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

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140033	01/31/2017	PMAO - PMA Origi	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ST. JUDE MEDICAL, INC.	Approval for the MR Conditional Pacemaker System (which includes the Assurity MRI (Models PM 1272, PM 2272) and Endurity MRI (Models PM 1172, PM 2172) pacemakers, Tendril MRI Lead (Model LPA 1200M), MRI Activator (Model EX4000), Merlin PCS Programmer Software (Model 3330 v 22.1.1), Merlin.net MN5000 7.4d, and Merlin@home EX2000 8.2.2). Implantation of a single-chamber pulse generator or dual-chamber pulse generator is indicated for in one or more of the following permananent conditions: 1) Syncope; 2) Presyncope; 3) Fatigue; 4) Disorientation; or 5) Any combination of those symptoms MR Conditional pulse generator is safe for use in the MRI environment when used as a complete MR Conditional pacing system, and according to the instructions in the MRI Procedure Information document for the St. Jude Medical MR Conditional Pacing System. Rate-Modulated Pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. Chronotropic incompetence has not been rigorously defined. A conservative approach, supported by the literature, defines chronotropic incompetence as the failure to achieve an intrinsic heart rate of 70% of the age-predicted maximum heart rate or 120 bpm during exercise testing, whichever is less, where the age-predicted heart rate is calculated as 197 (0.56 x age). Dual-Chamber Pacing (Dual-chamber pulse generators) is indicated for those patients exhibiting: 1) Sick sinus syndrome 2)Chronic, symptomatic second- and third-degree AV block 3) Recurrent Adams-Stokes syndrome; and 4) Symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. Atrial Pacing is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. Ventricular Pacing is indicated for patients with significant bradycardia and: 1) Normal sinus rhythm with only rare episodes of A-V block or sinus arrest 2) Chronic atrial fibrillation; and 3) Severe physical disability

					AF Suppression (Dual-chamber pulse generators) is indicated for suppression of paroxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications. The Tendril MRI lead is a 7.9 French, transvenous, steroid eluting, bipolar, IS-1 compliant active fixation lead designed for permanent sensing and pacing in either the right atrium or the right ventricle, in combination with a compatible device. Active fixation leads such as the Tendril MRI lead may be indicated for patients where permanent fixation of passive fixation leads is suspected to be unstable. In atrial applications, the use of screw-in leads such as Tendril MRI lead may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage. The MRI Activator handheld device is used to evaluate the status of, and to enable and disable, the previously stored MRI settings. The activator is intended for use with St. Jude Medical MR Conditional pulse generators.
P160008	01/12/2017	PMAO - PMA Origi	HEARTSINE TECHNOLOGIES LLC'S SAMARITAN PUBLIC ACCESS AUTOMATED EXTERNAL DEFIBRILLATORS (SAM 350P, SAM 360P AND SAM 450P) AND ACCESSORIES	HEARTSINE TECHNOLOGIES LLC	Approval for the HeartSine samaritan® PAD 350P (SAM 350P), PAD 360P (SAM 360P), and PAD 450P (SAM 450P) public access automated external defibrillators and battery/electrode accessories. These AEDs are indicated for use on victims of cardiac arrest who are exhibiting the following signs: 1) Unconscious; 2) Not breathing; and 3) Without circulation (without a pulse) The devices are intended for use by personnel who have been trained in their operation. Users should have received training in basic life support/AED, advanced life support or a physician-authorized emergency medical response training program. The devices are indicated for use on patients greater than 8 years old or over 55 lbs. (25 kg) when used with the adult Pad-Pak (Pad-Pak-01 or Pad-Pak-07). They are indicated for use on children between 1 and 8 years of age or up to 55 lbs. (25 kg) when used with the Pediatric-Pak (Pad-Pak-02).
P160021	01/27/2017	PMAO - PMA Origi	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Approval for the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is indicated for the treatment of de novo or restenotic lesions found in iliac arteries with reference vessel diameters ranging from 5mm - 13mm and lesion lengths up to 110mm, including lesions at the aortic bifurcation.
P160031	01/10/2017	PMAO - PMA Origi	ASPIRE CRISTALLE DIGITAL BREAST TOMOSYNTHESIS OPTION	FUJIFILM MEDICAL SYSTEMS U.S.A., INC.	Approval for the Aspire Cristalle Digital Breast Tomosynthesis Option. The Fujifilm ASPIRE Cristalle with Digital Breast Tomosynthesis (DBT) Option acquires and generates FFDM and DBT images, and is intended for use in the screening and diagnosis of breast cancer. A screening examination may consist of sets of CC and MLO images acquired in: 1) the FFDM mode only, or 2) an FFDM image set and a DBT image set acquired in the ST (standard) mode. The FFDM image set and the DBT image set must be acquired with N-mode dose setting, and may be acquired in one compression (Tomo Set mode) or separate compressions (FFDM and DBT modes).

