PMA Monthly approvals from 3/1/2017 to 3/31/2017

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160009	03/24/2017	PMAO - PMA Origi	POWERLOOK® TOMO DETECTION SOFTWARE	ICAD INC	Approval for the iCAD PowerLook® Tomo Detection Software is a computer-assisted detection (CAD) software device intended to be used concurrently by radiologists while reading GE Senoclaire breast tomosynthesis exams. The system detects up to five soft tissue densities (masses, architectural distortions and asymmetries) in the 3D tomosynthesis images. The detections are blended with the standard 2D synthetic image and the CAD-enhanced 2D synthetic image is viewed on a mammography review workstation. The CAD-enhanced 2D synthetic image assists radiologists in identifying densities (masses, architectural distortions and asymmetries) that may be confirmed or dismissed by the radiologist in the digital breast tomosynthesis (DBT) images.
P160016	03/14/2017	PMAO - PMA Origi	VERSANT HCV GENOTYPE 2.0 ASSAY (LIPA)	SIEMENS HEALTHCARE DIAGNOSTICS , INC.	Approval for the VERSANT HCV Genotype 2.0 Assay (LiPA) is a line probe assay, which identifies Hepatitis C virus (HCV) genotypes 1 to 6 and subtypes 1a and 1b in human serum or plasma (K2EDTA, ACD-A CPD, and CPDA) samples. The VERSANT HCV Genotype 2.0 Assay (LiPA) is intended to be used as an aid in the management of patients with chronic HCV infection to guide the selection of antiviral treatment.
P160025	03/23/2017	PMAO - PMA Origi	ASTRON PULSAR STENT SYSTEM, PULSAR-18 STENT SYSTEM	BIOTRONIK, INC.	Approval for the Astron Pulsar Stent System and Pulsar-18 Stent System. These devices are indicated for use to improve luminal diameter in patients with symptomatic de novo, restenotic or occlusive lesions located in the superficial femoral or proximal popliteal arteries, with reference vessel diameters from 3.0 to 6.0mm and total lesion lengths up to 190mm.

Total: 3

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

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P810032/S065	03/03/2017	Y - 135 Review Tra	MULTI-PIECE POSTERIOR CHAMBER IOL	ALCON LABORATORIES	Approval to move the testing for bacterial endotoxins and microvacuoles from post-sterilization to pre-sterilization after device packaging.
P840060/S042	03/03/2017	Y - 135 Review Tra	SINGLE-PIECE POSTERIOR CHAMBER IOL	ALCON LABORATORIES	Approval to move the testing for bacterial endotoxins and microvacuoles from post-sterilization to pre-sterilization after device packaging.
P880087/S024	03/03/2017	Y - 135 Review Tra	SINGLE-PIECE ANTERIOR CHAMBER IOL	ALCON LABORATORIES	Approval to move the testing for bacterial endotoxins and microvacuoles from post-sterilization to pre-sterilization after device packaging.
P930014/S094	03/03/2017	Y - 135 Review Tra	ACRYSOF POSTERIOR CHAMBER INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Approval to move the testing for bacterial endotoxins and microvacuoles from post-sterilization to pre-sterilization after device packaging.
P930014/S099	03/02/2017	R - Real-Time Proc	ACRYSOF ASPHERIC UV ABSORBING TORIC INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Approval for Clear Toric and ReSTOR IOLS to be manufactured with the Clear AcrySof material.
P930021/S016	03/28/2017	N - Normal 180 Day	STRAUMANN EMDOGAIN (R)	THE STRAUMANN COMPANY	Approval for 1) adding an alternate glass syringe supplier (Design Change); 2) adding an alternate tamper- evident luer cap design (Design Change); 3) adding an alternate cavity design of the thermoformed tray; part of the secondary sterile barrier packaging (Design Change); 4) adding an alternate supplier of the Tyvek 1073B lid stock which includes a change in adhesive coating; part of the secondary sterile barrier packaging (Design Change); in addition, addressing the change to Transition Tyvek with this supplement; and 4) changing the configuration, artwork and labeling of the tertiary shelf packaging (Design Change).
P930027/S017	03/21/2017	Y - 135 Review Tra	IMMULITE/IMMULITE 1000 PSA, IMMULITE 2000 PSA	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Approval for a change to quality control testing procedure to reduce the number of dilution levels of WHO 96/670 used in the value assignment of the PSA Release panel and remove requirement to value assign the Male normal panel against WHO 96/670.
P930038/S084	03/29/2017	S - Special CBE	ANGIO SEAL VASCULAR CLOSURE DEVICE	TERUMO MEDICAL CORPORATION	Approval for the addition of one specification and three in-process inspections related to the device coating.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P950037/S167	03/24/2017	N - Normal 180 Day	EDORA 8 DR & DR-T, EVITY 8 DR-T,ENITRA 8 DR-T, ENTICOS 8 DR-T, EDORA 8 SR-T AND SR, EVITY 8 SR-T, ENITRA 8 SR-T,ENTICOS SR-T, EVITY 6 DR-T, ENITRA 6 DR-T, ENITRA 6 DR, EVITY 6 SR-T, ENITRA 6 SR-T, ENITRA 6 SR, ENTICOS 4 DR, ENTICOS 4 D, ENTICOS 4 SR, ENTICOS 4 S PSW 1601.U	BIOTRONIK, INC.	Approval for the Edora IPG/CRT-P family of pulse generators and programmer software PSW 1701.U.
P960009/S273	03/31/2017	S - Special CBE	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Approval for the addition of the DBS Lead Holder gap inspection.
P970020/S082	03/21/2017	N - Normal 180 Day	MULTI-LINK RX ULTRA CORONARY STENT SYSTEMS	ABBOTT VASCULAR INC.	Approval for update to device labeling.
P980018/S023	03/24/2017	R - Real-Time Proc	DAKO HERCEPTEST	DAKO A/S	Approval for an update to DakoLink software version 4.2.
P980035/S475	03/24/2017	N - Normal 180 Day	ADAPTA, VERSA, SENSIA IPD; RELIA IPG.	MEDTRONIC INC.	Approval for hardware, firmware, labeling, and manufacturing changes to the Adapta, Versa, Sensia, and Relia Implantable Pulse Generator families.
P980040/S077	03/03/2017	O - Normal 180 Day	TECNIS TORIC 1-PIECE INTRAOCULAR LENSES (IOLS) EXTENDED CYLINDER RANGE (ECR), MODELS ZCT450, ZCT525 AND ZCT600	ABBOTT MEDICAL OPTICS INC	Approval for changes to the protocol for the post-approval study (PAS) protocol.
P990056/S024	03/02/2017	O - Normal 180 Day	ELECSYS TOTAL PSA, TOTAL PSA CALSET II	ROCHE DIAGNOSTICS CORP.	Approval for a modification to the proprietary device names.
P990065/S009	03/24/2017	O - Normal 180 Day	SIR-SPHERES MICROSPHERES	SIRTEX MEDICAL LIMITED	Approval for a manufacturing site located at Sirtex Germany Manufacturing GMBH, Industriepark Hoechst, Building G808 65926 Frankfurt am Main Germany.
P990081/S035	03/13/2017	N - Normal 180 Day	PATHWAY ANTI-HER-2/NEU (4B5) RABBIT MONOCLONAL PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Approval for software modification in the BenchMark XT from NexES to VSS 12.5 and associated hardware changes.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000009/S069	03/24/2017	N - Normal 180 Day	PSW 1601.U PACEMAKER/ ICD/CRT NON IMPLANTED COMPONENTS	BIOTRONIK, INC.	Approval for the Edora IPG/CRT-P family of pulse generators and programming software PSW 1701.U.
P000027/S023	03/02/2017	O - Normal 180 Day	ELECSYS FREE PSA, FREE PSA CALSET, FREE PSA CALCHECK	ROCHE DIAGNOSTICS CORP.	Approval for a modification to the proprietary device names.
