PMA Monthly approvals from 5/1/2019 to 5/31/2019

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180013	05/02/2019	PMAO - PMA Origi	VICI VENOUS STENT SYSTEM	BOSTON SCIENTIFIC CORPORATIO N	Approval for improving luminal diameter in the iliofemoral veins for the treatment of symptomatic venous outflow obstruction.
P180031	05/16/2019	PMAO - PMA Origi	NEUROFORM ATLAS® STENT SYSTEM	STRYKER NEUROVASC ULAR	Approved for use with neurovascular embolization coils in the anterior circulation of the neurovasculature for the endovascular treatment of patients greater or equal to 18 years of age with saccular wide-necked (neck width greater or equal to 4 mm or a dome-to-neck ratio of < 2) intracranial aneurysms arising from a parent vessel with a diameter of greater or equal to 2.0 mm and less than or equal to 4.5 mm.
P190001	05/24/2019	PMAO - PMA Origi	THERASCREEN PIK3CA RGQ PCR KIT	QIAGEN GMBH	Approval for the therascreen PIK3CA RGQ PCR Kit. The therascreen PIK3CA RGQ PCR Kit is a real-time qualitative PCR test for the detection of 11 mutations in the phosphatidylinositol 3-kinase catalytic subunit alpha (PIK3CA) gene (Exon 7: C420R; Exon 9: E542K, E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R; and Exon 20: H1047L, H1047R, H1047Y) using genomic DNA (gDNA) extracted from formalin-fixed, paraffin-embedded (FFPE) breast tumor tissue or circulating tumor DNA (ctDNA) from plasma derived from K2EDTA anticoagulated peripheral whole blood taken from patients with breast cancer. The test is intended to aid clinicians in identifying breast cancer patients who may be eligible for treatment with PIQRAY® (alpelisib) based on a PIK3CA Mutation Detected result. Patients whose FFPE tissue or plasma specimen produces a positive therascreen PIK3CA RGQ PCR Kit test result for the presence of one or more PIK3CA mutations are eligible for treatment with PIQRAY (alpelisib). Patients whose plasma specimen produces a negative result using this test should be reflexed to testing with FFPE tumor tissue for the presence of PIK3CA mutations. FFPE tumor specimens are processed using the QIAamp DSP DNA FFPE Tissue Kit for manual sample preparation. K2EDTA anticoagulated whole peripheral venous blood plasma specimens are processed using the QIAamp DSP Circulating Nucleic Acid Kit for manual sample preparation. For both specimen types, the Rotor-Gene Q (RGQ) MDx (US) instrument is used for automated amplification and detection. The Kit is to be used by trained personnel in a professional laboratory environment.

Data as of 06/03/2019 03:12 AM

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P190004	05/24/2019	PMAO - PMA Origi	THERASCREEN PIK3CA RGQ PCR KIT	QIAGEN GMBH	Approval for the therascreen PIK3CA RGQ PCR Kit. The therascreen PIK3CA RGQ PCR Kit is a real-time qualitative PCR test for the detection of 11 mutations in the phosphatidylinositol 3-kinase catalytic subunit alpha (PIK3CA) gene (Exon 7: C420R; Exon 9: E542K, E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R; and Exon 20: H1047L, H1047R, H1047Y) using genomic DNA (gDNA) extracted from formalin-fixed, paraffin-embedded (FFPE) breast tumor tissue or circulating tumor DNA (ctDNA) from plasma derived from K2EDTA anticoagulated peripheral whole blood taken from patients with breast cancer. The test is intended to aid clinicians in identifying breast cancer patients who may be eligible for treatment with PIQRAY® (alpelisib) based on a PIK3CA Mutation Detected result. Patients whose FFPE tissue or plasma specimen produce a positive therascreen PIK3CA RGQ PCR Kit test result for the presence of one or more PIK3CA mutations are eligible for treatment with PIQRAY (alpelisib). Patients whose plasma specimens produces a negative result using this test should be reflexed to testing with FFPE tumor tissue for the presence of PIK3CA mutations. FFPE tumor specimens are processed using the QIAamp DSP DNA FFPE Tissue Kit for manual sample preparation. K2EDTA anticoagulated whole peripheral venous blood plasma specimens are processed using the QIAamp DSP Circulating Nucleic Acid Kit for manual sample preparation. For both specimen types, the Rotor-Gene Q (RGQ) MDx (US) instrument is used for automated amplification and detection. The Kit is to be used by trained personnel in a professional laboratory environment.

Total: 4

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S053	05/23/2019	R - Real-Time Proc	SURGICEL SNOW ABSORBABLE HEMOSTAT	ETHICON, INC.	Approval for modifications to the labeling to reflect current device testing for bactericidal effects.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N18033/S101	05/31/2019	N - Normal 180 Day	VISTAKON (ETAFILCON A) BRAND CONTACT LENSES.	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Approval to use alternate photoinitiator
N970003/S234	05/22/2019	N - Normal 180 Day	ALTRUA 2, ESSENTIO, PROPONENT, ACCOLADE	BOSTON SCIENTIFIC CORP.	Approval for modifying the Accolade family of pacemakers and CRT-P devices
N970012/S157	05/06/2019	R - Real-Time Proc	AMS 700 INFLATABLE PENILE PROSTHESIS, AMS AMBICOR PENILE PROSTHESIS	BOSTON SCIENTIFIC CORP.	Approval for the additional steam sterilizer for finished devices which are not treated with antimicrobials.
N970012/S158	05/06/2019	R - Real-Time Proc	AMS 700 INFLATABLE PENILE PROSTHESIS, AMS AMBICOR PENILE PROSTHESIS	BOSTON SCIENTIFIC CORP.	Approval for addition of an alternate DI water system and steam generation system to feed an alternate steam sterilizer for terminal sterilization of devices without antimicrobials.
P830055/S220	05/09/2019	R - Real-Time Proc	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for a change in raw material and manufacturing for the ATTUNE Revision Tibial Augments
P830055/S226	05/09/2019	O - Normal 180 Day	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for a manufacturing site located at Drayton Fields Industrial Estate Brunel Close, Daventry Northamptonshire, United Kingdom NN11 8RB for sterilization by gamma radiation of system components.
P830061/S168	05/30/2019	O - Normal 180 Day	CAPSURE SENSE MRI SURESCAN LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for labeling updates to the clinical study summary for the post-approval study.
P840001/S384	05/20/2019	Y - 135 Review Tra	MASTER RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Approval for the implementation of the INS Bacterial Endotoxin Testing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860003/S101	05/13/2019	R - Real-Time Proc	THERAKOS CELLEX PROCEDURAL KIT	MALLINCKRODT PHARMACEUTICALS IRELAND LIMITED	Approval for design changes to the pump tubing organizer assembly of the Therakos CELLEX Procedural Kit.
P880047/S030	05/13/2019	R - Real-Time Proc	GYNECARE INTERCEED ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Approval for packaging changes related to the automated process change from manual to automated foiling and cartoning at the Ethicon SARL, Neuchatel Switzerland site for GYNECARE INTERCEED Absorbable Adhesion Barrier.
P900056/S176	05/02/2019	R - Real-Time Proc	ROTAPRO ROTATIONAL ATHERECTOMY SYSTEM CONSOLE	BOSTON SCIENTIFIC CORP.	Approval for a new firmware component that will replace the default firmware on the microcontroller of the ROTAPRO Console.
P910023/S416	05/30/2019	R - Real-Time Proc	TORQUE WRENCH/ TORQUE DRIVER	ST. JUDE MEDICAL	Approval for changes to the Torque Wrench/Torque Driver, Model 442-2, accessory.
P920015/S229	05/30/2019	O - Normal 180 Day	SPRINT QUATTRO SECURE S MRI SURESCAN LEAD AND SPRINT QUATTRO SECURE MRI SURESCAN LEAD	MEDTRONIC INC.	Approval for labeling updates to the clinical study summary for the post-approval study.
P930016/S058	05/03/2019	R - Real-Time Proc	IDESIGN REFRACTIVE STUDIO	AMO MANUFACTURING USA, LLC	Approval for a custom-designed replacement micro display driver in your iDESIGN Refractive Studio.
P930016/S059	05/28/2019	O - Normal 180 Day	IDESIGN REFRACTIVE STUDIO AND STAR S4 IR EXCIMER LASER SYSTEMS	AMO MANUFACTURING USA, LLC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P930039/S197	05/30/2019	O - Normal 180 Day	CAPSUREFIX NOVUS MRI SURESCAN LEAD	MEDTRONIC, INC.	Approval for labeling updates to the clinical study summary for the post-approval study.
P940010/S016	05/09/2019	N - Normal 180 Day	OPTIGUIDE FIBER OPTIC DIFFUSER (PB 200, PB 700 SERIES)	CONCORDIA LABORATORIES, INC	Approval for the design update for the OPTIGUIDE Diffusing Fiber Optics for the new series identified as the PB200 and PB700 Series of OPTIGUIDE Diffusing Fiber Optics and for the approval of a new manufacturing site. The new manufacturing site is Laser Peripherals LLC, 13355 10th Avenue, North Suite #110, Plymouth, Minnesota.
P940016/S026	05/22/2019	Y - 135 Review Tra	HEPARIN-INDUCED EXTRACORPOREAL LDL PRECIPITATION (H.E.L.P.) FUTURA APHERESIS SYSTEM	B. BRAUN AVITUM AG	Approval to change the test method for Total Blood Volume (TBV) and to remove TBV acceptance criteria for the batch release of the H.E.L.P. Ultrafilter HIPS 20.
P960009/S303	05/15/2019	Y - 135 Review Tra	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Approval for the implementation of the INS Bacterial Endotoxin Testing.

