PMA Monthly approvals from 12/1/2019 to 12/31/2019

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170038	12/06/2019	PMAO - PMA Origi	CENTRIMAG CIRCULATORY SUPPORT SYSTEM	ABBOTT	Approval for temporary circulatory support for up to 30 days for one or both sides of the heart to treat postcardiotomy patients who fail to wean from cardiopulmonary bypass, providing a bridge to decision when it is unclear whether the patient's heart will recover or whether the patient will need alternative, longer-term therapy.
P180027	12/16/2019	PMAO - PMA Origi	FLOW RE-DIRECTION ENDOLUMINAL DEVICE (FRED®) SYSTEM	MICROVENTION TERUMO	Approval for The Flow Re-Direction Endoluminal Device (FRED®) System. The Flow Re-Direction Endoluminal Device (FRED®) System is indicated for use in the internal carotid artery from the petrous segment to the terminus for the endovascular treatment of adult patients (22 years of age or older) with wide-necked (neck width >= 4 mm or dome-to-neck ratio < 2) saccular or fusiform intracranial aneurysms arising from a parent vessel with a diameter >= 2.0 mm and <= 5.0 mm.

Total: 2

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970012/S164	12/30/2019	N - Normal 180 Day	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Approval for a Liquid Injection Molding process change and silicone material change.
P790007/S062	12/10/2019	R - Real-Time Proc	HANCOCK VALVED CONDUIT MODIFIED ORIFICE	MEDTRONIC HEART VALVES	Approval for a modification to the polypropylene resin material formulation used in the packaging lid and retainer assembly.
P830055/S236	12/23/2019	R - Real-Time Proc	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for minor changes in labeling for instructions for use (IFU).
P830055/S238	12/03/2019	S - Special CBE	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for an increase in the inspection frequency to 100% of the box width for every batch at the polish step when manufacturing the Attune Cementless PS Femoral Product Family
P830055/S239	12/23/2019	S - Special CBE	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for the addition of 100% inspection of the Cone Counterbore Depth feature (i.e., CTQ-15) for the Attune RP Revision Tibial Base product family.
P840001/S447	12/26/2019	R - Real-Time Proc	ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Approval for changing the suppliers of the battery electrode material.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P850022/S030	12/03/2019	R - Real-Time Proc	BIOMET ORTHOPAK NON-INVASIVE BONE GROWTH STIMULATOR SYSTEM AND BIOMET SPINALPAK NON-INVASIVE SPINE FUSION STIMULATOR SYSTEM	EBI, LLC	Approval for a modification to the cable housing material and design.
P870078/S047	12/10/2019	R - Real-Time Proc	HANCOCK VALVED CONDUIT LOW POROSITY	MEDTRONIC, INC.	Approval for a modification to the polypropylene resin material formulation used in the packaging lid and retainer assembly.
P880086/S307	12/23/2019	R - Real-Time Proc	ASSURITY, ASSURITY+, ENDURITY, ACCENT FAMILY OF PACEMAKER	ST. JUDE MEDICAL, INC.	Approval for changes to Merlin PCS 3650 Programmer Model 3330 Software.
P900009/S044	12/20/2019	N - Normal 180 Day	SONIC ACCELERATED FRACTURE HEALING SYSTEM MODEL 2A	BIOVENTUS LLC	Approval for modified indications for use to include adjunctive use in patients with internal or external fracture fixation hardware present, patients undergoing treatment for infection at the fracture site, and patients believed to have diminished bone quality.
P910023/S422	12/23/2019	R - Real-Time Proc	CURRENT, CURRENT ACCEL, CURRENT+, ELLIPSE, FORTIFY, FORTIFY ASSURA, EPIC/ EPIC+, ATLAS/II/+ FAMILY OF ICDS	ST. JUDE MEDICAL	Approval for Merlin PCS 3650 Programmer Model 3330 Software v24.6.1.
P910077/S174	12/16/2019	R - Real-Time Proc	MULTIPLE APPLICATION UTILITY (MAU) AND DATA MANAGEMENT SYSTEM (DM) LATITUDE PROGRAMMING SYSTEM) LPS)	BOSTON SCIENTIFIC	Approval for the Automatic Screening Tool on the Model 3300 LATITUDE Programming System and associated changes to the existing programming system support software Multiple Application Utility and Data Manager.
P930014/S120	12/30/2019	Y - 135 Review Tra	ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Approval for an alternate supplier for the UltraSert® Plunger, Spring and Main Body molded components.
P960058/S144	12/23/2019	R - Real-Time Proc	HIRESOLUTION BIONIC EAR SYSTEM	ADVANCED BIONICS	Approval for manufacturing changes for the HiRes Ultra Implant and labeling changes to the Surgeon Manual.
P970013/S081	12/23/2019	R - Real-Time Proc	MICRONY FAMILY OF PACEMAKERS	ST. JUDE MEDICAL, INC.	Approval for changes to Merlin PCS 3650 Programmer Model 3330 Software.
P970031/S067	12/10/2019	R - Real-Time Proc	FREESTYLE BIOPROSTHESIS	MEDTRONIC, INC.	Approval for a modification to the polypropylene resin material formulation used in the packaging lid and retainer assembly.
P970051/S187	12/04/2019	O - Normal 180 Day	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for a manufacturing site for two sound processing units: the CP910 and CP920.
P980016/S722	12/16/2019	R - Real-Time Proc	EVERA S DR/VR ICD, EVERA XT DR/VR ICD, EVERA MRI DF-1 ICD, EVERA MRI ICD, MIRRO MRI DR/VR ICD, AND PRIMO MRI DR/VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for RAMware updates to ICD and CRT-D devices and corresponding updates to the Medtronic CareLink 2090 Programmer Model SW016 and CareLink Encore 29901 Programmer Model SW033.
P980043/S072	12/10/2019	R - Real-Time Proc	HANCOCK II BIOPROSTHESIS	MEDTRONIC, INC.	Approval for a modification to the polypropylene resin material formulation used in the packaging lid and retainer assembly.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P990064/S080	12/10/2019	R - Real-Time Proc	MOSAIC BIOPROSTHESIS	MEDTRONIC, INC.	Approval for a modification to the polypropylene resin material formulation used in the packaging lid and retainer assembly.
P000015/S038	12/04/2019	O - Normal 180 Day	NUCLEUS 24 AUDITORY BRAINSTEM IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for a manufacturing site for two sound processing units: the CP910 and CP920.
P000053/S105	12/30/2019	N - Normal 180 Day	AMS SPHINCTER 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a Liquid Injection Molding process change and silicone material change.
P000054/S055	12/13/2019	R - Real-Time Proc	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval for an additional configuration of the vials used for the sterile water for injection used to reconstitute the lyophilized rhBMP-2 component of Infuse Bone Graft.
P000058/S074	12/13/2019	R - Real-Time Proc	INFUSE BONE GRAFT/ MEDTRONIC INTERBODY FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval for an additional configuration of the vials used for the sterile water for injection used to reconstitute the lyophilized rhBMP-2 component of Infuse Bone Graft.
P010030/S127	12/05/2019	R - Real-Time Proc	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Approval for a new version of the device software.
P010031/S683	12/16/2019	R - Real-Time Proc	BRAVA CRT-D, BRAVA QUAD CRT-D, VIVA QUAD CRT-D, VIVA QUAD S/XT CRT-D, AND VIVA S/XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for RAMware updates to ICD and CRT-D devices and corresponding updates to the Medtronic CareLink 2090 Programmer Model SW016 and CareLink Encore 29901 Programmer Model SW033.
P020004/S167	12/09/2019	R - Real-Time Proc	GORE EXCLUDER AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Approval for the Gore Excluder AAA Trunk component to adopt the packaging system used for the Gore Excluder Thoracoabdominal Branch Endoprosthesis.
P020004/S172	12/20/2019	S - Special CBE	GORE EXCLUDER AAA ENDOPROSTHESIS AND GORE EXCLUDER ILIAC BRANCH ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Approval for updates to the Instructions for Use. The updates include modifications to existing warning statements, addition of a new warning statement, addition of new procedural steps and recommended material, and addition of new adverse events that may occur and/or require reintervention or additional procedural time.
P020012/S032	12/18/2019	R - Real-Time Proc	ARTEFILL, BELLAFILL PMMA COLLAGEN PERMANENT DERMAL FILLER	SUNEVA MEDICAL, INC.	Approval to implement a change in raw material specifications for hydrochloric acid, sodium chloride, acetic acid, and citric acid monohydrate
P020012/S033	12/13/2019	R - Real-Time Proc	ARTEFILL, BELLAFILL PMMA COLLAGEN PERMANENT DERMAL FILLER	SUNEVA MEDICAL, INC.	Approval to implement a change in raw material specifications for Sodium Hydroxide
P020050/S034	12/13/2019	R - Real-Time Proc	WAVELIGHT EX500 LASER SYSTEM/ALLEGRO TOPOLYZER VARIO	ALCON LABORATORIES, INC.	Approval for changes to the software for the Allegro Topolyzer VARIO Diagnostic System related to the graphic user interface (GUI), workflow processing and improvements of picture recognition by increasing resolution.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030004/S021	12/10/2019	O - Normal 180 Day	APOLLO ONYX DELIVERY MICROCATHETER	EV3 NEUROVASCULAR	Approval for a manufacturing site located at Medtronic Distribution Center, 4340 Swinnea Road, Memphis, Tennessee 38118, for the repackaging of the Apollo Onyx Delivery Microcatheter and Pipeline Flex Embolization Device.
