PMA Monthly approvals from 10/1/2017 to 10/31/2017

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160039	10/06/2017	PMAO - PMA Origi	REMEDE® SYSTEM	RESPICARDIA	Approval for the remed® System. This device is an implantable phrenic nerve stimulator indicated for the treatment of moderate to severe central sleep apnea (CSA) in adult patients.
P170002	10/19/2017	PMAO - PMA Origi	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Approval for the RH-2. The RHA 2 is indicated for injection into the mid-to-deep dermis for the correction of moderate to severe dynamic facial wrinkles and folds, such as nasolabial folds (NLF), in adults aged 22 years or older. RHA 3 is indicated for injection into the mid-to-deep dermis for the correction of moderate to severe dynamic facial wrinkles and folds, such as nasolabial folds (NLF), in adults aged 22 years or older. RHA 4 is indicated for injection into the deep dermis to superficial subcutaneous tissue for the correction of moderate to severe dynamic facial wrinkles and folds, such as nasolabial folds (NLF), in adults aged 22 years or older.

Total: 2

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P810031/S059	10/31/2017	O - Normal 180 Day	HEALON DUET DUAL PACK	ABBOTT MEDICAL OPTICS INC	Approval for a manufacturing site located at Lifecore Biomedical, LLC, 1245 Lakeview Drive Chaska, Minnesota to be used for post-sterilization final packaging, warehousing, and distribution activities.
P830055/S191	10/19/2017	S - Special CBE	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for labeling changes to mandate the resurfacing of the patella with a LCS Complete Knee System in order to reduce higher incidence of postoperative patella-femoral pain when patella is not resurfaced.

