PMA Monthly approvals from 3/1/2020 to 3/31/2020

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190024	03/10/2020	PMAO - PMA Origi	CINTEC PLUS CYTOLOGY	VENTANA MEDICAL SYSTEMS, INC.	Approval for The CINtec® PLUS Cytology test. The device is a qualitative immunocytochemical assay intended for the simultaneous detection of the p16INK4a and Ki-67 proteins in cervical specimens collected by a clinician using an endocervical brush/ spatula or broom collection device and placed in the ThinPrep® Pap Test PreservCyt® Solution. The CINtec PLUS Cytology test includes a ready-to-use cocktail of primary antibodies which contains a mouse monoclonal antibody directed against human p16INK4a (p16) protein (clone E6H4), and a recombinant rabbit monoclonal antibody directed against human Ki-67 protein (clone 274-11AC3V1) for use on the BenchMark ULTRA instrument with 3,3-diaminobenzidine tetrahydrochloride (DAB) and Fast Red detection systems. The CINtec PLUS Cytology test is indicated: 1) To be used in women 25 - 65 years old with 12 Other High Risk (HR) HPV positive test results using the cobas® 4800 HPV Test in primary HPV screening, to determine the need for referral to colposcopy. To be used in women 25 - 65 years old with HPV16/18 positive test results using the cobas® 4800 HPV Test in primary HPV screening where the CINtec PLUS Cytology test results will be used in conjunction with the physicians assessment of patient screening history, other risk factors, and professional guidelines to guide patient management. 2) To be used in women 30 - 65 years old with NILM (Negative for Intraepithelial Lesion or Malignancy) and 12 Other HR HPV positive test results using the cobas 4800 HPV Test in adjunctive cervical cytology and HR HPV screening, to determine the need for referral to colposcopy. To be used in women 30 - 65 years old with NILM (Negative for Intraepithelial Lesion or Malignancy) and HPV16/18 positive test results using the cobas® 4800 HPV Test in adjunctive cervical cytology and HR HPV screening where the CINtec PLUS Cytology test results will be used in conjunction with the physicians assessment of patient screening history, other risk factors, and professional guidelines to guide patient management. Results from the CINtec PLUS Cytology test should be interpreted by a qualified pathologist.

Data as of 04/03/2020 03:30 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190025	03/23/2020	PMAO - PMA Origi	ALINITY M HCV	ABBOTT MOLECULAR, INC.	Approval for the Alinity m HCV. The assay is an in vitro reverse transcription-polymerase chain reaction (RT-PCR) assay for both the detection and quantitation of hepatitis C virus (HCV) RNA, in human plasma (EDTA, Acid Citrate Dextrose) or serum, from HCV antibody positive individuals. The assay is intended for use as an aid in the diagnosis of active HCV infection in individuals with antibody evidence of HCV infection, and to aid in the management of patients with known active HCV infection, including SVR determination. The results from the Alinity m HCV assay must be interpreted within the context of all relevant clinical and laboratory findings. The Alinity m HCV assay is not intended to be used in screening blood, plasma, serum, tissue or tissue donors for HCV.