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P970004/S263	05/15/2019	Y - 135 Review Tra	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Approval for the implementation of the INS Bacterial Endotoxin Testing.
P980016/S707	05/30/2019	O - Normal 180 Day	EVERA MRI XT DR/VR SURESCAN, EVERA MRI S DR/VR SURESCAN AND VISIA AF MRI VR SURESCAN AND IMPLANTABLE CARDIOVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for labeling updates to the clinical study summary for the post-approval study.
P980035/S587	05/30/2019	O - Normal 180 Day	MEDTRONIC REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC INC.	Approval for labeling updates.
P990056/S036	05/03/2019	R - Real-Time Proc	ELECSYS TOTAL PSA TEST SYSTEM	ROCHE DIAGNOSTICS CORP.	Approval for addition of K2-EDTA plasma as an approved sample type for the Elecsys total PSA and Elecsys free PSA test systems.
P990071/S040	05/08/2019	O - Normal 180 Day	COOLFLOW IRRIGATION TUBING SET	BIOSENSE WEBSTER, INC.	Approval of the addition of a second source supplier for the CoolFlow Irrigation Tubing Set, which is a manufacturing site located at: Lake Region Medical, Inc. Venusa de Mexico S. de R.L. de C.V. 1525 Calle Hertz Street Parque Industrial Antonio J. Bermudez Ciudad Juarez, Chihuahua 32470 Mexico

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P990081/S039	05/03/2019	N - Normal 180 Day	PATHWAY ANTI-HER-2/NEU (4B5) RABBIT MONOCLONAL PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the Ventana Medical Systems, Inc.'s (Ventana) PATHWAY anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody (PATHWAY HER2 (4B5)) is a rabbit monoclonal antibody intended for laboratory use for the semi-quantitative detection of HER2 antigen in sections of formalin-fixed, paraffin-embedded normal and neoplastic tissue following staining on a BenchMark XT or BenchMark ULTRA instrument. It is indicated as an aid in the assessment of breast cancer patients for whom Herceptin® (trastuzumab) or KADCYLA® (ado-trastuzumab emtansine) treatment is being considered. Note: All of the patients in the Herceptin clinical trials were selected using a clinical trial assay. None of the patients in those trials were selected using PATHWAY anti-HER-2/neu (4B5). PATHWAY anti-HER-2/neu (4B5) was compared to PATHWAY HER-2 (clone CB11) Primary Antibody on an independent sample set and found to provide acceptably concordant results. The actual correlation of PATHWAY anti-HER-2/neu (4B5) to clinical outcome has not been established. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
P000008/S045	05/02/2019	Y - 135 Review Tra	LAP-BAND ADJUSTABLE GASTRIC BANDING SYSTEM	RESHAPE LIFESCIENCES, INC.	Approval for the pneumatic assist to automatically load and unload catheter tubing on the punch mandrel.
P000025/S108	05/08/2019	R - Real-Time Proc	FINETUNER ECHO	MED-EL CORP.	Approval for the FineTuner Echo of the Med-El Cochlear Implant System, which is a remote control (optional accessory) for compatible audio processors. It is the hardware successor of the previously approved FineTuner and includes minor design changes to the graphical user interface.
P000025/S109	05/08/2019	R - Real-Time Proc	AUDIOKEY 1.0 AND AUDIOLINK	MED-EL CORP.	Approval for AudioKey 1.0 and AudioLink. AudioKey 1.0 is an optional mobile medical application (App) that runs on smartphones with either the iOS or Android operating systems. When used with a compatible audio processor, AudioKey 1.0 (with smartphone) permits the same remote-control functions as the existing approved FineTuner remote control. AudioLink is an optional wireless hardware accessory that serves as an interface between an existing compatible MED-EL audio processor and a smartphone installed with AudioKey 1.0.
P000027/S034	05/03/2019	R - Real-Time Proc	ELECSYS FREE PSA TEST SYSTEM	ROCHE DIAGNOSTICS CORP.	Approval for addition of K2-EDTA plasma as an approved sample type for the Elecsys total PSA and Elecsys free PSA test systems.
P000053/S100	05/06/2019	R - Real-Time Proc	AMS 800 ARTIFICIAL URINARY SPHINCTER	BOSTON SCIENTIFIC CORP.	Approval for the additional steam sterilizer for finished devices which are not treated with antimicrobials.

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P000053/S101	05/06/2019	R - Real-Time Proc	AMS 800 ARTIFICAL URINARY SPHINCHTER	BOSTON SCIENTIFIC CORP.	Approval for addition of an alternate DI water system and steam generation system to feed an alternate steam sterilizer for terminal sterilization of devices without antimicrobials
P010014/S087	05/15/2019	S - Special CBE	OXFORD PARTIAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Approval for the addition of an updated in-process package and box and label inspection
P010031/S667	05/30/2019	O - Normal 180 Day	AMPLIA MRI CRT-D SURESCAN, AMPLIA MRI QUAD CRT-D SURESCAN, COMPIA MRI CRT-D SURESCAN, COMPIA MRI QUAD CRT-D SURESCAN AND IMPLANTABLE CARDIOVERTER DEFIBRILLATORS WITH CARDIAC RESYNCHRONIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for labeling updates to the clinical study summary for the post approval study.
P010032/S148	05/03/2019	R - Real-Time Proc	PROCLAIM SCS NEUROSTIMULATION SYSTEM FW	ABBOTT MEDICAL	Approval for an update to the firmware version to v1.3 for the legally marketed family Proclaim Spinal Cord Stimulation (SCS) Implantable Pulse Generators.
P020012/S029	05/03/2019	S - Special CBE	BELLAFILL DERMAL FILLER	SUNEVA MEDICAL, INC.	Approval for an added warning for periocular use.
P020025/S118	05/29/2019	R - Real-Time Proc	MAESTRO ABLATION CONNECTION BOX, INTELLANAV¿ OI	BOSTON SCIENTIFIC	Approval to design and labeling changes for the Maestro Ablation Connection Box (ACB) to be compliant with IEC 60601-1-2:2014.
P030005/S180	05/23/2019	N - Normal 180 Day	VALITUDE CRT-P, VISIONIST CRT-P, VALITUDE X4 CRT-P, VISIONIST X4 CRT-P	GUIDANT CORP.	Approval for modifying the Accolade family including pacemakers and CRT-P devices.
P030017/S323	05/14/2019	R - Real-Time Proc	PRECISION SPINAL CORD STIMULATOR (SCS) SYSTEMS -PRECISION SPECTRA, SPECTRA WAVEWRITER, PRECISION NOVI, PRECISION MONTAGE AND PRECISION MONTAGE MRI FIRMWARE UPDATE TO THE FREELINK REMOTE CONTROL	BOSTON SCIENTIFIC CORP.	Approval to activate the on-board Bluetooth (BLE) functionality of your Freelink RC4 remote control device. The activation of the BLE is for data transmission from the Freelink RC4 to an application on a non-medical mobile device for the purpose of data logging.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030028/S008	05/14/2019	R - Real-Time Proc	ARTISAN MYOPIA INTRAOCULAR LENS	OPHTEC BV	Approval for minor labeling changes for the Physicians Labeling and Patient Brochure.
P040020/S088	05/28/2019	R - Real-Time Proc	ACHROMATIZING RESTOR 2.5 INTRAOCULAR LENSES (IOLS)	ALCON RESEARCH, LTD.	Approval for two achromatizing ReSTOR +2.5 D Intraocular Lenses.
P040024/S103	05/17/2019	N - Normal 180 Day	RESTYLANE	Q-MED AB	Approval for revisions to the clinician and patient labeling of Restylane to include updated safety information based on post marketing surveillance data.
P040043/S106	05/14/2019	N - Normal 180 Day	GORE TAG THORACIC STENT GRAFT WITH ACTIVE CONTROL SYSTEM	W. L. GORE & ASSOCIATES, INC.	Approval for the following: 1) Modifications to the delivery system; 2) Implementation of six additional implant lengths; 3) Reduction in profile for a subset of device sizes; and 4) Updates to the Instructions for Use to reflect the changes in the device design and directions for use.
P050006/S071	05/28/2019	N - Normal 180 Day	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Approval for the addition of the GORE® CARDIOFORM ASD Occluder configuration to the GORE® HELEX® Septal Occluder product line
P050031/S003	05/28/2019	R - Real-Time Proc	PARAGON Z CRT (TISILFOCON A) AND PARAGON Z CRT DUAL AXIS (TISILFOCON A) CONTACT LENSES	PARAGON VISION SCIENCES	Approval to change the solution used in wet shipping of the Paragon Z CRT and Paragon Z CRT Dual Axis Contact Lenses from Alcon Laboratories Unique pH Multipurpose Solution to Bausch & Lombs Boston SIMPLUS Multipurpose Solution
P050052/S110	05/03/2019	O - Normal 180 Day	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval for the post-approval study labeling update for Radiesse Injectable Implant.
P070001/S017	05/31/2019	O - Normal 180 Day	PRODISC C TOTAL DISC REPLACEMENT	CENTINEL SPINE, LLC	Approval for updated labeling to reflect the Post Approval Study Protocol.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P080006/S133	05/30/2019	O - Normal 180 Day	ATTAIN ABILITY MRI SURESCAN LEAD, ATTAIN ABILITY PLUS MRI SURESCAN LEAD, ATTAIN ABILITY STRAIGHT MRI SURESCAN LEAD, ATTAIN PERFORMA MRI SURESCAN LEAD, ATTAIN PERFORMA STRAIGHT MRI SURESCAN LEAD AND ATTAIN PERFORMA S MRI SURESCAN LEAD	MEDTRONIC INC.	Approval for labeling updates to the clinical study summary for the post-approval study.
P080025/S158	05/15/2019	Y - 135 Review Tra	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Approval for the implementation of the INS Bacterial Endotoxin Testing.
P090013/S298	05/30/2019	O - Normal 180 Day	CAPSUREFIX MRI SURESCAN LEAD	MEDTRONIC, INC	Approval for labeling updates to the clinical study summary for the post-approval study.
P100010/S086	05/01/2019	O - Normal 180 Day	ARCTIC FRONT, FRONT ADVANCE CARDIAC CRYOABLATION, FREEZOR MAX & CRYOCONSOLESYSTEM	MEDTRONIC CRYOCATH LP	Approval for a labeling update to incorporate post-approval study data from the STOP AF Post Approval Study.
P100027/S030	05/03/2019	N - Normal 180 Day	INFORM HER2 DUAL ISH DNA PROBE COCKTAIL ASSAYS	VENTANA MEDICAL SYSTEMS, INC.	Approval for the Ventana Medical Systems, Incs (Ventana) INFORM HER2 Dual ISH DNA Probe Cocktail is intended to determine HER2 gene status by enumeration of the ratio of the HER2 gene to Chromosome 17. The HER2 and Chromosome 17 probes are detected by light microscopy using two color chromogenic in situ hybridization (ISH) in formalin-fixed, paraffin-embedded human breast cancer tissue specimens following staining on a BenchMark XT or BenchMark ULTRA instrument. The INFORM HER2 Dual ISH DNA Probe Cocktail is indicated as an aid in the assessment of breast cancer patients for whom Herceptin® (trastuzumab) or KADCYLA® (ado-trastuzumab emtansine) treatment is being considered. This product should be interpreted by a qualified reader in conjunction with histological examination, relevant clinical information, and proper controls. This reagent is intended for in vitro diagnostic (IVD) use.
P110038/S022	05/31/2019	O - Normal 180 Day	RELAY THORACIC STENT-GRAFT WITH PLUS DELIVERY SYSTEM	BOLTON MEDICAL, INC.	Approval for a sterilization site, Sterigenics U.S. LLC, located at 1148 Porter Avenue, Haw River, North Carolina 27258, as a new gamma sterilization site for the RelayPlus Thoracic Stent Graft System.