Total: 4

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P880086/S276	01/31/2017	R - Real-Time Proc	ASSURITY, ASSURITY+, ENDURITY, ACCENT FAMILY OF PACEMAKERS	ST. JUDE MEDICAL, INC.	Approval for software updates to the Merlin@home v8.2.2 to increase the cybersecurity of the system.
P900033/S058	01/26/2017	R - Real-Time Proc	INTEGRA OMNIGRAFT DERMAL REGENERATION MATRIX	INTEGRA LIFESCIENCES CORP.	Approval for a new device size (2.5cm x 2.5 cm) for both the meshed and non-meshed forms of Integra Omnigraft Dermal Regeneration Matrix.
P910023/S378	01/31/2017	R - Real-Time Proc	LWS, OSR	ST. JUDE MEDICAL	Approval for software updates to the Merlin@home v8.2.2 to increase the cybersecurity of the system.
P930014/S096	01/13/2017	R - Real-Time Proc	ACRYSOF IQ ASPHERIC IOL WITH THE ULTRASERT PRE-LOADED DELIVERY SYSTEM	ALCON RESEARCH, LTD.	Approval for modifying the physician directions for use to include instructions for removing the IOL from the injector.
P950022/S095	01/13/2017	Y - 135 Review Tra	DURATA AND OPTISURE LEADS	ST. JUDE MEDICAL, INC.	Approval for changes to the extraction test method for steroid eluting leads.
P960013/S085	01/13/2017	Y - 135 Review Tra	TENDRIL SDX, TENDRIL ST, TENDRIL STS AND OPTISENSE LEADS	PACESETTER, INC.	Approval for changes to the extraction test method for steroid eluting leads.
P960030/S047	01/13/2017	Y - 135 Review Tra	ISOFLEX OPTIM LEADS	PACESETTER, INC.	Approval for changes to the extraction test method for steroid eluting leads.
P980016/S606	01/06/2017	R - Real-Time Proc	EVERA MRI, S DR, S VR, XT DR, XTVR ICD'S; MAXIMO II ICD; PROTECTA VR, XT ICD"S; SECURA DR ICD'S; VIRTUOSE II DR/VR ICD; VISTA AF MRI VR ICD, VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for minor changes to the printed wiring board.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980023/S075	01/05/2017	N - Normal 180 Day	PLEXA S 60, PLEXA SD 60/16, PLEXA PROMRI S 65, PLEXA PROMRI S 75, PLEXA PROMRI SD 65/16, PLEXA PROMRI SD 65/18, PLEXA PROMRI SD 75/18, DH IS 1/DF4	BIOTRONIK, INC.	Approval for introduction of the Plexa ICD Led family, which is a modified version of the current legally marketed Protego ICD Lead family.
P990009/S045	01/04/2017	S - Special CBE	FLOSEAL MATRIX HEMOSTATIC SEALANT	BAXTER HEALTHCARE CORP.	Approval for modification to the Instructions for Use to add clarity that the removal of excess product is done to avoid excessive inflammatory reaction, adhesion and/or granuloma formation.
P990065/S010	01/18/2017	S - Special CBE	SIR-SPHERES MICROSPHERES	SIRTEX MEDICAL LIMITED	Approval for changes in device package insert with insertion of BSA model to replace the current empirical model for calculation of individual required activity dose, change of lung shunt fraction to total lung dose, less than 30 Gy to apply in the dose calculation, re-define the Radio-Embolization Induced Liver Disease (REILD) and addition of dose reduction guidance in REILD, addition of guidance of lobar therapy using BSA model, and deletion of empirical model and partition model for dose calculation.
P010012/S438	01/20/2017	O - Normal 180 Day	ACUITY¿ SPIRAL HEART FAILURE LEADS	BOSTON SCIENTIFIC CORP.	Approval to discontinue the post-approval study (PAS) protocol.
P010013/S067	01/10/2017	N - Normal 180 Day	NOVASURE IMPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM	HOLOGIC, INC.	Approval for design modifications to the NovaSure Disposable Device (Gen 4.1).
P010031/S567	01/06/2017	R - Real-Time Proc	AMPLIA MRI/MRI QUAD CRT-D'S; BRAVA CRT-D; COMPIA MRI/MRI QUAD CRT-D"S; CONCERTO II CRT-D; CONSULTA CRT-D; MAXIMO II CRT-D; PROCETA CRT-D; PROTECTA XT CRT-D; VIVA QUAD S /XT CRT-D; VIVA S/ XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for minor changes to the printed wiring board.
P010032/S124	01/09/2017	R - Real-Time Proc	PRODIGY LEADS AND EXTENSION INSERTION TOOL	ST. JUDE MEDICAL	Approval for expanding the compatibility of an optional accessory, the Lead and Extension Insertion Tool (Model 1803), for use with approved SJM Implantable Pulse Generators (IPGs) and compatible leads, extensions, and adapters.