P030008/S030	12/13/2019	R - Real-Time Proc	WAVELIGHT EX500 LASER SYSTEM/ALLEGRO TOPOLYZER VARIO	ALCON LABORATORIES, INC.	Approval for changes to the software for the Allegro Topolyzer VARIO Diagnostic System related to the graphic user interface (GUI), workflow processing and improvements of picture recognition by increasing resolution.
P030035/S177	12/23/2019	R - Real-Time Proc	ANTHEM, ALLURE/RF, ALLURE QUADRA/RF FAMILY OF CRT-PS	ST. JUDE MEDICAL, INC.	Approval for changes to Merlin PCS 3650 Programmer Model 3330 Software.
P030054/S372	12/20/2019	O - Normal 180 Day	QUADRIPOLAR PACING	ST. JUDE MEDICAL	Approval for updates to the user¿s manual to include a new section that reflects long-term safety and effectiveness data from the Quadripolar Pacing Post Approval Study.
P030054/S373	12/23/2019	R - Real-Time Proc	PROMOTE/+/RF/Q, PROMOTE ACCEL, PROMOTE QUADRA, UNIFY, UNIFY ASSURA, UNIFY QUADRA, QUADRA ASSURA, EPIC+/HF/HF+/II HF/II+ HF FAMILY OF CRT-DS	ST. JUDE MEDICAL	Approval for changes to Merlin PCS 3650 Programmer Model 3330 Software.
P050010/S022	12/05/2019	R - Real-Time Proc	PRODISC L	CENTINEL SPINE, LLC	Approval for modifications to the packaging of the prodisc L
P050023/S138	12/17/2019	R - Real-Time Proc	CARDIOMESSENGER SMART 4G LTE	BIOTRONIK, INC.	Approval for a new updated version of the CardioMessenger Smart device that supports 4G capabilities.
P050027/S018	12/20/2019	Y - 135 Review Tra	KARL STORZ PHOTODYNAMIC DIAGNOSTIC D-LIGHT C (PDD) SYSTEM	KARL STORZ ENDOSCOPY-AMERICA, INC.	Approval for a change to the light output spectral analysis measuring method of the D-Light C Light Source
P050053/S046	12/16/2019	R - Real-Time Proc	INFUSE BONE GRAFT	MEDTRONIC INC.	Approval for an additional configuration of the vials used for the sterile water for injection used to reconstitute the lyophilized rhBMP-2 component of Infuse Bone Graft.
P070004/S019	12/18/2019	R - Real-Time Proc	SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Approval for changes to the quality acceptance criteria used in the manufacturing process of Sientra OPUS Silicone Gel Breast Implants
P070026/S068	12/23/2019	R - Real-Time Proc	CERAMAX CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Approval for minor changes in labeling for instructions for use (IFU).
P080011/S100	12/17/2019	N - Normal 180 Day	BIOFINITY (COMFILCON A) TORIC MULTIFOCAL SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION, INC.	Approval for the addition of a new lens design, toric multifocal, for the Biofinity (comfilcon A) Soft (hydrophilic) Extended Wear Contact Lenses.
P100006/S011	12/06/2019	O - Normal 180 Day	AUGMENT BONE GRAFT AND AUGMENT INJECTABLE	BIOMIMETIC THERAPEUTICS,LLC	Approval for a manufacturing site located at BioMimetic Therapeutics, LLC, 11576 Memphis-Arlington Road, Building C at the Memphis Arlington Campus, Arlington, Tennessee 38002 as an alternate site for product assembly and final kit packaging.
P100018/S022	12/10/2019	O - Normal 180 Day	PIPELINE FLEX EMBOLIZATION DEVICE	MICRO THERAPEUTICS DBA EV3 NEUROVASCULAR	Approval for a manufacturing site located at Medtronic Distribution Center, 4340 Swinnea Road, Memphis, Tennessee 38118 for the repackaging of the Apollo Onyx Delivery Micro Catheter and Pipeline Flex Embolization Device.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100026/S075	12/17/2019	R - Real-Time Proc	NEUROPACE RNS SYSTEM	NEUROPACE INC	Approval for 1) a firmware update (RAM 7.101) to the RNS Neurostimulator (model RNS-320) to disable Long Episode counting during telemetry; and 2) an adjustment to the crystal oscillator trim value (from 00h to 64h) on the neurostimulator to mitigate the possibility of the device unnecessarily transitioning into passive mode.
P100042/S024	12/16/2019	N - Normal 180 Day	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Approval for the addition of a Multi-tube unit (MTU) sidecar, Continuous Fluids Module, Waste-to-Drain Module, and Shuttle Module to the Panther and Panther Fusion instruments.
P110013/S097	12/18/2019	O - Normal 180 Day	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for changes to the directions for use to include the most currently available long-term clinical follow-up data for the Resolute Integrity US XI Sub-study.
P110014/S010	12/02/2019	O - Normal 180 Day	MARGINPROBE SYSTEM	DUNE MEDICAL DEVICES INC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P110042/S129	12/16/2019	R - Real-Time Proc	EMBLEM S-ICD AUTOMATED SCREENING TOOL	BOSTON SCIENTIFIC CORPORATION	Approval for the Automatic Screening Tool on the Model 3300 LATITUDE Programming System and associated changes to the existing programming system support software Multiple Application Utility and Data Manager.
P120007/S022	12/16/2019	N - Normal 180 Day	APTIMA HPV 16 18/45 GENOTYPE ASSAY	GEN-PROBE INCORPORATED	Approval for the addition of a Multi-tube unit (MTU) sidecar, Continuous Fluids Module, Waste-to-Drain Module, and Shuttle Module to the Panther and Panther Fusion instruments.
P130016/S038	12/04/2019	O - Normal 180 Day	NUCLEUS HYBRID L24 IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for a manufacturing site located at Cochlear Malaysia Sdn Bhd, Unit UG-1, Upper Ground Floor, Vertical Podium, Avenue 3, Bangsar South, No. 8 Jalan Kerinchi, 59200 Kuala Lumpur, Malaysia, for two sound processing units: the CP910 and CP920.
P130021/S064	12/10/2019	R - Real-Time Proc	EVOLUT R AND EVOLUT PRO	MEDTRONIC COREVALVE LLC	Approval for a modification to the polypropylene resin material formulation used in the packaging lid and retainer assembly.
P130022/S024	12/18/2019	N - Normal 180 Day	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for a new optional accessory tool - Nevro passing elevator accessory tool (PEAT) for use with Nevros Senza Spinal Cord Stimulation (SCS) System.
P130024/S030	12/19/2019	N - Normal 180 Day	LUTONIX 018 DRUG COATED BALLOON PTA CATHETER (LUTONIX 018 DCB)	LUTONIX	Approval for the addition of a maximum balloon length of 300 mm for the 4, 5 and 6 mm balloon diameter sizes, a new colorant in the base catheter, and an increase in marker band length for the Lutonix 018 Drug Coated Balloon PTA Catheter indicated for use in native superficial femoral or popliteal arteries.
P130028/S025	12/31/2019	N - Normal 180 Day	ALGOVITA SPINAL CORD STIMULATION SYSTEM	NUVECTRA CORPORATION	Approval for whole-body MRI labeling indication for implanted components of the Algovita SCS System for use in closed bore, horizontal, static magnetic field strength of 1.5T MR environments.
P140004/S016	12/02/2019	R - Real-Time Proc	SUPERION INDIRECT DECOMPRESSION SYSTEM	BOSTON SCIENTIFIC NEUROMODULATION	Approval for modifications made to the packaging of the implant.
P140011/S006	12/10/2019	R - Real-Time Proc	MAMMOMAT REVELATION WITH TOMOSYNTHESIS OPTION	SIEMENS MEDICAL SOLUTIONS USA, INC.	Approval for changes to the detector software and the tomosynthesis reconstruction pipeline.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140017/S016	12/10/2019	R - Real-Time Proc	MELODY	MEDTRONIC INC.	Approval for a modification to the polypropylene resin material formulation used in the packaging lid and retainer assembly.
P140018/S017	12/20/2019	R - Real-Time Proc	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Approval for a change to the de-nesting coating agent added to the polyethylene terephthalate glycol (PET-G) film component of the packaging.
P140020/S019	12/27/2019	N - Normal 180 Day	BRACANALYSIS CDX	MYRIAD GENETIC LABORATORIES	Approval for expansion of the indications for use as a companion diagnostic for LYNPARZA (olaparib) in pancreatic cancer patients
P140033/S049	12/23/2019	R - Real-Time Proc	ASSURITY MRI AND ENDURITY MRI FAMILY OF PACEMAKERS	ST. JUDE MEDICAL, INC.	Approval for changes to Merlin PCS 3650 Programmer Model 3330 Software.