Total: 2

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830063/S015	03/25/2020	S - Special CBE	GAMBRO FIBER PLASMAFILTER	BAXTER INTERNATIONAL, INC.	Approval for the following changes in the instructions for use: 1) A labeling change to align the sterile symbol to current sterile fluid path description in the instructions for use of the Prismaflex TPE2000 set; and 2) The addition of the following warning statement: Use only drugs compatible with plastics listed in the specifications section. Some plastics can be incompatible with drugs when in contact with solutions with pH > 10.
P850048/S053	03/17/2020	R - Real-Time Proc	ACCESS HYBRITECH PSA REAGENTS ON THE ACCESS IMMUNOASSAY SYSTEMS	BECKMAN COULTER, INC.	Approval for modification to the UniCel DxI Immunoassay System¿s pick and place gantries.
P860004/S334	03/23/2020	N - Normal 180 Day	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval for labeling changes for the Synchromed II and Isomed infusion systems including clarifications of the Ascenda catheter implant technique, the development of a standalone MRI guideline manual and updates to adverse event labeling/minor administrative changes.
P890003/S425	03/02/2020	R - Real-Time Proc	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Approval for firmware updates to the MyCareLink Patient Monitor Models 24950 and 24952.
P910056/S039	03/26/2020	Y - 135 Review Tra	SOFLEX UV-ABSORBING SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS	BAUSCH & LOMB, INC.	Approval for changes to the polishing manufacturing process for the enVista® Hydrophobic Acrylic IOLs, Models MX60, MX60E, MX60ET, and MX60T.
P950020/S097	03/17/2020	Y - 135 Review Tra	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Approval for the addition of a component manufacturing site.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P950037/S206	03/10/2020	Y - 135 Review Tra	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Approval for the use of a new header removal solvent (80% dichloromethane + 20% formic acid).
P970003/S225	03/20/2020	R - Real-Time Proc	VNS THERAPY SYSTEM	LIVANOVA USA, INC.	Approval for a New Multi-Product Sales Packaging Kit and Alternate Universal Inner Generator Medical Tray.
P970038/S041	03/17/2020	R - Real-Time Proc	TANDEM-R FREE PSA IMMUNORADIOMETRIC ASSAY/TANDEM-MP FREE PSA IMMUNOENZYMETRIC ASSAY	BECKMAN COULTER, INC.	Approval for the modification to the UniCel DxI Immunoassay Systems pick and place gantries.
P970051/S172	03/17/2020	P - Panel Track	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for the IFU for Nucleus 24 Cochlear Implant System: 1) The Nucleus 24 Cochlear Implant System is intended for individuals 18 years of age or older who have bilateral, pre, peri or postlinguistic sensorineural hearing impairment and obtain limited benefit from appropriate binaural hearing aids. 2) These individuals typically have moderate to profound hearing loss in the low frequencies and profound (>= 90 dB HL) hearing loss in the mid to high speech frequencies. Limited benefit from amplification is defined by test scores of 50% correct or less in the ear to be implanted (60% or less in the best-aided listening condition) on tape-recorded tests of open set sentence recognition. 3) The Nucleus 24 cochlear implant system is intended for use in children 9 to 24 months of age who have bilateral profound sensorineural deafness and demonstrate limited benefit from appropriate binaural hearing aids. 4) Children two years of age or older may demonstrate severe to profound hearing loss bilaterally. 5) In younger children, limited benefit is defined as lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in intensive aural habilitation over a three to six-month period. It is recommended that limited benefit be quantified on a measure such as the Meaningful Auditory Integration Scale or the Early Speech Perception test. 6) In older children, limited benefit is defined as <= 30% correct on the open set Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the childs cognitive and linguistic skills. A three to six-month hearing aid trial is recommended for children without previous aided experience.
P980016/S728	03/02/2020	R - Real-Time Proc	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for firmware updates to the MyCareLink Patient Monitor Models 24950 and 24952.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980033/S050	03/17/2020	P - Panel Track	WALLSTENT ENDOPROSTHESIS	BOSTON SCIENTIFIC CORPORATION	Approval for the VENOUS WALLSTENT for expanding the indications to include improving luminal diameter in the iliofemoral veins for the treatment of symptomatic venous outflow obstruction. This device is indicated for the following: The VENOUS WALLSTENT is indicated for improving central venous luminal diameter following unsuccessful angioplasty in patients on chronic hemodialysis with stenosis of the venous outflow tract. Unsuccessful angioplasty is defined as residual stenosis >= 30% for a vein <= 10mm in diameter or >= 50% for a vein > 10 mm in diameter; a tear which interrupts the integrity of the intima or lumen; abrupt lesion site occlusion, or refractory spasm. The vessels that can be treated with the VENOUS WALLSTENT are the innominate and subclavian veins, ranging from 8 mm to 15 mm in diameter. The VENOUS WALLSTENT is also indicated for improving luminal diameter in the iliofemoral veins for the treatmet of symptomatic venous outflow obstruction.
P980035/S614	03/02/2020	R - Real-Time Proc	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Approval for firmware updates to the MyCareLink Patient Monitor Models 24950 and 24952.
P980041/S046	03/17/2020	R - Real-Time Proc	ACCESS AFP REAGENTS ON THE ACCESS IMMUNOASSAY SYSTEMS	BECKMAN COULTER, INC.	Approval for modification to the UniCel DxI Immunoassay Systems pick and place gantries.
P990034/S039	03/23/2020	N - Normal 180 Day	MEDTRONIC ISOMED INFUSION SYSTEM	MEDTRONIC INC.	Approval for labeling changes for the Synchromed II and Isomed infusion systems including clarifications of the Ascenda catheter implant technique, the development of a standalone MRI guideline manual and updates to adverse event labeling/minor administrative changes.
P990081/S042	03/31/2020	R - Real-Time Proc	PATHWAY ANTI-HCR-2/ NCU (4B5) RABBIT MONOCLONAL PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Approval for minor software changes.
P010013/S075	03/02/2020	R - Real-Time Proc	NOVASURE IMPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM	HOLOGIC, INC.	Approval for the replacement of the current LCD screen of the NovaSure Impedance Controlled Endometrial Ablation System controller.
P010015/S426	03/02/2020	R - Real-Time Proc	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Approval for firmware updates to the MyCareLink Patient Monitor Models 24950 and 24952.
P010031/S689	03/02/2020	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for firmware updates to the MyCareLink Patient Monitor Models 24950 and 24952.
P020045/S092	03/02/2020	N - Normal 180 Day	7F FREEZOR CARDIAC CRYOABLATION CATHETER AND CCT.2 CRYOCONSOLE SYSTEM	MEDTRONIC CRYOCATH LP	Approval for an alternate manufacturing site (Medtronic Mexico, Tijuana Baja California, Mexico), as well as a new sterilization site (Midwestern Sterilization, Jackson, Missouri)and packaging improvements for Coaxial umbilical component of the CryoAblation System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P020047/S072	03/19/2020	Y - 135 Review Tra	MULTI-LINK 8, MULTI-LINK 8 SV/LL CORONARY STENT SYSTEMS	ABBOTT VASCULAR	Approval for changing the ethylene oxide (EO) sterilization release process for the affected products from the traditional method of biological indicator testing to a parametric release process.
P020055/S022	03/31/2020	R - Real-Time Proc	VENTANA MEDICAL SYSTEMS PATHWAY ANTI-C-KIT (9.7) PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Approval for minor software changes.
P030011/S070	03/05/2020	N - Normal 180 Day	SYNCARDIA TEMPORARY CARDIO WEST TOTAL ARTIFICIAL HEART (TAH-T)	SYNCARDIA SYSTEMS, LLC	Approval for marketing of the 50cc temporary Total Artificial Heart (TAH-t) device.
P050023/S137	03/10/2020	Y - 135 Review Tra	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval for the use of a new header removal solvent (80% dichloromethane + 20% formic acid).