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P110042/S123	05/21/2019	R - Real-Time Proc	EMBLEM PROGRAMMER	BOSTON SCIENTIFIC CORPORATIO N	Approval for updates to the programmer software and minor labeling changes.
P120021/S008	05/23/2019	O - Normal 180 Day	AMPLATZER PFO OCCLUDER	ABBOTT MEDICAL	Approval for change to the inclusion/exclusion criteria, and the study timeline, for the PAS protocol.
P120024/S008	05/13/2019	R - Real-Time Proc	ACTIVEL ARTIFICIAL DISC	AESCULAP IMPLANT SYSTEMS, LLC	Approval for MR Conditional labeling for the activeL keel endplates.
P130017/S027	05/14/2019	N - Normal 180 Day	COLOGUARD	EXACT SCIENCES CORPORATIO N	Approval for removing the restriction that the assay may only be run at the single site located at 145 E. Badger Rd., Suite 100, Madison, Wisconsin. The device, as modified, will be marketed under the trade name Cologuard. Cologuard is intended for the qualitative detection of colorectal neoplasia associated DNA markers and for the presence of occult hemoglobin in human stool. Cologuard is for use with the Cologuard collection kit and the following instruments: BioTek® Epoch 2 Absorbance Microplate Reader; Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument; Hamilton Microlab® STARlet; and the Exact Sciences System Software with Cologuard Test Definition. Cologuard is intended for the qualitative detection of colorectal neoplasia associated DNA markers and for the presence of occult hemoglobin in human stool. A positive result may indicate the presence of colorectal cancer (CRC) or advanced adenoma (AA) and should be followed by diagnostic colonoscopy. Cologuard is indicated to screen adults of either sex, 50 years or older, who are at typical average-risk for CRC. Cologuard is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high risk individuals.
P130024/S027	05/23/2019	R - Real-Time Proc	LUTONIX 018 DRUG COATED BALLOON PTA CATHETER (LUTONIX DCB)	LUTONIX	Approval for the addition of 80, 100, 120, 150 and 220 mm balloon size lengths to the 7 mm diameter balloon on a .018 guidewire compatible catheter (Lutonix 018).
P140003/S049	05/06/2019	R - Real-Time Proc	IMPELLA 5.0	ABIOMED, INC.	Approval for a modification to the labeling to extend the duration of support from 6 days to 14 days.
P150005/S043	05/29/2019	R - Real-Time Proc	MAESTRO¿ ABLATION CONNECTION BOX, INTELLANAV¿ XP AND INTELLANAV¿ MIFI XP	BOSTON SCIENTIFIC CORP.	Approval for design and labeling changes for the Maestro Ablation Connection Box (ACB) to be compliant with IEC 60601-1-2:2014.
P150012/S068	05/23/2019	N - Normal 180 Day	ESSENTIO MRI, PROPONENT MRI, ACCOLADE MRI	BOSTONSCIE NTIFIC	Approval for modifying the Accolade family including pacemakers and CRT-P devices.
P160001/S038	05/29/2019	O - Normal 180 Day	OBALON BALLOON	OBALON	Approval for the revised protocol for the post-approval study (PAS) protocol.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160013/S002	05/31/2019	P - Panel Track	ORGAN CARE SYSTEM (OCS) LUNG SYSTEM	TRANSMEDICS, INC	Approval for the Organ Care System (OCS¿) Lung System. The TransMedics Organ Care System (OCS) Lung is a portable, normothermic organ perfusion, ventilation and monitoring medical device indicated for preservation of standard criteria donor lung pairs and for preservation of donor lung pairs initially deemed unacceptable for procurement and transplantation based on limitations of cold static preservation. The device allows for ex vivo assessment of donor lungs prior to transplantation.
P160030/S031	05/06/2019	N - Normal 180 Day	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval for adding the FreeStyle LibreLink App for Android as a compatible reading device and alternative primary display for the FreeStyle Libre System and FreeStyle Libre 14 Day System.
P160037/S002	05/13/2019	R - Real-Time Proc	ONCLARITY HPV ASSAY	BECTON, DICKINSON AND COMPANY	Approval for use of a modified SurePath vial for collection of specimens to be tested with the Onclarity HPV Assay, and the automated transfer of pre- and post- cytology aliquots using the BD Totalys Multiprocessor for testing with the BD Onclarity Assay.
P160050/S001	05/07/2019	O - Normal 180 Day	BARRICAID ANULAR CLOSURE DEVICE	INTRINSIC THERAPEUTICS	Approval of two protocols for the post-approval study (PAS) protocol.
P160050/S002	05/03/2019	Y - 135 Review Tra	BARRICAID ANULAR CLOSURE DEVICE	INTRINSIC THERAPEUTICS	Approval for the addition of a manufacturing site for manual lapping and the addition of an automated lapping step.
P160053/S001	05/08/2019	R - Real-Time Proc	MAGTRACETM AND SENTIMAG(R) MAGNETIC LOCATIZATION SYSTEM	ENDOMAGNETICS LTD.	Approval for packaging Magtrace vials with new replacement stoppers (i.e., West 1358).
P160054/S018	05/01/2019	N - Normal 180 Day	HEARTMATE 3 (HM3) LEFT VENTRICULAR ASSIST SYSTEM (LVAS)	THORATEC CORPORATION	Approval for various design modifications to the Pump Cover component.
P170003/S006	05/23/2019	R - Real-Time Proc	LUTONIX 018 DRUG COATED BALLOON PTA CATHETER (LUTONIX DCB)	LUTONIX	Approval for the addition of 80, 100, 120, 150 and 220 mm balloon size lengths to the 7 mm diameter balloon on a .018 guidewire compatible catheter (Lutonix 018).
P170011/S011	05/21/2019	O - Normal 180 Day	IMPELLA RP	ABIOMED, INC.	Approval of the revised protocol for the Impella RP-RWE Eval and Reporting post-approval study protocol.

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P170018/S003	05/02/2019	R - Real-Time Proc	LIFEPAK CR2 DEFIBRILLATOR	PHYSIO-CONTROL, INC	Approval for use of an alternate high-voltage capacitor from an alternate supplier.
P170035/S003	05/08/2019	N - Normal 180 Day	BAUSCH + LOMB ULTRA (SAMFILCON A) MULTIFOCAL FOR ASTIGMATISM CONTACT LENS	BAUSCH AND LOMB, INC.	Approval for Multifocal for Astigmatism.
P180002/S003	05/03/2019	O - Normal 180 Day	THE PULMONX ZEPHYR ENDOBRONCHIAL VALVE SYSTEM (EBV)	PULMONX CORPORATIO N	Approval for the Pulmonx Zephyr® Endobronchial Valves. These are implantable bronchial valves which are indicated for the bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation.
P180007/S003	05/21/2019	O - Normal 180 Day	SPIRATION VALVE SYSTEM	SPIRATION, INC.	Approval of the protocol for the post-approval study (PAS) protocol.
P180011/S004	05/02/2019	R - Real-Time Proc	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval to extend the shelf life of your device from 18 months to 24 months.
P180025/S001	05/24/2019	R - Real-Time Proc	MANTA VASCULAR CLOSURE DEVICE	ESSENTIAL MEDICAL, INC.	Approval for a reduction in the diameter of the lock advancement tube.
P180036/S001	05/21/2019	R - Real-Time Proc	OPTIMIZER SMART SYSTEM (IPG)	IMPULSE DYNAMICS (USA), INC.	Approval for updated labeling reflecting the increase in projected battery longevity of the OPTIMIZER SMART IPG.

Total: 78

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N12159/S055	05/15/2019	X - 30-Day Notice	SURGICEL ABSORBABLE HEMOSTATS	ETHICON, INC.	Replacement equipment.