P150012/S083	12/16/2019	N - Normal 180 Day	INGEVITY + LEAD - ACTIVE FIXATION	BOSTONSCIENTIFIC	Approval to add the INGEVITY+ (plus) leads to the INGEVITY MRI lead family.
P150014/S030	12/11/2019	Y - 135 Review Tra	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Approval for a change in material used to manufacture a critical instrument component.
P150015/S032	12/11/2019	Y - 135 Review Tra	COBAS HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Approval for a change in material used to manufacture a critical instrument component.
P160013/S005	12/20/2019	R - Real-Time Proc	ORGAN CARE SYSTEM (OCS) LUNG SYSTEM	TRANSMEDICS, INC	Approval for a change in the OCS Monitor Battery printed circuit board.
P160013/S006	12/20/2019	R - Real-Time Proc	ORGAN CARE SYSTEM (OCS) LUNG SYSTEM	TRANSMEDICS, INC	Approval for a change in the material of the Large Valve Ball of the OCS Perfusion Module.
P160014/S009	12/24/2019	N - Normal 180 Day	COBRA PZF NANOCOATED CORONARY STENT SYSTEM	CELONOVA BIOSCIENCES, INC.	Approval for changes to the labeling, including the maximum post-dilatation limits.
P160014/S012	12/06/2019	R - Real-Time Proc	COBRA PZF NANOCOATED CORONARY STENT SYSTEM	CELONOVA BIOSCIENCES, INC.	Approval for a change in the bonding method of the hypotube bond.
P160021/S023	12/03/2019	O - Normal 180 Day	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Approval for updating the Instructions for Use with results from the Post Approval Study.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160022/S008	12/16/2019	R - Real-Time Proc	X SERIES®, R SERIES®, AED PRO®, AED 3¿ BLS PROFESSIONAL DEFIBRILLATORS, PRO-PADZ RADIOTRANSPARENT ELECTRODE, SUREPOWER BATTERY PACK, SUREPOWER II BATTERY PACK, AED PRO® NON-RECHARGEABLE LITHIUM BATTERY PACK, AED 3 BATTERY PACK, SUREPOWER CHARGER, AND SUREPOWER SINGLE BAY CHARGER	ZOLL MEDICAL CORPORATIO N	Approval for the Mobile Streaming feature on the X Series/Propaq MD device software.
P160023/S015	12/16/2019	N - Normal 180 Day	APTIMA HCV QUANT DX ASSAY	HOLOGIC, INC.	Approval for the addition of a Multi-tube unit (MTU) sidecar, Continuous Fluids Module, Waste-to-Drain Module, and Shuttle Module to the Panther and Panther Fusion instruments.
P160035/S010	12/20/2019	Y - 135 Review Tra	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Approval for optimization of the PU-A solution used in the production of the driving membranes.
P160039/S005	12/23/2019	N - Normal 180 Day	REMEDE® SYSTEM	RESPICARDIA	Approval for software changes to the Model 7001 Remede Reports Application and the addition of Respistim LQ/LQS stimulation lead models to the family of respistim L (left) leads.
P160041/S023	12/11/2019	Y - 135 Review Tra	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Approval for a change in material used to manufacture a critical instrument component.
P160054/S024	12/30/2019	S - Special CBE	HEARTMATE 3 LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATIO N	Approval for a revision of the Instructions for Use and Patient Handbook to provide further instructions on the management of electrostatic discharge.
P170003/S011	12/09/2019	R - Real-Time Proc	LUTONIX® 035 DRUG COATED BALLOON PTA CATHETER	LUTONIX	Approval for an extension to the device balloon size matrix (7.0, 8.0 and 9.0 mm diameters in 80 and 100 mm lengths and 12.0 mm diameter available in 60 mm length) and a reduction in the cone angle for the 8 through 12 mm diameter balloons to accommodate a reduction in sheath compatibility.
P170006/S016	12/10/2019	R - Real-Time Proc	AVALUS	MEDTRONIC INC.	Approval for a modification to the polypropylene resin material formulation used in the packaging lid and retainer assembly.
P170019/S006	12/03/2019	P - Panel Track	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval order for extending the label claim to include an indication for PIQRAY (alpelisib) in breast cancer patients with PIK3CA C420R, E542K, E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R, H1047L, H1047R, and H1047Y alterations.
P170019/S010	12/16/2019	O - Normal 180 Day	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval of a second site.
P170025/S013	12/16/2019	N - Normal 180 Day	APTIMA HBV QUANT ASSAY	HOLOGIC, INC	Approval for the addition of a Multi-tube unit (MTU) sidecar, Continuous Fluids Module, Waste-to-Drain Module, and Shuttle Module to the Panther and Panther Fusion instruments.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170034/S002	12/10/2019	O - Normal 180 Day	HYDRUS MICROSTENT	IVANTIS, INC.	Approval for a manufacturing site located at Norman Noble, Inc.; 5507 Avion Park Drive; Highland Heights, Ohio 44143, Contract Manufacturer (microstent).
P170034/S003	12/13/2019	O - Normal 180 Day	HYDRUS MICROSTENT	IVANTIS, INC.	Approval for a manufacturing site located at Ivantis, Inc.; 201 Technology; Irvine, California 92618.
P180002/S011	12/23/2019	R - Real-Time Proc	ZEPHYR ENDOBRONCHIAL VALVE SYSTEM	PULMONX CORPORATION	Approval for including a smaller outer shipper box option which has the capacity for up to five (5) Zephyr Endobronchial Delivery Catheter (EDC) devices.
P180029/S003	12/06/2019	O - Normal 180 Day	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval of the protocol for the Post Approval Study "RWU of LOTUS Edge Valve System."
P190006/S002	12/12/2019	R - Real-Time Proc	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for changes to the Charging Device (CD), model 1401, which included a new rechargeable Li-ion battery, a new speaker, and corresponding software changes.

Total: 86

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S067	12/03/2019	X - 30-Day Notice	SURGICEL ABSORBABLE HEMOSTATS	ETHICON, INC.	Duplication of the existing Secondary Packaging Room to a new location inside Building #4 in the Ethicon, San Lorenzo, Puerto Rico facility.
N18286/S033	12/03/2019	X - 30-Day Notice	GELFOAM (ABSORBABLE GELATIN) STERILE SPONGE	PFIZER, INC.	Changes to the quality control testing used at the GELFOAM Brick crosslinked (sub-assembly) stage of the GEL-FLOW NT.
N970003/S246	12/04/2019	X - 30-Day Notice	ESSENTIO SR, ESSENTIO DR, ESSENTIO EL DR, PROPONENT SR, PROPONENT DR, PROPONENT EL DR, ACCOLADE SR, ACCOLADE DR, ACCOLADE EL DR, ALTRUA 2 SR, ALTRUA 2 DR, AND ALTRUA 2 EL DR	BOSTON SCIENTIFIC CORP.	Add a post-reflow manufacturing inspection for printed circuit boards.
N970012/S170	12/04/2019	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE/INFLATABLE PENILE PROSTHESIS (IPP) WITH AND WITHOUT INHIBIZONE TREATMENT	BOSTON SCIENTIFIC CORP.	Addition of Boston Scientifics St. Paul facility as an alternate manufacturing site for the Kink Resistant Tubing Components.
N970012/S171	12/12/2019	X - 30-Day Notice	AMS 700 INFLATABLE PENILE PROSTHESIS (IPP) WITH AND WITHOUT INHIBIZONE	BOSTON SCIENTIFIC CORP.	Changes to the manufacture of the texturized polyethylene terephthalate (PET) yarn located in the cylinders of the AMS 700.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970012/S172	12/11/2019	X - 30-Day Notice	AMS 700 INFLATABLE PENILE PROSTHESIS (IPP) WITH AND WITHOUT INHIBIZONE, AMS AMBICOR IPP	BOSTON SCIENTIFIC CORP.	Software upgrade of the programmable logic controller for preconditioning and aeration cells used for Cycle 101, and utility update of the preconditioning cell steam supply from steam boilers to a pre-existing steam supply at the BSC Coventry, Rhode Islands facility.
N970012/S173	12/13/2019	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE/ INFLATABLE PENILE PROSTHESIS (IPP) WITH AND WITHOUT INHIBIZONE TREATMENT	BOSTON SCIENTIFIC CORP.	Changes to the milling and molding manufacturing process for the front tip component of the AMS 700 Inflatable Penile Prosthesis (IPP) with and without InhibiZone Treatment.
P830055/S240	12/04/2019	X - 30-Day Notice	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Addition of an additional CNC machine for manufacture of the Attune Rotating Platform Tray components.
P830055/S241	12/03/2019	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Addition of a new laser marking machine for the LCS Mobile Bearing Trays.
P830061/S176	12/13/2019	X - 30-Day Notice	CAPSURE SENSE LEAD; VITATRON CRYSTALLINE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update pull test control limits and sampling size used to monitor special manufacturing process in leads manufacturing.
P830061/S177	12/03/2019	X - 30-Day Notice	CAPSURE SENSE LEAD, CAPSURE SP NOVUS LEAD AND VITATRON CRYSTALLINE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement FACTORYworks version 9.7 at MECC, MSO, and MTC.