Data as of 11/03/2017 04:05 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840001/S373	10/26/2017	Y - 135 Review Tra	RESTORE, LTREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES AND VECTRIS SPINAL CORD STIMULATION LEAD	MEDTRONIC NEUROMODULATION	Approval of a new manufacturer for the header plug and tubing clasp assembly.
P840064/S062	10/31/2017	O - Normal 180 Day	VISCOAT OPHTHALMIC VISCOSURGICAL DEVICE; DUOVISC OPHTHALMIC VISCOSURGICAL DEVICE (WITH PROVISC IN LATEX-FREE PACK)	ALCON LABORATORIES	Approval for a manufacturing site change located at Lifecore Biomedical, LLC., 3515 Lyman Boulevard, Chaska, Minnesota, USA, and Lifecore Biomedical, LLC, 1245 Lakeview Drive, Chaska, Minnesota, USA.
P840064/S064	10/25/2017	Y - 135 Review Tra	OPHTHALMIC VICOSURGICAL DEVICE (OVD)	ALCON LABORATORIES	Approval for the use of Alcon Ireland Cork (AIC) as an alternative supplier of the cannula component to be used as part of the finished Ophthalmic Viscosurgical Devices (OVDs) at Alcon-Couvreur (Purrs) manufacturing facility.
P850007/S037	10/31/2017	N - Normal 180 Day	PHYSIO-STIM	ORTHOFIX, INC.	approval for design modifications to garment, control unit housing, liquid crystal display (LCD), battery, printed circuit assembly, power supply, firmware, and mobile application to the Physio-Stim non-invasive bone growth stimulator devices. Labeling was updated to reflect design changes.
P860004/S271	10/06/2017	N - Normal 180 Day	SYNCROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETER PRODUCT CODE:LKK	MEDTRONIC INC.	Approval for design and manufacturing changes to the Ascenda Intrathecal Catheter kits and accessories which make up part of the SynchroMed II Implantable Infusion System.
P880086/S279	10/20/2017	R - Real-Time Proc	ASSURITY, ASSURITY+, ENDURITY, ACCENT FAMILY OF PACEMAKERS	ST. JUDE MEDICAL, INC.	Approval for Merlin.net MN5000 v7.5 Software to add support for the Confirm Rx Insertable Cardiac Monitor.
P880086/S280	10/20/2017	R - Real-Time Proc	ASSURITY, ENDURITY, ACCENT, ADDVENT, IDENTITY, ENTITY, PARAGON III SUSTAIN	ST. JUDE MEDICAL, INC.	Approval for the Merlin Patient Care System (PCS) Model 3330 version 23.0.1 Software for the Merlin PCS Model 3650 Programmer.
P890003/S378	10/19/2017	N - Normal 180 Day	MYCARELINK PATIENT MONITOR, DEVICE COMMAND LIBRARY (DCL) , DEVICE DATA MANAGEMENT APPLICATION (DDMA) CARELINK EXPRESS, CARDIOSIGHT READER.	MEDTRONIC, INC.	Approval for CareLink Support of Percepta/Percepta Quad, Serena/Serena Quad, and Solara/Solara Quad CRT-P MRI SureScan Implantable Pulse Generators with Cardiac Resynchronization Therapy.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P890047/S048	10/31/2017	O - Normal 180 Day	PROVISC OPHTHALMIC VISCOSURGICAL DEVICE (LATEX-FTEE PACKAGING CONFIGURATION)	ALCON RESEARCH, LTD.	Approval for a manufacturing site change located at Lifecore Biomedical, LLC., 3515 Lyman Boulevard, Chaska, Minnesota, USA, and Lifecore Biomedical, LLC, 1245 Lakeview Drive, Chaska, Minnesota, USA.
P890047/S049	10/25/2017	Y - 135 Review Tra	PROVISC OPHTHALMIC VISCOSURGICAL DEVICE	ALCON RESEARCH, LTD.	Approval for the use of Alcon Ireland Cork (AIC) as an alternative supplier of the cannula component to be used as part of the finished Ophthalmic Viscosurgical Devices (OVDs) at Alcon-Couvreur (Purrs) manufacturing facility.
P910023/S381	10/20/2017	R - Real-Time Proc	CURRENT, CURRENT ACCEL, CURRENT+, ELLIPSE, FORTIFY, FORTIFY ASSURA, EPIC/ EPIC+, ATLAS/II/+ FAMILY OF ICDS	ST. JUDE MEDICAL	Approval for Merlin.net MN5000 v7.5 Software to add support for the Confirm Rx Insertable Cardiac Monitor.
P910023/S382	10/20/2017	R - Real-Time Proc	CURRENT, CURRENT ACCEL, CURRENT+, ELLIPSE, FORTIFY, FORTIFY ASSURA, EPIC/ EPIC +, ATLAS/II/+, CONVERT/+, PHOTON	ST. JUDE MEDICAL	Approval for the Merlin Patient Care System (PCS) Model 3330 version 23.0.1 Software for the Merlin PCS Model 3650 Programmer.
P930027/S018	10/11/2017	S - Special CBE	IMMULITE / IMMULITE 1000 THIRD GENERATION PSA	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Approval for temporary changes to the product quality controls that enhances the safety of IMMULITE® 3rd Generation PSA High Adjustor (LUPH).
P950005/S064	10/24/2017	Y - 135 Review Tra	WEBSTER DIAG/ ABLATION DEFLECTABLE TIP CATHETER	CORDIS CORP.	Approval for expansion of manufacturing capacity for extrusion and reflow manufacturing processes.
P950022/S110	10/18/2017	R - Real-Time Proc	DURATA AND OPTISURE HIGH VOLTAGE LEAD	ST. JUDE MEDICAL, INC.	Approval for extending the length of the helix shaft and modifying the crimping components at the shock coil(s) and ring electrode.
P960009/S291	10/26/2017	Y - 135 Review Tra	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Approval for a new manufacturer for the header plug and tubing clasp assembly.
P960009/S297	10/20/2017	S - Special CBE	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Approval for the addition of new safety information (tunneling procedure unintended nerve tissue injury warning and adverse event, loss of coordination precaution, weight gain/loss adverse event) and safety enhancement clarifications (update guidance on avoiding damage to the neurostimulator (Physician Labeling), clarify text that accompanies the figure for accurate right and left hemisphere lead-extension connection when placing dual lead systems (Physician Labeling), remove incorrect length of the DBS lead placed under the scalp (Patient Labeling)).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970003/S210	10/03/2017	N - Normal 180 Day	VNS THERAPY SYSTEM	LIVANOVA USA, INC.	Approval for the introduction of the Model 1000 Generator and the Model 2000 Programming Wand into interstate commerce as well as updated MRI Conditional Labeling for the VNS system.
P970003/S211	10/03/2017	N - Normal 180 Day	VNS THERAPY MODEL 3000 PROGRAMMER	LIVANOVA USA, INC.	Approval for the introduction of the Model3000 Programmer into interstate commerce.
P970004/S252	10/26/2017	Y - 135 Review Tra	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Approval for a new manufacturer for the header plug and tubing clasp assembly.
P970013/S070	10/20/2017	R - Real-Time Proc	MICRONY SR+ REGENCY SC+	ST. JUDE MEDICAL, INC.	Approval for the Merlin Patient Care System (PCS) Model 3330 version 23.0.1 Software for the Merlin PCS Model 3650 Programmer.
P980016/S639	10/25/2017	R - Real-Time Proc	EN TRUST ICD, INTRINSIC ICD, MARQUIS DR & VR ICD, MAXIMO II DR ICD, MAXIMO II ICD, MAXIMO VR ICD, PROTECTA ICD /XT ICD, SECURA ICD, VIRTUOSO ICD, VIRTUOSO II DR/VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for several updates to the web-based battery longevity tool.
P980037/S066	10/16/2017	R - Real-Time Proc	ANGIOJET ULTRA XMI / SPIROFLEX / SPIROFLEX VG / DISTAFLEX THROMBECTOMY SET	BOSTON SCIENTIFIC CORP.	Approval for design and processing changes to the outlet adapter assembly for the Angiojet Thrombectomy Sets.
P980049/S123	10/26/2017	N - Normal 180 Day	PLATINIUM VR 1210, 1240; DR 1510, 1540, CRT-D 1711, 1741	LIVANOVA USA, INC.	Approval for feature and hardware changes to Platinium models.
P990025/S052	10/24/2017	Y - 135 Review Tra	NAVI-STAR DIAGNOSTICS/ ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC.	Approval for expansion of manufacturing capacity for extrusion and reflow manufacturing processes.
P990074/S038	10/13/2017	Y - 135 Review Tra	NATRELLE SALINE-FILLED BREAST IMPLANTS	ALLERGAN	Approval of a planned manufacturing capacity expansion at the Costa Rica manufacturing facility and the addition of manufacturing equipment.
P000008/S039	10/02/2017	O - Normal 180 Day	LAP-BAND ADJUSTABLE GASTRIC BANDING SYSTEM	APOLLO ENDOSURGERY INC	Approval for the addition of the long-term data from the HERO-002 post-approval study, the addition of the MR Conditional labeling claim, and the addition of warnings for adverse events associated with device erosion and device migration/twisting/slipping.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S340	10/19/2017	N - Normal 180 Day	PERCEPTA QUAD CRT-P MRI SURESCAN / PERCEPTA CRT-P MRI SURESCAN / SERENA QUAD CRT-P MRI SURESCAN / SPLAR QUAD CRT-P MRI SURESCAN / SOLARA CRT-P MRI SURESCAN / IMPLANTABLE PULSE GENERATOR WITH CARDIAC RESYNCHRONIZATION THERAPY	MEDTRONIC INC.	Approval for CareLink Support of Percepta/Percepta Quad, Serena/Serena Quad, and Solara/Solara Quad CRT-P MRI SureScan Implantable Pulse Generators with Cardiac Resynchronization Therapy.
P010019/S053	10/17/2017	Y - 135 Review Tra	LOTRAFILCON A & B SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Approval for elimination of duplicate, redundant in- process QC testing of raw materials used in the production of Alcon lotrafilcon A and B soft contact lens products for daily and extended wear.
P010031/S600	10/25/2017	R - Real-Time Proc	CONCERTO ICD, CONCERTO II CRT-D, CONSLTA DR4 ICD, CONSULTA ICD, INSYNC MAXIMO ICD, MAXIMO II CRT-D, PROTECTA CRT-D, PROTECTA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for several updates to the web-based battery longevity tool.
P010068/S053	10/24/2017	Y - 135 Review Tra	NAVISTAR/CELSIUS DS DIAGNOSTIC/ABLATION DEFLECTABLE 8MM TIP CATHETER	BIOSENSE WEBSTER, INC.	Approval for expansion of manufacturing capacity for extrusion and reflow manufacturing processes.
P020045/S083	10/03/2017	R - Real-Time Proc	FREEZOR CRYOABLATION SYSTEM (CRYOCONSOLE)	MEDTRONIC CRYOCATH LP	Approval for modifications to a CryoConsole control valve.
P020056/S041	10/13/2017	Y - 135 Review Tra	NATRELLE SILICONE FILLED BREAST IMPLANTS	ALLERGAN	Approval of a planned manufacturing capacity expansion at the Costa Rica manufacturing facility and the addition of manufacturing equipment.
P030009/S092	10/04/2017	R - Real-Time Proc	INTEGRITY CORONARY STENT SYSTEMS	MEDTRONIC IRELAND	Approval for a material change to the distal inner shaft of the Integrity Coronary Stent Systems (RX & OTW).
P030017/S279	10/17/2017	O - Normal 180 Day	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Guidant Puerto Rico B.V., No. 12, Road 698, Dorado, Puerto Rico.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030031/S080	10/24/2017	Y - 135 Review Tra	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Approval for expansion of manufacturing capacity for extrusion and reflow manufacturing processes.
P030035/S153	10/20/2017	R - Real-Time Proc	ANTHEM, ALLURE/RF, QUADRA ALLURE /RF FAMILY OFCRT-PS	ST. JUDE MEDICAL, INC.	Approval for Merlin.net MN5000 v7.5 Software to add support for the Confirm Rx Insertable Cardiac Monitor.
P030035/S154	10/20/2017	R - Real-Time Proc	ALLURE QUADRA, QUADRA ALLURE MP, FRONTIER	ST. JUDE MEDICAL, INC.	Approval for the Merlin Patient Care System (PCS) Model 3330 version 23.0.1 Software for the Merlin PCS Model 3650 Programmer.
P030053/S043	10/10/2017	R - Real-Time Proc	MENTOR MEMORYGEL SILICONE GEL - FILLED BREAST IMPLANTS	MENTOR CORP.	Approval for a product line extension to the MemoryGel® Silicone Gel-Filled Breast Implants family of products.
P030054/S320	10/20/2017	R - Real-Time Proc	PROMOTE/+/RF/Q, PROMOTE ACCEL, PROMOTE QUADRA, UNIFY, UNIFY ASSURA, UNIFY QUADRA, QUADRA ASSURA, EPIC+/HF/HF+/II HF/II+HF,ATLAS+HF/II HH/II + HF FAMILY OF CRT-PS	ST. JUDE MEDICAL	Approval for Merlin.net MN5000 v7.5 Software to add support for the Confirm Rx Insertable Cardiac Monitor.
P030054/S321	10/20/2017	R - Real-Time Proc	PROMOTE ACCEL, PROMOTE QUADRA, UNIFY ASSURA, QUADRA ASSURA, EPIC+/HF/HF+/ IIHF/II+HF, ATLAS +HF/IIHF/ II+HF/III+HF	ST. JUDE MEDICAL	Approval for the Merlin Patient Care System (PCS) Model 3330 version 23.0.1 Software for the Merlin PCS Model 3650 Programmer.
P030054/S327	10/20/2017	R - Real-Time Proc	MERLIN PATIENT CARE SYSTEM PROGRAMMER	ST. JUDE MEDICAL	Approval for the accessory Bluetooth dongle, Model BLU1000, to be used with the Merlin Patient Care System (PCS) Model 3650 programmer.
P040024/S096	10/11/2017	N - Normal 180 Day	RESTYLANE SILK	Q-MED AB	Approval for use of a small bore, blunt tip cannula with Restylane Silk for submucosal implantation for lip augmentation in patients over the age of 21.
P040036/S058	10/24/2017	Y - 135 Review Tra	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTICS/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Approval for expansion of manufacturing capacity for extrusion and reflow manufacturing processes.
P040043/S096	10/31/2017	S - Special CBE	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Approval for updates to the Gore CTAG Thoracic Endoprosthesis Instructions for Use (IFU), including additional language in the Warnings and Precautions and Patient Counseling sections.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040046/S022	10/13/2017	Y - 135 Review Tra	NATRELLE 410 HIGHLY COHESIVE ANATOMICALLY SHAPED SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Approval of a planned manufacturing capacity expansion at the Costa Rica manufacturing facility and the addition of manufacturing equipment.
P050006/S058	10/11/2017	Y - 135 Review Tra	GORE CARDIOFORM SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Approval for modifications to the hydrophilic coating processing.
P060027/S088	10/26/2017	N - Normal 180 Day	PLATINIUM VR 1210, 1240; DR 1510, 1540, CRT-D 1711, 1741 (IS1) AND 1744 (IS4)	LIVANOVA USA, INC.	Approval for feature and hardware changes to Platinium models.
P080025/S147	10/26/2017	Y - 135 Review Tra	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (BOWEL)	MEDTRONIC NEUROMODULATION	Approval for a new manufacturer for the header plug and tubing clasp assembly.
P100010/S065	10/03/2017	R - Real-Time Proc	ARCTIC FRONT CRYOABLATION SYSTEM (CRYOCONSOLE)	MEDTRONIC CRYOCATH LP	Approval for modifications to a CryoConsole control valve.
P100044/S031	10/13/2017	S - Special CBE	PROPEL CONTOUR SINUS IMPLANT	INTERSECT ENT	Approval for labeling modifications to clarify instructions for an alternative implant loading method into the delivery system, and for appropriately orienting the delivery system distal tip for the specific sinus being treated.
P110007/S009	10/31/2017	O - Normal 180 Day	HEALON ENDOCOAT OPHTHALMIC VISCOSURGICAL DEVICE (OVD) (3% SODIUM HYALURONATE), MODEL VT585	ABBOTT MEDICAL OPTICS INC	Approval for a manufacturing site located at Lifecore Biomedical, LLC, 1245 Lakeview Drive Chaska, Minnesota to be used for post-sterilization final packaging, warehousing, and distribution activities.
P110013/S080	10/04/2017	R - Real-Time Proc	RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEMS	MEDTRONIC VASCULAR	Approval for a material change to the distal inner shaft of the Resolute Integrity Zotarolimus-Eluting Coronary Stent Systems (RX & OTW).
P110033/S031	10/27/2017	R - Real-Time Proc	JUVEDERM VOLBELLA XC	ALLERGAN	Approval for a change to the needle packaged with Juvederm Volbella XC, from 30G 1/2 inch to 32G 1/2 inch needles.
P120006/S028	10/13/2017	R - Real-Time Proc	OVATION IX ABDOMINAL STENT GRAFT SYSTEM	TRIVASCULAR INC	Approval for the use of a thermoformed tray for packaging of the Ovation iX Aortic Body, Iliac Limb, and the associated delivery systems.
P120010/S101	10/11/2017	O - Normal 180 Day	MINIMED 530G SYSTEM	MEDTRONIC INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130005/S018	10/20/2017	N - Normal 180 Day	DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM (OAS) CLASSIC CROWN	CARDIOVASCULAR SYSTEMS, INC.	Approval of a software change to implement a feature referred to as GlideAssist.
P130007/S027	10/27/2017	Y - 135 Review Tra	ANIMAS VIBE SYSTEM	ANIMAS CORP.	Approval for changes to the manufacturer of two fastener screws and the lead screw used in the pump drive mechanism for the Animas Vibe Insulin pump. The Animas Vibe Insulin pump is a component of the Animas Vibe System.
P130025/S003	10/24/2017	R - Real-Time Proc	KONING BREAST CT, KBCT	KONING CORPORATION	Approval for changes to the input power requirements to 210-240 VAC, 30 AMP service and software changes associated with an added light switch, camera and touch screen interface.
P130026/S026	10/02/2017	R - Real-Time Proc	TACTISYS QUARTZ MOUNTING BRACKET, TACTISYS QUARTZ EQUIPMENT	ST. JUDE MEDICAL	Approval for two new styles of mounting brackets used to mount the TactiSys Quartz equipment.
P130029/S007	10/05/2017	O - Normal 180 Day	FLUENCY PLUS ENDOVASCULAR STENT GRAFT	BARD PERIPHERAL VASCULAR, INC.	Approval for an update to the labeling to include the 24-month data on patients enrolled in the clinical study.
P140033/S012	10/30/2017	R - Real-Time Proc	SJM MRI ACTIVATOR	ST. JUDE MEDICAL, INC.	Approval for the Model EX4001 SJM MRI Activator.
P150001/S020	10/16/2017	R - Real-Time Proc	MINIMED 630G SYSTEM WITH SMARTGUARD / GUARDIAN SENSOR (3)	MEDTRONIC MINIMED	Approval for minor design changes to automate the manufacturing of the Adhesive Disk and the Needle-Hub assembly. In addition, approval to transfer the manufacture of the Guardian Sensor (3) from the Northridge, California facility to Medtronics Juncos, Puerto Rico facility.
P150001/S022	10/31/2017	R - Real-Time Proc	MINIMED 630G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED	Approval for design changes to the Contour Next Link 2.4 Wireless Blood Glucose Meter. The Contour Next Link 2.4 Wireless Blood Glucose Meter is a component of the Medtronic MiniMed 630G System and Medtronic MiniMed 670G System.
P150023/S003	10/10/2017	O - Normal 180 Day	ABSORB GT1 BIORESORBABLE VASCULAR SCAFFOLD (BVS) SYSTEM	ABBOTT VASCULAR INC.	Approval for your premarket approval application (PMA) request that we place your study on hold.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150028/S001	10/24/2017	P - Panel Track	CHEATHAM PLATINUM (CP) STENT SYSTEM (COVERED CP STENT, COVERED MOUNTED CP STENT, CP STENT, MOUNTED CP STENT)	NUMED, INC.	Approval for the Covered CP Stent and Covered Mounted CP Stent Models. This device is indicated for use in the treatment of right ventricle to pulmonary artery (right ventricular outflow tract, RVOT) conduit disruptions that are identified during conduit pre-dilatation procedures performed in preparation for transcatheter pulmonary valve replacement (TPVR). In addition, approval for additional sizes (10-zig and lengths up to 60 mm for 8- and 10-zig configurations) for the Cheatham Platinum Stent System.
P150038/S004	10/13/2017	O - Normal 180 Day	EXABLATE NEURO THALAMOTOMY	INSIGHTEC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P160017/S016	10/16/2017	R - Real-Time Proc	MINIMED 670G SYSTEM/ GUARDIAN SENSOR (3)	MEDTRONIC MINIMED, INC.	Approval for minor design changes to automate the manufacturing of the Adhesive Disk and the Needle-Hub assembly. In addition, approval to transfer the manufacture of the Guardian Sensor (3) from the Northridge, California facility to Medtronics Juncos, Puerto Rico facility.
P160017/S018	10/31/2017	R - Real-Time Proc	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval for design changes to the Contour Next Link 2.4 Wireless Blood Glucose Meter. The Contour Next Link 2.4 Wireless Blood Glucose Meter is a component of the Medtronic MiniMed 630G System and Medtronic MiniMed 670G System.
P160024/S002	10/13/2017	R - Real-Time Proc	LIFESTREAM BALLOON EXPANDABLE VASCULAR COVERED STENT	BARD PERIPHERAL VASCULAR, INC.	Approval for a minor change to the design of the stent guard component.
P160042/S001	10/02/2017	O - Normal 180 Day	REVANESSE ULTRA (REVANESSE VERSA)	PROLLENIUM MEDICAL TECHNOLOGIES INC.	Approval for a name change from Revanesse Ultra to Revanesse Versa.
P160049/S001	10/23/2017	R - Real-Time Proc	STELLAREX 0.035 OTW DRUG-COATED ANGIOPLASTY BALLOON	THE SPECTRANETICS CORP.	Approval for a new balloon length of 100 mm.