P000046/S026	03/31/2017	O - Normal 180 Day	OPHTHAALMIC VISCOELASTIC	ANIKA THERAPEUTICS, INC.	Approval for the addition of a new trade name, Ophthalmic Viscoelastic.
P010030/S087	03/10/2017	R - Real-Time Proc	LIFE VEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Approval for the addition of three new packaging configurations for the LifeVest 4000.
P010031/S563	03/24/2017	N - Normal 180 Day	CLARIA MRI QUAD CRT-D SURESCAN, AMPLIA MRI QUAD CRT-D, IMPLANTABLE CARDIOVERTER DEFIBRILLATORS WITH CARDIAC RESYNCHRONIZATION.	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the dual cathode left ventricular (LV) pacing feature for the Claria MRI Quad CRT-D SureScan and the Amplia MRI Quad CRT-D SureScan devices.
P020004/S137	03/06/2017	O - Normal 180 Day	GORE EXCLUDER AAA ENDOPROSTHESIS, GORE EXCLUDER ILIAC BRANCH ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Approval for a manufacturing site located at W. J. Gore & Associates, Inc., 2890 De La Cruz, Santa Clara, California.
P020047/S064	03/21/2017	N - Normal 180 Day	MULTI-LINK VISION/MULTI-LINK 8 LL/SV CORONARY STENT SYSTEMS	ABBOTT VASCULAR	Approval for update to device labeling.
P020055/S019	03/13/2017	N - Normal 180 Day	PATHWAY ANTI-C-KIT	VENTANA MEDICAL SYSTEMS, INC.	Approval for software modification in the BenchMark XT from NexES to VSS 12.5 and associated hardware changes.
P030011/S049	03/31/2017	S - Special CBE	SYNCARDIA TEMPORARY CARDIO WEST TOTAL ARTIFICIAL HEART (TAH-T)	SYNCARDIA SYSTEMS, LLC	Approval for labeling changes to the Freedom Driver System.
P030016/S022	03/08/2017	O - Normal 180 Day	STAAR SURGICAL IMPLANTABLE COLLAMER LENS (VISION ICL)	STAAR SURGICAL CO.	Approval for modification of the labeling to reflect the findings of the Follow-up Continuation Post-Approval Study.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030017/S271	03/13/2017	R - Real-Time Proc	SPECTRA WAVEWRITER SPINAL CORD STIMULATOR SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for firmware/software updates to their Precision Spectra System Implantable Pulse Generator (IPG)/External Trial Stimulator (ETS), Freelink Remote Control (RC) and the Bionic Navigator (BN) Software. The Precision Spectra System will be rebranded under the name Spectra WaveWriter SCS System. The firmware/software has been updated to support new features. No changes were made to the hardware or material of any components in the existing system.
P030017/S274	03/23/2017	R - Real-Time Proc	PRECISION, PRECISION SPECTRA, PRECISION NOVI, PRECISION MONTAGE, AND PRECISION MONTAGE MRI SCS SYSTEMS	BOSTON SCIENTIFIC CORP.	Approval for modifications to the design and materials of the Entrada Needle Insertion Tool including additional length configurations, plastic needle hubs, a custom sheath, and improved loss of resistance performance.
P030054/S314	03/15/2017	N - Normal 180 Day	QUARTET 1457Q LV LEAD	ST. JUDE MEDICAL	Approval for Quartet 1457Q left ventricular lead model.
P040020/S064	03/03/2017	Y - 135 Review Tra	ACRYSOF RESTOR POSTERIOR CHAMBER IOL	ALCON RESEARCH, LTD.	Approval to move bacterial endotoxin and microvacuole testing from post-sterilization to pre-sterilization, after device packaging.
P040020/S066	03/02/2017	R - Real-Time Proc	ACRYSOF ASPHERIC UV-ABSORBING RESTOR +2.5 INRAOCULAR LENS & ACRTSOF ASPHERIC UV-ABSORBING RESTOR +3.0 INTRAOCULAR LENS	ALCON RESEARCH, LTD.	Approval for Clear Toric and ReSTOR IOLS to be manufactured with the Clear AcrySof material.
P040020/S067	03/21/2017	R - Real-Time Proc	ACRYSOF RESTOR +2.5 D MULTIFOCAL INTRAOCULAR LENS	ALCON RESEARCH, LTD.	Approval for the AcrySof® IQ ReSTOR® +2.5 D Multifocal Toric IOLs, Models SV25T3 to SV25T6.
P040027/S054	03/22/2017	R - Real-Time Proc	GORE VIATORR TIPS ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Approval for the following modifications to the Instructions for Use (IFU): 1) to include the GORE® TIPS Sheath as an additional recommended accessory; and 2) to revise the post-placement management instructions.
P040029/S004	03/27/2017	N - Normal 180 Day	EUCLID SYSTEMS ORTHOKERATOLOGY CONTACT LENSES FOR OVERNIGHT WEAR	EUCLID SYSTEMS CORPORATIO N	Approval to manufacture, market and distribute the Euclid Systems Orthokeratology (tisilfocon A) Contact Lenses for Overnight Wear.
P050023/S104	03/24/2017	N - Normal 180 Day	PSW 1601.U PACEMAKER/ ICD/CRT NON IMPLANTED COMPONENTS	BIOTRONIK, INC.	Approval for the Edora IPG/CRT-P family of pulse generators and programming software PSW 1701.U.
P060040/S064	03/02/2017	R - Real-Time Proc	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORP.	Approval for a change to the HeartMate II Mobile Power Unit (MPU) Power Cord.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P070008/S076	03/24/2017	N - Normal 180 Day	EDORA 8, EVITY 8, ENITRA 8, ENTICOS 8 HF-T QPS,EDORA 8, EVITY 8, ENITRA 8, ENTICOS 8 HF-TS AND PSW 1601.U PACEMAKER/ICD/CRT NON IMPLANTED COMPONENTS	BIOTRONIK, INC.	Approval for the Edora IPG/CRT-P family of pulse generators and programming software PSW 1701.U.
P070015/S133	03/03/2017	O - Normal 180 Day	XIENCE V NANO, XIENCE PRIME XIENCE XPEDITION EVEROLIMUS ELUTING CORONARY STENT SYSTEM; HI-TORQUE PROGRESS, PILOT GUIDE WIRE; MINI-TREK CORONARY DILATATION CATHETER.	ABBOTT VASCULAR INC.	Approval for changes to the protocol for the post-approval study (PAS) protocol.
P080004/S016	03/31/2017	R - Real-Time Proc	CLARISERT PRELOADED IOL SYSTEM	HOYA SURGICAL OPTICS, INC.	Approval for changes in the spherical aberration and thickness of the optic lens for your iSert® IOLs. You also requested approval for this lens to be distributed under a new private label under Bausch + Lomb Inc. as the ClarisertTM Preloaded IOL System (Model CLSRT).
P080011/S049	03/10/2017	O - Normal 180 Day	PEARL VISION MONTHLY (CONFILCON A) SOFT (HYDRIOHILIC) CONTACT LENSES , PEARLE VISION MONTHLY FOR ASTIGMATISM (COMFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES	COOPERVISION MANUFACTURING, LTD.	Approved for Cooper Vision comfilcon A soft extended wear contact lenses to add a new private label name Pearl Vision Monthly and Pearl Vision Monthly for Astigatism.
P080012/S036	03/31/2017	Y - 135 Review Tra	PROMETRA PATIENT THERAPY CONTROLLER	FLOWONIX MEDICAL, INC.	Approval for a hardware change to the Patient Therapy Controller (Catalog No. 12860) that includes an updated Bluetooth Chip and removal of redundant circuitry in the battery protection circuit. This submission also requests an update to the device software (Version 1.02) to accommodate the change in hardware.