P830063/S014	12/11/2019	X - 30-Day Notice	PRISMAFLEX TPE2000	BAXTER INTERNATIONAL, INC.	Addition of an anti-error tubing connector feature to the support plate of the Prismaflex TPE2000 Set and a move of the manufacturing of several set components (e.g., striped tubes, luer components, and injection sites) to Marsa, Malta from Medolla, Italy.
P840001/S448	12/11/2019	X - 30-Day Notice	RESTORE, 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 (Release 9.7), which is comprised of (1) FW Business Rule Client 9.7, (2) FW Configuration Client 9.2.2, and (3) Integrated Manufacturing Process Management (iMPM) Web Services (WS) 3.6.
P840001/S449	12/19/2019	X - 30-Day Notice	ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Modify ionic contamination monitoring of implantable neurostimulator (INS) devices.
P850064/S042	12/13/2019	X - 30-Day Notice	LIFEPULSE HIGH FREQUENCY VENTILATOR	BUNNELL, INC.	Change to a test fixture used for the Patient Circuit post assembly.

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P850089/S145	12/03/2019	X - 30-Day Notice	CAPSURE SP NOVUS LEAD, CAPSURE SP Z LEAD, CAPSURE SP NOVUS LEAD AND VITATRON IMPULSE II LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement FACTORYworks version 9.7 at MECC, MSO, and MTC.
P860004/S347	12/11/2019	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM AND ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Update Medtronics manufacturing software, Manufacturing Execution System to Factory Works (Release 9.7), which is comprised of (1) FW Business Rule Client 9.7, (2) FW Configuration Client 9.2.2, and (3) Integrated Manufacturing Process Management (iMPM) Web Services (WS) 3.6.
P860004/S348	12/19/2019	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Perform retest activities of the SynchroMed® Infusion System and Ascenda® Intrathecal Catheters port helium leak test (catheter leak test) manufacturing step and to separate the tube inflate inspection from the catheter leak test step.
P880047/S033	12/04/2019	X - 30-Day Notice	GYNECARE INTERCEED ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Duplication of the existing Secondary Packaging Room to a new location inside Building #4 in the Ethicon, San Lorenzo, Puerto Rico facility.
P880086/S309	12/06/2019	X - 30-Day Notice	ENDURITY, ENDURITY CORE, ASSURITY AND ASSURITY +	ST. JUDE MEDICAL, INC.	Alternate supplier for the RF antenna and ribbon carrier components used in Scalable Brady Platform SR/DR pacemakers.
P890003/S421	12/13/2019	X - 30-Day Notice	CAPSURE VDD-2 LEAD; VITATRON BRILLIANT S+ VDD LEAD	MEDTRONIC, INC.	Update pull test control limits and sampling size used to monitor special manufacturing process in leads manufacturing.
P890003/S422	12/03/2019	X - 30-Day Notice	CAPSURE VDD-2 LEAD, CARELINK SMARTSYNC DEVICE MANAGER PROGRAMMER AND VITATRON BRILLIANT S+ VDD LEAD	MEDTRONIC, INC.	Implement FACTORYworks version 9.7 at MECC, MSO, and MTC.
P890003/S423	12/18/2019	X - 30-Day Notice	CARELINK SMARTSYNC DEVICE MANAGER PROGRAMMER	MEDTRONIC, INC.	Modify testing procedures for the Mixed Signal Integrated Circuit.
P890003/S424	12/19/2019	X - 30-Day Notice	MYCARELINK SMART PATIENT READER, CARELINK ENCORE PROGRAMMER	MEDTRONIC, INC.	Add a X-Ray inspection in the printed circuit board manufacturing process used in the MyCare Link Smart Patient Reader and CareLink Encore Programmer.
P890023/S040	12/18/2019	X - 30-Day Notice	BIOMEDICS 55 ASPHERE (OCUFILCON D) EXTENDED WEAR SOFT CONTACT LENSES	THE COOPER COMPANIES	Implementation of the manufacture of Biomedics 55 Asphere with a base curve of 8.9 mm in the Scottsville facility.
P900061/S156	12/03/2019	X - 30-Day Notice	EPICARDIAL PATCH LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement FACTORYworks version 9.7 at MECC, MSO, and MTC.

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P920015/S237	12/04/2019	X - 30-Day Notice	SPRINT QUATTRO LEAD	MEDTRONIC INC.	Add an additional visual inspection of the helix.
P920015/S238	12/13/2019	X - 30-Day Notice	SPRINT QUATTRO LEAD; SUBCUTANEOUS LEAD; TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Update pull test control limits and sampling size used to monitor special manufacturing process in leads manufacturing.
P920015/S239	12/03/2019	X - 30-Day Notice	HV SPLITTER/ADAPTOR KIT, IS-1 CONNECTOR PORT PIN PLUG KIT, SPRINT QUATTRO LEAD, SUBCUTANEOUS LEAD AND TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Implement FACTORYworks version 9.7 at MECC, MSO, and MTC.
P930027/S022	12/19/2019	X - 30-Day Notice	IMMULITE 2000 PSA	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Modify the resin used in manufacture of reaction tubes.
P930038/S097	12/13/2019	X - 30-Day Notice	ANGIO-SEAL VASCULAR CLOSURE DEVICES	TERUMO MEDICAL CORPORATIO N	Transfer of the Gearbox Assembly Machine for ANGIO-SEAL Evolution devices from Abbott to Terumo Puerto Rico (TPR).
P930039/S205	12/04/2019	X - 30-Day Notice	CAPSUREFIX NOVUS; VITATRON CRYSTALLINE ACTIVE FIXATION LEAD	MEDTRONIC, INC.	Add an additional visual inspection of the helix.
P930039/S206	12/13/2019	X - 30-Day Notice	CAPSUREFIX NOVUS LEAD; VITATRON CRYSTALLINE ACTIVE FIXATION LEAD	MEDTRONIC, INC.	Update pull test control limits and sampling size used to monitor special manufacturing process in leads manufacturing.
P930039/S207	12/03/2019	X - 30-Day Notice	CAPSUREFIX LEAD, CAPSUREFIX NOVUS LEAD AND VITATRON CRYSTALLINE ACTIVE FIXATION LEAD	MEDTRONIC, INC.	Implement FACTORYworks version 9.7 at MECC, MSO, and MTC.
P950009/S023	12/06/2019	X - 30-Day Notice	BD FOCALPOINT GS IMAGING SYSTEM	BD DIAGNOSTICS	Like-for-like replacement of Lamp House components.
P950024/S089	12/13/2019	X - 30-Day Notice	CAPSURE EPICARDIAL PACING LEAD	MEDTRONIC INC.	Update pull test control limits and sampling size used to monitor special manufacturing process in leads manufacturing.
P950024/S090	12/03/2019	X - 30-Day Notice	CAPSURE EPICARDIAL PACING LEAD	MEDTRONIC INC.	Implement FACTORYworks version 9.7 at MECC, MSO, and MTC.
P950037/S208	12/20/2019	X - 30-Day Notice	SIELLO/SOLIA S LEADS TIP	BIOTRONIK, INC.	Automate the manufacturing of lead tips used in Solia and Siello pacemaker electrodes.
P960009/S362	12/11/2019	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Update Medtronics manufacturing software, Manufacturing Execution System to Factory Works (Release 9.7), which is comprised of (1) FW Business Rule Client 9.7, (2) FW Configuration Client 9.2.2, and (3) Integrated Manufacturing Process Management (iMPM) Web Services (WS) 3.6.

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P960009/S364	12/19/2019	X - 30-Day Notice	ACTIVE DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Modify ionic contamination monitoring of implantable neurostimulator (INS) devices.
P960013/S110	12/17/2019	X - 30-Day Notice	TENDRIL ST AND TENDRIL STS LOW VOLTAGE LEADS	ST JUDE MEDICAL	Manufacturing process improvements for MCRD components in Tendril leads.
P960040/S445	12/04/2019	X - 30-Day Notice	ORIGEN MINI ICD VR, ORIGEN MINI ICD DR, INOGEN MINI ICD VR, INOGEN MINI ICD DR, DYNAGEN MINI ICD VR, DYNAGEN MINI ICD DR, ORIGEN EL ICD VR, ORIGEN EL ICD DR, MOMENTUM EL ICD VR, MOMENTUM EL ICD DR, INOGEN EL ICD VR, INOGEN EL ICD DR, DYNAGEN EL ICD VR, DYNAGEN EL ICD DR, ICD AUTOGEN, VIGILANT, VIGILANT EL ICD VR, VIGILANT EL ICD DR, PERCIVA, PERCIVA ICD VR, PERCIVA ICD DR, RESONATE, RESONATE EL ICD VR, AND RESONATE EL ICD DR	BOSTON SCIENTIFIC	Add a post-reflow manufacturing inspection for printed circuit boards.
P960058/S146	12/17/2019	X - 30-Day Notice	HIRESOLUTION BIONIC EAR SYSTEM	ADVANCED BIONICS	Change of acceptable test limits for the Naida cochlear implant sound processor.