Total: 74

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N17679/S037	10/17/2017	X - 30-Day Notice	TETRAFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION, INC.	Installation of a new sterilizer.
N18033/S095	10/20/2017	X - 30-Day Notice	VISTAKON (ETAFILCON A) BRAND CONTACT LENSES	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Change in transport conditions of a raw material.
N970003/S214	10/18/2017	X - 30-Day Notice	ALTRUA / ESSENTIO / PROPONENT / ACCOLADE / ACCOLADE NON-MRI PACEMAKERS	BOSTON SCIENTIFIC CORP.	Changes to the terminal pin bend inspection.
N970003/S215	10/26/2017	X - 30-Day Notice	ALTRUA, ESSENTIO, PROPONENT, ACCOLADE - ACCOLADE NON-MRI PACEMAKERS	BOSTON SCIENTIFIC CORP.	Addition of a dual illumination source solder print inspection system.
N970003/S216	10/20/2017	X - 30-Day Notice	ACCOLADE NON-MRI PACEMAKERS: ALTRUA 2, ESSENTIO, PROPONENT, ACCOLADE	BOSTON SCIENTIFIC CORP.	Updates to the torque and final pack electrical test software.
N970012/S138	10/06/2017	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE / IMPLANTABLE PENILE PROSTHESIS WITH AND WITHOUT INHIBIZONE TREATMENT	BOSTON SCIENTIFIC CORP.	Removal of redundant in-process cytotoxicity testing during the washed fabric assembly operations.
P790007/S053	10/03/2017	X - 30-Day Notice	HANCOCK MODIFIED ORIFIC VALVED CONDUIT.	MEDTRONIC HEART VALVES	Reduction of the sample size for tissue microbial monitoring.
P810006/S078	10/25/2017	X - 30-Day Notice	COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC SPONGE AND COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC AGEMT-MICROFIBRILLAR FORM	INTEGRA LIFESCIENCES CORPORATION	Modification of bioburden test method for microfibrillar collagen.
P830055/S189	10/18/2017	X - 30-Day Notice	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Addition of a second supplier of raw materials used at the DePuy Raynham and Cork manufacturing facilities.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830055/S190	10/18/2017	X - 30-Day Notice	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Addition of an alternate tumbler to be used for processing tibial insert components.
P830061/S150	10/24/2017	X - 30-Day Notice	CAPSURE SENSE LEAD (4074, 4574)	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Add an alternate site to perform the monolithic controlled release device (MCRD) receipt acceptance test.
P840001/S379	10/06/2017	X - 30-Day Notice	MASTER RESTORE, ITREL, SYNERGY AND INTELLIS; SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODU LATION	Change to the chemical used for the chrome silicon (CrSi) via etch process for the l .5 um HD BiCMOS and 0.8 um HV BiCMOS IC technologies.
P850010/S077	10/25/2017	X - 30-Day Notice	HELISTAT ABSORBABLE COLLAGEN HEMOSTATIC AGENT AND HELITENE ABSORBABLE COLLAGEN HEMOSTATIC AGENT-FIBRILLAR FORM	INTEGRA LIFESCIENCE S CORPORATIO N	Modification of bioburden test method for microfibrillar collagen.
P850048/S048	10/24/2017	X - 30-Day Notice	ACCESS HYBRITECH PSA ASSAY	BECKMAN COULTER, INC.	Addition of a supplier manufacturing site for the production of the UniCel DxI reaction vessels.
P850079/S075	10/17/2017	X - 30-Day Notice	METHAFILCON A AND METHAFILCON B SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISIO N, INC.	Installation of a new sterilizer.
P860003/S096	10/06/2017	X - 30-Day Notice	THERAKOS CELLEX PROCEDURAL KIT	THERAKOS, INC.	Manufacturing process change to the mold tool for the illumination plate in the CELLEX Procedural Kit.
P870078/S038	10/03/2017	X - 30-Day Notice	HANCOCK VALVED CONDUIT	MEDTRONIC, INC.	Reduction of the sample size for tissue microbial monitoring.