P010059/S006	01/26/2017	O - Normal 180 Day	FORTIEYE CAPSULAR TENSION RINGS, TYPES 14, 14A AND 14C	MORCHER GMBH	Approval for new private labeling for an alternative distributor.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P020045/S078	01/17/2017	R - Real-Time Proc	FREEZOR CRYOABLATION SYSTEM	MEDTRONIC CRYOCATH LP	Approval for replacement of the operating system within the CryoConsole from Windows XP Embedded (WinXPE) to the Windows Embedded Standard 2009 (WES2009).
P030017/S266	01/25/2017	R - Real-Time Proc	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for updating the Clinician Programmer computer to the Microsoft Surface Pro 3 and updating the labeling for the associated software.
P030022/S042	01/12/2017	S - Special CBE	REFLECTION CERAMIC ACETABULAR SYSTEM	SMITH & NEPHEW, INC.	Approval for a change to the surgical technique labeling.
P030035/S151	01/31/2017	R - Real-Time Proc	ANTHEM, ALLURE/RF, ALLURE QUADRA/RF FAMILY OF CRT-PS	ST. JUDE MEDICAL, INC.	Approval for software updates to the Merlin@home v8.2.2 to increase the cybersecurity of the system.
P030054/S311	01/13/2017	Y - 135 Review Tra	QUICKFLEX U AND QUARTET LEADS	ST. JUDE MEDICAL	Approval for changes to the extraction test method for steroid eluting leads.
P030054/S316	01/31/2017	R - Real-Time Proc	PROMOTE/+/RF/Q, PROMOTE ACCEL, PROMOTE QUADRA, UNIFY,UNIFY ASSURA, UNIFY QUADRA	ST. JUDE MEDICAL	Approval for software updates to the Merlin@home v8.2.2 to increase the cybersecurity of the system.
P040012/S057	01/05/2017	O - Normal 180 Day	ACCULINK CAROTID STENT SYSTEM AND RX ACCULINK CAROTID STENT SYSTEM	ABBOTT VASCULAR	Approval for the addition of the CANOPY Post-Approval Study (PAS) results to the Instructions for Use (IFU).
P090018/S033	01/26/2017	R - Real-Time Proc	ESTEEM	ENVOY MEDICAL CORPORATIO N	Approval for changes to the header connector design of the Esteem Model 2001 Sound Processor and for manufacturing process improvements.
P100005/S007	01/11/2017	O - Normal 180 Day	M-VU ALGORITHM ENGINE	ICAD, INC.	Approval for a manufacturing site located at iCAD, Inc., 4 Townsend West, Suite 9, Nashua, New Hampshire.
P100010/S060	01/17/2017	R - Real-Time Proc	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Approval for replacement of the operating system within the CryoConsole from Windows XP Embedded (WinXPE) to the Windows Embedded Standard 2009 (WES2009).
P100021/S054	01/13/2017	Y - 135 Review Tra	ENDURANT,ENDURANT II AND ENDURANT II AOTYO-UNI-LIAC (AUI) STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Approval for implementation of use of disassembled finished devices in the quarterly dose audit process.
P110004/S016	01/31/2017	Y - 135 Review Tra	NIRXCELL COCR CORONARY STENT ON RX SYSTEM	MEDINOL LTD.	Approval to reduce the sampling frequency for routine product bioburden testing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110013/S077	01/13/2017	R - Real-Time Proc	RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for updates to the labeling to align with the current ACC/AHA guidelines on dual antiplatelet therapy.
P110015/S002	01/06/2017	Y - 135 Review Tra	13C-SPIRULINA GEBT/13C-SPIRULINA GASTRIC EMPTYING BREATH TEST (GEBT)	ADVANCED BREATH DIAGNOSTICS	Approval of the qualification of additional service providers and the addition of a new test specification for the lyophilized egg (excipient) used in the production of the drug component of the 13C-Spirulina Gastric Emptying Breath Test (GEBT).
P130015/S009	01/13/2017	O - Normal 180 Day	ELECSYS HBEAG AND PRECICONTROL HBEAG	ROCHE DIAGNOSTICS OPERATIONS INC	Approval for the change of proprietary names of Elecsys HBeAg Immunoassay and Elecsys PreciControl HBeAg to Elecsys HBeAg and PreciControl HBeAg.
P130020/S001	01/05/2017	N - Normal 180 Day	SENOCLAIRE	GE HEALTHCARE	Approval for GE SenoClaire Digital Breast Tomosynthesis system indicated for acquisition of multiple projection views to produce 3D digital mammography images suitable to be used in screening and diagnosis of breast cancer. A screening examination may consist of a 3D DBT image set consisting of a CC and MLO view, and a 2D synthesized image set consisting of a CC and MLO V-Preview images.
P130022/S009	01/12/2017	R - Real-Time Proc	SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for a design change for the Surpass Surgical Lead to remove the marker band and change the color of one lead leg.
P140002/S006	01/05/2017	Y - 135 Review Tra	MISAGO RX SELF-EXPANDING PERIPHERAL STENT	TERUMO MEDICAL CORPORATION	Approval for an additional supplier for silicone oil used to lubricate the stent release mechanism of the delivery catheter.