P970004/S303	12/11/2019	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM AND VERIFY EVALUATION SYSTEM (SNS URINARY)	MEDTRONIC NEUROMODULATION	Update Medtronics manufacturing software, Manufacturing Execution System to Factory Works (Release 9.7), which is comprised of (1) FW Business Rule Client 9.7, (2) FW Configuration Client 9.2.2, and (3) Integrated Manufacturing Process Management (iMPM) Web Services (WS) 3.6.
P970004/S304	12/19/2019	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS URINARY)	MEDTRONIC NEUROMODULATION	Modify ionic contamination monitoring of implantable neurostimulator (INS) devices.
P970020/S084	12/13/2019	X - 30-Day Notice	MULTI-LINK ULTRA RX CORONARY STENT SYSTEM	ABBOTT VASCULAR INC.	Change to an alternate supplier for hypotube components.
P970051/S194	12/13/2019	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Manufacturing change of the silicone overmoulding used in the CI500 Series Cochlear Implant and the ABI541 Auditory Brainstem Implant.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S723	12/10/2019	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	Expanding the battery manufacturing facility to include additional production floor space with new identical equipment and relocated equipment.
P980016/S724	12/03/2019	X - 30-Day Notice	EVERA MRI DF-1 ICD, EVERA MRI ICD, EVERA S VR/DR/ICD, EVERA XT DR/ VR/ ICD, MIRROR MRI DR/ VR ICD, PRIMO MRI DR/VR ICD, PROTECTA ICD, PROTECTA VR/XT ICD, SECURA DR ICD, SECURA ICD, VISIA AF MRI DF1 ICD, VISIA AF MRI VR ICD AND VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement FACTORYworks version 9.7 at MECC, MSO, and MTC.
P980035/S607	12/04/2019	X - 30-Day Notice	ASTRA S DR/SR MRI IPG, ASTRA XT DR/SR MRI IPG AND AZURE S DR/SR MRI IPG, AZURE XT DR/SR MRI IPG	MEDTRONIC INC.	Update the Post Sterilization process to prevent an incorrect feature activation for select implantable devices.
P980035/S608	12/10/2019	X - 30-Day Notice	ADVISA DR, ADVISA DR MRI, ADVISA SR MRI, ASTRA S DR MRI, ASTRA S SR MRI, ASRTRA XT DR MRI, ASTRA XT SR MRI, AZURE S DR MRI, AZURE S SR MRI, AZURE XT DR MRI, AND AZURE XT SR MRI IPG	MEDTRONIC INC.	Expanding the battery manufacturing facility to include additional production floor space with new identical equipment and relocated equipment.
P980035/S609	12/03/2019	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ADVISA DR IPG, ADVISA DR/SR MRI, ASTRA S DR/SR MRI IPG, ASTRA XT DR/SR MRI IPG, ATTESTA DR/SR MRI IPG, AZURE S DR/SR MRI IPG, AXURE XT DR/SR MRI IPG, RELIA IPG, AND SPHERA DR/SR MRI IPG	MEDTRONIC INC.	Implement FACTORYworks version 9.7 at MECC, MSO, and MTC.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980035/S610	12/18/2019	X - 30-Day Notice	ASTRA S DR/SR MRI IPG, ASTRA XT DR/DR MRI IPG AND AZURE S SR MRI IPG XT DR/SR MRI IPG	MEDTRONIC INC.	Modify testing procedures for the Mixed Signal Integrated Circuit.
P980037/S077	12/19/2019	X - 30-Day Notice	ANGIOJET RHEOLYTHIC THROMBECTOMY CATHETER	BOSTON SCIENTIFIC CORP.	Reduce the Ethylene Oxide gas concentration, and qualify additional process challenge devices used in the BSC856 sterilization cycle at the BSC Coventry, RI facility Chamber 7.
P980050/S123	12/13/2019	X - 30-Day Notice	TRANSVENE CS-SVC LEAD	MEDTRONIC INC.	Update pull test control limits and sampling size used to monitor special manufacturing process in leads manufacturing.
P980050/S124	12/03/2019	X - 30-Day Notice	TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Implement FACTORYworks version 9.7 at MECC, MSO, and MTC.
P990009/S059	12/20/2019	X - 30-Day Notice	FLOSEAL HEMOSTATIC MATRIX	BAXTER HEALTHCARE CORP.	Increase the size of the reaction vessel for crosslinking the gelatin component of the device from 200L to 300L
P990074/S043	12/04/2019	X - 30-Day Notice	NATRELLE SALINE-FILLED BREAST IMPLANTS	ALLERGAN	Changes in the sterilization validation of Natrelle Saline-Filled Breast Implants, including a change in the D-value of the biological indicators and a change in the sterilization validation approach.
P000015/S042	12/13/2019	X - 30-Day Notice	NUCLEUS ABI541 AUDITORY BRAINSTEM IMPLANT	COCHLEAR AMERICAS	Manufacturing change of the silicone overmoulding used in the CI500 Series Cochlear Implant and the ABI541 Auditory Brainstem Implant.
P000029/S086	12/19/2019	X - 30-Day Notice	DEFLUX INJECTABLE GEL	PALETTE LIFE SCIENCES	Use of an in-house prepared NaCl solution.
P000053/S109	12/04/2019	X - 30-Day Notice	AMS 800 SERIES PRODUCT LINE/ARTIFICIAL URINARY SPHINCTER WITH AND WITHOUT INHIBIZONE TREATMENT	BOSTON SCIENTIFIC CORP.	Addition of Boston Scientifics St. Paul facility as an alternate manufacturing site for the Kink Resistant Tubing Components.
P000053/S110	12/11/2019	X - 30-Day Notice	AMS 800 ARTIFICIAL URINARY SPHINCTER	BOSTON SCIENTIFIC CORP.	Software upgrade of the programmable logic controller for preconditioning and aeration cells used for Cycle 101, and utility update of the preconditioning cell steam supply from steam boilers to a pre-existing steam supply at the BSC Coventry, Rhode Islands facility.
P000054/S058	12/04/2019	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Modifications to the equipment and flow hoods used in the manufacturing of the collagen component of INFUSE Bone Graft.
P000058/S077	12/04/2019	X - 30-Day Notice	INFUSE BONE GRAFT/ MEDTRONIC INTERBODY FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Modifications to the equipment and flow hoods used in the manufacturing of the collagen component of INFUSE Bone Graft.
P010003/S037	12/20/2019	X - 30-Day Notice	BIOGLUE SURGICAL ADHESIVE	CRYOLIFE, INC.	1) An alternate supplier for a device component; 2) a change in quality control sampling of another device component; and 3) a change in the 5mL syringe plungers dimension lower tolerance.
P010007/S011	12/19/2019	X - 30-Day Notice	IMMULITE 2000 AFP	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Modify the resin used in manufacture of reaction tubes.

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P010012/S512	12/06/2019	X - 30-Day Notice	ACUITY X4 ELECTRODE 2, 3, AND (E24)	BOSTON SCIENTIFIC CORP.	Add an inspection to the ACUITY X4 Electrode 2, 3, and 4 (E24) component manufacturing process.
P010012/S513	12/04/2019	X - 30-Day Notice	ORIGEN CRT-D, ORIGEN X4 CRT-D, MOMENTUM, MOMENTUM CRT-D, MOMENTUM X4 CRT-D, INOGEN CRT-D, INOGEN X4 CRT-D, DYNAGEN CRT-D, DYNAGEN X4 CRT-D, ICD AUTOGEN, VIGILANT, VIGILANT X4 CRT-D, RESONATE, AND RESONATE X4 CRT-D	BOSTON SCIENTIFIC CORP.	Add a post-reflow manufacturing inspection for printed circuit boards.
P010015/S421	12/10/2019	X - 30-Day Notice	CONSULTA, PERCEPTA BIPOLAR, PERCEPTA QUADRIPOLAR, SERENA BIPOLAR, SERENA QUADRIPOLAR, SOLARA BIPOLAR, SOLARA QUADRIPOLAR, SYNCRA AND VIVA CRT-P	MEDTRONIC INC.	Expanding the battery manufacturing facility to include additional production floor space with new identical equipment and relocated equipment.
P010015/S422	12/03/2019	X - 30-Day Notice	ATTAIN BIPOLAR OTW LEAD, ATTAIN OTW LV LEAD, CONSULTA CRT-P, PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P, SOLAR BIPOLAR CRT-P, SOLARA QUADRIPOLAR CRT-P , SYNCARA CRT-P AND VIVA CRT-P	MEDTRONIC INC.	Implement FACTORYworks version 9.7 at MECC, MSO, and MTC.
P010015/S423	12/18/2019	X - 30-Day Notice	PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P AND SOLARA BIPOLAR/QUADRIPOLAR CRT-P	MEDTRONIC INC.	Modify testing procedures for the Mixed Signal Integrated Circuit.
P010019/S074	12/12/2019	X - 30-Day Notice	LOTRAFILCON B SOFT CONTACT LENSES FOR EXTENDED WEAR	ALCON LABORATORIES, INC.	Extension of the lotrafilcon B soft contact lens manufacturing operations at the Alcon Batam, Indonesia production site for inclusion of AIR OPTIX plus Hydraglyde (lotrafilcon B) spherical soft contact lenses.

