100023/S025 10/28/11	ION (Taxus Element) Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Modification to the sampling plan for the laser cutting set up.
P100023/S026 10/31/11	ION (TAXUS Element) Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove, MN 55311	Hardware and software updates for the Plasma Treater.
P100029/S009 10/19/11	Trifecta Valve	St. Jude Medical, Inc. St. Paul, MN 55117	Change to the in-process limit for total valve score during the visual inspection and functional test.
P110020/S001 10/17/11	cobas® 4800 BRAF V600 mutation test	Roche Molecular Systems, Inc. Pleasanton, CA 94588	Addition of functional testing at the final vial stage in the manufacture of the device mutation positive control (MU) and the wild-type control (WT).
P110020/S002	cobas® 4800 BRAF	Roche Molecular	Changes to the

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10/26/11	V600 mutation test	Systems, Inc. Pleasanton, CA 94588	filling and labeling equipment and location for certain vial intermediate components. The firm has proposed relocation to Building 502 Rooms 1F24 and 1F26 from Building 502 Rooms 1F23 and 1F31 for use of new equipment Kugler Linoline 120 Filing and Screw-capping Line which includes the Accraply 4000 and 35T Labeling Machines.
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Summary of PMA Originals & Supplements Approved

Originals: 4

Supplements: 52

Summary of PMA Originals Under Review

Total Under Review: 88

Total Active: 41

Total On Hold: 47

Number Greater Than 180 Days: 3

Summary of PMA Supplements Under Review

Total Under Review: 554

Total Active: 437

Total On Hold: 117

Number Greater Than 180 Days: 11

Summary of All PMA Submissions Received

Originals: 2

Supplements: 66

Summary of PMA Supplement PMA Approval/Denial Decision Times

Number of Approvals: 52

Number of Denials: 0

Average Days Fr Receipt to Decision (Total Time): 210.9

FDA Time: 127.9 Days MFR Time: 83 Days

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