P050037/S100	03/02/2020	R - Real-Time Proc	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Approval for the plunger design change for RADIESSE Injectable Implant and RADIESSE (+) Lidocaine Dermal Filler.
P050052/S117	03/02/2020	R - Real-Time Proc	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval for the plunger design change for RADIESSE Injectable Implant and RADIESSE (+) Lidocaine Dermal Filler.
P050052/S119	03/17/2020	N - Normal 180 Day	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval for a modification to the Lidocaine HCl shelf life specifications
P060023/S008	03/18/2020	O - Normal 180 Day	BRYAN CERVICAL DISC	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval for labeling for the BRYAN® Cervical Disc which incorporate the final results of the 10-year Post-Approval Study and Enhanced Surveillance findings.
P070006/S012	03/03/2020	R - Real-Time Proc	T SPOT-TB TEST	OXFORD IMMUNOTEC,LTD.	Approval for extension of the shelf life of the T-SPOT.TB50 kit, including Panel A, Panel B, and Positive Control, from 12 months to 18 months.
P070008/S109	03/10/2020	Y - 135 Review Tra	STRATOS LV CRT-P AND STRATOS LV-T CRT-P, COROX OTW BP LEAD AND COROX OTW-S BP LEAD	BIOTRONIK, INC.	Approval for the use of a new header removal solvent (80% dichloromethane + 20% formic acid).
P070015/S146	03/19/2020	Y - 135 Review Tra	XIENCE AND PROMUS EVEROLIMUS ELUTING CORONARY STENT SYSTEMS	ABBOTT VASCULAR INC.	Approval for changing the ethylene oxide (EO) sterilization release process for the affected products from the traditional method of biological indicator testing to a parametric release process.
P090026/S027	03/17/2020	R - Real-Time Proc	ACCESS HYBRITECH P2PSA ON THE ACCESS IMMUNOASSAY SYSTEMS	BECKMAN COULTER, INC.	Approval for modification to the UniCel DxI Immunoassay System¿s pick and place gantries.
P090029/S013	03/06/2020	O - Normal 180 Day	PRESTIGE LP CERVICAL DISC	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval for labeling for the Prestige LP Cervical Disc which incorporated the final results of the 10-year Extended Follow-Up of IDE Subjects Post-Approval Study.
P100020/S049	03/04/2020	N - Normal 180 Day	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Approval for using cervical samples collected in PreservCyt with the broom cervical collection device for identification of high-grade cervical disease.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100027/S032	03/31/2020	R - Real-Time Proc	INFORM HER2 DUAL ISH DNA PROBE COCKTAIL	VENTANA MEDICAL SYSTEMS, INC.	Approval for minor software changes.
P110019/S108	03/19/2020	Y - 135 Review Tra	XIENCE PRIME AND XIENCE PRIME LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Approval for changing the ethylene oxide (EO) sterilization release process for the affected products from the traditional method of biological indicator testing to a parametric release process.
P110033/S052	03/18/2020	R - Real-Time Proc	JUVEDERM VOLUMA XC	ALLERGAN	Approval for use of Voluma XC with a cannula with a threaded hub.
P110042/S132	03/20/2020	N - Normal 180 Day	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for alternate hardware components and design modifications (with associated manufacturing changes), firmware update to version 3.1.543 (Models A209/A219), and software to version 4.08 (Model 2877).
P120006/S031	03/13/2020	P - Panel Track	OVATION ABDOMINAL STENT GRAFT SYSTEM	ENDOLOGIX, INC.	Approval for the Alto Abdominal Stent Graft System. The device is indicated for treatment of patients with infrarenal abdominal aortic aneurysms having the vascular morphology suitable for endovascular repair with the device, which includes the following: 1) Adequate iliac/femoral access compatible with vascular access techniques (femoral cutdown or percutaneous), devices, and/or accessories; 2) A proximal aortic landing zone for the sealing ring 7mm below the inferior renal artery; 3) An aortic sealing zone comprised of healthy aorta defined as; a. Lack of significant thrombus > 8 mm in thickness; at any point along the aortic circumference at the level of 7mm below the inferior renal artery; b. Lack of significant calcification at the level of 7mm below the inferior renal artery; c. Conicity < 10% as measured from the inferior renal artery to the aorta 7mm below the inferior renal artery; d. An inner wall diameter of no less than 16 mm and no greater than 30 mm at 7 mm below the inferior renal artery; and e. An aortic angle of <= 60 degrees. 4) A distal iliac landing zone: a. With a length of at least 10 mm; and b. With an inner wall diameter of no less than 8 mm and no greater than 25 mm.
P130021/S073	03/20/2020	O - Normal 180 Day	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Approval for the revised protocols for the post-approval studies protocol.
P130024/S031	03/20/2020	O - Normal 180 Day	LUTONIX DRUG COATED BALLOON PTA CATETER	LUTONIX	Approval for updates to the labeling.
P130024/S033	03/02/2020	R - Real-Time Proc	LUTONIX DRUG COATED BALLOON PTA CATETER	LUTONIX	Approval for a shelf-life extension from 24 months to 36 months for the Lutonix 018 Drug Coated Balloon PTA Catheter.
P140025/S012	03/31/2020	R - Real-Time Proc	VENTANA ALK (D5F3) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for minor software changes.
P140029/S021	03/26/2020	P - Panel Track	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Approval for Restylane Kysse. The device is intended for injection into the lips for lip augmentation and for correction of upper perioral rhytids in patients over the age of 21.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140031/S104	03/10/2020	R - Real-Time Proc	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for adding the peel-away feature that currently exists on the Commander loader to the Ultra loader.
P150002/S007	03/17/2020	Y - 135 Review Tra	INCRAFT(R) AAA STENT GRAFT SYSTEM	CORDIS CORPORATION	Approval for a change to the hypotube supplier for the delivery system of the INCRAFT AAA Stent Graft System.
P150013/S017	03/19/2020	N - Normal 180 Day	PD-L1 IHC 22C3 PHARMDX	DAKO NORTH AMERICA, INC.	Approved to migrate the PD-L1 IHC 22C3 pharmDx assay for NSCLC indication for use on the Dako Omnis automated staining system per approval letter.
P150033/S065	03/02/2020	R - Real-Time Proc	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval for firmware updates to the MyCareLink Patient Monitor Models 24950 and 24952.
P160001/S046	03/30/2020	S - Special CBE	OBALON BALLOON SYSTEM	OBALON THERAPEUTICS, INC.	Approval for revised labeling to include current post-market surveillance information.
P160002/S011	03/31/2020	R - Real-Time Proc	VENTANA PD-L1(SP142) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for minor software changes.
P160007/S032	03/20/2020	R - Real-Time Proc	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Approval for protocols to determine whether design changes are needed for the Guardian Connect Application component of the Guardian Connect System
P160014/S010	03/29/2020	Y - 135 Review Tra	COBRA PZF NANOCOATED CORONARY STENT SYSTEM	CELONOVA BIOSCIENCES, INC.	Approval for moving finished good testing from post-sterilization to pre-sterilization and implementing new ultraviolet cure equipment for the delivery catheter.
P160035/S006	03/13/2020	Y - 135 Review Tra	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Approval for the use of an alternative supplier for printed circuit boards (PCBs).
P160046/S007	03/31/2020	R - Real-Time Proc	VENTANA PD-L1 (SP263) ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for minor software changes.
P160050/S003	03/17/2020	R - Real-Time Proc	BARRICAID ANULAR CLOSURE DEVICE (ACD)	INTRINSIC THERAPEUTICS	Approval to change the supplier and specifications of the polyester yarn used to make the mesh of the woven fabric for the flexible occlusion component of the Barricaid Anular Closure Device (ACD).
P170027/S002	03/11/2020	N - Normal 180 Day	THEROX DOWNSTREAM SYSTEM	THEROX, INC.	Approval for the DS-2 Console. The DS-2 Console uses the same cartridge as the DS-1 Console; however, it has updated hardware and software to accommodate a touchscreen display in addition to modified electrical components to comply with the EU RoHS Standard.
P170038/S001	03/20/2020	O - Normal 180 Day	CENTRIMAG CIRCULATORY SUPPORT SYSTEM	ABBOTT	Approval for a manufacturing site located at Gerresheimer Regensburg GmbH in Pfreimd, Germany for assembling and packaging the blood pump.