P080012/S039	03/30/2017	S - Special CBE	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Approval for MRI Conditional Labeling changes within the Instructions for Use, Patients Guide, Patient ID Cards which are associated with the Prometra Programmable Pump, Prometra II Programmable Pump, Intrathecal Catheter, and Catheter Revision Kit.
P090016/S019	03/29/2017	Y - 135 Review Tra	BELOTERO BALANCE	MERZ NORTH AMERICA, INC	Approval of the addition of temperature monitoring devices to trans-Atlantic shipments and changes to the incoming inspection procedure.
P100024/S011	03/24/2017	R - Real-Time Proc	HER2 CISH PHARMDX KIT	DAKO DENMARK A/S	Approval for an update to DakoLink software version 4.2.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100025/S012	03/30/2017	R - Real-Time Proc	BREATHTEK UBT FOR H. PYLORI KIT AND PEDIATRIC UREA HYDROLYSIS RATE CALCULATION APPLICATION (PUHR-CA), VERSION 1.0	OTSUKA AMERICA PHARMACEUTICAL, INC.	Approval for software upgrade from Version 1.1 to Version 2.0
P100027/S026	03/13/2017	N - Normal 180 Day	INFORM HER2 DUAL ISH DNA PROBE COCKTAIL	VENTANA MEDICAL SYSTEMS, INC.	Approval for software modification in the BenchMark XT from NexES to VSS 12.5 and associated hardware changes.
P110002/S016	03/03/2017	O - Normal 180 Day	MOBI-C CERVICAL DISC PROSTHESIS.	LDR SPINE USA	Approval for a manufacturing site located at Millstone Medical Outsourcing, 8836 Polk Lane, Suite 100, Olive Branch Mississippi for kitting and shipping of new components as well as reconditioning and servicing of used instruments from the field for reuse.
P110005/S002	03/10/2017	N - Normal 180 Day	GELSYN-3	IBSA INSTITUT BIOCHIMIQUE SA	Approval for revisions to the labeling of GELSYN-3 as follows: 1) Deletion of the statement, The safety and effectiveness of repeat treatment cycles of Gel-Syn have not been established from the Patient Information leaflet and addition of the statement, The effectiveness of repeat treatment cycles of GELSYN-3 has not been established. to the Product Information and Patient Information leaflets; and 2) Addition of the statements, Adverse experience data from clinical use does not show an increased safety risk from retreatment with GELSYN-3. The frequency and severity of adverse events occurring during repeat treatment cycles did not increase over that reported for a single treatment cycle to the Product Information and Patient Information leaflets.
P110008/S007	03/10/2017	O - Normal 180 Day	COFLEX INTERLAMINAR TECHNOLOGY	PARADIGM SPINE, LLC	Approval of changes to the protocol for the post-approval study (PAS) protocol.
P110009/S016	03/03/2017	O - Normal 180 Day	MOBI-C CERVICAL DISC PROSTHESIS	LDR SPINE USA INC.	Approval for a manufacturing site located at Millstone Medical Outsourcing, 8836 Polk Lane, Suite 100, Olive Branch Mississippi for kitting and shipping of new components as well as reconditioning and servicing of used instruments from the field for reuse.
P110010/S137	03/23/2017	O - Normal 180 Day	PROMUS PREMIER EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Boston Scientific Maple Grove, Two Scimed Place, Maple Grove, Minnesota for the Poly n-Butyl Methacrylate (PBMA) purification of the Promus PREMIER Stent system

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110019/S085	03/03/2017	O - Normal 180 Day	XIENCE V NANO, XIENCE PRIME XIENCE XPEDITION EVEROLIMUS ELUTING CORONARY STENT SYSTEM; HI-TORQUE PROGRESS, PILOT GUIDE WIRE; MINI-TREK CORONARY DILATATION CATHETER.	ABBOTT VASCULAR	Approval for changes to the protocol for the post-approval study (PAS) protocol.
P110019/S089	03/21/2017	N - Normal 180 Day	XIENCE XPEDITION & ALPINE EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Approval for update to device labeling.
P110022/S019	03/03/2017	O - Normal 180 Day	ELECSYS ANTI-HBC IGM, PRECICONTROL ANTI-HBC IGM	ROCHE DIAGNOSTICS CORP.	Approval for a modification to the proprietary device names.
P110025/S017	03/03/2017	O - Normal 180 Day	ELECSYS ANTI-HBC IGM, PRECICONTROL ANTI-HBC IGM	ROCHE DIAGNOSTICS CORP.	Approval for a modification to the proprietary device names.
P110031/S016	03/03/2017	O - Normal 180 Day	ELECSYS ANTI-HBC IGM, PRECICONTROL ANTI-HBC IGM	ROCHE DIAGNOSTICS CORP.	Approval for a modification to the proprietary device names.
P110033/S020	03/17/2017	P - Panel Track	JUVEDERM VOLLURE XC	ALLERGAN	Approval for injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds) in adults over the age of 21.
P110038/S013	03/23/2017	Y - 135 Review Tra	RELAY THORACIC STENT-GRAFT WITH PLUS DELIVERY SYSTEM	BOLTON MEDICAL, INC.	Approval for the ability to remove the Relay Thoracic Stent Graft from a non-conforming device and load the implant into a new delivery system.
P120005/S050	03/08/2017	N - Normal 180 Day	DEXCOM G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Approval for a new touchscreen receiver component for the G5 Mobile Continuous Glucose Monitoring (CGM) System
P120010/S100	03/27/2017	R - Real-Time Proc	MINIMED 530G SYSTEM	MEDTRONIC INC.	Approval for revisions to patient labeling to include instructions for how users should apply a second Enlite Overtape over the Enlite Sensor.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130005/S014	03/19/2017	N - Normal 180 Day	DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY DEVICE (OAD), ORBITAL ATHERECTOMY SYSTEM PUMP (OAS PUMP), VIPERWIRE ADVANCE CORONARY GUIDE WIRE, VIPERSLIDE.	CARDIOVASCULAR SYSTEMS, INC.	Approval for a change in the design of the DIAMONDBACK 360 Coronary Orbital Atherectomy System (OAS), called OAS Micro Crown.
P130019/S013	03/22/2017	S - Special CBE	MAESTRO RECHARGEABLE SYSTEM	ENTEROMEDICS INC.	Approval for changes to the incoming inspection, shelf storage, and preparation for shipment procedures for evaluating the battery of the Mobile Charger.
P130020/S002	03/03/2017	N - Normal 180 Day	SENOGRAPHE PRISTINA 3D	GE HEALTHCARE	Approval for GE Senographe Pristina 3D 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. Senographe Pristina 3D uses similar DBT technology as SenoClaire and consists of a software and hardware upgrade option that enables the acquisition of projection images of the breast in order to reconstruct tomosynthesis images.
P130021/S029	03/20/2017	N - Normal 180 Day	MEDTRONIC COREVALVE EVOLUT PRO SYSTEM	MEDTRONIC COREVALVE LLC	Approval for a design iteration of the 23, 26, and 29 mm Medtronic CoreValve Evolut R System. The new components include the CoreValve Evolut PRO Transcatheter Aortic Valves, models EVOLUTPRO-23-US, EVOLUTPRO-26-US, and EVOLUTPRO-29-US, and the EnVeo R Loading Systems, models LS-MDT2-23-US and LS-MDT2-2629-US.
P130030/S036	03/15/2017	R - Real-Time Proc	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE	BOSTON SCIENTIFIC CORP.	Approval for minor dimensional and material changes to the Over-The-Wire (OTW) manifold component used on the REBEL OTW Platinum Chromium Coronary Stent System.
P140002/S002	03/08/2017	N - Normal 180 Day	MISAGO PERIPHERAL SELF-EXPANDING STENT SYSTEM	TERUMO MEDICAL CORPORATION	Approval for changes to the device delivery system, associated labeling changes, new manufacturing equipment and new material suppliers.