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N12159/S056	05/17/2019	X - 30-Day Notice	SURGICEL ABSORBABLE HEMOSTATS	ETHICON, INC.	Modifications to the Respooling equipment.
N18033/S103	05/17/2019	X - 30-Day Notice	VISTAKON (ETAFILCON A) BRAND CONTACT LENSES	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Like-for-like replacement part used during the manufacturing process of VISTAKON (senofilcon A) and (etafilcon A) Contact Lenses.
N18033/S104	05/29/2019	X - 30-Day Notice	VISTAKON (ETAFILCON A) BRAND CONTACT LENSES	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Replacement of a steam sterilizer unit that is to be used in the manufacturing process of VISTAKON® (etafilcon A) Brand Contact Lenses.
P810006/S087	05/07/2019	X - 30-Day Notice	COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC SPONGE AND COLLSTAT ABSORBABLE COLLAGEN HEMOSTATIC - MICROFIBRILLAR FORM	INTEGRA LIFESCIENCES CORPORATION	Delete select surface contact sites from Routine Environmental Monitoring for the following rooms: CMC-105 and CMC-109 at the Integra LifeSciences Corporation, Collagen Manufacturing Center in Plainsboro, New Jersey.
P810006/S088	05/07/2019	X - 30-Day Notice	COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC SPONGE AND COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC - MICROFIBRILLAR FORM	INTEGRA LIFESCIENCES CORPORATION	Qualification of two (2) new Total Organic Carbon (TOC) Analyzers at the Quality Control (QC) Analytical Laboratory at the Collagen Manufacturing Center (CMC).
P830055/S229	05/10/2019	X - 30-Day Notice	LCS TOTAL KNEE SYSTEM - ATTUNE REVISION FEMORAL AND TIBIAL SLEEVES	DEPUY, INC.	Changes to the current processing of the ATTUNE Revision Femoral and Tibial Sleeves at the DePuy Warsaw, Indiana manufacturing site.
P830055/S230	05/17/2019	X - 30-Day Notice	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Manufacturing changes to the current in-process inspections of the ATTUNE CR and ATTUNE PS Femoral Components at the DePuy Raynham, Massachusetts manufacturing site.
P840001/S428	05/01/2019	X - 30-Day Notice	ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Update Medtronics manufacturing software, Manufacturing Execution System to Factory Works, to Release 9.6.

