PMA Monthly approvals from 11/1/2019 to 11/30/2019

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180035	11/15/2019	PMAO - PMA Origi	MISIGHT 1 DAY (OMAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES FOR DAILY WEAR	COOPERVISION, INC.	Approval for MiSight 1 Day (omafilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear. This device indicated for the correction of myopic ametropia and for slowing the progression of myopia in children with non-diseased eyes, who at the initiation of treatment are 8-12 years of age and have a refraction of -0.75 to -4.00 diopters (spherical equivalent) with less than or equal to 0.75 diopters of astigmatism. The lens is to be discarded after each removal.
P180046	11/13/2019	PMAO - PMA Origi	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for the Axonics Sacral Neuromodulation System. The device is indicated for the treatment of urinary retention and the symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments.
P180047	11/26/2019	PMAO - PMA Origi	LIAISON QUANTIFERON - TB GOLD PLUS, LIAISON CONTROL QUANTIFERON - TB GOLD PLUS AND LIAISON QUANTIFERON SOFTWARE	DIASORIN, INC.	Approval for the LIAISON QuantiFERON-TB Gold Plus assay, the LIAISON Control QuantiERON-TB Gold Plus, and the LIAISON QuantiFERON Software. The LIAISON QuantiFERON-TB Gold Plus assay is an in vitro diagnostic test intended for the detection of interferon-y (IFN-y) in human lithium heparin plasma by chemiluminescence immunoassay (CLIA) using the LIAISON XL Analyzer. QIAGEN QuantiFERON-TB Gold Plus Blood Collection Tubes, containing a peptide cocktail simulating ESAT-6, and CFP-10 proteins, are used in conjunction with the LIAISON QuantiFERON-TB Gold Plus assay to stimulate cells in heparinized whole blood. Detection of IFN-y is used to identify in vitro responses to these peptide antigens that are associated with Mycobacterium tuberculosis infection. The assay is a qualitative indirect test for M. tuberculosis infection (including disease) and is intended for use in conjunction with risk assessment, radiography, and other medical and diagnostic evaluations to assist the clinician in making individual patient management decisions. The LIAISON QuantiFERON-TB Gold Plus assay must be performed using the LIAISON XL Analyzer. The LIAISON Control QuantiFERON-TB Gold Plus is intended for use as assayed quality control samples to monitor the performance of the LIAISON QuantiFERON-TB Gold Plus assay. The performance characteristics of LIAISON Control QuantiFERON-TB Gold Plus have not been established for any other assays or instrument platforms other than the LIAISON XL Analyzer. The LIAISON QuantiFERON Software (LQS) is optional software intended to analyze the data generated by the LIAISON QuantiFERON-TB Gold Plus assay on the LIAISON XL Analyzer. LQS reports assay results as positive, negative, or indeterminate by an algorithm that combines the individual results associated with the four QIAGEN QuantiFERON-TB Gold Plus Blood Collection Tubes into a final result.
P190008	11/21/2019	PMAO - PMA Origi	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Approval for the IN.PACT AV Paclitaxel-coated PTA Balloon Catheter. The device is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, for the treatment of obstructive lesions up to 100 mm in length in the native arteriovenous dialysis fistulae with reference vessel diameters of 4 to 12 mm.

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P190016	11/25/2019	PMAO - PMA Origi	TULA® SYSTEM	TUSKER MEDICAL, INC.	Approval for the Tula® System. This device is intended to create a myringotomy and insert a tympanostomy tube using the Tula Tube Delivery System in pediatric (aged 6 months and older) and adult patients indicated to receive tympanostomy tubes. The Tula System is used to deliver a tympanostomy tube under local anesthesia induced using the Tula Iontophoresis System and TYMBION, a combination of an amide local anesthetic and an alpha- and beta-adrenergic agonist. TYMBION, a combination of an amide local anesthetic and an alpha- and beta-adrenergic agonist, is indicated for the induction of local anesthesia of the tympanic membrane via iontophoresis using the Tula® Iontophoresis System in pediatric (aged 6 months and older) and adult patients undergoing tympanostomy tube placement using the Tula Tube Delivery System Drug Indications and Usage: TYMBION, a combination of an amide local anesthetic and an alpha- and beta-adrenergic agonist, is indicated for the induction of local anesthesia of the tympanic membrane via iontophoresis using the Tula® Iontophoresis System in pediatric (aged 6 months and older) and adult patients undergoing tympanostomy tube placement using the Tula Tube Delivery System.