P140003/S013	01/31/2017	R - Real-Time Proc	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for an alternative Guidewire Repositioning Unit on Impella 2.5.
P140009/S020	01/09/2017	R - Real-Time Proc	INFINITY LEAD AND EXTENSION INSERTION TOOL	ST. JUDE MEDICAL NEUROMODULATION	Approval for expanding the compatibility of an optional accessory, the Lead and Extension Insertion Tool (Model 1803), for use with approved SJM Implantable Pulse Generators (IPGs) and compatible leads, extensions, and adapters.
P140020/S008	01/30/2017	N - Normal 180 Day	BRACANALYSIS CDX	MYRIAD GENETIC LABORATORIES	Approval for the inclusion of the BRACAnalysis CDx - DNA Quantification Technical Manual, the BRACAnalysis CDx - Sanger Technical Manual, and the BRACAnalysis CDX ¿ BART Technical Manual in place of several laboratory Standard Operating Procedures.
P150001/S003	01/06/2017	R - Real-Time Proc	MINIMED 630G PUMP	MEDTRONIC MINIMED	Approval for a design modification to the vibrator motor assembly in the MiniMed 630G Insulin Pump; a reduced sampling plan for acceptance testing by the vibrator motor assembly supplier; and for elimination of incoming acceptance testing of the vibrator motor assembly. The MiniMed 630G Insulin Pump is a component of the MiniMed 630G System with Smartguard.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150011/S006	01/10/2017	S - Special CBE	PERCEVAL HEART VALVE	LIVANOVA CANADA CORP.	Approval for labeling changes.
P150019/S024	01/25/2017	R - Real-Time Proc	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Approval for adding the requirement for a chemical exposure durability test to the pump product specifications and for a manufacturing process change of adding an annealing process during the assembly of the pump cases.

Total: 40

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N18033/S085	01/12/2017	X - 30-Day Notice	VISTAKON (ETAFILCON A) BRAND CONTACT LENSES	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Acceptance for a modification to the raw material testing for VISTAKON® (senofilcon A) and VISTAKON® (etafilcon A) Brand Contact Lenses.
N970003/S201	01/11/2017	X - 30-Day Notice	FROMIO, VITALIO, INGENIO, ADVANTIO, ALTRUA, ALTRUA 2, ACCOLADE, PROPONENT AND ESSENTIO	BOSTON SCIENTIFIC CORP.	Implementation of two new leak testers with updated software.
P840001/S349	01/26/2017	X - 30-Day Notice	SCS NEUROSTIMULATORS IMPLANTABLE ITREL FAMILY	MEDTRONIC NEUROMODULATION	Addition of a second supplier for the barbed fastener component.
P840001/S350	01/26/2017	X - 30-Day Notice	RESTORE, ITREL, AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	New electrical discharge machining (EDM) equipment used during the manufacturing process of subcomponents for Medtronic Neuromodulation leads and extensions.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840062/S059	01/19/2017	X - 30-Day Notice	COLLAPLUG®, ABSORBABLE COLLAGEN WOUND DRESSING FOR DENTAL SURGERY	COLLA-TEC, INC.	Clearance for the manufacturing process change for CollaPlug Absorbable Wound Dressings for Dental Surgery: elimination of the first percent solids test following dispersion preparation and reliance upon the second percent solids test, which occurs further down the process, after the centrifugation step and before the lyophilization step.
P850079/S071	01/17/2017	X - 30-Day Notice	HYDRASOFT CONTACT LENS	COOPERVISION, INC.	Acceptance of validation of dry molding line X to manufacture Frequency 55 Aspheric Z1 methafilcon A contact lenses.
P860004/S266	01/13/2017	X - 30-Day Notice	ASCENDA CATTHETER ORIENTATION	MEDTRONIC INC.	Reorient the spinal segment catheter and the spinal segment catheter revision kit within the Ascenda Catheter Assembly (Model 8780) and the Ascenda Catheter Revision Kit Assembly (Model 8782) sterile packages.
P860057/S157	01/19/2017	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT PERICARDIAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Add a bovine abattoir for tissue sourcing.
P900009/S041	01/12/2017	X - 30-Day Notice	EXOGEN ULTRASOUND BONE HEALING SYSTEM	BIOVENTUS LLC	Addition of a new rechargeable battery pack supplier for the EXOGEN Ultrasound Bone Healing System.
P900033/S059	01/17/2017	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE, INTEGRA MESHED DERMAL REGENERATION TEMPLATE, INTEGRA OMNIGRAFT DERMAL REGENERATION MATRIX	INTEGRA LIFESCIENCES CORP.	Modifications to the Water for Injection pretreatment, generation and distribution system.
P910001/S090	01/05/2017	X - 30-Day Notice	ELCA	SPECTRANETICS CORP.	Use of a replacement laser micrometer inspection tool.