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P010030/S129	12/09/2019	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Implement an updated injection molding steel tool.
P010030/S130	12/19/2019	X - 30-Day Notice	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Use of an alternate automated gel dispensing method during the manufacture of the LifeVest model 4000 therapy electrodes.
P010031/S684	12/10/2019	X - 30-Day Notice	AMPLIA MRI, AMPLIA MRI QUAD, BRAVA, BRAVA QUAD, CLARIA MRI, CLARIA MRI QUAD, COMPIA MRI, COMPIA MRI QUAD, CONSULTA, PROTECTA, PROTECTA XT, VIVA QUAD S, VIVA QUAD XT, VIVA S, AND VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Expanding the battery manufacturing facility to include additional production floor space with new identical equipment and relocated equipment.
P010031/S685	12/03/2019	X - 30-Day Notice	AMPLIA MRI CRT-D, AMPLIA/CLARIA/COMPIA MRI QUAD CRT-D, BRAVA CRT-D, BRAVA QUAD CRT-D, COMPIA MRI CRT-D,CONSULTA/PROTECTA CRT-D, PROTECTA XT CRT-D, VIVA QUAD S CRT-D, VIVA S CRT-D AND VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement FACTORYworks version 9.7 at MECC, MSO, and MTC.
P010033/S046	12/06/2019	X - 30-Day Notice	QUANTIFERON ¿ TB GOLD AND QUANTIFERON-TB GOLD PLUS	QIAGEN	Addition of a new alternative supplier for a critical raw material.
P010050/S017	12/19/2019	X - 30-Day Notice	IMMULITE 2000 HBSAG & HBS AG CONFIRMATORY	SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS, LTD	Modify the resin used in manufacture of reaction tubes.
P010051/S012	12/19/2019	X - 30-Day Notice	IMMULITE 2000 ANTI-HBC	SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS, LTD	Modify the resin used in manufacture of reaction tubes.
P010052/S013	12/19/2019	X - 30-Day Notice	IMMULITE 2000 ANTI-HBS	SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS, LTD	Modify the resin used in manufacture of reaction tubes.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010053/S011	12/19/2019	X - 30-Day Notice	IMMULITE 2000 ANTI HBC IGM	SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS, LTD	Modify the resin used in manufacture of reaction tubes.
P020016/S011	12/17/2019	X - 30-Day Notice	TOTAL TEMPOROMANDIBULAR JOINT REPLACEMENT SYSTEM	BIOMET MICROFIXATION, INC.	Implementation of updates to the Prints, Inspection Overlays, and Machine program headers of the TMJ Fossa Components.
P030004/S022	12/19/2019	X - 30-Day Notice	ONYX LIQUID EMBOLIC SYSTEM AND APOLLO ONYX DELIVERY MICRO CATHETER	EV3 NEUROVASCULAR	Changes to packaging operations and qualification of additional heat sealing equipment.
P030005/S192	12/04/2019	X - 30-Day Notice	VALITUDE CRT-P, VALITUDE X4 CRT-P, VISIONIST CRT-P, AND VISIONIST X4 CRT-P	GUIDANT CORP.	Add a post-reflow manufacturing inspection for printed circuit boards.
P030017/S332	12/05/2019	X - 30-Day Notice	PRECISION, PRECISION SPECTRA, SPECTRA WAVEWRITER, PRECISION NOVI, PRECISION MONTAGE, AND PRECISION MONTAGE MRI SPINAL CORD STIMULATOR (SCS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Increase the maximum proximal end backfill cure time from 4 hours to 48 hours for the leads and lead extensions product family of the Precision Spinal Cord Stimulator (SCS) Systems.
P030036/S114	12/13/2019	X - 30-Day Notice	SELECTSURE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update pull test control limits and sampling size used to monitor special manufacturing process in leads manufacturing.
P030036/S115	12/03/2019	X - 30-Day Notice	SELECTSECURE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement FACTORYworks version 9.7 at MECC, MSO, and MTC.
P040021/S042	12/04/2019	X - 30-Day Notice	BIOCOR, BIOCOR SUPRA, EPIC AND EPIC SUPRA HEART VALVES	ST. JUDE MEDICAL, INC.	Implementation of differential pressure monitoring data loggers for use with the VAISALA Environmental Monitoring System (EMS) at the SJM/Abbott Brazil manufacturing site.
P040027/S075	12/06/2019	X - 30-Day Notice	GORE VIATORR TIPS ENDOPROSTHESIS AND GORE VIATORR TIPS ENDOPROSTHESIS WITH CONROLLED EXPANSION	W. L. GORE & ASSOCIATES, INC.	Alternate manufacturing equipment as well as the changes this equipment introduces into the stent winding and heat treatment process for the GORE VIATORR TIPS Endoprosthesis and the GORE VIATORR TIPS Endoprosthesis with Controlled Expansion.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040027/S076	12/18/2019	X – 30-Day Notice	GORE VIATORR TIPS ENDOPROSTHESIS AND GORE VIATORR TIPS ENDOPROSTHESIS WITH CONTROLLED EXPANSION	W. L. GORE & ASSOCIATES, INC.	Modified manufacturing process for the laminated film used in manufacture of the GORE VIATORR TIPS Endoprosthesis and the GORE VIATORR TIPS Endoprosthesis with Controlled Expansion.
P040045/S112	12/18/2019	X – 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Modification to the processing aids used during the post-hydration process for the manufacture of VISTAKON® (senofilcon A) Brand Contact Lenses.
P050023/S140	12/19/2019	X – 30-Day Notice	IMPLANTAV CARDIOVERTER DEFIBRILLATOR (NON-CRT), DEFIBRILLATOR, IMPLANTABLE, DUAL-CHAMBER AND DEFIBRILLATOR, AUTOMATIC IMPLANTABLE CARDIVOERTER WITH RESYNCHRONIZATION (CRT-D)	BIOTRONIK, INC.	Manufacturing improvements at the supplier for batteries used in the Acticor and Rivacor families of ICDs and CRT-Ds, and add BIOTRONIK Nuernberg as a second supplier of 12-fold feedthroughs used in Acticor devices.
P050037/S101	12/26/2019	X – 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Addition of an automated application of in process production labels.
P050047/S074	12/03/2019	X – 30-Day Notice	JUVEDERM INJECTABLE GEL IMPLANTS	ALLERGAN	Implementation of an additional cold room at the Pringy II manufacturing facility for the storage of raw materials for Juvéderm® injectable gel implants.
P050051/S036	12/03/2019	X – 30-Day Notice	ARCHITECT AUSAB, LN 1L82	ABBOTT LABORATORIES INC	Change the upstream testing criteria for a critical material used in kit components.
P050052/S118	12/26/2019	X – 30-Day Notice	RADIESSE INJECABLE IMPLANT, RADIESSE (+) LIDOCAINE DERMAL FILLER	MERZ NORTH AMERICA, INC	Addition of an automated application of in process production labels.
P050053/S049	12/04/2019	X – 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC INC.	Modifications to the equipment and flow hoods used in the manufacturing of the collagen component of INFUSE Bone Graft.
P060005/S010	12/19/2019	X – 30-Day Notice	IMMULITE 2000 FREE PSA	SIEMENS MEDICAL SOLUTIONS DIAGNOSTICS LIMITED	Modify the resin used in manufacture of reaction tubes.
P060027/S100	12/04/2019	X – 30-Day Notice	PLATINIUM 4LV CRT-D	MICROPORT CRM USA INC.	Modification of the insert block machining process.
P060039/S097	12/13/2019	X – 30-Day Notice	ATTAIN STARFIX LEAD	MEDTRONIC INC.	Update pull test control limits and sampling size used to monitor special manufacturing process in leads manufacturing.
P060039/S098	12/03/2019	X – 30-Day Notice	ATTAIN STARFIX LEAD	MEDTRONIC INC.	Implement FACTORYworks version 9.7 at MECC, MSO, and MTC.

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P080004/S026	12/04/2019	X – 30-Day Notice	ISYMM, ISPHERIC IOL	HOYA SURGICAL OPTICS, INC.	Change to the supplier of the lens case for non-preloaded IOLs.
P080004/S027	12/04/2019	X – 30-Day Notice	ISERT PRELOADED SYSTEM, ISPHERIC, ISYMM IOL MODELS, CLARISERT PRELOADED SYSTEM	HOYA SURGICAL OPTICS, INC.	Alternate supplier for applying ceramic coating to stainless steel jigs.
P080004/S029	12/30/2019	X – 30-Day Notice	ISERT PRELOADED IOL MODELS, ISYMM, CLARISERT IOL MODELS	HOYA SURGICAL OPTICS, INC.	Addition of a second supplier of ethylene oxide gas for use in the ethylene oxide sterilization process.
P080006/S142	12/13/2019	X – 30-Day Notice	ATTAIN ABILITY LEAD	MEDTRONIC INC.	Update pull test control limits and sampling size used to monitor special manufacturing process in leads manufacturing.
P080006/S143	12/03/2019	X – 30-Day Notice	ATTAIN ABILITY LEAD, ATTAIN PERFORMA LEAD AND ATTAIN STABILITY QUAD MRI LEAD	MEDTRONIC INC.	Implement FACTORYworks version 9.7 at MECC, MSO, and MTC.