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P840001/S431	05/14/2019	X - 30-Day Notice	ITREL, SYNERGY, AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Inclusion of additional controls for reducing damages at the stylet coil assembly seals areas during the manufacturing process execution. This change also includes a new heat equipment model that modifies temperature operating parameters for the heat shrinking process.
P840001/S432	05/17/2019	X - 30-Day Notice	ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Change in the lid attach rework process for devices.
P840001/S433	05/23/2019	X - 30-Day Notice	ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Addition of alternate second tier suppliers to your primary component supplier.
P840001/S434	05/24/2019	X - 30-Day Notice	ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Use the new Loctite DAG 1050 material and to increase the graphite target solids concentration in the DAG material solution at Medtronic Tier II supplier, AVX Biddeford.
P840001/S435	05/30/2019	X - 30-Day Notice	ITREL, SYNERGY, AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Implementation of the Sterilization Automated Release (StAR) System to the sterilization operation at Medtronic Puerto Rico Operations Company (MPROC) Villalba facility in Puerto Rico.
P840062/S074	05/07/2019	X - 30-Day Notice	COLLACOTE, COLLATAPE, AND COLLAPLUG ABSORBABLE COLLAGEN WOUND DRESSINGS FOR DENTAL SURGERY	INTEGRA LIFESCIENCES CORP.	Delete select surface contact sites from Routine Environmental Monitoring for the following rooms: CMC-105 and CMC-109 at the Integra LifeSciences Corporation, Collagen Manufacturing Center in Plainsboro, New Jersey.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840062/S075	05/07/2019	X - 30-Day Notice	COLLACOTE, COLLATAPE, AND COLLAPLUG ABSORBABLE COLLAGEN WOUND DRESSINGS FOR DENTAL SURGERY	INTEGRA LIFESCIENCES CORP.	Qualification of two (2) new Total Organic Carbon (TOC) Analyzers at the Quality Control (QC) Analytical Laboratory at the Collagen Manufacturing Center (CMC).
P850010/S087	05/07/2019	X - 30-Day Notice	HELISTAT AND HELITENE ABSORBABLE COLLAGEN HEMOSTATIC AGENTS	INTEGRA LIFESCIENCES CORPORATION	Delete select surface contact sites from Routine Environmental Monitoring for the following rooms: CMC-105 and CMC-109 at the Integra LifeSciences Corporation, Collagen Manufacturing Center in Plainsboro, New Jersey.
P850010/S088	05/07/2019	X - 30-Day Notice	HELISTAT AND HELITENE ABSORBABALE COLLAGEN HEMOSTATIC AGENTS	INTEGRA LIFESCIENCES CORPORATION	Qualification of two (2) new Total Organic Carbon (TOC) Analyzers at the Quality Control (QC) Analytical Laboratory at the Collagen Manufacturing Center (CMC).
P850079/S082	05/08/2019	X - 30-Day Notice	METHAFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION, INC.	Relocation of three packaging/labeling lines to the new packaging and labeling facility in Mountpark. Southampton, United Kingdom.
P860004/S329	05/01/2019	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Update Medtronics manufacturing software, Manufacturing Execution System to Factory Works, to Release 9.6.
P860004/S331	05/24/2019	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM AND ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Use the new Loctite DAG 1050 material and to increase the graphite target solids concentration in the DAG material solution at Medtronic Tier II supplier, AVX Biddeford.
P890003/S410	05/13/2019	X - 30-Day Notice	CARELINK ENCORE PROGRAMMER, CARELINK ENCORE PROGRAMMER HEAD, CARELINK SMARTSYNC DEVICE MANAGER PATIENT CONNECTOR, CARELINK SMARTSYNC DEVICE MANAGER PROGRAMMER, MYCARELINK PATIENT MONITOR,MYCARELINK PATIENT MONITOR - READER, AND MYCARELINK SMART PATIENT READER	MEDTRONIC, INC.	Change in the Global Shop Floor software to include Part Load Verification functionality.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P900033/S079	05/07/2019	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE, INTERGRA MESHED DERMAL REGENERATION TEMPLATE, AND INTEGRA OMNIGRAFT DERMAL REGENERATION MATRIX	INTEGRA LIFESCIENCES CORP.	Delete select surface contact sites from Routine Environmental Monitoring for the following rooms: CMC-105 and CMC-109 at the Integra LifeSciences Corporation, Collagen Manufacturing Center in Plainsboro, New Jersey.
P900033/S080	05/07/2019	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE, INTEGRA MESHED DERMAL REGENERATION TEMPLATE AND INTEGRA OMNIGRAFT DERMAL REGENERATION MATRIX	INTEGRA LIFESCIENCES CORP.	Qualification of two (2) new Total Organic Carbon (TOC) Analyzers at the Quality Control (QC) Analytical Laboratory at the Collagen Manufacturing Center (CMC).
P900056/S178	05/30/2019	X - 30-Day Notice	ROTABLATOR ROTATIONAL ANGIOPLASTY SYSTEM GUIDEWIRE WITH WIRECLIP TORQUER	BOSTON SCIENTIFIC CORP.	Add an alternate external Process Challenge Device (ePCD) to the 40°C sterilization cycle.
P900061/S153	05/20/2019	X - 30-Day Notice	EPICARDIAL PATCH LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer of the parts passivation process for connectors and guide rings from Medtronic Rice Creek to Medtronic Puerto Rico Operations.
P910018/S026	05/22/2019	X - 30-Day Notice	LIPOSORBER LA-15 SYSTEM	KANEKA PHARMA AMERICA CORP.	Layout change of the manufacturing site for the LIPOSORBER LA-15 LDL Adsorption Column, a component of the LIPOSORBER LA-15 System device.
P920015/S228	05/01/2019	X - 30-Day Notice	HV SPLITTER/ADAPTOR KIT, SPRIINT QUATTRO LEAD	MEDTRONIC INC.	Manufacturing process update to the lead connector subassembly for high voltage leads.
P920047/S115	05/03/2019	X - 30-Day Notice	BLAZER II, BLAZER II HTD, BLAZER PRIME HTD, INTELLANAV ST	BOSTON SCIENTIFIC CORP.	Add a supplier for the yarn used for the control wire sleeve sub-assembly.
P930031/S064	05/30/2019	X - 30-Day Notice	WALLSTENT TIPS ENDOPROSTHESIS WITH UNISTEP PLUS	BOSTON SCIENTIFIC CORP.	Add an alternate external Process Challenge Device (ePCD) to the 40°C sterilization cycle.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P930038/S095	05/23/2019	X - 30-Day Notice	ANGIO-SEAL VASCULAR CLOSURE DEVICES	TERUMO MEDICAL CORPORATIO N	Transfer the procurement of, and receiving inspection activities for, certain components and raw materials used to manufacture ANGIO-SEAL Evolution devices from Abbott to Terumo Puerto Rico (TPR).
P940019/S055	05/30/2019	X - 30-Day Notice	WALLSTENT ILIAC ENDOPROSTEHSIS WITH UNISTEP PLUS DELIVERY SYSTEM	BOSTON SCIENTIFIC SCIMED, INC.	Add an alternate external Process Challenge Device (ePCD) to the 40°C sterilization cycle.
P950037/S201	05/07/2019	X - 30-Day Notice	PULSE GENEERATOR, PERMANENT, IMPLANTABLE	BIOTRONIK, INC.	Replacement vacuum and a new automated welding step.
P960009/S345	05/01/2019	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Update Medtronics manufacturing software, Manufacturing Execution System to Factory Works, to Release 9.6.
P960009/S348	05/24/2019	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Use the new Loctite DAG 1050 material and to increase the graphite target solids concentration in the DAG material solution at Medtronic Tier II supplier, AVX Biddeford.
P960009/S349	05/30/2019	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Implementation of the Sterilization Automated Release (StAR) System to the sterilization operation at Medtronic Puerto Rico Operations Company (MPROC) Villalba facility in Puerto Rico.
P960011/S031	05/01/2019	X - 30-Day Notice	BIOLON	AMRING PHARMACEUT ICALS	Qualification of an additional chamber and use of a modified ethylene oxide sterilization cycle for the BIOLON® Ophthalmic Viscosurgical Device (OVD).
P960016/S078	05/07/2019	X - 30-Day Notice	LIVEWIRE TC ABLATION CATHETER (LIVEWIRE TC)	ST. JUDE MEDICAL	Change in the air sampling methodology and equipment utilized in Controlled Access Environments.
P960043/S104	05/23/2019	X - 30-Day Notice	PROSTAR XL PERCUTANEOUS VASCULAR SURGICAL SYSTEM	ABBOTT VASCULAR INC.	Manufacturing move within an approved facility for the Prostar XL Percutaneous Vascular Surgical System and the StarClose SE Vascular Closure System.
P970003/S224	05/22/2019	X - 30-Day Notice	VNS THERAPY SYSTEM	LIVANOVA USA, INC.	Add an alternate hydrogen peroxide (HP) sterilizer (STERIS DLTS-V-S7) to the manufacturing process for the sterilization of all sterile VNS Therapy products including Generators (M102, M102R, M103, M104, M106, M1000, M7103 and M8103), Leads (M302, M303, M304 and M7304), Tunneler (M402), and the Accessory Pack (M502).
P970004/S286	05/01/2019	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS URINARY)	MEDTRONIC NEUROMODU LATION	Update Medtronics manufacturing software, Manufacturing Execution System to Factory Works, to Release 9.6.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970004/S287	05/17/2019	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (URINARY NEUROSTIMULATOR)	MEDTRONIC NEUROMODULATION	Change in the lid attach rework process for devices.
P970004/S288	05/23/2019	X - 30-Day Notice	SNS URINARY INTERSTIM THERAPY SYSTEM AND VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Addition of alternate second tier suppliers to your primary component supplier.
P970004/S289	05/24/2019	X - 30-Day Notice	SNS URINARY: INTERSTIM THERAPY SYSTEM AND VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	to use the new Loctite DAG 1050 material and to increase the graphite target solids concentration in the DAG material solution at Medtronic Tier II supplier, AVX Biddeford
P970029/S039	05/02/2019	X - 30-Day Notice	TMR HOLMIUM LASER SYSTEM	CRYOLIFE, INC.	Additional equipment to measure the seal strength of product pouches.
P980003/S089	05/03/2019	X - 30-Day Notice	CHILLI II	BOSTON SCIENTIFIC CORP.	Add a supplier for the yarn used for the control wire sleeve sub-assembly.
P980016/S704	05/01/2019	X - 30-Day Notice	EVERA MRI DF-1, EVERA MRI, EVERA S DR, EVERA S VR, EVERA XT DR, EVERA XT VR, MIRRO MRI DR, MIRRO MRI VR, PRIMO MRI DR, PRIMO MRI VR, PROTECTA, PROTECTA VR, PROTECTA XT, SECURA DR, SECURA, VISIA AF MRI DF1, VISIA AF MRI VR, AND VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Change to the lid attach rework process.
P980016/S705	05/03/2019	X - 30-Day Notice	EVER MRI DF-1 ICD, EVER MRI ICD, EVER S DR/VR ICD, EVERA XT DR/VR ICD, MIRRO MRI DR/VR ICD, PRIMO MRI DR/VR ICD, VISIA AF MRI DF1/VR ICD, VISIA AF VR IC, SECURA DR ICD, SECURA/ PROTECTA ICD, PROTECTA VR/XT ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modify ionic contamination monitoring.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S706	05/20/2019	X - 30-Day Notice	EVERA MRI DF-1 ICD, EVERA MRI ICD, EVERA S DR ICD, EVERA S VR ICD, MIRRO MRI DR ICD, PRIMO MRI DR ICD, PROTECTA ICD, PROTECTA VR ICD, PROTECTA XT ICD, SECURA DR ICD, SECURA ICD, VISIA AF MRI DF1 ICD, VISIA AF MRI VR ICD, VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer of the parts passivation process for connectors and guide rings from Medtronic Rice Creek to Medtronic Puerto Rico Operations.
P980023/S092	05/24/2019	X - 30-Day Notice	PHYLAX ICD SYSTEM	BIOTRONIK, INC.	Additional supplier for the 8F ring electrodes used in tachycardia leads.
P980024/S020	05/08/2019	X - 30-Day Notice	PATHVYSION HER-2 DA PROBE KIT	ABBOTT MOLECULAR, INC.	Change to a critical reagent supplier¿s location.
P980033/S054	05/30/2019	X - 30-Day Notice	WALLSTENT VENOUS ENDOPROSTHESIS WITH UNISTEP PLUS	BOSTON SCIENTIFIC CORPORATION	Add an alternate external Process Challenge Device (ePCD) to the 40°C sterilization cycle.
P980035/S586	05/01/2019	X - 30-Day Notice	ADAPTA, VERSA, SENSIA, ADVISA DR, ADVISA DR MRI, ADVISA SR MRI, ASTRA S DR MRI, ASTRA S SR MRI, ASTRA XT DR MRI, ASTRA XT SR MRI, ATTESTA DR MRI, ATTESTA SR MRI, AZURE S DR MRI, AZURE XT DR MRI, AZURE XT SR MRI, RELIA, SPHERA DR MRI, AND SPHERA SR MRI IPG	MEDTRONIC INC.	Change to the lid attach rework process.
P980035/S588	05/06/2019	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ATTESTA DR/SR MRI IPG, RELIA IPG, AND SPHERA DR/SR MRI IPG	MEDTRONIC INC.	Changes to the Prodigy Hybrid Tester.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980035/S589	05/03/2019	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ATTESTA DR/SR MRI IPG, RELIA IPG, SPHERA DR/SR MRI IPG, ASTRA S DDR/SR MRI IPG, ASTRA XT DR/SR MRI IPG, AZURE S DR/SR MRI IPG, AZURE XT DR/SR MRI IPG, ADVISA DR IPG AND ADVISA DR/SR MRI IPG	MEDTRONIC INC.	Modify ionic contamination monitoring.
P980035/S590	05/20/2019	X - 30-Day Notice	ADVISA DR IPG, ADVISA DR MRI VR ICD, ADVISA DR MRI IPG, ASTRA S DR MRI IPG, ASTRA S SR MRI IPG, ASTRA XT DR IPG, ASTRA XT SR MRI IPG, AZURE S DR MRI IPG, AZURE S SR MRI IPG, AZURE XT DR MRI IPG, AZURE XT SR MRI IPG	MEDTRONIC INC.	Transfer of the parts passivation process for connectors and guide rings from Medtronic Rice Creek to Medtronic Puerto Rico Operations.
P980035/S591	05/20/2019	X - 30-Day Notice	ADAPTA, VERSA, AND SENSIA IPG, ADVISA SR MRI IPG, ATTESTA DR MRI IPG, ATTESTA SR MRI IPG, RELIA IPG, SPHERA DR MRI IPG, AND SPHERA SR MRI IPG.	MEDTRONIC INC.	Addition of the Relative Humidity monitoring process to monitor the internal relative humidity in the device.