P910073/S140	01/10/2017	X - 30-Day Notice	ENDOTAK RELIANCE SYSTEM	BOSTON SCIENTIFIC	Additional supplier of molded components.
P920015/S192	01/18/2017	X - 30-Day Notice	SPRINT QUATTRO LEAD MODELS 6935, 6944, 6947	MEDTRONIC INC.	New dry chamber time and temperature settings, a new go no go system for measurement, modified inspection methods and consolidated process operation descriptions.
P920015/S193	01/19/2017	X - 30-Day Notice	TUNNELING TOOL 6996T	MEDTRONIC INC.	Updates to the package tray manufacturing processes and the addition of a peel strength test.
P930016/S049	01/11/2017	X - 30-Day Notice	STAR EXCIMER LASER SYSTEM	AMO MANUFACTURING USA, LLC	Revision of the span and zero calibration procedure of the fluorine (F2) sensor of the STAR S4 IR Excimer Laser System according to the sensor¿s manufacturer specification.
P940015/S038	01/18/2017	X - 30-Day Notice	SYNVISC	GENZYME CORP.	Reduction in the testing intervals for routine marketed product surveillance stability studies for Synvisc and Synvisc-One.
P950022/S098	01/08/2017	X - 30-Day Notice	DURATA AND OPTISURE LEADS (HV ACTIVE AND PASSIVE)	ST. JUDE MEDICAL, INC.	Addition of an alternate vendor to supply Polyhexamethylene Oxide used in the manufacturing of Optim.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P950037/S172	01/31/2017	X - 30-Day Notice	PULSE GENERATOR, PERMANENT, IMPLANTABLE	BIOTRONIK, INC.	Use of supplemental sterilization equipment and a new sterilization process.
P960009/S268	01/26/2017	X - 30-Day Notice	DBS NEUROSTIMULATORS IMPLANTABLE ACTIVA FAMILY	MEDTRONIC INC.	Addition of a second supplier for the barbed fastener component.
P960009/S268	01/26/2017	X - 30-Day Notice	DBS NEUROSTIMULATORS IMPLANTABLE ACTIVA FAMILY	MEDTRONIC INC.	Addition of a second supplier for the barbed fastener component.
P960009/S269	01/26/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	New electrical discharge machining (EDM) equipment used during the manufacturing process of subcomponents for Medtronic Neuromodulation leads and extensions.
P960009/S269	01/26/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	New electrical discharge machining (EDM) equipment used during the manufacturing process of subcomponents for Medtronic Neuromodulation leads and extensions.
P960013/S087	01/08/2017	X - 30-Day Notice	TENDRIL SDX, TENDRIL ST, TENDRIL STS AND OPTISENSE LEADS (LV ACTIVE)	PACESETTER, INC.	Addition of an alternate vendor to supply Polyhexamethylene Oxide used in the manufacturing of Optim.
P960030/S049	01/08/2017	X - 30-Day Notice	ISOFLEX OPTIM LEADS (LV PASSIVE)	PACESETTER, INC.	Addition of an alternate vendor to supply Polyhexamethylene Oxide used in the manufacturing of Optim.
P960040/S387	01/11/2017	X - 30-Day Notice	INCEPTA, ENERGEN, PUNCTUA, AUTOGEN, DYNAGEN, INOGEN, ORIGEN, RESONATE, VIGILANT, MOMENTUM, AND PERCIVA ICDS	BOSTON SCIENTIFIC	Implementation of two new leak testers with updated software.
P960042/S055	01/05/2017	X - 30-Day Notice	SLS II/GLIDELIGHT CATHETERS	SPECTRANETICS CORP.	Use of a replacement laser micrometer inspection tool.
P970003/S208	01/18/2017	X - 30-Day Notice	VNS THERAPY SYSTEM	CYBERONICS, INC.	Update that is being made to the X-Ray inspection criteria for the presence of solders under the Application Specific Integrated Circuit (ASIC) of the Model 103/104 and Model 105/106 Generator Printed Circuit Board Assemblies (PCBA).
P970004/S234	01/18/2017	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY INCONTINENCE	MEDTRONIC NEUROMODULATION	Transfer of manufacturing sites of the lead/stylet assembly, wire coating equipment, and pin 209563002.
P970004/S235	01/26/2017	X - 30-Day Notice	SNS URINARY NEUROSTIMULATORS IMPLANTABLE INTERSTIM	MEDTRONIC NEUROMODULATION	Addition of a second supplier for the barbed fastener component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970004/S236	01/26/2017	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM (URINARY)	MEDTRONIC NEUROMODULATION	New electrical discharge machining (EDM) equipment used during the manufacturing process of subcomponents for Medtronic Neuromodulation leads and extensions.
P970051/S155	01/19/2017	X - 30-Day Notice	NUCLEUS COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Addition of an alternative PCB supplier for the CP900 Sound Processor. This update will add AT&S, an already approved Cochlear vendor, as an addition to the existing CP900 Sound Processor PCB supplier, GS Swiss
P970054/S012	01/19/2017	X - 30-Day Notice	PARVOVIRUS B19 IGG ENZYME IMMUNOASSAY (V5191GUS)	DIASORIN	Addition of new instrumentation for in-process QC and final kit release testing.