P140004/S005	03/24/2017	N - Normal 180 Day	SUPERION® INDIRECT DECOMPRESSION SYSTEM (IDS)	VERTIFLEX (R), INCORPORATED	Approval for design modifications to the manual instrumentation used to implant the Superion® device.
P140011/S003	03/23/2017	N - Normal 180 Day	MAMMOMAT INSPIRATION WITH TOMOSYNTHESIS OPTION	SIEMENS MEDICAL SOLUTIONS USA, INC.	Approval for a new reconstruction algorithm called EMPIRE (Enhanced Multiple Parameter Iterative Reconstruction). The device, as modified, will be marketed under the trade name Mammomat Inspiration With Tomosynthesis Option and is indicated for The MAMMOMAT Inspiration with Tomosynthesis Option with the EMPIRE reconstruction algorithm is indicated for acquisition of 2D as well as 3D digital mammography images to be used in screening and diagnosis of breast cancer.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140015/S016	03/06/2017	R - Real-Time Proc	T:SLIM G4 INSULIN PUMP WITH DEXCOM G4 PLATINUM CGM	TANDEM DIABETES CARE, INC.	Approval for a secondary supplier to the pump motor gearbox assembly in the t:slim G4 Insulin Pump, and manufacturing process changes for installing the pump motor gearbox assembly. The t:slim G4 Insulin Pump is a component of the t:slim G4 Insulin Pump with Dexcom G4 Platinum CGM System.
P140015/S017	03/20/2017	R - Real-Time Proc	T:SLIM G4 INSULIN PUMP WITH DEXCOM G4 PLATINUM CGM	TANDEM DIABETES CARE, INC.	Approval for a design change to the connector between the cartridge and the infusion set.
P140020/S009	03/27/2017	N - Normal 180 Day	BRACANALYSIS CDX	MYRIAD GENETIC LABORATORIES	Approval for extending the label claim of the BRACAnalysis CDx to include an indication for ZEJULA (niraparib).
P140025/S004	03/13/2017	N - Normal 180 Day	VENTANA ALK (D5F3)	VENTANA MEDICAL SYSTEMS, INC.	Approval for software modification in the BenchMark XT from NexES to VSS 12.5 and associated hardware changes.
P150001/S009	03/27/2017	R - Real-Time Proc	MINIMED 630G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED	Approval for revisions to patient labeling to include instructions for how users should apply a second Enlite Overtape over the Enlite Sensor.
P150005/S008	03/02/2017	N - Normal 180 Day	INTELLATIP MIFI OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval for design changes to incorporate three mini electrodes into the Blazer Open Irrigated Ablation Catheter. The device, as modified, will be marketed under the trade name IntellaTip MiFi Open-Irrigated Ablation Catheter and is indicated for: The IntellaTip MiFi Open-Irrigated Ablation Catheter, when used with a Maestro 4000 Radiofrequency (RF) Controller and MetriQ Irrigation Pump, is indicated for cardiac electrophysiological mapping, delivering diagnostic pacing stimuli, and radiofrequency ablation of sustained or recurrent Type I Atrial Flutter (AFL) in patients age 18 or older.
P150013/S004	03/24/2017	R - Real-Time Proc	PD-L1 IHC 22C3 PHARMDX	DAKO NORTH AMERICA, INC.	Approval for an update to DakoLink software version 4.2.
P150017/S005	03/01/2017	S - Special CBE	CARTIVA SYNTHETIC CARTILAGE IMPLANT	CARTIVA, INC	Approval for modifications to the Surgical Implantation Technique Guide for the Cartiva Synthetic Cartilage Implant to enhance safe use of the device.
P150019/S027	03/27/2017	R - Real-Time Proc	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Approval for revisions to patient labeling to include instructions for how users should apply a second Enlite Overtape over the Enlite Sensor.
P150025/S004	03/24/2017	R - Real-Time Proc	PD-L1 IHC 28-8 PHARMDX	DAKO NORTH AMERICA, INC.	Approval for an update to DakoLink software version 4.2.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150027/S004	03/24/2017	R - Real-Time Proc	PD-L1 IHC 28-8 PHARMDX	DAKO NORTH AMERICA, INC.	Approval for an update to DakoLink software version 4.2.
P150029/S006	03/27/2017	R - Real-Time Proc	IPRO2 CGM SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Approval for revisions to patient labeling to include instructions for how users should apply a second Enlite Overtape over the Enlite Sensor.
P150037/S002	03/15/2017	O - Normal 180 Day	CYPASS SYSTEM	ALCON RESEARCH, LTD	Approval of the protocol for the post-approval study (PAS) protocol.
P160001/S005	03/09/2017	S - Special CBE	OBALON BALLOON SUSTEM	OBALON THERAPEUTICS, INC.	Approval for labeling changes have been requested by the Office of Surveillance and Biometrics, Signal Management Program as a result of a safety signal with fluid filled gastric balloons.

Total: 83

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S043	03/29/2017	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Addition of three shelving units to the filling and packing process for the SURGICEL Family of Absorbable Hemostats and GYNECARE INTERCEED Absorbable Adhesion Barrier products manufactured at Ethicon, Sarl in Neuchatel, Switzerland.
N18033/S088	03/01/2017	X - 30-Day Notice	VISTAKON BRAND CONTACT LENSES	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Acceptance for a modification to the raw material testing for VISTAKON® brand contact lenses.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S202	03/21/2017	X - 30-Day Notice	ALTRUA 2 MODELS: S701, S702, S722	BOSTON SCIENTIFIC CORP.	Additional manufacturing inspection step and associated specification and inspection criteria to distinguish case half discontinuities from dents.
N970003/S203	03/29/2017	X - 30-Day Notice	ESSENTIO MODELS: L100, L101, L121; PROPONENT MODELS: L200, L201, L221; ACCOLADE MODELS: L300, L301, L321; ALTRUA 2 MODELS: S701, S702, S722	BOSTON SCIENTIFIC CORP.	Change to the method of cleaning a soldering iron tip; 2) changes to the cleaning process of the trays; 3) modification of the solder fixture; and 4) changes to the cleaning of the solder fixture.
P790005/S055	03/27/2017	X - 30-Day Notice	EBI OSTEOGEN IMPLANTABLE BONE GROWTH STIMULATORS	EBI, LLC	Alternate water supplier to conduct device-specific, manufacturing final washing operations when the existing, deionized water produced is unavailable due to preventive maintenance activities.
P790007/S050	03/09/2017	X - 30-Day Notice	HANCOCK VALVED CONDUIT	MEDTRONIC HEART VALVES	Implementation of a continuous monitoring system for certain manufacturing areas and equipment.
P810006/S075	03/01/2017	X - 30-Day Notice	COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	INTEGRA LIFESCIENCES CORPORATION	Acknowledge Integras revisions to Integras LifeSciences Standard Operating Procedure (SOP) QTM-10-007 - Design Output Variable, and Manufacturing Control Quality Assurance Levels, to align with the recently updated ISO 14971:2012 Medical devices - Application of risk management to medical devices.
P840001/S353	03/23/2017	X - 30-Day Notice	RESTORE, ITREL, AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Updated feedthrough electrical test system.
P840062/S061	03/01/2017	X - 30-Day Notice	COLLACOTE(TM) COLLATAPE COLLAPLUG ABSORBABLE COLLAGEN WOUND DRESSINGS FOR DENTAL SURGERY	COLLA-TEC, INC.	Acknowledge Integras revisions to Integras LifeSciences Standard Operating Procedure (SOP) QTM-10-007 - Design Output Variable, and Manufacturing Control Quality Assurance Levels, to align with the recently updated ISO 14971:2012 Medical devices - Application of risk management to medical devices.
P840064/S065	03/15/2017	X - 30-Day Notice	VISCOAT, DISCOCISC OPHTHALMIC VISCOSURGICAL DEVICE	ALCON LABORATORIES	Change to the preheating parameters for the foil used in the blistering of the OVD packaging trays.