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P190014/S002	03/23/2020	R - Real-Time Proc	MYCHOICE HRD CDX	MYRIAD GENETIC LABORATORIES, INC	Approval of the final revised labeling (IU) for the Myriad myChoice® CDx. The device is a next generation sequencing-based in vitro diagnostic test that assesses the qualitative detection and classification of single nucleotide variants, insertions and deletions, and large rearrangement variants in protein coding regions and intron/exon boundaries of the BRCA1 and BRCA2 genes and the determination of Genomic Instability Score (GIS) which is an algorithmic measurement of Loss of Heterozygosity (LOH), Telomeric Allelic Imbalance (TAI), and Large-scale State Transitions (LST) using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens. The results of the test are used as an aid in identifying ovarian cancer patients with positive homologous recombination deficiency (HRD) status who are eligible, because of a positive test result for deleterious or suspected deleterious mutations in BRCA1 or BRCA2 genes, or may become eligible, because of a positive test result for deleterious or suspected deleterious mutations in BRCA1 or BRCA2 genes or a positive Genomic Instability Score, for treatment with the approved targeted therapy for Zejula® (niraparib).

Total: 58

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S068	03/04/2020	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Relocation of the existing secondary packaging equipment within the existing facility.
N18286/S035	03/19/2020	X - 30-Day Notice	GELFOAM	PFIZER, INC.	Change in the incoming specifications for the gelatin component.
N970003/S249	03/05/2020	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Replace particle size analyzer test equipment with functionally equivalent test equipment.
N970003/S250	03/17/2020	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Implement the CMS system for the monitoring of environmental conditions at the Boston Scientific Clonmel facility.
N970012/S175	03/06/2020	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Changes to the annealing and inspection of the straight, right-angle (elbow), and Y suture-tie connectors.
P830061/S179	03/06/2020	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN	Transfer two incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company Villalba/Juncos sites.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840001/S455	03/01/2020	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Implementation of additional equipment and equipment upgrades for the manufacturing line of the Intellis family of products.
P840001/S456	03/20/2020	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Process change to transfer incoming inspection visual testing of adhesive components to another Medtronic facility.
P840001/S457	03/27/2020	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Implementation of an automated optical inspection system to replace manual inspection at their capacitor component supplier.
P850007/S044	03/27/2020	X - 30-Day Notice	PHYSIO-STIM(TM) I & II MODEL 6000 & 7000	ORTHOFIX, INC.	Implementing an alternative machine to produce the device¿s transducer coil.
P850079/S086	03/12/2020	X - 30-Day Notice	HYDRASOFT (METHAFILCON B) CONTACT LENS	COOPERVISION, INC.	Introduction of a new Total Organic Carbon (TOC) analyzer for the testing of purified water supplies at the CooperVision Manufacturing, Ltd. facilities located in Hamble, UK and Chandlers Ford, UK.
P850089/S146	03/06/2020	X - 30-Day Notice	CAPSURE SP, CAPSURE, CAPSURE 2 LEADS, EXCELLENCE S, IMPULSE, IMPLUSE II EXCELLENCE SS, LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer two incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company Villalba/Juncos sites.
P860057/S198	03/05/2020	X - 30-Day Notice	EDWARDS LIFESCIENCES PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Replacement of the Preliminary Packaging Optical Characterization Verification (OCV) system with the Optical Characterization Recognition Printing (OCRP) system for non-RESILIA valves and removal of the OCV system for RESILIA valves.
P860057/S199	03/11/2020	X - 30-Day Notice	EDWARDS LIFESCIENCES PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Eliminate the specification of "elastic" characteristic in pericardial tissue for tissue leaflets and the related visual inspection in the valve manufacturing process.
P890003/S426	03/06/2020	X - 30-Day Notice	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Transfer two incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company Villalba/Juncos sites.
P900061/S157	03/06/2020	X - 30-Day Notice	MEDTRONIC PCD TACHYARRHYTHMIA CONTROL SYSTEM	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer two incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company Villalba/Juncos sites.
P910023/S426	03/13/2020	X - 30-Day Notice	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ST. JUDE MEDICAL	Alternate supplier of the battery boot component and change to an in-house application of the heat shield tape to the battery boot assembly used in Ellipse DR and VR ICD devices.
P910054/S007	03/30/2020	X - 30-Day Notice	INOUE BALLOON CATHETER	TORAY INDUSTRIES (AMERICA), INC.	Change to the raw material of the dilator accessory.
P920015/S242	03/06/2020	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Transfer two incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company Villalba/Juncos sites.