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P980035/S592	05/13/2019	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ADVISA DR IPG, ADVISA DR MRI IPG, ADVISA SR MRI IPG, ASTRA S DR MRI IPG, ASTRA S SR MRI IPG, ASTRA XT DR MRI IPG, ASTRA XT SR MRI IPG, ATTESTA DR MRI IPG, ATTESTA SR MRI IPG, AZURE S DR MRI IPG, AZURE S SR MRI IPG, AZURE XT DR MRI IPG, AZURE XT SR MRI IPG, RELIA IPG, SPHERA DR MRI IPG AND SPHERA SR MRI IPG	MEDTRONIC INC.	Change to an alternate formulation of a dispersion of aqueous graphite and to increase the graphite solids concentration used in tantalum capacitors.
P980035/S593	05/29/2019	X - 30-Day Notice	ASTRA S DR/SR MRI IPG, ASTRA XT DR/SR MRI IPG, AZURE S DR/SR MRI IPG, AND AZURE XT DR/SR MRI IPG	MEDTRONIC INC.	Changes to Orion and CRT-P hybrid testing procedures.
P990009/S054	05/15/2019	X - 30-Day Notice	FLOSEAL HEMOSTATIC MATRIX	BAXTER HEALTHCARE CORP.	Modify the water purification system that is used to provide water for the manufacture of Floseal Hemostatic Matrix.
P990081/S040	05/06/2019	X - 30-Day Notice	PPATHWAY ANTI-HER-2/ NEU (4B5) RABBIT MONOCLONAL PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Manufacturing process changes in Pathway anti-her-2/neu (4b5) rabbit monoclonal primary antibody.
P010012/S503	05/13/2019	X - 30-Day Notice	ACUITY X4 LINERS	BOSTON SCIENTIFIC CORP.	Addition of a mold release agent to the liner supply items during the distal silicone body manufacturing process.
P010014/S086	05/02/2019	X - 30-Day Notice	OXFORD PARTIAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Introduction of a new formulation for the production face coat slurry used in the casting process for Oxford femoral and tibial components.
P010014/S088	05/15/2019	X - 30-Day Notice	OXFORD PARTIAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Implement a continuous environmental monitoring system.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S402	05/01/2019	X - 30-Day Notice	CONSULTA, PERCEPTA BIPOLAR, PERCEPTA QUADRIPOLAR, SERENA BIPOLAR, SERENA QUADRIPOLAR, SOLARA BIPOLAR, SOLARA QUADRIPOLAR, SYNCA, AND VIVA CRT-P	MEDTRONIC INC.	Change to the lid attach rework process.
P010015/S403	05/03/2019	X - 30-Day Notice	PERCEPTA/SERENA/ SOLARA BIPOLAR CRT-P, PERCEPTA/SERENA ADN SOLARA QUADRIPOLAR CRT-P, CONSULTA, SYNCRA AND VIVA CRT-P	MEDTRONIC INC.	Modify ionic contamination monitoring.
P010015/S404	05/20/2019	X - 30-Day Notice	PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P, SOLARA BIPOLAR CRT-P, SOLARA QUADRIPOLAR CRT-P	MEDTRONIC INC.	Transfer of the parts passivation process for connectors and guide rings from Medtronic Rice Creek to Medtronic Puerto Rico Operations.
P010015/S405	05/13/2019	X - 30-Day Notice	CONSULTA, SYNCRA, AND VIVA CRT-P	MEDTRONIC INC.	Change to an alternate formulation of a dispersion of aqueous graphite and to increase the graphite solids concentration used in tantalum capacitors.
P010015/S406	05/29/2019	X - 30-Day Notice	PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIOPOLAR CRT-P AND SERENA QUADRIPOLAR	MEDTRONIC INC.	Changes to Orion and CRT-P hybrid testing procedures.
P010029/S028	05/08/2019	X - 30-Day Notice	EUFLEXXA (1% SODIUM HYALURONATE)	FERRING PHARMACEUTICALS, INC.	Addition of an alternative supplier of the syringes used to inject EUFLEXXA.
P010030/S117	05/20/2019	X - 30-Day Notice	LIFE VEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Updates to the Automated Monitor Detect and Treat test software.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S664	05/01/2019	X - 30-Day Notice	AMPLIA MRI, AMPLIA MRI QUAD, BRAVA, BRAVA QUAD, CLARIA MRI, CLARIA MRI QUAD, CONSULTA, PROTECTA, PROTECTA XT, VIVA QUAD S, VIVA QUAD XT, VIVA S, AND VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Change to the lid attach rework process.
P010031/S665	05/03/2019	X - 30-Day Notice	AMPLIA/CLARIA/COMPIA MRI CRT-D, AMPLA/ CLARIA/COMPIA MRI QUAD CRT-D, BRAVA CRT-D, BRAVA QUAD CRT-D, VIVA QUAD S/XT CRT-D, VIVA S/ XT CRT-D, CONSULTA/ PROTECTA CRT-D AND PROTECTA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modify ionic contamination monitoring.
P010031/S666	05/20/2019	X - 30-Day Notice	AMPLIA MRI CRT-D, AMPLIA MRI QUAD CRT-D, BRAVA CRT-D, BRAVA QUAD CRT-D, CLARIA MRI CRT-D, CLARIA MRI QUAD CRT-D, COMPIA MRI CRT-D, CONSULTA 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	Transfer of the parts passivation process for connectors and guide rings from Medtronic Rice Creek to Medtronic Puerto Rico Operations.
P020004/S165	05/13/2019	X - 30-Day Notice	GORE EXCLUDER AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Add a manufacturing line at a packaging component supplier.
P020025/S119	05/03/2019	X - 30-Day Notice	BLAZER II XP, BLAZER PRIME XP, INTELLATIP MIFI XP, INTELLANAV XP, INTELLANAV MIFI XP	BOSTON SCIENTIFIC	Add a supplier for the yarn used for the control wire sleeve sub-assembly.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030036/S109	05/29/2019	X - 30-Day Notice	SELECTSECURE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to finished product release and stability test methods for identity, assay, content uniformity and related substances.
P030045/S005	05/23/2019	X - 30-Day Notice	VISI-PRO BALLOON-EXPANDABLE PERIPHERAL STENT SYSTEM	MEDTRONIC VASCULAR INC	Implement new heat sealing equipment.
P030052/S025	05/08/2019	X - 30-Day Notice	UROVYSION BLADDER CANCER KIT	ABBOTT MOLECULAR	Change to a critical reagent suppliers location.
P040021/S041	05/20/2019	X - 30-Day Notice	BIOCOR, BIOCOR SUPRA, EPIC, AND EPIC SUPRA VALVES	ST. JUDE MEDICAL, INC.	Two new tissue suppliers for bioprosthetic heart valves.
P040024/S110	05/15/2019	X - 30-Day Notice	RESTYLANE AND PERLANE	Q-MED AB	Alternative to the sodium chloride solution utilized in the manufacturing of Restylane and Perlane.
P040027/S073	05/13/2019	X - 30-Day Notice	GORE VIATORR TIPS ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Add a manufacturing line at a packaging component supplier.
P040037/S132	05/13/2019	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Add a manufacturing line at a packaging component supplier.
P040043/S111	05/13/2019	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Add a manufacturing line at a packaging component supplier.
P040045/S107	05/17/2019	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Like-for-like replacement part used during the manufacturing process of VISTAKON (senofilcon A) and (etafilcon A) Contact Lenses.
P040045/S108	05/22/2019	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Alternate supplier for a raw material used in the VISTAKON (senofilcon A) Brand Contact Lenses.

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P050007/S038	05/23/2019	X - 30-Day Notice	STARCLOSE SE VASCULAR CLOSURE SYSTEM	ABBOTT VASCULAR DEVICES	Manufacturing move within an approved facility for the Prostar XL Percutaneous Vascular Surgical System and the StarClose SE Vascular Closure System.
P050023/S131	05/07/2019	X - 30-Day Notice	TUPOS LV/ATX AND KRONOS LV-T CRT-D SYSTEM	BIOTRONIK, INC.	Replacement vacuum and a new automated welding step.
P050028/S075	05/08/2019	X - 30-Day Notice	COBAS TAQMAN HBV TEST FOR USE ON THE HIGH PURE SYSTEM AND COBAS AMPLIPREP/COBAS TAQMAN HBV TEST, V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Modifications to current oligo purification manufacturing processes.
P050028/S076	05/22/2019	X - 30-Day Notice	COBAS TAQMAN HBV TEST FOR USE WITH THE HIGH PURE SYSTEM AND COBAS AMPLIPREP/COBAS TAQMAN HBV TEST, V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Changes in manufacturing gowning procedures
P050037/S094	05/17/2019	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Qualification of a newer model thermal validation system.
P050047/S070	05/10/2019	X - 30-Day Notice	JUVÉDERM INJECTABLE GEL IMPLANTS	ALLERGAN	Implementation of an additional identical tank used to manufacture high molecular weight hyaluronic acid (HA) at the raw material supplier.
P050052/S111	05/17/2019	X - 30-Day Notice	RADIESSSE HANDS, AND RADIESSE (+) LIDOCAINE DERMAL FILLER	MERZ NORTH AMERICA, INC	Qualification of a newer model thermal validation system.
P060001/S027	05/23/2019	X - 30-Day Notice	PROTEGE RX CAROTID STENT SYSTEMS AND PROTEGE GPS PERIPHERAL STENT SYSTEMS	MEDTRONIC VASCULAR INC	Implement new heat sealing equipment.
P060030/S074	05/08/2019	X - 30-Day Notice	COBAS TAQMAN HCV TEST, V2.0 FOR USE ON THE HIGH PURE SYSTEM	ROCHE MOLECULAR SYSTEMS, INC.	Modifications to current oligo purification manufacturing processes.
P060030/S075	05/09/2019	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST, V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Addition of instrumentation qualified to be used to purify oligonucleotides.

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P060030/S076	05/22/2019	X - 30-Day Notice	COBAS TAQMAN HCV TEST, V2.0, FOR USE WITH THE HIGH PURE SYSTEM AND COBAS AMPLIPREP/ COBAS TAQMAN HCV TEST, V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Changes in manufacturing gowning procedures
P070008/S103	05/07/2019	X - 30-Day Notice	STRATOS LV/LV-T CRT-P SYSTEM	BIOTRONIK, INC.	Replacement vacuum and a new automated welding step.
P080006/S132	05/14/2019	X - 30-Day Notice	ATTAIN STABILITY QUAD MRI SURESCAN	MEDTRONIC INC.	Align the manufacturing process of the Attain Stability Quad lead with existing manufacturing of predecessor Attain Performa leads.
P080011/S092	05/08/2019	X - 30-Day Notice	COMFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION MANUFACTURING, LTD.	Relocation of three packaging/labeling lines to the new packaging and labeling facility in Mountpark. Southampton, United Kingdom.
P080011/S093	05/31/2019	X - 30-Day Notice	COMFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION MANUFACTURING, LTD.	Alternate manufacturer for a raw material for use in the manufacture of Biofinity (comfilcon A) soft contact lenses at both the CooperVision Hamble, United Kingdom and Juana Diaz, Puerto Rico manufacturing sites.
P080025/S181	05/01/2019	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS BOWEL)	MEDTRONIC NEUROMODULATION	Update Medtronics manufacturing software, Manufacturing Execution System to Factory Works, to Release 9.6.
P080025/S182	05/17/2019	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (BOWEL NEUROSTIMULATORS)	MEDTRONIC NEUROMODULATION	Change in the lid attach rework process for devices.
P080025/S183	05/23/2019	X - 30-Day Notice	SNS BOWEL INTERSTIM THERAPY SYSTEM AND VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Addition of alternate second tier suppliers to your primary component supplier.
P080025/S184	05/24/2019	X - 30-Day Notice	SNS BOWEL: INTERSTIM THERAPY SYSTEM AND VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Use the new Loctite DAG 1050 material and to increase the graphite target solids concentration in the DAG material solution at Medtronic Tier II supplier, AVX Biddeford.
P080026/S022	05/15/2019	X - 30-Day Notice	REALTIME HBV	ABBOTT MOLECULAR, INC.	Implement additional QC to device accessory kits.