P850010/S074	03/01/2017	X - 30-Day Notice	HELISTAT(TM) ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	INTEGRA LIFESCIENCES CORPORATION	Acknowledge Integras revisions to Integras LifeSciences Standard Operating Procedure (SOP) QTM-10-007 - Design Output Variable, and Manufacturing Control Quality Assurance Levels, to align with the recently updated ISO 14971:2012 Medical devices - Application of risk management to medical devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P850035/S044	03/27/2017	X - 30-Day Notice	SPF IMPLANTABLE SPINAL FUSION STIMULATORS	EBI, LLC	Alternate water supplier to conduct device-specific, manufacturing final washing operations when the existing, deionized water produced is unavailable due to preventive maintenance activities.
P860004/S269	03/08/2017	X - 30-Day Notice	MEDTRONIC (R) SYNCHROMED (TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Allow the current pouch manufacturer (Oliver Tolas Healthcare Packaging) to pre-cut a Tyvek pouch that is per the specifications for the affected products, Spinal needle model number 8786 and 8787.
P870078/S035	03/09/2017	X - 30-Day Notice	HANCOCK VALVED CONDUIT	MEDTRONIC INC.	Implementation of a continuous monitoring system for certain manufacturing areas and equipment.
P880047/S026	03/29/2017	X - 30-Day Notice	GYNECARE INTERCEED ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Addition of three shelving units to the filling and packing process for the SURGICEL Family of Absorbable Hemostats and GYNECARE INTERCEED Absorbable Adhesion Barrier products manufactured at Ethicon, Sarl in Neuchatel, Switzerland.
P880086/S281	03/30/2017	X - 30-Day Notice	VICTORY, ZEPHYR, ACCENT, ASSURITY, ASSURITY+, ENDURITY, IDENTITY ADX, VERITY ADX	ST. JUDE MEDICAL, INC.	Use of a new sterilizer at the Sylmar, California facility.
P890047/S050	03/15/2017	X - 30-Day Notice	PROVISC OPHTHALMIC VISCOSURGICAL DEVICES	ALCON RESEARCH, LTD.	Change to the preheating parameters for the foil used in the blistering of the OVD packaging trays.
P900033/S060	03/01/2017	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Acknowledge Integras revisions to Integras LifeSciences Standard Operating Procedure (SOP) QTM-10-007 - Design Output Variable, and Manufacturing Control Quality Assurance Levels, to align with the recently updated ISO 14971:2012 Medical devices - Application of risk management to medical devices.
P900056/S158	03/24/2017	X - 30-Day Notice	ROTABLATOR ROTATIONAL ANGIOPLASTY SYSTEM GUIDEWIRE	BOSTON SCIENTIFIC CORP.	Update the vacuum pump settings used in sterilization Chambers 9 and 10 at the BSC Coventry Rhode Island facility.
P900060/S056	03/03/2017	X - 30-Day Notice	CARBOMEDICS PROSTHETIC HEART VALVE (CPHV).	SORIN GROUP ITALIA S.R.L	Change to acceptance criteria for the visual inspection of the Carbomedics Prosthetic Heart Valve orifice
P910007/S050	03/28/2017	X - 30-Day Notice	AXSYM TOTAL PSA & ARCHITECT TOTAL PSA	ABBOTT LABORATORIES	Change to convert the microparticle coating process from the automated microparticle processing system (AMPS) to the magnetic separation (MagSep) process.
P910023/S383	03/30/2017	X - 30-Day Notice	CURRENT+, FORTIFY, FORTIFY ASSURA, ELLIPSE, PROMOTE+	ST. JUDE MEDICAL	Use of a new sterilizer at the Sylmar, California facility.
P920047/S096	03/24/2017	X - 30-Day Notice	BLAZER II CARDIAC ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC CORP.	Update the vacuum pump settings used in sterilization Chambers 9 and 10 at the BSC Coventry Rhode Island facility.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P940015/S039	03/29/2017	X - 30-Day Notice	SYNVISC	GENZYME CORP.	Modifications to the filtration process for a component of Synvisc and Synvisc-One.
P950022/S101	03/14/2017	X - 30-Day Notice	DURATA AND OPTISURE LEADS (HV ACTIVE AND PASSIVE)	ST. JUDE MEDICAL, INC.	Updates to assay and content uniformity acceptance criteria for finished leads.
P950022/S103	03/21/2017	X - 30-Day Notice	DURATA AND OPTISURE LEADS (HV ACTIVE AND PASSIVE)	ST. JUDE MEDICAL, INC.	Changes to acceptance criteria for impurities.
P950022/S104	03/30/2017	X - 30-Day Notice	DURATA, DURATA, OPTISURE	ST. JUDE MEDICAL, INC.	Use of a new sterilizer at the Sylmar, California facility.
P960009/S271	03/23/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	updated feedthrough electrical test system.
P960013/S089	03/14/2017	X - 30-Day Notice	TENDRIL SDX/ST/STS AND OPTISENSE LEADS (LV ACTIVE)	PACESETTER, INC.	Updates to assay and content uniformity acceptance criteria for finished leads.
P960013/S091	03/21/2017	X - 30-Day Notice	TENDRIL SDX/ST/STS AND OPTISENSE LEADS (LV ACTIVE)	PACESETTER, INC.	Changes to acceptance criteria for impurities.
P960013/S092	03/30/2017	X - 30-Day Notice	TENDRIL SDX LEAD, TENDRIL ST LEAD, OPTISENCE, TENDRIL STS LEAD	PACESETTER, INC.	Use of a new sterilizer at the Sylmar, California facility.
P960030/S051	03/14/2017	X - 30-Day Notice	ISOFLEX OPTIM LEADS (LV PASSIVE)	PACESETTER, INC.	Updates to assay and content uniformity acceptance criteria for finished leads.
P960030/S053	03/21/2017	X - 30-Day Notice	ISOFLEX OPTIM LEADS (LV PASSIVE)	PACESETTER, INC.	Changes to acceptance criteria for impurities.
P960030/S054	03/30/2017	X - 30-Day Notice	ISOFLEX OPTIM	PACESETTER, INC.	Use of a new sterilizer at the Sylmar, California facility.
P970031/S055	03/09/2017	X - 30-Day Notice	FREESTYLE BIOPROSTHESIS	MEDTRONIC HEART VALVES	Implementation of a continuous monitoring system for certain manufacturing areas and equipment.
P970031/S056	03/24/2017	X - 30-Day Notice	FREESTYLE BIOPROSTHESIS, MODELS 995, 995CS AND 995MS	MEDTRONIC HEART VALVES	Addition of a new terminal sterilization oven at the Medtronic Heart Valves Division facility in Santa Ana, California.
P970051/S156	03/09/2017	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Change from adhesion to insert molding of the white silicone rubber alignment marker to the electrode.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970051/S158	03/29/2017	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Manufacturing change to the CP950 Sound Processor.
P970054/S013	03/09/2017	X - 30-Day Notice	PARVOVIRUS B19 IGG ENZYME IMMUNOASSAY	DIASORIN	Addition of a variation test for materials used in the manufacture of kit reagents.
P970055/S015	03/09/2017	X - 30-Day Notice	PARVOVIRUS B19 IGM ENZYME IMMUNOASSAY	DIASORIN	Addition of a variation test for materials used in the manufacture of kit reagents.
P980003/S072	03/24/2017	X - 30-Day Notice	CHILLI II COOLED ABLATION CATHETER ANDCABLE	BOSTON SCIENTIFIC CORP.	Update the vacuum pump settings used in sterilization Chambers 9 and 10 at the BSC Coventry Rhode Island facility.
P980016/S622	03/08/2017	X - 30-Day Notice	EVERA MRI DF-1 ICD/ EVERA MRI ICD/EVERA S DR ICD/ EVERA S VR ICD/ EVERA XT DR ICD/EVERA XT VR ICD/ VISIA AF MRI DF1 ICD/ VISIA AF MRI VR ICD/VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates to the current resistance spot weld process for the manufacture of capacitor assemblies.