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P880086/S288	10/16/2017	X - 30-Day Notice	VICTORY 5816, 5810, 5610; ZEPHYR 5820, 5826, 5620, 5626; ACCENT PM1110, PM1210, PM2110, PM2210; ASSURITY PM1240, PM2240; ASSURITY+ PM1260, PM2260; ENDURITY PM1160, PM2160; IDENTITY XL, IDENTITY ADX XL 5286, 5180, 5376, 5380, 5386, 5480; VERITY ADX XL 5157M/S, 5357M/S, 5056, 5156, 5256, 5356, 5456, 5456I;	ST. JUDE MEDICAL, INC.	Automation of the tray packaging inspection process to ensure the required components are in the tray.
P890055/S070	10/16/2017	X - 30-Day Notice	MEDSTREAM PROGRAMMABLE INFUSION PUMP CONTROL UNIT	CODMAN	Transfer of the downstream manufacturing processes for the MedStream Control Unit from the Medos Sarl facility to the Medos International facility.
P910023/S393	10/16/2017	X - 30-Day Notice	CURRENT+ CD1211-36, CD2211-36, CD1211-36Q, CD2211-36Q; FORTIFY CD1231-40, CD1231-40Q, CD2231-40, CD2231-40Q; FORTIFY ASSURA CD1257-40, CD1257-40Q, CD2257-40, CD2257-40Q, CD1357-40, CD1357-40Q, CD1357-40C, CD1357-40QC, CD2357-40, CD2357-40Q, CD2357-40C, CD2357-40QC; ELLIPSE CD1275-36, CD1275-36Q, CD1311-36, CD1311-36Q, CD2275-36, CD2275-36Q, CD2311-36, CD2311-36Q, CD1411-36, CD1411-36Q, CD1411-36C, CD1411-36QC, CD2411-36, CD2411-36Q, CD2411-36C, CD2411-36QC;	ST. JUDE MEDICAL	Automation of the tray packaging inspection process to ensure the required components are in the tray.
P910023/S394	10/18/2017	X - 30-Day Notice	FORTIFY / FORTIFY ASSURA / ELLIPSE	ST. JUDE MEDICAL	Addition of an alternate supplier of high voltage hybrid components for use in ICD and CRT-D devices.

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P920047/S103	10/11/2017	X - 30-Day Notice	BLAZER II HTD / BLAZER PRIME HTD	BOSTON SCIENTIFIC CORP.	Implementation of an automated wire pulling and stripping process.
P930014/S105	10/04/2017	X - 30-Day Notice	ACRYSF POSTERIOR CHAMBER SINGLE PIECE INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Implementation of a new endotoxin detection method for the AcrySof lenses and purified water.
P930038/S085	10/24/2017	X - 30-Day Notice	ANGIO SEAL VASCULAR CLOSURE DEVICE	TERUMO MEDICAL CORPORATION	Transfer of distribution centers for the Angio-Seal device.
P930038/S086	10/26/2017	X - 30-Day Notice	ANGIO SEAL VASCULAR CLOSURE DEVICE	TERUMO MEDICAL CORPORATION	Implementation of an automated environmental monitoring system.
P930039/S176	10/24/2017	X - 30-Day Notice	CAPSURE FIX NOVUS LEAD (4076, 5076)	MEDTRONIC, INC.	Add an alternate site to perform the monolithic controlled release device (MCRD) receipt acceptance test.
P950005/S067	10/10/2017	X - 30-Day Notice	WEBSTER CATHETER, CELSIUS THERMOCOOL CATHETER, CELSIUS CATHETER	CORDIS CORP.	Transfer of the extrusion process of the Braided Dual Lumen and Braided Triple Lumen subcomponent catheter part.
P950005/S068	10/17/2017	X - 30-Day Notice	WEBSTER DIAG./ABLATION DEFLECTABLE TIP CATHETER	CORDIS CORP.	Transfer the location of activities associated with receiving, inspection, pre-release and final release.
P950020/S084	10/27/2017	X - 30-Day Notice	BSC WOLVERINE CORONARY CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Changes to the settings of the plasma process used in the manufacture of the WOLVERINE Coronary Cutting Balloon.
P950022/S111	10/16/2017	X - 30-Day Notice	DURATA AND OPTISURE FAMILY OF HIGH VOLTAGE LEADS	ST. JUDE MEDICAL, INC.	Addition of an automated tube cutter for use during lead manufacturing.
P950034/S049	10/25/2017	X - 30-Day Notice	SEPRAFILM ADHESION BARRIER	GENZYME CORP.	Implementation of a new foil pouch for the device packaging.
P960009/S296	10/06/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Change to the chemical used for the chrome silicon (CrSi) via etch process for the l .5um HD BiCMOS and 0.8um HV BiCMOS IC technologies.
P960009/S298	10/18/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Change in supplier for the Burr Hole Blank.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960016/S070	10/24/2017	X - 30-Day Notice	SAFIRE BI-DIRECTIONAL ABLATION CATHETERS, LIVEWIRE TC ABLATION CATHETER	ST. JUDE MEDICAL	Installation of additional data loggers for use with the Vaisala Environmental Monitoring System (EMS).
P960028/S040	10/27/2017	X - 30-Day Notice	REZOOM 3-PIECE MULTIFOCAL IOL	ABBOTT MEDICAL OPTICS INC	Change to the acceptance criteria and inspection test method for the intraocular lens material.
P960040/S404	10/11/2017	X - 30-Day Notice	ICDS: PUNCTUA, ENERGEN, INCEPTA	BOSTON SCIENTIFIC	Modifications to the manufacturing process for the spring contact housing components.
P960040/S407	10/26/2017	X - 30-Day Notice	AUTOGEN, DYNAGEN, INOGEN,ORIGEN / NG3 IMPLANTABLE CARDIAC DEFIBRILLATORS / MOMENTUR, VIGILANT, PERCIVA, RESONATE / NG4 ICDS	BOSTON SCIENTIFIC	Addition of a dual illumination source solder print inspection system.
P960058/S123	10/05/2017	X - 30-Day Notice	HIRESOLUTION BIONIC EAR SYSTEM	ADVANCED BIONICS	Manufacturing change for the HiFocus Mid-Scala electrode array.
P960058/S124	10/25/2017	X - 30-Day Notice	HIRESOLUTION BIONIC EAR SYSTEM	ADVANCED BIONICS	Change to the in-house sterilization load configuration.
P960058/S125	10/26/2017	X - 30-Day Notice	HIRESOLUTION BIONIC EAR SYSTEM - UNIVERSAL HEADPIECE (UHP) 2.0	ADVANCED BIONICS	Change the manufacturing process for the Universal Headpiece (UHP) which is part of the HiResolution Bionic Ear System.
P970004/S257	10/06/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODU LATION	Change to the chemical used for the chrome silicon (CrSi) via etch process for the l .5um HD BiCMOS and 0.8um HV BiCMOS IC technologies.
P970013/S073	10/16/2017	X - 30-Day Notice	MICRONY 2525T	ST. JUDE MEDICAL, INC.	Automation of the tray packaging inspection process to ensure the required components are in the tray.
P970031/S059	10/03/2017	X - 30-Day Notice	FREESTYLE BIOPROSTHESIS	MEDTRONIC, INC.	Reduction of the sample size for tissue microbial monitoring.
P970038/S036	10/24/2017	X - 30-Day Notice	ACCESS HYBRITECH FREE PSA REAGENTS/ CALIBRATOR KIT IMMUNOASSAY SYSTEMS	BECKMAN COULTER, INC.	Addition of a supplier manufacturing site for the production of the UniCel DxI reaction vessels.
P970051/S171	10/25/2017	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Removal of a redundant measurement of critical dimensions of electrode combs (models EA22 and EA32) for the Nucleus 24 cochlear implant system.
P980003/S080	10/11/2017	X - 30-Day Notice	CHILLI II	BOSTON SCIENTIFIC CORP.	Implementation of an automated wire pulling and stripping process.