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P090003/S046	05/30/2019	X - 30-Day Notice	EXPRESS LD ILIAC PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORPORATIO N	Add an alternate external Process Challenge Device (ePCD) to the 40°C sterilization cycle.
P100010/S090	05/29/2019	X - 30-Day Notice	ARCTIC FRONT ADVANCE AND ARCTIC FRONT ADVANCE PRO CARDIAC CRYOABLATION CATHETERS	MEDTRONIC CRYOCATH LP	Add inspections on the inner balloon and catheter handle and to include an alternate process monitoring using variable data.
P100010/S091	05/03/2019	X - 30-Day Notice	ARCTIC FRONT ADVANCE CARDIAC CRYOABLATION CATHETERS	MEDTRONIC CRYOCATH LP	Addition of a pin gauge inspection to verify catheter tubing diameter.
P100010/S092	05/08/2019	X - 30-Day Notice	ARTIC FRONT ADVANCE CARDIAC CRYOABLATION CATHETERS	MEDTRONIC CRYOCATH LP	Modification of the bonding process for two check valves.
P100013/S019	05/01/2019	X - 30-Day Notice	CORDIS EXOSEAL VASCULAR CLOSURE DEVICE	CORDIS CORPORATIO N	Change in 2nd tier supplier for the Brite Finish Indicator Wire Lumen Tube component.
P100017/S022	05/15/2019	X - 30-Day Notice	REALTIME HCV	ABBOTT MOLECULAR, INC.	Implement additional QC to device accessory kits.
P100018/S020	05/22/2019	X - 30-Day Notice	PIPELINE FLEX EMBOLIZATION DEVICE	MICRO THERAPEUTI CS DBA EV3 NEUROVASC ULAR	Upgrades to the laser equipment used to form the distal tip of the introducer sheath of the Pipeline Flex Embolization device.
P100020/S044	05/03/2019	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Increase in scale and other process changes for the manufacture of synthesized oligonucleotides.
P100020/S045	05/08/2019	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Modifications to current oligo purification manufacturing processes.
P100020/S046	05/09/2019	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Addition of instrumentation qualified to be used to purify oligonucleotides.

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P100020/S047	05/22/2019	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Changes in manufacturing gowning procedures.
P100021/S076	05/05/2019	X - 30-Day Notice	ENDURANT, ENDURANT II AND ENDURANT IIS STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Implement a bioburden reduction step in the manufacturing process for the Endurant and Valiant Captivia endovascular grafts.
P100026/S068	05/24/2019	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Addition of a new wafer sort test to the manufacturing flow of the RNS® Neurostimulator (model RNS-320). This testing service will be performed at a new supplier, NeuroPace¿s approved supplier Integra Technologies (located at 1635 McCarthy Blvd, Milpitas, CA 95035).
P100029/S040	05/20/2019	X - 30-Day Notice	TRIFECTA VALVE AND TRIFECTA VALVE WITH GLIDE TECHNOLOGY (TRIFECTA GT)	ST. JUDE MEDICAL, INC.	Two new tissue suppliers for bioprosthetic heart valves.
P100040/S038	05/05/2019	X - 30-Day Notice	VALIANT THORACIC STENT GRAFT WITH THE CAPTIVIA DELIVERY SYSTEM	MEDTRONIC VASCULAR	Implement a bioburden reduction step in the manufacturing process for the Endurant and Valiant Captivia endovascular grafts.
P100044/S039	05/23/2019	X - 30-Day Notice	PROPEL, PROPEL MINI AND PROPEL CONTOUR SINUS IMPLANTS	INTERSECT ENT	Adding an alternate warehouse facility for the Propel, Propel Mini and Propel Contour Sinus Implants.
P100044/S040	05/31/2019	X - 30-Day Notice	PROPEL CONTOUR SINUS IMPLANT	INTERSECT ENT	Change to the in-process acceptance criterion for the mometasone furoate (MF) coating solution assay from a concentration range of 5.9- 6.2 mg/mL to 5.8- 6.1 mg/mL to align with the manufacturing target and lot history data.
P100044/S041	05/31/2019	X - 30-Day Notice	PROPEL CONTOUR SINUS IMPLANT	INTERSECT ENT	Alternate supplier for the raw fibers used in the manufacture of the Propel Contour Sinus Implant.
P110012/S018	05/08/2019	X - 30-Day Notice	VYSIS ALK BREAK APART FISH PROBE KIT	ABBOTT MOLECULAR, INC.	Change to a critical reagent suppliers location.
P110016/S062	05/07/2019	X - 30-Day Notice	FLEXABILITY ABLATION CATHETER (FLEX) AND FLEXABILITY ABLATION CATHETER, SENSOR ENABLE (FLEX SE)	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Change in the air sampling methodology and equipment utilized in Controlled Access Environments.
P110020/S032	05/22/2019	X - 30-Day Notice	COBAS BRAF V600 MUTTAION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Changes in manufacturing gowning procedures.

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P110023/S026	05/23/2019	X - 30-Day Notice	EVERFLEX SELF-EXPANDING PERIPHERAL STENT SYSTEMS AND EVERFLEX SELF-EXPANDING PERIPHERAL STENT WITH ENTRUST DELIVERY SYSTEMS	MEDTRONIC VASCULAR INC	Implement new heat sealing equipment.
P110033/S045	05/10/2019	X - 30-Day Notice	JUVÉDERM INJECTABLE GEL IMPLANTS	ALLERGAN	Implementation of an additional identical tank used to manufacture high molecular weight hyaluronic acid (HA) at the raw material supplier.
P110035/S049	05/09/2019	X - 30-Day Notice	EPIC VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Replace a Tier 2 material supplier.
P110037/S046	05/09/2019	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN CMV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Addition of instrumentation qualified to be used to purify oligonucleotides.
P110037/S047	05/22/2019	X - 30-Day Notice	COBAS® AMLIPREP/ COBAS® TAQMAN® CMV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Changes in manufacturing gowning procedures
P120012/S018	05/15/2019	X - 30-Day Notice	ABBOTT REALTIME HCV GT II	ABBOTT MOLECULAR	Implement additional QC to device accessory kits.
P120019/S028	05/22/2019	X - 30-Day Notice	COBAS EGFR MUTATION TEST AND COBAS EGFR MUTATION TEST, V2.0	ROCHE	Changes in manufacturing gowning procedures.
P130006/S071	05/13/2019	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Add a manufacturing line at a packaging component supplier.
P130017/S030	05/16/2019	X - 30-Day Notice	COLOGUARD STOOL DNA-BASED COLORECTAL CANCER SCREENING TEST	EXACT SCIENCES CORPORATION	Alternative supplier for components.
P130026/S045	05/07/2019	X - 30-Day Notice	TACTICATH CONTACT FORCE ABLATION CATHETER, SENSOR ENABLED (TACTICATH SE)	ST. JUDE MEDICAL	Change in the air sampling methodology and equipment utilized in Controlled Access Environments.

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P130028/S023	05/31/2019	X - 30-Day Notice	ALGOVITA SPINAL CORD STIMULATION (SCS): 12-ELECTRODE PERCUTANEOUS LEADS, AND TRIAL LEADS	NUVECTRA CORPORATION	Implementation of an update to the injection molding process for the distal subassembly of the Algovita Spinal Cord Stimulation (SCS) Leads.
P140003/S051	05/06/2019	X - 30-Day Notice	IMPELLA 5.0 SYSTEM	ABIOMED, INC.	Alternative manufacturing method for the Impella 5.0 cannula.
P140010/S044	05/10/2019	X - 30-Day Notice	IN.PACT ADMIRAL PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Use of an optical aid during the drug-coating process.
P140010/S045	05/23/2019	X - 30-Day Notice	IN.PACT ADMIRAL PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CHATHETER	MEDTRONIC INC.	Changes to sampling requirements for Bacterial Endotoxin Testing (BET).
P140023/S020	05/22/2019	X - 30-Day Notice	COBAS KRAS MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Changes in manufacturing gowning procedures.
P140028/S039	05/09/2019	X - 30-Day Notice	LNNOVA SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Replace a Tier 2 material supplier.
P140032/S031	05/01/2019	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Update Medtronics manufacturing software, Manufacturing Execution System to Factory Works, to Release 9.6.
P140032/S033	05/24/2019	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Use the new Loctite DAG 1050 material and to increase the graphite target solids concentration in the DAG material solution at Medtronic Tier II supplier, AVX Biddeford.
P140033/S045	05/29/2019	X - 30-Day Notice	TENDRIL MRI STEROID ELUTING CARDIAC LEADS	ST. JUDE MEDICAL, INC.	Manufacturing process improvements for monolithic controlled release devices used in Tendril MRI1200M leads.
P150001/S063	05/01/2019	X - 30-Day Notice	MINIMED 630G SYSTEM	MEDTRONIC MINIMED	Addition of a second production line for the printed circuit board assembly (PCBA) component to increase manufacturing capacity for the Guardian Sensor (3) continuous lucose monitoring sensor. The Guardian Sensor (3) is a component of the MiniMed 630G, Guardian Connect System, and MiniMed 670G systems.
P150001/S064	05/01/2019	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED	New manufacturing equipment for the sensor component of the Guardian Connect System, the MiniMed 630G System, and the MiniMed 670G System.