P980016/S623	03/10/2017	X - 30-Day Notice	EVERA MRI DF-1, PROTECTA XT ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to the acceptance parameter specification limits for certain wafers and associated process changes.
P980016/S625	03/13/2017	X - 30-Day Notice	EVERA MRI DF-1, EVERA MRI, EVERA S DR, EVERA S VR, EVERA XT DR, EVERA XT VR, VISIA AF MRI DF1, VISIA AF MRI VR, VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updated test equipment for use in battery manufacturing.
P980016/S626	03/30/2017	X - 30-Day Notice	EVERA MRI ICD, EVERA S DR/ S VR ICD'S; EVERA XT DR ICD/ XT VR ICD; MAXIMO II ICD; PROTECTA VR/XT ICD; SECURA DR ICD, SECURA ICD; VISIA AF MRI DFI ICD, VISIA AF MRI VR ICD, VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Change to the monitoring frequency for the battery header laser weld inspection.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980023/S080	03/29/2017	X - 30-Day Notice	KAINOX VCS; LINOX TD 65/18 & 65/16; SD 75/18, 65/18, 65/18, 60/16; T65, S75,S65, S60; S DX 65/17; S DX 65/15; PROTEGO DF-1 S60, S65, S75; PROTEGO DF-1S DX 65-15, 65-17; PROTEGO DF-1 T 65; PLEXA DF-1 S 60, S65, S75; PLEXA DF-1 SD 60/16; VOLTA 2CR TD 65/18, 65/16; VOLTA 2CR SD 75/18, 65/18, 65/16; VOLTA 2CR SD 60/16; VOLTA 2CR T 65/ S75/ S65/S60; VOLTA 2CDR S DX 65/17; PROTOGO DF-1 SD 60-16; PLEXA PROMRI DF-1 SD 65/16	BIOTRONIK, INC.	Addition of a tensile test and removal of an in-process visual inspection for the IS-1 connector.
P980035/S490	03/10/2017	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG	MEDTRONIC INC.	Changes to the acceptance parameter specification limits for certain wafers and associated process changes.
P980035/S491	03/30/2017	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ADVISA DR IPG, ADVISA DR MRI IPG, ADVISA SR MRI IPG, RELIA IPG	MEDTRONIC INC.	Change to the monitoring frequency for the battery header laser weld inspection.
P980040/S078	03/23/2017	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	ABBOTT MEDICAL OPTICS INC	Add the AMO Kulim, Malaysia manufacturing site for your Tecnis Multifocal IOL Models ZKB00, ZLB00, and ZMB00.
P980040/S079	03/24/2017	X - 30-Day Notice	TECNIS TORIC 1-PIECE IOL MODEL ZCT	ABBOTT MEDICAL OPTICS INC	Addition of the AMO Kulim, Malaysia manufacturing site for the production of your TECNIS Toric IOL Models ZCT150, ZCT225, ZCT300, ZCT375, ZCT400, ZCT450, ZCT525, and ZCT600.
P980043/S057	03/09/2017	X - 30-Day Notice	HANCOCK II BIOPROSTHESIS, ULTRA BIOPROSTHESIS	MEDTRONIC HEART VALVES	Implementation of a continuous monitoring system for certain manufacturing areas and equipment.
P980043/S058	03/24/2017	X - 30-Day Notice	HANCOCK II BIOPROSTHESIS, MODELS T505 AND T510	MEDTRONIC HEART VALVES	Addition of a new terminal sterilization oven at the Medtronic Heart Valves Division facility in Santa Ana, California.
P980044/S037	03/21/2017	X - 30-Day Notice	SUPARTZ DEVICE FAMILY	SEIKAGAKU CORP.	Update microbiological incubators used for quality control testing and environmental monitoring of products for SUPARTZ FX and VISCO-3.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980044/S038	03/29/2017	X - 30-Day Notice	SUPARTZ FX AND VISCO-3	SEIKAGAKU CORP.	Changes to the sterilization equipment used in the manufacture of SUPARTZ FX and VISCO-3.
P980049/S124	03/20/2017	X - 30-Day Notice	PLATINIUM VR AND PLATINIUM DR ICD'S (IMPLANTABLE CARDIOVERTER DEFOBRILLATOR)	SORIN GROUP- CRM	Addition of a robotic arm for use during electrical testing.
P990004/S030	03/08/2017	X - 30-Day Notice	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEDICAL DEVICES A/S	Change in the ethylene oxide sterilization process and change in the biological indicator
P990064/S066	03/09/2017	X - 30-Day Notice	MOSAIC BIOPROSTHESIS, MOSAIC ULTRA BIOPROSTHESIS	MEDTRONIC HEART VALVES	Implementation of a continuous monitoring system for certain manufacturing areas and equipment.
P990064/S067	03/24/2017	X - 30-Day Notice	MOSAIC BIOPROSTHESIS, MODELS 305 AND 310	MEDTRONIC HEART VALVES	Addition of a new terminal sterilization oven at the Medtronic Heart Valves Division facility in Santa Ana, California.
P000008/S038	03/23/2017	X - 30-Day Notice	LAP-BAND ADJUSTABLE GASTRIC BANDING SYSTEM	APOLLO ENDOSURGERY INC	Removal of the Ultrasonic Thickness Gauge (UTG) inspection step of the ¿shell ¿ thickness of the band of the LAP-BAND Adjustable Gastric Banding System from the incoming product inspection protocol.
P000021/S030	03/16/2017	X - 30-Day Notice	DIMENSION TPSA FLEX REAGENT CARTRIDGE	SIEMENS HEALTHCARE DIAGNOSTICS	Internal supplier to manufacture tested subassembly components, which are used in the Dimension® EXL integrated systems manufacturing process.
P000025/S093	03/29/2017	X - 30-Day Notice	COMBI 40+ COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Change in the test method of the feedthrough components of the cochlear implants.
P000053/S077	03/29/2017	X - 30-Day Notice	AMS 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Replacement of a manufacturing aid used in the pump assembly (kink resistant tubing to valve block bond operation) and removal of the corresponding gap inspection.
P000054/S046	03/03/2017	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Various source manufacturing changes for the rhBMP-2 drug product component of Infuse Bone Graft.
P000058/S064	03/03/2017	X - 30-Day Notice	INFUSE BONE GRAFT/ MEDTRONIC INTERBODY FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Various source manufacturing changes for the rhBMP-2 drug product component of Infuse Bone Graft.
P010014/S061	03/11/2017	X - 30-Day Notice	OXFORD PARTIAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Align the UHMWPE fabricated form material testing requirements to ASTM F648 for the Oxford Partial Knee direct compression molded meniscal (tibial) components.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S321	03/10/2017	X - 30-Day Notice	CONSULTA CRT-P, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	Changes to the acceptance parameter specification limits for certain wafers and associated process changes.
P010015/S322	03/30/2017	X - 30-Day Notice	CONSULTA CRT-P, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	Change to the monitoring frequency for the battery header laser weld inspection.
P010030/S092	03/10/2017	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFE VEST"	ZOLL MANUFACTURING CORPORATION	Implementation of corrections and new features to the automated test software used for performing the Automated Detect and Treat Test during manufacturing and service
P010031/S581	03/08/2017	X - 30-Day Notice	AMPLIA MRI CRT-D/AMPLIA MRI QUAD CRT-D/ BRAVA CRT-D/CLARIA QUAD CRT-D/ BRAVA QUAD CRT-D/ COMPIA MRI QUAD CRT-D/ VIVA QUAD S CRT-D/ VIVA S & XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates to the current resistance spot weld process for the manufacture of capacitor assemblies.
P010031/S582	03/10/2017	X - 30-Day Notice	AMPLIA MRI CRT-D, AMPLIA MRI QUAD CRT-D, BRAVA CRT-D, EVERA MRI ICD, MAXIMO II ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to the acceptance parameter specification limits for certain wafers and associated process changes.