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P930036/S013	03/19/2020	X - 30-Day Notice	ADVIA CENTAUR AFP REAGENTS AND CALIBRATORS	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Scale-up and implementation of a common mixing process for all kit bulk reagents.
P930039/S210	03/06/2020	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Transfer two incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company Villalba/Juncos sites.
P950020/S103	03/05/2020	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Add an additional blade bonding cell.
P950020/S104	03/05/2020	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Additional blade casting cell.
P950020/S105	03/25/2020	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Add additional equipment to the manufacturing of the device.
P950021/S020	03/19/2020	X - 30-Day Notice	ADVIA CENTAUR & ADVIA CENTAUR CP PSA IMMUNOASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Scale-up and implementation of a common mixing process for all kit bulk reagents.
P950022/S130	03/26/2020	X - 30-Day Notice	TVL(TM) LEAD SYSTEM	ST. JUDE MEDICAL, INC.	Update the dexamethasone and total impurities specification limits for annual stability testing.
P950024/S091	03/06/2020	X - 30-Day Notice	MEDTRONIC(R) CAPSURE (R) EPI PACING LEAD MODEL 4695	MEDTRONIC INC.	Transfer two incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company Villalba/Juncos sites.
P950029/S124	03/06/2020	X - 30-Day Notice	CHORUS RM MODEL 7034 DDDR PACEMAKER INCL. OPUS RM MODEL 4534 SSIR PACEMAKER	MICROPORT CRM USA INC.	Implement sterilization cycle MicroPort01 at Steris SpA contactor.
P950029/S125	03/26/2020	X - 30-Day Notice	CHORUS RM MODEL 7034 DDDR PACEMAKER INCL. OPUS RM MODEL 4534 SSIR PACEMAKER	MICROPORT CRM USA INC.	Implement automatic equipment for the interconnection electrical welding process used in pacemaker devices.
P960009/S369	03/20/2020	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Process change to transfer incoming inspection visual testing of adhesive components to another Medtronic facility.
P960009/S370	03/27/2020	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Implementation of an automated optical inspection system to replace manual inspection at their capacitor component supplier.
P960013/S111	03/26/2020	X - 30-Day Notice	TENDRIL DX MODEL 1388T & 1388K ENDOCARDIAL PACING LEADS	ST JUDE MEDICAL	Update the dexamethasone and total impurities specification limits for annual stability testing.
P960030/S068	03/26/2020	X - 30-Day Notice	PASSIVE PLUS DX ENDOCARDIAL STEROID ELUTING, PASSIVE-FIXATION PACING LEADS	ST. JUDE MEDICAL	Update the dexamethasone and total impurities specification limits for annual stability testing.

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P960040/S448	03/05/2020	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Replace particle size analyzer test equipment with functionally equivalent test equipment.
P960040/S449	03/17/2020	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Implement the CMS system for the monitoring of environmental conditions at the Boston Scientific Clonmel facility.
P970003/S232	03/26/2020	X - 30-Day Notice	VNS THERAPY SYSTEM	LIVANOVA USA, INC.	Updates that are being made to the M1000 Accelerometer Trim Electrical Test System (ETS) Software.
P970004/S308	03/20/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Process change to transfer incoming inspection visual testing of adhesive components to another Medtronic facility.
P970051/S196	03/18/2020	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Existing Cochlear manufacturing site in Kuala Lumpur, Malaysia, to expand their capacity to manufacture the Kanso ® CP950 Sound Processor.
P980016/S729	03/06/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer two incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company Villalba/Juncos sites.
P980035/S615	03/06/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Transfer two incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company Villalba/Juncos sites.
P980035/S617	03/03/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Modify the seam weld inspection process.
P980035/S620	03/05/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Update the Soft Straight Line Finish rework process used at Medtronic Singapore Operations.
P980049/S136	03/06/2020	X - 30-Day Notice	DEFENDER II MODEL 9201 IMPLANTABLE CARDIOVERTER DEFIBRILLATOR	MICROPORT CRM USA INC.	Implement sterilization cycle MicroPort01 at Steris SpA contactor.
P990004/S037	03/19/2020	X - 30-Day Notice	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Change of donor catalyst used in the manufacturing of polypropylene resins.

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P990013/S040	03/31/2020	X - 30-Day Notice	COLLAMER ULTRAVIOLET ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	STARR SURGICAL CO.	Add an alternate in-process control method for collagen solution.
P990046/S056	03/20/2020	X - 30-Day Notice	ATS OPEN PIVOT BILEAFLET HEART VALVE	MEDTRONIC ATS MEDICAL, INC.	Modification to the manufacturing in-process inspection acceptance criteria for percent silicon weight of pyrolytic carbon coated orifices and leaflets.
P990046/S057	03/24/2020	X - 30-Day Notice	ATS OPEN PIVOT BILEAFLET HEART VALVE	MEDTRONIC ATS MEDICAL, INC.	New real-time radiography equipment for identifying high density inclusions (HDIs) in the carbon orifice.
P990055/S020	03/19/2020	X - 30-Day Notice	BAYER IMMUNO 1 COMPLEXED PSA ASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Scale-up and implementation of a common mixing process for all kit bulk reagents.
P000053/S111	03/06/2020	X - 30-Day Notice	AMS SPHINCTER 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Changes to the annealing and inspection of the straight, right-angle (elbow), and Y suture-tie connectors.
P010012/S516	03/05/2020	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Replace particle size analyzer test equipment with functionally equivalent test equipment.
P010012/S517	03/17/2020	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Implement the CMS system for the monitoring of environmental conditions at the Boston Scientific Clonmel facility.
P010015/S427	03/06/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Transfer two incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company Villalba/Juncos sites.
P010019/S076	03/19/2020	X - 30-Day Notice	FOCUS NIGHT AND DAY (LOTRAFILCON A) SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Addition of an alternate polypropylene resin and supplier used in the blister shells for primary packaging of lotrafilcon A and B extended wear soft contact lenses.
P010030/S132	03/26/2020	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	New electrical test equipment for the LifeVest 4000 Electrode Belt cable.