P970055/S014	01/19/2017	X - 30-Day Notice	PARVOVIRUS B19 IGM ENZYME IMMUNOASSAY (V619IMUS)	DIASORIN	Addition of new instrumentation for in-process QC and final kit release testing.
P980044/S036	01/19/2017	X - 30-Day Notice	SUPARTZ FX & VISCO-3	SEIKAGAKU CORP.	Relocate within the manufacturing site the production of a component used in the manufacture of SUPARTZ FX and VISCO-3.
P000029/S082	01/18/2017	X - 30-Day Notice	DEFLUX INJECTABLE GEL	VALEANT PHARMACEUTICALS NORTH AMERICA, LLC	Change of the internal standard used in the test method for detection of residual solvents.
P010012/S441	01/10/2017	X - 30-Day Notice	ACUITY X4 STRAIGHT/ SPIRAL S/SPIRAL L MODELS	BOSTON SCIENTIFIC CORP.	Additional supplier of molded components.
P010012/S442	01/11/2017	X - 30-Day Notice	INCEPTA, ENERGEN, PUNCTUA, AUTOGEN, DYNAGEN, INOGEN, ORIGEN, RESONATE, VIGILANT, AND MOMENTUM CRT-DS	BOSTON SCIENTIFIC CORP.	Implementation of two new leak testers with updated software.
P010030/S088	01/19/2017	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Implementation of a Battery Discharge System to prepare lithium-Ion battery pack for international shipment by air
P010030/S089	01/26/2017	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Addition of an alternate supplier (Walco Corporation; Glenshaw, PA) to provide the pre-cut Urethane Foam (.500 x .219) used to cushion the SD card in the LifeVest units.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030004/S012	01/25/2017	X - 30-Day Notice	ONYX LIQUID EMBOLIC SYSTEM	EV3 NEUROVASCULAR	Acceptance for manufacturing equipment/process changes related to the production of the Onyx Liquid Embolic System (LES), which include addition of an alternative cleaning and de-pyrogenation method for the Onyx LES, addition of an alternative dry heat sterilization oven for the Onyx LES, and change of bioburden testing lab for the Onyx vial subassembly.
P030005/S149	01/11/2017	X - 30-Day Notice	INTUA, INVIVE, VALITUDE, AND VISIONIST CRT-PS	GUIDANT CORP.	Implementation of two new leak testers with updated software.
P030016/S030	01/25/2017	X - 30-Day Notice	VISIAN ICL (IMPLANTABLE COLLAMER LENS) FOR MYOPIA	STAAR SURGICAL CO.	Manufacture of an in-process aid at the STAAR Monrovia, CA manufacturing site as an alternative to the current supplier.
P030017/S272	01/17/2017	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Adding an alternate qualified supplier for the monofilament used in the Infinion 16 and Infinion CX Leads.
P030054/S315	01/08/2017	X - 30-Day Notice	QUICKFLEX U AND QUARTET LEADS (CRT)	ST. JUDE MEDICAL	Addition of an alternate vendor to supply Polyhexamethylene Oxide used in the manufacturing of Optim.
P040027/S053	01/09/2017	X - 30-Day Notice	GORE VIATORR TIPS ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implementation of an alternate laser equipment during manufacturing of the VIATORR TIPS Endoprosthesis and the VIATORR TIPS Endoprosthesis with Controlled Expansion.
P040045/S063	01/10/2017	X - 30-Day Notice	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Change the minimum hydration residence time.
P040045/S064	01/12/2017	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRANDED CONTACT LENSES.	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Acceptance for a modification to the raw material testing for VISTAKON® (senofilcon A) and VISTAKON® (etafilcon A) Brand Contact Lenses.
P050006/S056	01/11/2017	X - 30-Day Notice	GORE CARDIOFORM SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Modify the test sample preparation process for cytotoxicity testing.
P050023/S106	01/31/2017	X - 30-Day Notice	DEFIBRILLATOR, IMPLANTABLE, DUAL CHAMBER, AUTOMATIC IMPLANTABLE CARDIOVERTER, WITH CARDIAC RESYNCHRONIZATION	BIOTRONIK, INC.	Use of supplemental sterilization equipment and a new sterilization process.
P050037/S077	01/17/2017	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Modification of the particle manufacturing process steps to change the minimum number of required pH reduction steps.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P050047/S055	01/17/2017	X - 30-Day Notice	JUVEDERM 24HV, JUVEDERM 30 AND JUVEDERM 30HV GEL IMPLANTS	ALLERGAN	Change to the cleaning procedure of mixing and transfer vessels used during the manufacturing of Juvederm injectable gel products.
P050052/S089	01/17/2017	X - 30-Day Notice	RADIESSE (+) LIDOCAINE DERMAL FILLER	MERZ NORTH AMERICA, INC	Modification of the particle manufacturing process steps to change the minimum number of required pH reduction steps.