P010031/S585	03/13/2017	X - 30-Day Notice	AMPLIA MRI, AMPLIA MRI QUAD, BRAVA, BRAVA QUAD, CLARIA MRI, CLARIA QUAD, COMPIA MRI, COMPIA MRI QUAD, VIVA QUAD S, VIVA QUAD XT, VIVA S, VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updated test equipment for use in battery manufacturing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S586	03/30/2017	X - 30-Day Notice	AMPLIA MRI CRT-D,MRI QUAD CRT-D; BRAVA CRT-D, BRAVA QUAD CRT-D, CLARIA MRI CRT-D, CLARIA MRI QUAD CRT-D; CONCERTO II CRT-D; CONSULTA CRT-D; MAXIMO II CRT-D; PROTECTA CRT-D, PROTECTA XT 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	Change to the monitoring frequency for the battery header laser weld inspection.
P010033/S032	03/07/2017	X - 30-Day Notice	QUANTIFERON-TB GOLD TEST	QIAGEN	Add an alternate critical raw material supplier and an additional vendor for testing of kit components.
P020025/S097	03/24/2017	X - 30-Day Notice	BLAZER II XP CARDIAC ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC	Update the vacuum pump settings used in sterilization Chambers 9 and 10 at the BSC Coventry Rhode Island facility.
P020027/S025	03/16/2017	X - 30-Day Notice	DIMENSION FPSA FLEX REAGENT CARTRIDGE	SIEMENS HEALTHCARE DIAGNOSTICS	Internal supplier to manufacture tested subassembly components, which are used in the Dimension® EXL integrated systems manufacturing process.
P020045/S080	03/20/2017	X - 30-Day Notice	COAXIAL UMBILICAL CABLE	MEDTRONIC CRYOCATH LP	Implementation of an additional step to the manufacturing process for enhanced reliability of the coaxial umbilical cable.
P020045/S081	03/22/2017	X - 30-Day Notice	FREEZOR CATHETER, FREEZOR XTRA CATHETER, FREEZOR MAX SURGICAL DEVICE, ELECTRICAL UMBILICAL CABLE, COAXIAL UMBILICAL CABLE	MEDTRONIC CRYOCATH LP	Additional equivalent sterilization chamber that was qualified within the current sterilization facility.
P030005/S151	03/29/2017	X - 30-Day Notice	VALITUDE MODELS: U125, U128; VISIONIST MODELS: U225, U226, U228	GUIDANT CORP.	Change to the method of cleaning a soldering iron tip; 2) changes to the cleaning process of the trays; 3) modification of the solder fixture; and 4) changes to the cleaning of the solder fixture.
P030011/S047	03/09/2017	X - 30-Day Notice	SYNCARDIA TEMPORARY TOTAL ARTIFICIAL HEART	SYNCARDIA SYSTEMS, LLC	Supplier location change of the manufacturing of the TAH-t cannula.
P030017/S282	03/22/2017	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Add a rework process and software tool to allow retesting of the Precision Spectra, Precision Montage MRI, and Montage IPG battery.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030017/S283	03/20/2017	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION (SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Integrate the Continuity and HiPot testing into one test system (91073032) to be used for testing Continuity and HiPot on the M1 Adapter, M8 Adapter, 2x8 Splitter, D4 Splitter, W4 Splitter and 8 Contact Extensions.
P030017/S284	03/24/2017	X - 30-Day Notice	PRECISION MONTAGE AND PRECISION MONTAGE MRI	BOSTON SCIENTIFIC CORP.	Addition of an alternate qualified supplier for the cables used in the Avista MRI leads for the Precision Montage MRI and Precision Montage system.
P030017/S285	03/24/2017	X - 30-Day Notice	PRECISION MONTAGE MRI SPINAL CORD STIMULATOR (SCS) SYSTEM; PRECISION MONTAGE SPINAL CORD STIMULATOR (SCS) SYSTEM; PRECISION SPECTRA SPINAL CORD STIMULATOR (SCS) SYSTEM; PRECISION NOVI SPINAL CORD STIMULATOR (SCS) SYSTEM.	BOSTON SCIENTIFIC CORP.	Updating the test equipment software (remove certain tests) used for testing the Printed Circuit Board Assembly (PCBA) of the Remote Control (RC) of the Precision Montage MRI, Precision Montage, Precision Spectra and Precision Novi Systems.
P030017/S286	03/28/2017	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATOR (SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Alternate QC Final Acceptance Sampling Methodology -Acceptable Quality Limit (AQL) instead of the existing LTPD sampling method.
P030035/S155	03/30/2017	X - 30-Day Notice	ANTHEM, ALLURE, ALLURE RF, ALLURE QUADRA, ALLURE QUADRA RF, QUADRA ALLURE MP	ST. JUDE MEDICAL, INC.	Use of a new sterilizer at the Sylmar, California facility.
P030054/S322	03/14/2017	X - 30-Day Notice	QUICKFLEX µ AND QUARTET LEADS (CRT)	ST. JUDE MEDICAL	Updates to assay and content uniformity acceptance criteria for finished leads.
P030054/S324	03/21/2017	X - 30-Day Notice	QUICKFLEX U AND QUARLET LEADS (CRT)	ST. JUDE MEDICAL	Changes to acceptance criteria for impurities.
P030054/S325	03/30/2017	X - 30-Day Notice	UNIFY, UNIFY QUADRA, UNIFY ASSURA, QUADRA ASSURA, QUADRA ASSURA MP, QUICKFLEX U, QUARTET	ST. JUDE MEDICAL	Use of a new sterilizer at the Sylmar, California facility.
P050027/S008	03/17/2017	X - 30-Day Notice	KARL STORZ PHOTODYNAMIC D-LIGHT C (PDD) SYSTEM	KARL STORZ ENDOSCOPY-AMERICA, INC.	Change of manufacturing facility.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P050044/S033	03/02/2017	X - 30-Day Notice	VITAGEL RT3 SUTGICAL HEMOSTAT	STRYKER CORP.	New tray tooling fixture, new sealing parameters and increased outer tray dimensions.
P050053/S037	03/03/2017	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC INC.	Various source manufacturing changes for the rhBMP-2 drug product component of Infuse Bone Graft.
P060006/S079	03/15/2017	X - 30-Day Notice	EXPRESS SD RENAL MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Reconfiguration of the Top Assembly Laser (TAL) manufacturing line and implementation of changes to the cut-to-length process.
P060006/S080	03/24/2017	X - 30-Day Notice	EXPRESS SD MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Update the vacuum pump settings used in sterilization Chambers 9 and 10 at the BSC Coventry Rhode Island facility.
P060027/S089	03/20/2017	X - 30-Day Notice	PLATINIUM CRT-DS (CARDIAC RESYNCHRONIZATION THERAPY-DEFIBRILLATOR)	SORIN GROUP CRM USA, INC	Addition of a robotic arm for use during electrical testing.
P070026/S047	03/28/2017	X - 30-Day Notice	CERAMAX® CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Addition of an inspection step for re-tapped stems.
P080020/S025	03/21/2017	X - 30-Day Notice	GEL-ONE	SEIKAGAKU CORP.	Update microbiological incubators used for quality control testing and environmental monitoring of products for Gel-One.
P090013/S250	03/10/2017	X - 30-Day Notice	REVO MRI SURESCAN IPG	MEDTRONIC, INC	Changes to the acceptance parameter specification limits for certain wafers and associated process changes.
P090013/S251	03/30/2017	X - 30-Day Notice	REVO MRI SURESCAN IPG	MEDTRONIC, INC	Change to the monitoring frequency for the battery header laser weld inspection.
P090022/S032	03/15/2017	X - 30-Day Notice	LENSTEC SOFTEC HD POSTERIOR CHAMBER INTRAOCULAR LENS	LENSTEC, INC.	Include the Lenstec manufacturing facility in Florida as the manufacturer of the lens polishing compound that is used during the manufacture of intraocular lenses.