P080006/S144	12/10/2019	X – 30-Day Notice	ATTAIN ABILITY LEADS, ATTAIN PERFORMA LEADS, ATTAINS STABILITY QUAD MRI LEAD	MEDTRONIC INC.	Update the mold and press used in manufacturing the Core Molded Flanged Insert.
P080025/S198	12/11/2019	X – 30-Day Notice	INTERSTIM THERAPY SYSTEM AND VERIFY EVALUATION SYSTEM (SNS BOWEL)	MEDTRONIC NEUROMODULATION	Update Medtronics manufacturing software, Manufacturing Execution System to Factory Works (Release 9.7), which is comprised of (1) FW Business Rule Client 9.7, (2) FW Configuration Client 9.2.2, and (3) Integrated Manufacturing Process Management (iMPM) Web Services (WS) 3.6.
P080025/S199	12/19/2019	X – 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS BOWEL)	MEDTRONIC NEUROMODULATION	Modify ionic contamination monitoring of implantable neurostimulator (INS) devices.
P090013/S302	12/04/2019	X – 30-Day Notice	CAPSUREFIX MRI LEAD	MEDTRONIC, INC	Add an additional visual inspection of the helix.
P090013/S303	12/03/2019	X – 30-Day Notice	CAPSUREFIX MRI LEAD	MEDTRONIC, INC	Implement FACTORYworks version 9.7 at MECC, MSO, and MTC.
P100010/S099	12/10/2019	X – 30-Day Notice	ARCTIC FRONT ADVANCE AND ARCTIC FRONT ADVANCE PRO	MEDTRONIC CRYOCATH LP	Minor manufacturing changes to the Artic Front Advance and Arctic Front Advance Pro Cryoablation catheters.
P100014/S023	12/19/2019	X – 30-Day Notice	SOLESTA INJECTABLE GEL	PALETTE LIFE SCIENCES	Use of an in-house prepared NaCl solution.
P100029/S042	12/04/2019	X – 30-Day Notice	TRIFECTA AND TRIFECTA GT HEART VALVES	ST. JUDE MEDICAL, INC.	Implementation of differential pressure monitoring data loggers for use with the VAISALA Environmental Monitoring System (EMS) at the SJM/Abbott Brazil manufacturing site.
P100049/S028	12/10/2019	X – 30-Day Notice	LINX REFLUX MANAGEMENT SYSTEM	TORAX MEDICAL	Implementation of a new automatic measuring system and measuring test method.

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P110010/S173	12/04/2019	X – 30-Day Notice	PROMUS PREMIER/ PROMUS ELITE EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Alternate manufacturer for Everolimus used in the Promus and SYNERGY product families.
P110033/S051	12/03/2019	X – 30-Day Notice	JUVEDERM INJECTABLE GEL IMPLANTS	ALLERGAN	Implementation of an additional cold room at the Pringy II manufacturing facility for the storage of raw materials for Juvéderm® injectable gel implants.
P110035/S054	12/19/2019	X – 30-Day Notice	EPIC VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Reduce the Ethylene Oxide gas concentration, and qualify additional process challenge devices used in the BSC856 sterilization cycle at the BSC Coventry, RI facility Chamber 7.
P110042/S131	12/19/2019	X – 30-Day Notice	EMBLEM SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (S-ICD)	BOSTON SCIENTIFIC CORPORATION	New assembly level moisture specification and vacuum oven drying process.
P120010/S137	12/19/2019	X – 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Update sterilization procedure for the Enlite Sensor and Guardian Sensor (3). The Enlite Sensor and Guardian Sensor (3) are components of the MiniMed 530G, 630G, and 670G Systems; the Paradigm Real-Time Revel System; the iPro2 CGM System; and the Guardian Connect System.
P120017/S020	12/03/2019	X – 30-Day Notice	MYOCARDIAL PACING LEAD	MEDTRONIC INC.	Implement FACTORYworks version 9.7 at MECC, MSO, and MTC.
P130013/S034	12/12/2019	X – 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE (LAAC) DEVICE WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORP.	Add the Maple Grove facility as an alternate laser cutting vendor.
P130021/S069	12/10/2019	X – 30-Day Notice	ENVEO R, ENVEO PRO AND EVOLUT PRO+ DELIVERY CATHETER SYSTEMS OF THE EVOLUT R/PRO/PRO+ SYSTEMS	MEDTRONIC COREVALVE LLC	Modification to the leak test acceptance criterion.
P130021/S070	12/17/2019	X – 30-Day Notice	ENVEO R, ENVEO PRO AND EVOLUT PRO+ DELIVERY CATHETER SYSTEMS OF THE EVOLUT R, PRO, PRO+ SYSTEMS	MEDTRONIC COREVALVE LLC	Update to the acceptance criteria for the visual inspection of the outer shaft of the EnVeo R, EnVeo PRO and Evolut PRO+ Delivery Catheter Systems.
P130024/S032	12/18/2019	X – 30-Day Notice	LUTONIX 018 DRUG COATED BALLOON PTA CATHETERS	LUTONIX	Implement a minor change affecting the hub component of drug coated balloon catheter.
P130026/S054	12/16/2019	X – 30-Day Notice	TACTICATH QUARTZ CONTACT FORCE ABLATION CATHETER (TACTICATH QUARTZ)	ST. JUDE MEDICAL	Adding a proximity sensor to a laser welder, a fixture to assist in cutting Kapton tubing pieces, and a cleaning step to when a rework is needed while placing the spacer tape.
P130030/S064	12/18/2019	X – 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM (MONRAIL AND OVER-THE-WIRE)	BOSTON SCIENTIFIC CORP.	Changes to software to add controls for hydrophilic coating system.

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P140002/S020	12/05/2019	X – 30-Day Notice	MISAGO RX SELF-EXPANDING PERIPHERAL STENT	TERUMO MEDICAL CORPORATION	Changes to the visual inspection criteria and methods for foreign matter on the stent delivery catheter.
P140010/S048	12/17/2019	X – 30-Day Notice	IN.PACT ADMIRAL PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Implementation of a bracketing approach for retaining reserve samples.
P140015/S029	12/19/2019	X – 30-Day Notice	T:SLIM X2 INSULIN PUMP WITH DEXCOM G5 MOBILE CGM SYSTEM	TANDEM DIABETES CARE, INC.	Rework process change related to the assembling of the Printed Circuit Board Assembly (PCBA) at a Tandem supplier. The PCBA is a component of the Tandem t:slim X2 Insulin Pump system.
P140028/S047	12/04/2019	X – 30-Day Notice	INNOVA SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Additional nitinol gundrilling supplier.
P140028/S048	12/04/2019	X – 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Alternative diameter inspection equipment for the delivery system sheath.
P140028/S049	12/04/2019	X – 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Alternative supplier equipment for the production of delivery system shaft braiding material.
P140028/S050	12/18/2019	X – 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Update to the stent microblasting process.
P140028/S051	12/19/2019	X – 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Reduce the Ethylene Oxide gas concentration, and qualify additional process challenge devices used in the BSC856 sterilization cycle at the BSC Coventry, RI facility Chamber 7.
P140028/S052	12/13/2019	X – 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Modification of the stent electropolishing process.
P140030/S011	12/04/2019	X – 30-Day Notice	ASTRON PERIPHERAL SELF-EXPANDING NITINOL STENT SYSTEM	BIOTRONIK, INC.	Modifications to routine bioburden and endotoxin monitoring.
P140032/S043	12/11/2019	X – 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Update Medtronics manufacturing software, Manufacturing Execution System to Factory Works (Release 9.7), which is comprised of (1) FW Business Rule Client 9.7, (2) FW Configuration Client 9.2.2, and (3) Integrated Manufacturing Process Management (iMPM) Web Services (WS) 3.6.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140032/S044	12/19/2019	X – 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Perform retest activities of the SynchroMed® Infusion System and Ascenda® Intrathecal Catheters port helium leak test (catheter leak test) manufacturing step and to separate the tube inflate inspection from the catheter leak test step.
P140033/S051	12/06/2019	X – 30-Day Notice	ASSURITY MRI AND ENDURITY MRI PACEMAKERS	ST. JUDE MEDICAL, INC.	Alternate supplier for the RF antenna and ribbon carrier components used in Scalable Brady Platform SR/DR pacemakers.
P150001/S078	12/19/2019	X – 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED	Changes to the bonding of the sensor to sensor base for the Guardian Sensor (3). The Guardian Sensor (3) is a component of the MiniMed 630G System with SmartGuard, Guardian Connect System, and MiniMed 670G System.
P150001/S079	12/19/2019	X – 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED	Adding a new Chemical Vapor Deposition (CVD) line to increase manufacturing capacity for the Guardian Sensor (3) continuous glucose monitoring sensor. The Guardian Sensor is a component of the Guardian Connect, MiniMed 630G, and MiniMed 670G systems.