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P010031/S690	03/06/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Transfer two incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company Villalba/Juncos sites.
P010032/S159	03/04/2020	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Implementation of an alternative sampling plan for bacterial endotoxin testing performed at the Arecibo, Puerto Rico facility.
P020004/S173	03/04/2020	X - 30-Day Notice	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,I NC	Update the trunk component specifications.
P030005/S195	03/05/2020	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Replace particle size analyzer test equipment with functionally equivalent test equipment.
P030005/S196	03/17/2020	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Implement the CMS system for the monitoring of environmental conditions at the Boston Scientific Clonmel facility.
P030011/S078	03/12/2020	X - 30-Day Notice	SYNCARDIA TEMPORARY CARDIO WEST TOTAL ARTIFICIAL HEART (TAH-T)	SYNCARDIA SYSTEMS, LLC	Change of location for a component supplier for the Companion 2 Driver.
P030016/S040	03/31/2020	X - 30-Day Notice	VISIAN ICL (IMPLANTABLE COLLAMER LENS)	STAAR SURGICAL COMPANY	Add an alternate in-process control method for collagen solution.
P030017/S333	03/17/2020	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Alternate EO sterilization cycle and upgraded sterilization equipment to sterilize all sterile products and accessories of the SCS Systems.
P030031/S103	03/31/2020	X - 30-Day Notice	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Implementation of an automated inspection process.
P030036/S118	03/06/2020	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Transfer two incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company Villalba/Juncos sites.

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P030040/S016	03/19/2020	X - 30-Day Notice	ADVIA CENTAUR HBC IGM READYPACK REAGENTS, ADVIA CENTAUR HBC IGM QUALITY CONTROL MATERIALS	SIEMENS HEALTHCARE DIAGNOSTICS	Scale-up and implementation of a common mixing process for all kit bulk reagents.
P030049/S014	03/19/2020	X - 30-Day Notice	ADVIA CENTAUR HBSAG READY PACK REAGENTS/ CONFIRMATORY READY PACK REAGENTS/QUALITY CONTROL MATERIAL	SIEMENS HEALTHCARE DIAGNOSTICS	Scale-up and implementation of a common mixing process for all kit bulk reagents.
P030054/S377	03/26/2020	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ST. JUDE MEDICAL	Update the dexamethasone and total impurities specification limits for annual stability testing.
P030056/S015	03/19/2020	X - 30-Day Notice	ADVIA CENTAUR HCV READY PACK REAGENTS, ADVIA CENTAUR HCV QUALITY CONTROL MATERIALS	SIEMENS HEALTHCARE DIAGNOSTICS	Scale-up and implementation of a common mixing process for all kit bulk reagents.
P040004/S016	03/19/2020	X - 30-Day Notice	ADVIA CENTAUR HBC TOTAL READYPACK REAGENTS/ADVIA CENTAUR HBC TOTAL QUALITY CONTROL MATERIALS	SIEMENS HEALTHCARE DIAGNOSTICS	Scale-up and implementation of a common mixing process for all kit bulk reagents.
P040014/S038	03/04/2020	X - 30-Day Notice	IBI THERAPY CARDIAC ABLATION SYSTEM ERS/ 1500T RF GENERATOR	IRVINE BIOMEDICAL, INC.	Add a second sterilization cycle for previously sterilized product.
P040027/S078	03/04/2020	X - 30-Day Notice	GORE VIATORR TIPS	W. L. GORE & ASSOCIATES, INC.	Addition of a camera-based error-proofing mechanism to a machine that manufactures a component of the delivery system.
P040036/S071	03/31/2020	X - 30-Day Notice	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Implementation of an automated inspection process.
P040037/S136	03/04/2020	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Addition of a camera-based error-proofing mechanism to a machine that manufactures a component of the delivery system.
P040042/S044	03/04/2020	X - 30-Day Notice	THERAPY DUAL 8 CARDIAC ABLATION SYSTEM,THERAM 8MM THERMISTER ABLATION CATHETER SAFIRE TX ABLATION CATHETER	IRVINE BIOMEDICAL,INC.(IBI)	Add a second sterilization cycle for previously sterilized product.
P050007/S039	03/25/2020	X - 30-Day Notice	STARCLOSE VASCULAR CLOSURE SYSTEM	ABBOTT VASCULAR DEVICES	Implementation of a process monitoring control plan for a device attribute.