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P980003/S081	10/06/2017	X - 30-Day Notice	CHILLI II COOLED ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of an alternate vendor for the catheter tip and insert components.
P980016/S641	10/05/2017	X - 30-Day Notice	EVERA MRI DF ICD, MRI ICD, S DR ICD, S VR ICD, XT DR ICD, XT VR ICD - VISIA AF MRI DFI ICD, AF MRI VR ICD, AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement residual moisture and ionic contamination monitoring.
P980016/S642	10/19/2017	X - 30-Day Notice	EVERA MRI ICD/EVERA S DR/VR ICD/EVERA XT DR/ VR ICD/VISIA AF MRI VR ICD/VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Addition of first shot assembly equipment.
P980016/S643	10/20/2017	X - 30-Day Notice	EVERA MRI ICD/EVERA S DR/VR ICD/EVERA XT DR/ VR ICD/VISIA AF MRI VR ICD/VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Addition of injection molding equipment.
P980016/S644	10/20/2017	X - 30-Day Notice	EVERA MRI ICD/EVERA S DR/VR ICD/EVERA XT DR/ VR ICD/VISIA AF MRI VR ICD/VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Addition of manufacturing equipment for use in the connector second shot molding process.
P980016/S645	10/26/2017	X - 30-Day Notice	EVERA MRI DF ICD /MRI ICD / S DR / S VR / XT DR / XT VR ICD'S; VISIA AF MRI DFI ICD / AF MRI VR ICD / AF VR ICD.	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Addition of a cooling process step, updates to the weld process parameters, and the addition of an inspection step during capacitor manufacturing.
P980035/S520	10/05/2017	X - 30-Day Notice	AZURE XT DR/SR MRI SURESCAN IPG; AZURE S DR/SR MRI SURE SCAN IPG	MEDTRONIC INC.	Update to the manufacturing execution system to FACTORYworks 9.1, an additional vision system for inspection of final packaged devices, and changes to heavy metal testing for silicone.

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P980035/S521	10/24/2017	X - 30-Day Notice	ORION: ASTRA XT DR MIR IPG, ASTRA S DR MRI IPG, ASTRA S SR MRI IPG, ASTRA XT SR MRI IPG, AZURE S DR MRI IPG, AZURE S SR MRI IPG, AZURE XT DR MRI IPG, AZURE XT SR MRI IPG	MEDTRONIC INC.	Change the inspection method for radiopaque presence and connector mix inspections from a human visual inspection to a semi-automated inspection using a vision system.
P980035/S522	10/31/2017	X - 30-Day Notice	ATTESTA DR MRI SURESCAN, L DR MRI SURESCAN, S DR MRI SURESCAN, SR MRI SURESCAN, SPHERA DR MRI SURESCAN, L DR MRI SURESCAN, SR MRI SURESCAN	MEDTRONIC INC.	Implementation of the following previously accepted changes: modifications to heavy metal testing for silicone, additional vision system for inspection of final packaged devices, additional laser welder for use in manufacturing of the battery header subassembly, a change to the chemical used for the etch process for integrated circuit components, an update to the hybrid testing process, changes to the integrated circuit tests used for pacemaker devices, and an update to the software used in the final functional device tester.
P980040/S084	10/27/2017	X - 30-Day Notice	SENSAR 1-PIECE IOL, TECNIS 1-PIECE IOL, PRELOADED TECNIS 1-PIECE IOL, TECNIS MULTIOCAL 1-PIECE IOL, TECNIS TORIC 1-PIECE IOLS, TECNIS SYMFONY EXTENDED RANGE OF VISION IOL, TECNIS SYMFONY TORIC EXTENDED RANGE OF VISION IOL, TECNIS ITEC PRELOADED DELIVERY SYSTEM, SENSAR 3-PIECE MONOFOCAL	ABBOTT MEDICAL OPTICS INC	Change to the acceptance criteria and inspection test method for the intraocular lens material.
P980041/S039	10/24/2017	X - 30-Day Notice	ACCESS AFP IMMUNOASSAY	BECKMAN COULTER, INC.	Addition of a supplier manufacturing site for the production of the UniCel DxI reaction vessels.
P980043/S063	10/03/2017	X - 30-Day Notice	HANCOCK II AND HANCOCK ULTRA II BIOPROSTHESIS	MEDTRONIC, INC.	Reduction of the sample size for tissue microbial monitoring.
P990025/S054	10/10/2017	X - 30-Day Notice	NAVISTAR CATHETER	BIOSENSE WEBSTER, INC.	Transfer of the extrusion process of the Braided Dual Lumen and Braided Triple Lumen subcomponent catheter part.