P150001/S080	12/19/2019	X – 30-Day Notice	MINIMED 630G SYSTEM	MEDTRONIC MINIMED	Update sterilization procedure for the Enlite Sensor and Guardian Sensor (3). The Enlite Sensor and Guardian Sensor (3) are components of the MiniMed 530G, 630G, and 670G Systems; the Paradigm Real-Time Revel System; the iPro2 CGM System; and the Guardian Connect System.
P150003/S056	12/04/2019	X – 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Alternate manufacturer for Everolimus used in the Promus and SYNERGY product families.
P150011/S017	12/16/2019	X – 30-Day Notice	PERCEVAL SUTURELESS HEART VALVE	LIVANOVA CANADA CORP.	Modification to the carbofilm coating quality control verification tests.
P150012/S085	12/16/2019	X – 30-Day Notice	INGEVITY	BOSTONSCIENTIFIC	Modify the terminal pin to pin cap laser welding process for INGEVITY leads.
P150012/S087	12/04/2019	X – 30-Day Notice	ESSENTIO MRI SR, ESSENTIO MRI DR, ESSENTIO MRI EL DR, PROPONENT, ACCOLADE MRI SR, ACCOLADE MRI DR AND ACCOLADE MRI EL DR	BOSTONSCIENTIFIC	Add a post-reflow manufacturing inspection for printed circuit boards.
P150014/S034	12/18/2019	X – 30-Day Notice	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Automate manufacturing of a critical assay component.
P150015/S036	12/18/2019	X – 30-Day Notice	COBAS HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Automate manufacturing of a critical assay component.
P150019/S061	12/19/2019	X – 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Update sterilization procedure for the Enlite Sensor and Guardian Sensor (3). The Enlite Sensor and Guardian Sensor (3) are components of the MiniMed 530G, 630G, and 670G Systems; the Paradigm Real-Time Revel System; the iPro2 CGM System; and the Guardian Connect System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150021/S047	12/16/2019	X – 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Addition of a 100% in-process check for additional, missing, and/or misplaced springs in the sensor applicator subassembly of the FreeStyle Libre 14-day Flash Glucose Monitoring System and FreeStyle Libre Pro Flash Glucose Monitoring System.
P150028/S004	12/19/2019	X – 30-Day Notice	CP STENT, COVERED CP STENT, MOUNTED CP STENT, COVERED AND MOUNTED CP STENT, MOUNTED CP STENT, NUDEL	NUMED, INC.	Addition of two laser welders.
P150029/S034	12/19/2019	X – 30-Day Notice	IPRO2 CGM SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Update sterilization procedure for the Enlite Sensor and Guardian Sensor (3). The Enlite Sensor and Guardian Sensor (3) are components of the MiniMed 530G, 630G, and 670G Systems; the Paradigm Real-Time Revel System; the iPro2 CGM System; and the Guardian Connect System.
P150031/S027	12/04/2019	X – 30-Day Notice	VERCISE, VERCISE PC, AND VERCISE GEVIA DEEP BRAIN STIMULATION (DBS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Increase the maximum proximal end backfill cure time from 4 hours to 48 hours for its Leads and Lead Extension for the Vercise, Vercise PC, and Vercise Gevia VNS Systems.
P150033/S062	12/10/2019	X – 30-Day Notice	MICRA TPS	MEDTRONIC INC.	Expanding the battery manufacturing facility to include additional production floor space with new identical equipment and relocated equipment.
P150033/S063	12/03/2019	X – 30-Day Notice	MICRA TPS	MEDTRONIC INC.	Implement FACTORYworks version 9.7 at MECC, MSO, and MTC.
P160003/S009	12/04/2019	X – 30-Day Notice	PRO-KINETIC ENERGY CORONARY STENT SYSTEM	BIOTRONIK, INC.	Modifications to routine bioburden and endotoxin monitoring.
P160007/S030	12/19/2019	X – 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Changes to the bonding of the sensor to sensor base for the Guardian Sensor (3). The Guardian Sensor (3) is a component of the MiniMed 630G System with SmartGuard, Guardian Connect System, and MiniMed 670G System.
P160007/S031	12/19/2019	X – 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Adding a new Chemical Vapor Deposition (CVD) line to increase manufacturing capacity for the Guardian Sensor (3) continuous glucose monitoring sensor. The Guardian Sensor is a component of the Guardian Connect, MiniMed 630G, and MiniMed 670G systems.
P160007/S033	12/19/2019	X – 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Update sterilization procedure for the Enlite Sensor and Guardian Sensor (3). The Enlite Sensor and Guardian Sensor (3) are components of the MiniMed 530G, 630G, and 670G Systems; the Paradigm Real-Time Revel System; the iPro2 CGM System; and the Guardian Connect System.
P160017/S077	12/19/2019	X – 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Changes to the bonding of the sensor to sensor base for the Guardian Sensor (3). The Guardian Sensor (3) is a component of the MiniMed 630G System with SmartGuard, Guardian Connect System, and MiniMed 670G System.
P160017/S078	12/19/2019	X – 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Adding a new Chemical Vapor Deposition (CVD) line to increase manufacturing capacity for the Guardian Sensor (3) continuous glucose monitoring sensor. The Guardian Sensor is a component of the Guardian Connect, MiniMed 630G, and MiniMed 670G systems.
P160017/S079	12/19/2019	X – 30-Day Notice	MEDTRONIC MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Update sterilization procedure for the Enlite Sensor and Guardian Sensor (3). The Enlite Sensor and Guardian Sensor (3) are components of the MiniMed 530G, 630G, and 670G Systems; the Paradigm Real-Time Revel System; the iPro2 CGM System; and the Guardian Connect System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160025/S009	12/04/2019	X – 30-Day Notice	ASTRON PULSAR STENT SYSTEM AND PULSAR-18 STENT SYSTEM	BIOTRONIK, INC.	Modifications to routine bioburden and endotoxin monitoring.
P160030/S040	12/16/2019	X – 30-Day Notice	FREESTYLE LIBRE 14-DAY FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Addition of a 100% in-process check for additional, missing, and/or misplaced springs in the sensor applicator subassembly of the FreeStyle Libre 14-day Flash Glucose Monitoring System and FreeStyle Libre Pro Flash Glucose Monitoring System.
P160041/S027	12/18/2019	X – 30-Day Notice	COBAS CMV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Automate manufacturing of a critical assay component.
P160043/S029	12/17/2019	X – 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEMS	MEDTRONIC VASCULAR	Implementation of a bracketing approach for retaining reserve samples.
P170002/S007	12/13/2019	X – 30-Day Notice	RHA2, RHA3, AND RHA4 DERMAL FILLERS	TEOXANE S.A.	Change in the receiving procedure for raw material Hyaluronic Acid.
P170003/S015	12/18/2019	X – 30-Day Notice	LUTONIX® 035 DRUG COATED BALLOON PTA CATHETER	LUTONIX	Implement a minor change affecting the hub component of drug coated balloon catheter.
P170007/S005	12/18/2019	X – 30-Day Notice	DUROLANE, HYALURONIC ACID, STABILIZED SINGLE INJECTION	BIOVENTUS LLC	Outsource the method of analysis for D-value determination of biological indicators to a contract lab.
P170030/S005	12/04/2019	X – 30-Day Notice	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Modifications to routine bioburden and endotoxin monitoring.
P170035/S007	12/18/2019	X – 30-Day Notice	BAUSCH + LOMB ULTRA (SAMFILCON A) VISIBILITY TINTED SOFT (HYDROPHILIC) CONTACT LENSES	BAUSCH AND LOMB, INC.	Addition of an alternate supplier for a raw material component.
P180002/S014	12/06/2019	X – 30-Day Notice	ZEPHYR ENDOBRONCHIAL VALVE (EBV) SYSTEM	PULMONX CORPORATION	Manufacturing change of adding the option of performing lot release testing of the Zephyr Endobronchial Delivery Catheter (EDC) before sterilization.
P180008/S007	12/19/2019	X – 30-Day Notice	T:SLIM X2 INSULIN PUMP WITH BASAL-IQ TECHNOLOGY	TANDEM DIABETES CARE, INC.	Rework process change related to the assembling of the Printed Circuit Board Assembly (PCBA) at a Tandem supplier. The PCBA is a component of the Tandem t:slim X2 Insulin Pump system.
P180011/S017	12/04/2019	X – 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Additional nitinol gundrilling supplier.
P180011/S018	12/04/2019	X – 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Alternative diameter inspection equipment for the delivery system sheath.
P180011/S019	12/04/2019	X – 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Alternative supplier equipment for the production of delivery system shaft braiding material.

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P180011/S020	12/18/2019	X – 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Update to the stent microblasting process.
P180011/S021	12/13/2019	X – 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Modification of the stent electropolishing process.
P180013/S003	12/02/2019	X – 30-Day Notice	VICI VENOUS STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Implementation of an alternate stent crimper for use during the stent loading process.
P180029/S018	12/17/2019	X – 30-Day Notice	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	Several modifications to the equipment, software, and inspection associated with the Hydrodynamic Tester (HDT) used for valve inspections.
P180029/S019	12/11/2019	X – 30-Day Notice	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	Changes to the adaptive seal component of the 25-mm and 23-mm LOTUS Edge Valve.
Total: 182					