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P150002/S002	05/30/2019	X - 30-Day Notice	INCRAFT AAA STENT GRAFT SYSTEM	CORDIS CORPORATIO N	Movement of INCRAFT manufacturing to another building at the same facility and addition of a semi-automated process step during the inner member assembly.
P150005/S044	05/03/2019	X - 30-Day Notice	BLAZER OPEN-IRRIGATED ABLATION CATHETER, INTELLANAV OPEN-IRRIGATED ABLATION CATHETER, INTELLATIP MIFI OPEN-IRRIGATED ABLATION CATHETERS, INTELLANAV MIFI OPEN-IRRIGATED ABLATION CATHETERS	BOSTON SCIENTIFIC CORP.	Add a supplier for the yarn used for the control wire sleeve sub-assembly.
P150005/S046	05/23/2019	X - 30-Day Notice	OPEN IRRIGATION (OI) ABLATION CATHETER FAMILIES: BLAZER OI, INTELLATIP MIFI OI, INTELLANAV OI, AND INTELLANAV MIFI OI ABLATION CATHETERS	BOSTON SCIENTIFIC CORP.	Alternative supplier for the Dual Taper Cooling Lumen used in the Open Irrigation (OI) Ablation Catheter families.
P150012/S077	05/23/2019	X - 30-Day Notice	INGEVITY LEADS	BOSTONSCIE NTIFIC	Replace the current manual trimming process with a new Outer Coil Cutting Fixture.
P150014/S024	05/03/2019	X - 30-Day Notice	COBAS HBV	ROCHE MOLECULAR SYSTEMS, INC.	Increase in scale and other process changes for the manufacture of synthesized oligonucleotides.
P150014/S025	05/09/2019	X - 30-Day Notice	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Addition of instrumentation qualified to be used to purify oligonucleotides.
P150014/S026	05/24/2019	X - 30-Day Notice	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Change the cleaning procedures for equipment used to manufacture a bulk reagent.
P150014/S027	05/22/2019	X - 30-Day Notice	COBAS HBV	ROCHE MOLECULAR SYSTEMS, INC.	Changes in manufacturing gowning procedures

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P150015/S025	05/03/2019	X - 30-Day Notice	COBAS HCV	ROCHE MOLECULAR SYSTEMS, INC.	Increase in scale and other process changes for the manufacture of synthesized oligonucleotides.
P150015/S026	05/08/2019	X - 30-Day Notice	COBAS HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Modifications to current oligo purification manufacturing processes.
P150015/S027	05/09/2019	X - 30-Day Notice	COBAS HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Addition of instrumentation qualified to be used to purify oligonucleotides.
P150015/S028	05/22/2019	X - 30-Day Notice	COBAS HCV	ROCHE MOLECULAR SYSTEMS, INC.	Changes in manufacturing gowning procedures
P150015/S029	05/24/2019	X - 30-Day Notice	COBAS HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Change the cleaning procedures for equipment used to manufacture a bulk reagent.
P150021/S041	05/10/2019	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Introduction of an additional circuit printing line used in the fabrication of the glucose sensor, which is a common component of the Freestyle Libre Flash Glucose Monitoring System, Freestyle Libre Pro Flash Glucose Monitoring System, and Freestyle Libre 14 day Flash Glucose Monitoring System.
P150031/S018	05/02/2019	X - 30-Day Notice	VERCISE, VERCISE PC, AND VERCISE GEVIA DEEP BRAIN STIMULATION (DBS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Expansion of Controlled Environmental Areas (CEA) for manufacturing of leads and accessories for the Vercise Deep Brain Stimulation (DBS) systems.
P150031/S019	05/03/2019	X - 30-Day Notice	VERCISE, VERCISE PC, AND VERCISE GEVIA DEEP BRAIN STIMULATION (DBS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Alternate shielding gas (100% Argon) to the current shielding gas comprised of Argon (75%) and Helium (25%) during the laser welding process.
P150033/S054	05/03/2019	X - 30-Day Notice	MICRA TPS	MEDTRONIC INC.	Modify ionic contamination monitoring.
P150041/S005	05/08/2019	X - 30-Day Notice	VYSIS CLL FISH PROBE KIT	ABBOTT MOLECULAR, INC.	Change to a critical reagent suppliers location.
P160001/S037	05/16/2019	X - 30-Day Notice	OBALON NAVIGATION BALLOON KIT	OBALON THERAPEUTICS, INC.	Add an inspection step for the Navigation Catheter¿s proximal luer.

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P160004/S028	05/13/2019	X - 30-Day Notice	GORE TIGRIS VASCULAR STENT	W. L. GORE & ASSOCIATES, INC.	Add a manufacturing line at a packaging component supplier.
P160007/S017	05/01/2019	X - 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	New manufacturing equipment for the sensor component of the Guardian Connect System, the MiniMed 630G System, and the MiniMed 670G System.
P160017/S059	05/01/2019	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Addition of a second production line for the printed circuit board assembly (PCBA) component to increase manufacturing capacity for the Guardian Sensor (3) continuous lucose monitoring sensor. The Guardian Sensor (3) is a component of the MiniMed 630G, Guardian Connect System, and MiniMed 670G systems.
P160017/S060	05/01/2019	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	New manufacturing equipment for the sensor component of the Guardian Connect System, the MiniMed 630G System, and the MiniMed 670G System.
P160021/S021	05/13/2019	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Add a manufacturing line at a packaging component supplier.
P160021/S022	05/24/2019	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Modification to your heparin activity sampling plan.
P160023/S013	05/21/2019	X - 30-Day Notice	APTIMA HCV QUANT DX ASSAY	HOLOGIC, INC.	Remove QC release testing for a device ancillary kit.
P160026/S006	05/09/2019	X - 30-Day Notice	LIFEPAK® 20E DEFIBRILLATOR/MONITOR	PHYSIO-CONTROL. INC.	Manufacturing process change that impacts the pulse oximetry (Sp02) module component of the LIFEPAK 20e defibrillator/monitor.
P160026/S008	05/17/2019	X - 30-Day Notice	LIFEPAK AUTOMATED EXTERNAL DEFIBRILLATORS (AED)	PHYSIO-CONTROL. INC.	Manufacturing site location and equipment change for a critical component of the LIFEPAK 15 monitor/defibrillator Li-ion rechargeable battery accessory.
P160030/S033	05/10/2019	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM; FREESTYLE LIBRE 14 DAY FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Introduction of an additional circuit printing line used in the fabrication of the glucose sensor, which is a common component of the Freestyle Libre Flash Glucose Monitoring System, Freestyle Libre Pro Flash Glucose Monitoring System, and Freestyle Libre 14 day Flash Glucose Monitoring System.
P160038/S012	05/16/2019	X - 30-Day Notice	PRAXIS EXTENDED RAS PANEL	ILLUMINA, INC.	Critical raw material manufacturing site change.
P160041/S017	05/03/2019	X - 30-Day Notice	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Increase in scale and other process changes for the manufacture of synthesized oligonucleotides.

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P160041/S018	05/09/2019	X - 30-Day Notice	COBAS CMV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Addition of instrumentation qualified to be used to purify oligonucleotides.
P160041/S019	05/22/2019	X - 30-Day Notice	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Changes in manufacturing gowning procedures
P160041/S020	05/24/2019	X - 30-Day Notice	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Change the cleaning procedures for equipment used to manufacture a bulk reagent.
P160044/S002	05/15/2019	X - 30-Day Notice	ABBOTT REALTIME CMV	ABBOTT MOLECULAR	Implement additional QC to device accessory kits.
P160045/S015	05/21/2019	X - 30-Day Notice	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Change of supplier for the subassembly dNTPs.
P160049/S005	05/03/2019	X - 30-Day Notice	STELLAREX 0.035 OTW DRUG-COATED ANGIOPLASTY BALLON	THE SPECTRANETICS CORP.	Extension of the drug substance retest period and modification of heavy metals testing requirements.
P170006/S011	05/13/2019	X - 30-Day Notice	AVALUS BIOPROSTHESIS	MEDTRONIC INC.	Addition of one new bovine tissue supplier with two slaughterhouse locations in Mexico.
P170006/S012	05/31/2019	X - 30-Day Notice	AVALUS BIOPROSTHESIS	MEDTRONIC INC.	Utilization of an existing manufacturing facility for raw tissue processing.
P170008/S016	05/14/2019	X - 30-Day Notice	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Revisions to the ridaforolimus incoming inspection specifications.
P170012/S016	05/15/2019	X - 30-Day Notice	HEMOBLAST BELLOWS	BIOM'UP SA	Change the manufacturing process for the Human Thrombin component of HEMOBLAST Bellows (For Further Manufacturing Use (FFMU).
P170012/S017	05/21/2019	X - 30-Day Notice	HEMOBLAST BELLOWS	BIOM'UP SA	Removal of heavy metal analysis from the certificate of analysis (CoA) for pyrogen free water and change of dosimeter from radiochromic to alanine dosimeters.
P170025/S012	05/21/2019	X - 30-Day Notice	APTIMA HBV QUANT ASSAY	HOLOGIC, INC	Remove QC release testing for a device ancillary kit.
P170036/S002	05/10/2019	X - 30-Day Notice	M6-C ARTIFICIAL CERVICAL DISC	SPINAL KINETICS LLC	Addition of a new supplier for the instrument trays.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170043/S004	05/30/2019	X - 30-Day Notice	ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM (MODEL G2-M-IS)	GLAUKOS CORPORATION	Modification to the endotoxin specification for the injector handpiece for the Glaukos® iStent inject® Trabecular Micro-Bypass System (Model G2-M-IS)
P180011/S007	05/09/2019	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Replace a Tier 2 material supplier.
P180025/S002	05/15/2019	X - 30-Day Notice	MANTA VASCULAR CLOSURE DEVICE	ESSENTIAL MEDICAL, INC.	Adjustment to the collagen plug weight acceptance criterion for the 18F MANTA VCD.

Total: 195