P100010/S062	03/22/2017	X - 30-Day Notice	ARCTIC FRONT CATHETER, ARCTIC FRONT ADVANCE CATHETER, ARCTIC FRONT ADVANCE ST CATHETER, FREEZOR MAX CATHETER, MANUAL RETRACTION KIT	MEDTRONIC CRYOCATH LP	Additional equivalent sterilization chamber that was qualified within the current sterilization facility.
P100034/S017	03/15/2017	X - 30-Day Notice	NOVOCURE LTD.'S OPTUNE	NOVOCURE, LTD.	Addition of two second source component suppliers related to the INE transducer array subassembly as well as automation of a related soldering procedure.
P100047/S091	03/14/2017	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Change in the package sealing parameters for the implant kit, implant accessories, and surgical tools trays.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110010/S138	03/24/2017	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING STENT SYSTEM/PROMUS PREMIER EVEROLIMUS-ELUTING PLATINUM CHRONIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Update the vacuum pump settings used in sterilization Chambers 9 and 10 at the BSC Coventry Rhode Island facility.
P110016/S038	03/07/2017	X - 30-Day Notice	FLEXABILITY ABLATION CATHETER AND FLEXABILITY ABLATION CATHETER, SENSOR ENABLED	ST. JUDE MEDICAL, INC.	Change to the tuner-pin press manufacturing process and specification for handle assembly.
P110042/S076	03/01/2017	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Additional supplier for the transformer component.
P110042/S078	03/06/2017	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM.	BOSTON SCIENTIFIC CORPORATION	Update to the manufacturing test software to verify reworked devices.
P110042/S079	03/21/2017	X - 30-Day Notice	EMBLEM S-ICD PROGRAMMER - PLEXUS SMT MFG. LINE	BOSTON SCIENTIFIC CORPORATION	New manufacturing line for the programmer radio board printed circuit board assembly for the Model 3200 EMBLEM Programmer.
P130009/S070	03/09/2017	X - 30-Day Notice	SAPIEN XT TRANSCATHETER HEART VALVE (FRAME ONLY) ASCENDRA+DELIVERY SYSTEM/NOVAFLEX +DELIVERY SYSTEM/ EDWARDS EXPANDABLE INTRODUCER SHEATH SET/CRIMPER/ QUALCRIMP CRIMPING ACCESSORY(INCLUDE WITH NOVAFLEX+ DELIVERY SYSTEM PACKAGING	EDWARDS LIFESCIENCES, LLC.	Addition of a new cleanroom.
P130013/S012	03/16/2017	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE CLOSEURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Changes to the proximal weld process used in manufacturing the WATCHMAN Left Atrial Appendage Closure (LAAC) Device with Delivery System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130016/S023	03/29/2017	X - 30-Day Notice	NUCLEUS HYBRID L24 IMPLANT SYSTEM	COCHLEAR AMERICAS	Manufacturing change to the CP950 Sound Processor.
P130021/S030	03/09/2017	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM/MEDTRONIC EVOLUT R SYSTEM	MEDTRONIC COREVALVE LLC	Implementation of a continuous monitoring system for certain manufacturing areas and equipment.
P130022/S012	03/01/2017	X - 30-Day Notice	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATIO N	Implement manufacturing process changes to allow for the use of virtual machine software (VMware) to provide an isolated and safe environment from which to run the FDA approved PG2000 Clinician Programmer software v1.7.
P130024/S018	03/07/2017	X - 30-Day Notice	LUTONIX DRUG COATED BALLOON PTA CATETER	LUTONIX	Modifications to the preparation method for the coating solution.
P130028/S015	03/31/2017	X - 30-Day Notice	ALGOVITA SPINAL CORD STIMULATION SYSTEM	NUVECTRA CORPORATIO N	Changes to the Implantable Pulse Generator printed circuit board (PCB) functional test system software in order to improve system reliability and to better conform to device performance specifications.
P130028/S016	03/30/2017	X - 30-Day Notice	ALGOVITA SPINAL CORD STIMULATION SYSTEM	NUVECTRA CORPORATIO N	Discontinue the process for evaluation of specific Radiofrequency (RF) parameters, and subsequent approval by Nuvectra based on the RF performance.
P130030/S037	03/24/2017	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM (MONORAIL AND OVER-THE-WIRE)	BOSTON SCIENTIFIC CORP.	Update the vacuum pump settings used in sterilization Chambers 9 and 10 at the BSC Coventry Rhode Island facility.
P140010/S029	03/16/2017	X - 30-Day Notice	IN.PACT ADMIRAL PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Automation of the calculation of analytical test methods results.
P140010/S030	03/30/2017	X - 30-Day Notice	IN.PACT ADMIRAL PACLITAXEL-COATED BALLOON CATHETER	MEDTRONIC INC.	Use of European Pharmacopeia paclitaxel reference standard for lot release and stability testing.
P140030/S003	03/24/2017	X - 30-Day Notice	ASTRON PERIPHERAL SELF-EXPANDING NITINOL STENT SYSTEM	BIOTRONIK, INC.	Changes to the reference load and external process challenge device used for sterilization validation and routine product sterilization.
P140031/S030	03/01/2017	X - 30-Day Notice	EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCE S, LLC.	Modify aspects of quality control product verification testing for the Edwards Commander delivery system.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140031/S032	03/09/2017	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE (FRAME ONLY) COMMANDER DELIVERY SYSTEM/CERTITUDE DELIVERY SYSTEM/ CERTITUDE INTRODUCER SHEATH/ CRIMPER	EDWARDS LIFESCIENCES, LLC.	Addition of a new cleanroom.
P140033/S003	03/21/2017	X - 30-Day Notice	TENDRIL MRI LEADS (MRI)	ST. JUDE MEDICAL, INC.	Changes to acceptance criteria for impurities.
P140033/S004	03/30/2017	X - 30-Day Notice	ASSURITY MRI, ENDURITY MRI, TENDRIL MRI	ST. JUDE MEDICAL, INC.	Use of a new sterilizer at the Sylmar, California facility.
P140033/S005	03/06/2017	X - 30-Day Notice	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ST. JUDE MEDICAL, INC.	Sample preparation changes for the HPLC test method.
P150005/S016	03/24/2017	X - 30-Day Notice	BLAZER OPEN IRRIGATED CARDIAC ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Update the vacuum pump settings used in sterilization Chambers 9 and 10 at the BSC Coventry Rhode Island facility.
P150011/S009	03/16/2017	X - 30-Day Notice	PERCEVAL SUTURELESS HEART VALVE	LIVANOVA CANADA CORP.	Combine the dimensional inspection steps performed during stent manufacturing.
P150012/S026	03/29/2017	X - 30-Day Notice	ESSENTIO MRI MODELS: L110, L111, L131; PROPONENT MRI MODELS: L210, L211, L231; ACCOLADE MRI MODELS: L310, L311, L331	BOSTONSCIENTIFIC	Change to the method of cleaning a soldering iron tip; 2) changes to the cleaning process of the trays; 3) modification of the solder fixture; and 4) changes to the cleaning of the solder fixture.
P150033/S016	03/02/2017	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Changes to the battery leak test process.
P150033/S017	03/13/2017	X - 30-Day Notice	MICRA TPS	MEDTRONIC INC.	Updated test equipment for use in battery manufacturing.
P150033/S019	03/28/2017	X - 30-Day Notice	MICRA TRANSCATHETER PACING SYSTEM	MEDTRONIC INC.	Changes to sampling requirements for Bacterial Endotoxin Testing (BET).
P160003/S001	03/24/2017	X - 30-Day Notice	PRO-KINETIC ENERGY CORONARY STENT SYSTEM	BIOTRONIK, INC.	Changes to the reference load and external process challenge device used for sterilization validation and routine product sterilization.

Total: 131