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P990025/S055	10/17/2017	X - 30-Day Notice	NAVI-STAR DIAGNOSTIC/ ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC.	Transfer the location of activities associated with receiving, inspection, pre-release and final release.
P990038/S024	10/16/2017	X - 30-Day Notice	ETI MAK-2 PLUS AND HBSAG CONFIRMATORY TEST ASSAYS	DIASORIN, INC.	Relocation of manufacturing activities related to incoming components.
P990041/S023	10/16/2017	X - 30-Day Notice	ETI-AB-EBK PLUS ASSAY	DIASORIN, INC.	Relocation of manufacturing activities related to incoming components.
P990042/S020	10/16/2017	X - 30-Day Notice	ETI-AB-AUK PLUS ASSAY	DIASORIN, INC.	Relocation of manufacturing activities related to incoming components.
P990043/S024	10/16/2017	X - 30-Day Notice	ETI-EBK PLUS ASSAY	DIASORIN, INC.	Relocation of manufacturing activities related to incoming components.
P990044/S021	10/16/2017	X - 30-Day Notice	ETI-CORE-IGMK PLUS ASSAY	DIASORIN, INC.	Relocation of manufacturing activities related to incoming components.
P990046/S051	10/06/2017	X - 30-Day Notice	OPEN PIVOT HEART VALVE	MEDTRONIC ATS MEDICAL, INC.	Transfer of sewing operations for several Open Pivot Heart Valve models to Medtronic Tijuana, Mexico.
P990064/S071	10/03/2017	X - 30-Day Notice	MOSAIC BIOPROSTHESIS & MOSAIC ULTRA BIOPROSTHESIS	MEDTRONIC, INC.	Reduction of the sample size for tissue microbial monitoring.
P990071/S038	10/17/2017	X - 30-Day Notice	STOCKERT 70 RADIO FREQUENCY ABLATION GENERATOR	BIOSENSE WEBSTER, INC.	Transfer the location of activities associated with receiving, inspection, pre-release and final release.
P990080/S045	10/27/2017	X - 30-Day Notice	TECNIS 3-PIECE MULTIFOCAL IOL	ABBOTT MEDICAL OPTICS INC	Change to the acceptance criteria and inspection test method for the intraocular lens material.
P010012/S463	10/11/2017	X - 30-Day Notice	CRT-DS: DYNAGEN, VIGILANT, MOMENTUM	BOSTON SCIENTIFIC CORP.	Modifications to the manufacturing process for the spring contact housing components.
P010012/S466	10/26/2017	X - 30-Day Notice	AUTOGEN, DYNAGEN, INOGEN, ORIGEN - NG3 CARDIAC RESYNCHRONIZATION THERAPY / MOMENTUM, VIGILANT, RESONATE - NG4 CRT-D DEVICES	BOSTON SCIENTIFIC CORP.	Addition of a dual illumination source solder print inspection system.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010014/S066	10/06/2017	X - 30-Day Notice	OXFORD PARTIAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Transfer of crystallinity evaluation testing location for direct compression molded components.
P010014/S067	10/05/2017	X - 30-Day Notice	OXFORD PARTIAL KNEE SYSTEM - TIBIAL TRAY AND FEMORAL COMPONENTS	BIOMET MANUFACTURING CORP.	Repeat of a specific manufacturing step if needed and allowing that data from erratic sensors not be used to accept or reject a production run provided other sensors co-located with the erratic sensor conform to specification.
P010015/S344	10/24/2017	X - 30-Day Notice	CRTP-QUAD: PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P, SOLARA BIPOLAR CRT-P, SOLARA QUADRIPOLAR CRT-P	MEDTRONIC INC.	Change the inspection method for radiopaque presence and connector mix inspections from a human visual inspection to a semi-automated inspection using a vision system.
P010019/S060	10/20/2017	X - 30-Day Notice	LOTRAFILCON B SOFT CONTACT LENSES FOR DAILY AND EXTENDED WEAR	ALCON LABORATORIES, INC.	Rearrangement of certain fabrication steps in the production of lotrafilcon B Soft Contact Lenses.
P010031/S602	10/05/2017	X - 30-Day Notice	AMPLOA MRI CRT-D, QUAD CRT-D, BRAVA CRT-D, QUAD CRT-D, CLARIA MRI CRT-D, QUAD CRT-D, COMPIA MRI CRT-D QUAD CRT-D, VIVA QUAD S CRT-D, QUAD XT CRT-D, QUAD XT CRT-D, S CRT-D, XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement residual moisture and ionic contamination monitoring.
P010031/S603	10/19/2017	X - 30-Day Notice	AMPLIA MRI CRT-D/AMPLIA MRI QUAD CRT-D/BRAVA CRT-D/BRAVA QUAD CRT-D/CLARIA MRI CRT-D/ CLARIA MRI QUAD CRT-D/ COMPIA MRI CRT-D/ COMPIA MRI QUAD CRT-D/ VIVA QUAD S CRT-D/VIVA QUAD XT CRT-D/VIVA S CRT-D/VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Addition of first shot assembly equipment.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S604	10/20/2017	X - 30-Day Notice	AMPLIA MRI CRT-D/AMPLIA MRI QUAD CRT-D/BRAVA CRT-D/BRAVA QUAD CRT-D/CLARIA MRI CRT-D/ CLARIA MRI QUAD CRT-D/ COMPIA MRI CRT-D/ COMPIA MRI QUAD CRT-D/ VIVA QUAD S CRT-D/VIVA QUAD XT CRT-D/VIVA S CRT-D/VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Addition of injection molding equipment.
P010031/S605	10/20/2017	X - 30-Day Notice	AMPLIA MRI CRT-D/AMPLIA MRI QUAD CRT-D/BRAVA CRT-D/BRAVA QUAD CRT-D/CLARIA MRI CRT-D/ CLARIA MRI QUAD CRT-D/ COMPIA MRI CRT-D/ COMPIA MRI QUAD CRT-D/ VIVA QUAD S CRT-D/VIVA QUAD XT CRT-D/VIVA S CRT-D/VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Addition of manufacturing equipment for use in the connector second shot molding process.
P010031/S606	10/26/2017	X - 30-Day Notice	AMPLIA MRI CRT-D/ QUAD CRT_D; BRAVA CRT-D/ QUAD CRT-D; CLARIA MRI CRT-D / QUAD CRT-D; COMPIA MRI QUAD CRT-D; VIVA QUAD XT CRT-D/ S CRT-D/ XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Addition of a cooling process step, updates to the weld process parameters, and the addition of an inspection step during capacitor manufacturing.
P010047/S047	10/12/2017	X - 30-Day Notice	PROGEL PLEURAL AIR LEAK SEALANT (PALS); PROGEL SPARE TIPS ACCESSORY; PROGEL 6" EXTENDED TIPS ACCESSORY; PROGEL 11" EXTENDED TIPS ACCESSORY	NEOMEND, INC.	Manufacturing process change to the Human Serum Albumin (HSA) and Polyethylene Glycol (PEG) filling.
P010047/S048	10/12/2017	X - 30-Day Notice	PROGEL PLEURAL AIR LEAK SEALANT (PALS), PROGEL SPARE TIPS ACCESSORY, PROGEL 6" AND 11" EXTENDED TIPS ACCESSORY	NEOMEND, INC.	Changes to the manufacturing of the extended applicator tip, assembly/sealing/packaging, labeling processes, and environmental controls.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010047/S049	10/10/2017	X - 30-Day Notice	PROGEL PLEURAL AIR LEAK SEALANT (PALS), PROGEL SPARE TIPS ACCESSORY, PROGEL 6" AND 11" EXTENDED TIPS ACCESSORY	NEOMEND, INC.	Manufacturing process change to the Human Serum Albumin (HSA) and Polyethylene Glycol (PEG) processing.
P010068/S055	10/10/2017	X - 30-Day Notice	CELSIUS DS CATHETER, NAVISTAR DS CATHETER	BIOSENSE WEBSTER, INC.	Transfer of the extrusion process of the Braided Dual Lumen and Braided Triple Lumen subcomponent catheter part.
P010068/S056	10/17/2017	X - 30-Day Notice	NAVISTAR/CELSIUS DS DIAGNOSTIC/ABLATION DEFLECTABLE 8MM TIP CATHETER	BIOSENSE WEBSTER, INC.	Transfer the location of activities associated with receiving, inspection, pre-release and final release.
P020004/S148	10/18/2017	X - 30-Day Notice	GORE EXCLUDER AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Implementation of a new film wrapping machine for the manufacture of GORE® EXCLUDER® AAA Endoprosthesis contralateral limb components.
P020025/S107	10/11/2017	X - 30-Day Notice	BLAZER II XP/ BLAZER PRIME XP / INTELLA TIP MIFI XP / INTELLANAV, INTELLANAV MIFI XP	BOSTON SCIENTIFIC	Implementation of an automated wire pulling and stripping process.
P030004/S013	10/17/2017	X - 30-Day Notice	APOLLO ONYX DELIVERY MICRO CATHETER, 1.5CM, STRAIGHT/APOLLO ONYX DELIVERY MICRO CATHETER, 3.0CM, STRAIGHT	EV3 NEUROVASCULAR	Modifications and replacement of the hub mold.
P030005/S162	10/18/2017	X - 30-Day Notice	VALITUDE / VALITUDE X4 / VISIONIST / VISIONIST X4 / ACCOLADE CARDIAC RESYNCHRONIZATION THERAPY PACEMAKER (CRT-P) DEVICES	GUIDANT CORP.	Changes to the terminal pin bend inspection.
P030005/S163	10/26/2017	X - 30-Day Notice	VALITUDE, VALITUDE X4, VISIONIST, VISIONIST X4 - ACCOLADE CARDIAC RESYNCHRONIZATION THERAPY	GUIDANT CORP.	Addition of a dual illumination source solder print inspection system.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030005/S164	10/20/2017	X - 30-Day Notice	ACCOLADE CARDIAC RESYNCHRONIZATION THERAPY-PACEMAKER (CRT-P): VALITUDE, VALITUDE X4, VISIONIST, VISIONIST X4	GUIDANT CORP.	Updates to the torque and final pack electrical test software.
P030017/S303	10/31/2017	X - 30-Day Notice	PRECISION MONTAGE MRI SPINAL CORD STIMULATOR (SCS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Use of an alternate bonding method during the manufacture of the charging coil, an electronic component on the Printed Circuit Board Assembly (PCBA) of the Precision Spectra Implantable Pulse Generator (IPG)
P030017/S304	10/31/2017	X - 30-Day Notice	PRECISION MONTAGE MRI SPINAL CORD STIMULATOR (SCS) SYSTEMS	BOSTON SCIENTIFIC CORP.	use of an alternate bonding method during the manufacture of the telemetry coil, an electronic component on the Printed Circuit Board Assembly (PCBA) of the Precision Montage MRI Spinal Cord Stimulator (SCS) Systems
P030031/S083	10/10/2017	X - 30-Day Notice	CELSIUS THERMOCOOL CATHETER	BIOSENSE WEBSTER, INC.	Transfer of the extrusion process of the Braided Dual Lumen and Braided Triple Lumen subcomponent catheter part.
P030031/S084	10/17/2017	X - 30-Day Notice	NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Transfer the location of activities associated with receiving, inspection, pre-release and final release.
P030035/S160	10/16/2017	X - 30-Day Notice	ANTHEM PM3210 NKE; ALLURE, ALLURE QUADRA PM3120, PM3222, PM3140, PM3242; QUADRA ALLURE MP PM3160, PM3262;	ST. JUDE MEDICAL, INC.	Automation of the tray packaging inspection process to ensure the required components are in the tray.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030054/S337	10/16/2017	X - 30-Day Notice	PROMOTE+ CD3211-36, CD3211-36Q; UNIFY CD3231-40, CD3231-40Q; UNIFY QUADRA CD3249-40, CD3249-40Q; UNIFY ASSURA CD3257-40, CD3257-40Q, CD3357-40, CD3357-40Q, CD3357-40C, CD3357-40QC; QUADRA ASSURA CD3265-40, CD3265-40Q, CD3365-40, CD3365-40Q, CD3365-40C, CD3365-40QC; QUADRA ASSURA MP CD3269-40, CD3269-40C, CD3369-40, CD3369-40Q, CD3369-40C, CD3369-40QC;	ST. JUDE MEDICAL	Automation of the tray packaging inspection process to ensure the required components are in the tray.
P030054/S338	10/18/2017	X - 30-Day Notice	UNIFY / UNIFY QUADRA / UNIFY ASSURA / QUADRA ASSURA / QUADRA ASSURA MP	ST. JUDE MEDICAL	Addition of an alternate supplier of high voltage hybrid components for use in ICD and CRT-D devices.
P040020/S072	10/04/2017	X - 30-Day Notice	ACRYSOF IQ RESTOR POSTERIOR CHAMBER INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Implementation of a new endotoxin detection method for the AcrySof lenses and purified water.
P040027/S059	10/10/2017	X - 30-Day Notice	GORE VIATORR TIPS ENDOPROSTHESIS AND GORE VIATORR TIPS ENDOPROSTHESIS WITH CONTROLLED EXPANSION	W. L. GORE & ASSOCIATES, INC.	Use of additional machines for the manufacturing of the delivery systems for the GORE VIATORR TIPS Endoprosthesis with and without Controlled Expansion and the GORE VIABAHN Endoprosthesis with and without Heparin Bioactive Surface.
P040036/S061	10/17/2017	X - 30-Day Notice	NAVISTAR THERMO COOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Transfer the location of activities associated with receiving, inspection, pre-release and final release.
P040037/S104	10/10/2017	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Use of additional machines for the manufacturing of the delivery systems for the GORE VIATORR TIPS Endoprosthesis with and without Controlled Expansion and the GORE VIABAHN Endoprosthesis with and without Heparin Bioactive Surface.