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P050023/S143	03/10/2020	X - 30-Day Notice	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Update the passivation process of the battery lids used in their Acticor family of ICDs.
P050027/S020	03/25/2020	X - 30-Day Notice	KARL STORZ PHOTODYNAMIC DIAGNOSTIC D-LIGHT C (PDD) SYSTEM	KARL STORZ ENDOSCOPY-AMERICA, INC.	Process change to change the weld program and laser welder.
P060006/S099	03/02/2020	X - 30-Day Notice	BOSTON SCIENTIFIC EXPRESS SD RENAL MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Update final stent cleaning equipment and process.
P060011/S020	03/30/2020	X - 30-Day Notice	C-FLEX MODEL 570C INTRAOCULAR LENS (IOL)	RAYNER INTRAOCULAR LENSES LTD.	Introduce the option of allowing software toindependently and automatically check the critical parameters of a cycle and provide a verdict of the sterilization cycle outcome.
P060019/S046	03/04/2020	X - 30-Day Notice	IBI THERAPY COOL PATH ABLATION CATHETER & IBI-1500T9 RF	IRVINE BIOMEDICAL, INC.	Add a second sterilization cycle for previously sterilized product.
P060027/S102	03/06/2020	X - 30-Day Notice	OVATIO CRT SYSTEM	MICROPORT CRM USA INC.	Implement sterilization cycle MicroPort01 at Steris SpA contactor.
P060039/S099	03/06/2020	X - 30-Day Notice	ATTAIN STARFIX MODEL 4195 LEAD	MEDTRONIC INC.	Transfer two incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company Villalba/Juncos sites.
P070008/S113	03/16/2020	X - 30-Day Notice	STRATOS LV CRT-P AND STRATOS LV-T CRT-P, COROX OTW BP LEAD AND COROX OTW-S BP LEAD	BIOTRONIK, INC.	Update the manufacturing process to be semi-automatic for the silicone sleeve used in Sentus OTW QP leads.
P070015/S147	03/12/2020	X - 30-Day Notice	XIENCE AND PROMUS EVEROLIMUS ELUTING CORONARY STENT SYSTEMS	ABBOTT VASCULAR INC.	Extend the retest period from 96 months to 108 months of the repackaged drug API (variants 1, 2, and 3) for container closure Configuration I.
P080004/S032	03/12/2020	X - 30-Day Notice	HOYA ISPHERIC MODEL YA-60BB INTRAOCULAR LENS	HOYA SURGICAL OPTICS, INC.	Change in the tip coating process.
P080006/S145	03/19/2020	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Add Heraeus as a new alternate supplier for the Attain Stability Quad coils.
P080006/S146	03/06/2020	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Transfer two incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company Villalba/Juncos sites.
P080011/S102	03/12/2020	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Introduction of a new Total Organic Carbon (TOC) analyzer for the testing of purified water supplies at the CooperVision Manufacturing, Ltd. facilities located in Hamble, UK and Chandlers Ford, UK.
P080011/S103	03/24/2020	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Implementation of an alternative lensmeter for the QC1 (in process) measurement of the Biofinity Toric lenses produced at the Juana Diaz, Puerto Rico manufacturing site.
P080012/S065	03/17/2020	X - 30-Day Notice	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Increasing the sterilization load size of Ethylene Oxide sterilized accessories of the Prometra Pump System.

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P080020/S036	03/16/2020	X - 30-Day Notice	GEL-ONE	SEIKAGAKU CORP.	Installation of a new Ultra-filtration Water (UF Water) Treatment System within Preparation Building-3 for use in the manufacture of Gel-One.
P080020/S037	03/31/2020	X - 30-Day Notice	GEL-ONE	SEIKAGAKU CORP.	Modification of equipment required for manufacturing the new Finger Grip of the Gel-One container closure system.
P080025/S203	03/20/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Process change to transfer incoming inspection visual testing of adhesive components to another Medtronic facility.
P090003/S049	03/02/2020	X - 30-Day Notice	EXPRESS LD ILIAC PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Update final stent cleaning equipment and process.
P090013/S305	03/06/2020	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Transfer two incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company Villalba/Juncos sites.
P090024/S007	03/19/2020	X - 30-Day Notice	ADVIA CENTAUR HBEAG ASSAY AND QUALITY CONTROL MATERIAL	SIEMENS HEALTHCARE DIAGNOSTICS	Scale-up and implementation of a common mixing process for all kit bulk reagents.
P100010/S102	03/05/2020	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Re-sequence the manufacturing procedures at station P13.
P100026/S079	03/20/2020	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Modify the Telemetry Only System (TOS) and PXI Vader Temperature Test System Automatic Test Equipment (ATE) databases to improve yield of the components used to manufacture the RNS® Neurostimulator (model RNS-320).
P100034/S023	03/15/2020	X - 30-Day Notice	NOVOCURE LTD'S NOVOTTF-100A TREATMENT KIT	NOVOCURE GMBH	Move certain assembly activities performed for the Optune System from one building to another at the approved contract manufacturers site.
P100039/S008	03/19/2020	X - 30-Day Notice	ADVIA CENTAUR ANTI-HBS2 (AHBS2) ASSAY AND QAULITY CONTROL MATERIAL	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Scale-up and implementation of a common mixing process for all kit bulk reagents.
P100047/S153	03/03/2020	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Changes to implement a new multi part fixture inspection program and a Go/No-Go inspection as part of a Corrective and Preventive Action (CAPA).
P100047/S156	03/30/2020	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Addition of an inspection to verify the firmware version of the battery charger PCBA.
P100047/S158	03/20/2020	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Addition of an in-process inspection for a component of the HVAD battery.
P110010/S175	03/02/2020	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Update final stent cleaning equipment and process.

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P110013/S101	03/24/2020	X - 30-Day Notice	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Introduction of automation for transferring stents following the pre-weigh step.
P110016/S066	03/04/2020	X - 30-Day Notice	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Add a second sterilization cycle for previously sterilized product.
P110019/S111	03/12/2020	X - 30-Day Notice	XIENCE PRIME AND XIENCE PRIME LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Extend the retest period from 96 months to 108 months of the repackaged drug API (variants 1, 2, and 3) for container closure Configuration I.
P110041/S008	03/19/2020	X - 30-Day Notice	ADVIA CENTAUR HBSAGII	SIEMENS CORP.	Scale-up and implementation of a common mixing process for all kit bulk reagents.
P110042/S134	03/05/2020	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Replace particle size analyzer test equipment with functionally equivalent test equipment.
P110042/S135	03/17/2020	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Implement the CMS system for the monitoring of environmental conditions at the Boston Scientific Clonmel facility.
P130006/S075	03/04/2020	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Addition of a camera-based error-proofing mechanism to a machine that manufactures a component of the delivery system.
P130008/S050	03/30/2020	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Update design documents of Model 4063 stimulation lead and Model 4340 sensing lead to clarify manufacturing instructions for silicone adhesive backfill requirements.
P130008/S051	03/02/2020	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Notification of adding an alternate new supplier for the terminal ferrule used in the battery for Model 3028 IPG
P130009/S108	03/05/2020	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Replacement of the Preliminary Packaging Optical Characterization Verification (OCV) system with the Optical Characterization Recognition Printing (OCRP) system for non-RESILIA valves and removal of the OCV system for RESILIA valves.
P130017/S038	03/12/2020	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Process changes related to reagent manufacturing scale-up.
P130026/S057	03/27/2020	X - 30-Day Notice	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Add a second source supplier for the pull ring/pull wire subassembly utilized in the TactiCath SE devices.