P060037/S048	01/12/2017	X - 30-Day Notice	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Introduce an alternative manufacturing material (i.e., liquid penetrant) that is used during the Liquid Penetrant Inspection process of the NexGen Complete Knee Solution, Legacy Knee ¿ Posterior Stabilized (LPS), LPS-Flex Mobile Bearing Knee metal femoral components at the Shannon Ireland facility.
P070008/S080	01/31/2017	X - 30-Day Notice	PULSE GENERATOR, PACEMAKER, IMPLANTABLE WITH CARDIAC RESYNCHRONIZATION (CRT-P)	BIOTRONIK, INC.	Use of supplemental sterilization equipment and a new sterilization process.
P070026/S044	01/03/2017	X - 30-Day Notice	CERAMAX CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Removal of an in-process step in the manufacturing process of components in the CERAMAX® Ceramic Total Hip System.
P080020/S024	01/19/2017	X - 30-Day Notice	GEL-ONE	SEIKAGAKU CORP.	Relocate on-site the production of a component used in the manufacture of Gel-One.
P080025/S129	01/18/2017	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR BOWEL	MEDTRONIC NEUROMODULATION	Transfer of manufacturing sites of the lead/stylet assembly, wire coating equipment, and pin 209563002.
P080025/S130	01/26/2017	X - 30-Day Notice	SNS BOWEL NEUROSTIMULATORS IMPLANTABLE INTERSTIM	MEDTRONIC NEUROMODULATION	Addition of a second supplier for the barbed fastener component.
P080025/S131	01/26/2017	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM (BOWEL)	MEDTRONIC NEUROMODULATION	New electrical discharge machining (EDM) equipment used during the manufacturing process of subcomponents for Medtronic Neuromodulation leads and extensions.
P090016/S022	01/04/2017	X - 30-Day Notice	BELOTERO BALANCE DERMAL FILLER	MERZ NORTH AMERICA, INC	Refurbishment and requalification of the cleanroom facilities.
P090022/S030	01/11/2017	X - 30-Day Notice	LENSTEC SOFTEC HD POSTERIOR CHAMBER INTRAOCULAR LENS	LENSTEC, INC.	Addition of another lens analyzer unit for assessing lens power and quality.
P100010/S061	01/06/2017	X - 30-Day Notice	ARCTIC FRONT & ARCTIC ADVANCED CARDIAC CRYOABLATIN CATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Automatization of manufacturing processes (heat setting, bonding, flushing and stretching) for the Artic Front and Artic Front Advance Cardiac CryoAblation Catheters.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100014/S019	01/18/2017	X - 30-Day Notice	SOLESTA INJECTABLE GEL	VALEANT PHARMACEUTICALS NORTH AMERICA, LLC	Change of the internal standard used in the test method for detection of residual solvents.
P100021/S059	01/17/2017	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Implementation of a change in laser equipment at Medtronic's approved supplier for the suprarenal stents on the Endurant Stent Graft System, Endurant II Stent Graft System, Endurant II Aorto-Uni-Iliac Stent Graft System and Endurant IIs Stent Graft System.
P100025/S011	01/04/2017	X - 30-Day Notice	BREATHTEK UBT FOR H. PYLORI KIT AND PEDIATRIC UREA HYDROLYSIS RATE CALCULATION APPLICATION (PUHR-CA), VERSION 1.0	OTSUKA AMERICA PHARMACEUTICAL, INC.	Change to the DMF for a raw material used to produce the finished drug component of the device.
P100044/S026	01/27/2017	X - 30-Day Notice	PROPEL SINUS IMPLANT & PROPEL MINI SINUS IMPLANT	INTERSECT ENT	Addition of a new semi-automated heating/cooling system and implementation of new curing temperatures and times used to form the applicators of the implant delivery systems.
P100049/S019	01/12/2017	X - 30-Day Notice	LINX REFLUX MANAGEMENT SYSTEM	TORAX MEDICAL	Utilization of an additional, higher capacity laser welding system and to maintain 100% individual link length inspection conducted at final device inspection, but remove all in-process assembly weld link length inspections and the overall device length final inspection.
P110033/S025	01/17/2017	X - 30-Day Notice	JUVEDERM VOLUMA XC AND JUVEDERM VOLBELLA XC	ALLERGAN	Change to the cleaning procedure of mixing and transfer vessels used during the manufacturing of Juvederm injectable gel products.
P110042/S072	01/06/2017	X - 30-Day Notice	BUZZER COMPONENT	BOSTON SCIENTIFIC CORPORATION	Additional supplier for the buzzer component.
P110042/S073	01/11/2017	X - 30-Day Notice	EMBLEM AND EMBLEM MRI S-ICDS	BOSTON SCIENTIFIC CORPORATION	Implementation of two new leak testers with updated software.
P110042/S074	01/19/2017	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Perform the manufacturing electrical screening process for the flash memory in house.