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P040045/S083	10/20/2017	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Change in transport conditions of a raw material.
P040045/S084	10/24/2017	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Alternate supplier for a raw material used in VISTAKON® (senofilcon A) Brand Contact Lenses.
P050028/S058	10/13/2017	X - 30-Day Notice	COBAS TAQMAN HBV TEST / HIGH PURE SYSTEM VIRAL NUCLEIC ACID KIT	ROCHE MOLECULAR SYSTEMS, INC.	Use larger columns for purification steps in probe manufacturing.
P050034/S019	10/20/2017	X - 30-Day Notice	IMPLANTABLE MINIATURE TELESCOPE	VISIONCARE, INC.	Alternate supplier for a component of the telescope sub-assembly for Models Wide Angle 2.2X and Wide Angle 2.7X.
P060030/S060	10/13/2017	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST, V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Use larger columns for purification steps in probe manufacturing.
P060037/S051	10/05/2017	X - 30-Day Notice	ZIMMER NEXGEN LPS-FLEX MOBILE AND LPS MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Modify the manufacturing process flow.
P060037/S052	10/19/2017	X - 30-Day Notice	LPS-FLEX MOBILE AND LPS MOBIOE BEARING KNEE SYSTEM	ZIMMER, INC.	Change in manufacturing materials used during the manufacturing of the device.
P060040/S068	10/12/2017	X - 30-Day Notice	THORATEC HEARTMATE II AND HEARTMATE 3 VENTRICULAR ASSIST SYSTEM (LVAS)	THORATEC CORP.	Implement a supplier facility relocation for a Printed Circuit Board Assembly (PCBA) of the HeartMate II LVAS and HeartMate 3 LVAS.
P060040/S069	10/12/2017	X - 30-Day Notice	HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORP.	Qualifying of a second source supplier for a Housing component.
P070001/S016	10/20/2017	X - 30-Day Notice	PRODISC-C TOTAL DISC REPLACEMENT	SYNTHES SPINE	Change to the sealing parameters for the sterile packaging process.
P070014/S054	10/23/2017	X - 30-Day Notice	BARD LIFESTENT AND LIFESTENT CLVASCULAR STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	Modifications to the frequency of in-process packaging and stent delivery system testing.

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P080004/S018	10/13/2017	X - 30-Day Notice	HOYA AF-1 CASE LENS CASE LENS AND ISERT PRE-LOADED IOL INJECTOR SYSTEMS	HOYA SURGICAL OPTICS, INC.	Change in sample size for quality checks.
P080010/S014	10/27/2017	X - 30-Day Notice	TECNIS 3-PIECE MULTIFOCAL IOL	ABBOTT MEDICAL OPTICS INC	Change to the acceptance criteria and inspection test method for the intraocular lens material.
P080025/S152	10/06/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Change to the chemical used for the chrome silicon (CrSi) via etch process for the I .5um HD BiCMOS and 0.8um HV BiCMOS IC technologies.
P090026/S021	10/24/2017	X - 30-Day Notice	ACCESS HYBRITECH P2PSA REAGENTS ON THE ACCESS IMMUNOASSAY SYSTEM	BECKMAN COULTER, INC.	Addition of a supplier manufacturing site for the production of the UniCel DxI reaction vessels.
P090028/S011	10/26/2017	X - 30-Day Notice	VITROS IMMUNODIAGNOSTIC PRODUCTS HBEAG REAGENT PACK / VITROS IMMUNODIAGNOSTIC PRODUCTS HBEAG CALIBRATOR	ORTHO-CLINICAL DIAGNOSTICS, INC.	Current Size Exclusion Chromatography component purification system be replaced with a Tangential Flow Purification System.
P100018/S016	10/11/2017	X - 30-Day Notice	PIPELINE FLEX EMBOLIZATION DEVICE	MICRO THERAPEUTICS DBA EV3 NEUROVASCULAR	Change to the hypotube manufacturing process of a sub tier supplier in order to improve overall component yield and reduce scrap.
P100020/S026	10/23/2017	X - 30-Day Notice	ROCHE COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Use larger columns for purification steps in probe manufacturing.
P100045/S026	10/24/2017	X - 30-Day Notice	CARDIOMEMS HF SYSTEM	ST. JUDE MEDICAL	Installation of additional data loggers for use with the Vaisala Environmental Monitoring System (EMS).
P110013/S082	10/13/2017	X - 30-Day Notice	RESOLUTE INTEGRITY RX CORONARY STENT SYSTEM & RESOLUTE INTEGRITY OTW CORNARY STENT SYSTEM	MEDTRONIC VASCULAR	Changes to the work steps used in the manufacture of the bare metal stent.

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P110020/S022	10/13/2017	X - 30-Day Notice	ROCHE COBAS DNA SAMPLE PREPARATION KIT / ROCHE COBAS 4800 BRAF V600 MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Use larger columns for purification steps in probe manufacturing.
P110037/S032	10/13/2017	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN CYTOMEGALOVIRUS TEST	ROCHE MOLECULAR SYSTEMS, INC.	Use larger columns for purification steps in probe manufacturing.
P110042/S093	10/16/2017	X - 30-Day Notice	EMBLEM SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD)	BOSTON SCIENTIFIC CORPORATION	Addition of a post reflow inspection on the hybrid used in the S-ICD.
P110042/S094	10/27/2017	X - 30-Day Notice	EMBLEM S-ICD	BOSTON SCIENTIFIC CORPORATION	Modifications to the quartz crystal manufacturing process for EMBLEM S-ICD pulse generators.
P120019/S015	10/13/2017	X - 30-Day Notice	ROCHE COBAS EGFR MUTATION TEST / ROCHE COBAS DNA SAMPLE PREPARATION KIT	ROCHE	Use larger columns for purification steps in probe manufacturing.
P130006/S043	10/10/2017	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Use of additional machines for the manufacturing of the delivery systems for the GORE VIATORR TIPS Endoprosthesis with and without Controlled Expansion and the GORE VIABAHN Endoprosthesis with and without Heparin Bioactive Surface.
P130007/S031	10/24/2017	X - 30-Day Notice	ANIMAS VIBE SYSTEM	ANIMAS CORP.	Supplier change for the manufacturing of a molded component of the key pad assembled into the Animas Vibe Insulin pump which is part of the Animas Vibe System. The Animas Vibe System consists of the Animas Vibe Insulin Pump paired with the Dexcom G4 PLATINUM Sensor and Transmitter.
P130009/S082	10/04/2017	X - 30-Day Notice	EDWARDS EXPANDABLE INTRODUCER SHEATH SET	EDWARDS LIFESCIENCES, LLC.	Change to the quantity of adhesive applied to bonds of the eSheath.
P130021/S042	10/03/2017	X - 30-Day Notice	EVOLUT R TRANSCATHETER AORTIC VALVE (TAV)	MEDTRONIC COREVALVE LLC	Reduction of the sample size for tissue microbial monitoring.
P130022/S016	10/06/2017	X - 30-Day Notice	NEVRO CORP SENZA SPINAL CORD STIMULATION SYSTEM	NEVRO CORPORATION	Alternate supplier of the Litz Wire used for manufacturing the Nevro Senza Charger sub-assembly.