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P130030/S066	03/02/2020	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE	BOSTON SCIENTIFIC CORP.	Update final stent cleaning equipment and process.
P140009/S055	03/04/2020	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Implementation of an alternative sampling plan for bacterial endotoxin testing performed at the Arecibo, Puerto Rico facility
P140029/S024	03/19/2020	X - 30-Day Notice	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Revision of the criteria for the visual inspection of filled and sterilized syringes performed during manufacturing of Restylane Refyne and Restylane Defyne.
P140031/S108	03/05/2020	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Use an alternate ethylene oxide (EO) sterilization cycle at a previously approved sterilization site for the Crimper Model 9600CR.
P140031/S109	03/05/2020	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Replacement of the Preliminary Packaging Optical Characterization Verification (OCV) system with the Optical Characterization Recognition Printing (OCRP) system for non-RESILIA valves and removal of the OCV system for RESILIA valves.
P140031/S110	03/11/2020	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Eliminate the specification of "elastic" characteristic in pericardial tissue for tissue leaflets and the related visual inspection in the valve manufacturing process.
P140033/S056	03/26/2020	X - 30-Day Notice	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ST. JUDE MEDICAL, INC.	Update the dexamethasone and total impurities specification limits for annual stability testing.
P150012/S090	03/05/2020	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Replace particle size analyzer test equipment with functionally equivalent test equipment.
P150012/S091	03/17/2020	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Implement the CMS system for the monitoring of environmental conditions at the Boston Scientific Clonmel facility.
P150031/S029	03/17/2020	X - 30-Day Notice	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Alternate EO sterilization cycle and upgraded sterilization equipment to sterilize all sterile products and accessories of the DBS Systems, except for the Burr Hole Cover Kit.
P150033/S066	03/06/2020	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Transfer two incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company Villalba/Juncos sites.
P150036/S049	03/05/2020	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Replacement of the Preliminary Packaging Optical Characterization Verification (OCV) system with the Optical Characterization Recognition Printing (OCRP) system for non-RESILIA valves and removal of the OCV system for RESILIA valves.
P150036/S050	03/11/2020	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Eliminate the specification of "elastic" characteristic in pericardial tissue for tissue leaflets and the related visual inspection in the valve manufacturing process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150048/S044	03/05/2020	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Replacement of the Preliminary Packaging Optical Characterization Verification (OCV) system with the Optical Characterization Recognition Printing (OCRP) system for non-RESILIA valves and removal of the OCV system for RESILIA valves.
P160008/S010	03/12/2020	X - 30-Day Notice	HEARTSINE TECHNOLOGIES LLC'S SAMARITAN PUBLIC ACCESS AUTOMATED EXTERNAL DEFIBRILLATORS (SAM 350P, SAM 360P AND SAM 450P) AND ACCESSORIES	HEARTSINE TECHNOLOGIES, LTD.	Addition of an alternate supplier for the main printed circuit board assembly.
P160034/S002	03/01/2020	X - 30-Day Notice	POWERHEART® AED G3 PRO	ZOLL MEDICAL CORPORATION	Supplier change for plastic components for the Powerheart G3 Pro AED.
P160037/S006	03/19/2020	X - 30-Day Notice	BD ONCLARITY HPV ASSAY	BECTON, DICKINSON AND COMPANY	Change in materials used in manufacture of critical assay component.
P160043/S033	03/24/2020	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Introduction of automation for transferring stents following the pre-weigh step.
P160054/S027	03/30/2020	X - 30-Day Notice	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATION	Addition of an alternate supplier for the HeartMate 3 System Controller PCBA components.
P170002/S008	03/11/2020	X - 30-Day Notice	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Minor corrections of the weight tolerances during gel mixing (before filling) in the Device History Record for RHA®2, RHA®3, RHA®4.
P170002/S009	03/10/2020	X - 30-Day Notice	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Addition of an alternative supplier of the reference standard lidocaine hydrochloride monohydrate used for the lidocaine assay for RHA 2, RHA 3, and RHA 4.
P170011/S022	03/30/2020	X - 30-Day Notice	IMPELLA RP SYSTEM	ABIOMED, INC.	Upgrade the laser welding workstation and associated Computer Numeric Control (CNC) program for the manufacture of the Pump Housing Assembly of the Impella RP catheter.
P170036/S005	03/04/2020	X - 30-Day Notice	M6-C ARTIFICIAL CERVICAL DISC	SPINAL KINETICS LLC	Addition of a new Belco Tray Sealer (EQ 0048-02) to the M6-C production line.
P180003/S001	03/27/2020	X - 30-Day Notice	BIOMIMICS 3D VASCULAR STENT SYSTEM	VERYAN MEDICAL LTD.	Automate a portion of the label printing process.
P180029/S021	03/11/2020	X - 30-Day Notice	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	Removal of a duplicate cleaning process for several LOTUS Edge Valve System components.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180035/S005	03/12/2020	X - 30-Day Notice	MISIGHT 1 DAY (OMAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES FOR DAILY WEAR	COOPERVISION, INC.	Introduction of a new Total Organic Carbon (TOC) analyzer for the testing of purified water supplies at the CooperVision Manufacturing, Ltd. facilities located in Hamble, UK and Chandlers Ford, UK.

Total: 142