P120005/S058	01/19/2017	X - 30-Day Notice	DEXCOM G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Qualification of additional manufacturing space for the manufacture of the G5 Mobile Receiver. The G5 Mobile Receiver is a component of the G5 Mobile Continuous Glucose Monitoring System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130008/S019	01/06/2017	X - 30-Day Notice	MODEL 4323 PRESSURE SENSING LEAD ADAPTER COMPONENT	INSPIRE MEDICAL SYSTEMS	Supplier change for the lead adapter component used in the Model 4323 Pressure Sensing Lead.
P130009/S069	01/19/2017	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Add a bovine abattoir for tissue sourcing.
P130022/S011	01/17/2017	X - 30-Day Notice	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Packaging configuration change (i.e., pre-loaded percutaneous lead with the 0.014¿ curved stylet) to the Senza SCS System.
P140003/S015	01/25/2017	X - 30-Day Notice	IMPELLA	ABIOMED, INC.	Modification to the configuration of the Impella CP packaging tray insert.
P140010/S028	01/26/2017	X - 30-Day Notice	IN PACT ADMIRAL PACLITAXEL BALLOON CATHETER	MEDTRONIC INC.	Minor modifications to the incoming inspection of the active pharmaceutical ingredient to include expiry dates of the solutions.
P140010/S028	01/26/2017	X - 30-Day Notice	IN PACT ADMIRAL PACLITAXEL BALLOON CATHETER	MEDTRONIC INC.	Minor modifications to the incoming inspection of the active pharmaceutical ingredient to include expiry dates of the solutions.
P140012/S006	01/06/2017	X - 30-Day Notice	RESHAPE INTEGRATED DUAL BALLOON SYSTEM	RESHAPE MEDICAL, INC.	Change Receipt inspection of packaging materials, reseal Valve Sealant packaging after inspection, and increase HEPA filtration and particulate alert and action levels.
P140012/S007	01/06/2017	X - 30-Day Notice	RESHAPE INTEGRATED DUAL BALLOON SYSTEM	RESHAPE MEDICAL, INC.	Addition of a 100% visual inspection step of the flapper valve.
P140015/S018	01/18/2017	X - 30-Day Notice	T:SLIM G4 INSULIN PUMP WITH DEXCOM G4 PLATINUM CGM	TANDEM DIABETES CARE, INC.	Expand the epoxy curing temperature range used in insulin pump device subassemblies for the t:slim G4 Insulin Pump with Dexcom G4 Platinum CGM System.
P140026/S004	01/26/2017	X - 30-Day Notice	ENROUTE TRANSCAROTID STENT SYSTEM	SILK ROAD MEDICAL, INC	Introduction of new stent laser cutting equipment.
P140031/S029	01/19/2017	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Add a bovine abattoir for tissue sourcing.
P150001/S007	01/11/2017	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED	Adding a Cell Operating System (COS) for partial manual assembly of Enlite Sensors at Medtronic Puerto Rico Operations Company (MPROC) facility. The implementation of a COS includes adding new equipment and relocating existing equipment within the existing Enlite sensor manual assembly line. The Enlite sensor is a component of the MiniMed 630G System and the iPro2 CGM System with Enlite Sensor.
P150012/S022	01/08/2017	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Changes to an acceptance limit and sampling rate during battery testing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150012/S023	01/10/2017	X - 30-Day Notice	INGEVITY NON-MRI LEAD & INGEVITY MRI LEAD	BOSTONSCIENTIFIC	Additional supplier of molded components.
P150012/S024	01/11/2017	X - 30-Day Notice	ACCOLADE MRI, PROPONENT MRI, AND ESSENTIO MRI	BOSTONSCIENTIFIC	Implementation of two new leak testers with updated software.
P150012/S025	01/18/2017	X - 30-Day Notice	INGEVITY LEADS	BOSTONSCIENTIFIC	Updates to the software, equipment, and process steps for bond sealing.
P150017/S004	01/06/2017	X - 30-Day Notice	CARTIVA SYNTHETIC CARTILAGE IMPLANT	CARTIVA, INC	Change in supplier of a component used in the manufacture of the Cartiva SCI device.
P150021/S003	01/12/2017	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Using an alternative surfactant in the incoming material enzyme activity assay performed during the manufacture of the glucose sensors. The glucose sensor is a component of the FREESTYLE LIBRE PRO Flash Glucose Monitoring System.
P150029/S005	01/11/2017	X - 30-Day Notice	IPRO2 CGM SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Adding a Cell Operating System (COS) for partial manual assembly of Enlite Sensors at Medtronic Puerto Rico Operations Company (MPROC) facility. The implementation of a COS includes adding new equipment and relocating existing equipment within the existing Enlite sensor manual assembly line. The Enlite sensor is a component of the MiniMed 630G System and the iPro2 CGM System with Enlite Sensor.
P150036/S003	01/19/2017	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Add a bovine abattoir for tissue sourcing.

Total: 89