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P140009/S029	10/04/2017	X - 30-Day Notice	ST. JUDE MEDICAL INFINITY DBS SYSTEM 4CH LEAD & 8CH DIRECTIONAL LEAD	ST. JUDE MEDICAL NEUROMODULATION	Improvements to the lead tip manufacturing process: updating allowable molecular weight of Bionate 75D, replacing the inline dryer, updating the pre-grind diameter of the lead tip, and optimizing the mold.
P140012/S011	10/26/2017	X - 30-Day Notice	RESHAPE INTEGRATED DUAL BALLOON SYSTEM	RESHAPE MEDICAL, INC.	Reduce the frequency of sterility dose auditing for the ReShape Integrated Dual Balloon System and ReShape Removal Catheter.
P140017/S008	10/03/2017	X - 30-Day Notice	MELODY TRANSCATHETER PULMONARY VALVE (TPV)	MEDTRONIC INC.	Reduction of the sample size for tissue microbial monitoring.
P140020/S013	10/26/2017	X - 30-Day Notice	BRACANALYSIS CDX DEVICE	MYRIAD GENETIC LABORATORIES	Expansion of laboratory space.
P140023/S011	10/16/2017	X - 30-Day Notice	ROCHE COBAS KRAS MUTATION TEST /ROCHE COBAS DNA SAMPLE PREPARATION KIT	ROCHE MOLECULAR SYSTEMS, INC.	Improvement to the shipping and packaging of the cobas® KRAS Mutation Test Kit.
P140031/S053	10/04/2017	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Addition of an automated process for frame sanding.
P140031/S054	10/03/2017	X - 30-Day Notice	EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC.	Addition of a functional verification inspection step for the y-connector guidewire luer port threading.
P140033/S015	10/16/2017	X - 30-Day Notice	ASSURITY MRI PM1272, PM2272; ENDURITY MRI PM1172, PM2172	ST. JUDE MEDICAL, INC.	Automation of the tray packaging inspection process to ensure the required components are in the tray.
P150001/S023	10/11/2017	X - 30-Day Notice	MEDTRONIC MINIMED 630G INSULIN PUMP	MEDTRONIC MINIMED	New manufacturing process to allow printed circuit board assemblies to be harvested and re-used for construction of refurbished and loaner 630G and 670G insulin pumps. The 630G and 670G insulin pumps are components of the MiniMed 630G and MiniMed 670G systems, respectively.
P150001/S024	10/23/2017	X - 30-Day Notice	GUARDIAN SENSOR (3)	MEDTRONIC MINIMED	Additional test equipment for post-membrane and post-sterilization testing of the Guardian Sensor (3). The Guardian Sensor (3) is a component of MiniMed 630G System with SmartGuard and a component of the MiniMed 670G System.
P150001/S025	10/26/2017	X - 30-Day Notice	MINIMED 630G PUMP	MEDTRONIC MINIMED	Second manufacturing site for a molded plastic component that supports and cushions the printed circuit board assembly within the 630G and 670G insulin pumps. The 630G and 670G insulin pumps are components of the MiniMed 630G and MiniMed 670G systems, respectively.

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P150004/S015	10/13/2017	X - 30-Day Notice	DRG LEAD EXTENSION KIT	ST. JUDE MEDICAL	Changes to the dorsal root ganglion (DRG) lead extension manufacturing process at the St. Jude Medical (SJM) Plano, Texas facility. Specifically, it requested updates to the DRG lead extension socket assembly and header molding processes. These changes only apply to the DRG lead extension header component assembly and molding process.
P150005/S028	10/11/2017	X - 30-Day Notice	BLAZER OI / INTELLANAV OI / INTELLA TIP MIFI OI	BOSTON SCIENTIFIC CORP.	Implementation of an automated wire pulling and stripping process.
P150005/S029	10/06/2017	X - 30-Day Notice	BLAZER OI, INTELLANAV OI, INTELLATIP MIFI OI, AND INTELLANAV MIFI OI ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Addition of an alternate vendor for the catheter tip and insert components.
P150012/S038	10/05/2017	X - 30-Day Notice	INGEVITY ACTIVE-FIXATION NON-MRI / ACTIVE-FIXATION MRI	BOSTONSCIENTIFIC	Modifications to improve the helix to coupler weld process and implement tighter control at the proximal end of the tip helix component.
P150012/S040	10/18/2017	X - 30-Day Notice	ESSENTIO MRI / PROPONENT MRI / ACCOLADE MRI / ACCP;ADE MRI PACEMAKERS	BOSTONSCIENTIFIC	Changes to the terminal pin bend inspection.
P150012/S041	10/26/2017	X - 30-Day Notice	ESSENTIO MRI, PROPONENT MRI, ACCOLADE MRI - ACCOLADE MRI PACEMAKERS	BOSTONSCIENTIFIC	Addition of a dual illumination source solder print inspection system.
P150012/S042	10/20/2017	X - 30-Day Notice	ACCOLADE MRI PACEMAKERS: ESSENTIO MRI, PROPNENT MRI, ACCOLADE MRI	BOSTONSCIENTIFIC	Updates to the torque and final pack electrical test software.
P150014/S009	10/13/2017	X - 30-Day Notice	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Use larger columns for purification steps in probe manufacturing.
P150014/S010	10/26/2017	X - 30-Day Notice	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Increase the scale of bulk and vialing manufacturing processes and to change filling lines for reagent component vialing.
P150015/S008	10/13/2017	X - 30-Day Notice	COBAS HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Use larger columns for purification steps in probe manufacturing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150015/S009	10/26/2017	X - 30-Day Notice	COBAS HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Increase the scale of bulk and vialing manufacturing processes and to change filling lines for reagent component vialing.
P150034/S004	10/25/2017	X - 30-Day Notice	RAINDROP NEAR VISION INLAY	REVISION OPTICS, INCORPORATED	Removal of a redundant chemical evaluation for two incoming materials.
P160004/S006	10/04/2017	X - 30-Day Notice	GORE TIGRIS VASCULAR STENT	W. L. GORE & ASSOCIATES, INC.	Modifications to the FEP film processing.
P160017/S019	10/11/2017	X - 30-Day Notice	MEDTRONIC MINIMED 67G INSULIN PUMP	MEDTRONIC MINIMED, INC.	New manufacturing process to allow printed circuit board assemblies to be harvested and re-used for construction of refurbished and loaner 630G and 670G insulin pumps. The 630G and 670G insulin pumps are components of the MiniMed 630G and MiniMed 670G systems, respectively.
P160017/S021	10/23/2017	X - 30-Day Notice	GUARDIAN SENSOR (3)	MEDTRONIC MINIMED, INC.	Additional test equipment for post-membrane and post-sterilization testing of the Guardian Sensor (3). The Guardian Sensor (3) is a component of MiniMed 630G System with SmartGuard and a component of the MiniMed 670G System.
P160017/S023	10/26/2017	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Second manufacturing site for a molded plastic component that supports and cushions the printed circuit board assembly within the 630G and 670G insulin pumps. The 630G and 670G insulin pumps are components of the MiniMed 630G and MiniMed 670G systems, respectively.
P160041/S002	10/13/2017	X - 30-Day Notice	COBAS CMV TEST FOR USE ON THE COBAS 6800/8800 SYSTEM	ROCHE MOLECULAR SYSTEMS, INC.	Use larger columns for purification steps in probe manufacturing.
P160043/S008	10/20/2017	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC INC.	Implement equivalent equipment used to print the stent size, description (DES), and 2 dimensional barcode information on the catheter luer.
P160054/S001	10/12/2017	X - 30-Day Notice	THORATEC HEARTMATE II AND HEARTMATE 3 VENTRICULAR ASSIST SYSTEM (LVAS)	THORATEC CORPORATION	Implement a supplier facility relocation for a Printed Circuit Board Assembly (PCBA) of the HeartMate II LVAS and HeartMate 3 LVAS.
P160054/S002	10/12/2017	X - 30-Day Notice	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATION	Qualifying of a second source supplier for a Housing component.

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P170006/S001	10/03/2017	X - 30-Day Notice	AVALUS BIOPROSTHESIS VALVE	MEDTRONIC INC. HEART VALVE DIVISION	Reduction of the sample size for tissue microbial monitoring.

Total: 165