Total: 5

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S052	11/26/2019	Y - 135 Review Tra	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Approval for a change to the sampling plan for endotoxin testing.
P830055/S235	11/21/2019	R - Real-Time Proc	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for the use of components of the ATTUNE Revision Knee System with compatible components of the ATTUNE Primary Cemented and Cementless devices.
P840001/S422	11/06/2019	Y - 135 Review Tra	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Approval for an alternate supplier for the dimer diamine.
P860026/S009	11/04/2019	N - Normal 180 Day	DIAPHRAGMATIC PACEMAKER PHRENIC NERVE STIMULATOR	AVERY BIOMEDICAL DEVICES, INC.	Approval to replace the Mark IV transmitter with the digital Spirit transmitter.
P950037/S202	11/26/2019	N - Normal 180 Day	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Approval for a pre-assembled header core module for single and dual chamber devices.
P960009/S341	11/06/2019	Y - 135 Review Tra	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval for an alternate supplier for the dimer diamine.
P970004/S284	11/06/2019	Y - 135 Review Tra	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Approval for an alternate supplier for the dimer diamine.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970004/S299	11/26/2019	R - Real-Time Proc	INTERSTIM THERAPY SYSTEM AND VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Approval for an update to the inner packaging tray that holds the torque wrench.
P970051/S185	11/08/2019	N - Normal 180 Day	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for a design change for the electronic assemblies of the CI512, CI522, CI532 and the ABI541 implants.
P980037/S074	11/13/2019	O - Normal 180 Day	ANGIOJET RHEOLYTIC THROMBECTOMY LF140 CATHETER	BOSTON SCIENTIFIC CORP.	Approval to use the Boston Scientific Coventry facility as an alternate sterilization site for AngioJet Ultra Thrombectomy Sets.
P990018/S005	11/06/2019	N - Normal 180 Day	MENICON Z NIGHT (TISILFOCON A) CONTACT LENSES FOR OVERNIGHT WEAR	MENICON CO. LTD.	Approval for manufacture, market and distribute overnight orthokeratology contact lenses from the Menicon Z (tisilfocon A) rigid gas permeable contact lens material.
P990081/S041	11/19/2019	R - Real-Time Proc	PATHWAY ANTI-HER-2/NEU (4B) RABBIT MONOCLONAL PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Approval for minor software and firmware updates for Ventana System Software on the BenchMark ULTRA instruments.
P000008/S047	11/13/2019	R - Real-Time Proc	LAP-BAND ADJUSTABLE GASTRIC BANDING SYSTEM	RESHAPE LIFESCIENCES, INC.	Approval for updates to three LAP-BAND® System Directions for Use and the Surgical Aid instructions with a change of the initial post-operative band fluid volume adjustment period to four weeks post-implantation.
P000015/S036	11/08/2019	N - Normal 180 Day	NUCLEUS 24 AUDITORY BRAINSTEM IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for a design change for the electronic assemblies of the CI512, CI522, CI532 and the ABI541 implants.
P010003/S033	11/21/2019	N - Normal 180 Day	BIOGLUE SURGICAL ADHESIVE	CRYOLIFE, INC.	Approval for changes to the resin, design and shelf-life of the Spreader Applicator Tips.
P010014/S096	11/05/2019	S - Special CBE	OXFORD PARTIAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Approval for the firm to update their VEI Label Verification system.
P010019/S072	11/27/2019	O - Normal 180 Day	LOTRAFILCON A AND B SOFT CONTACT LENSES FOR EXTENDED WEAR	ALCON LABORATORIES, INC.	Approval for a repackaging site located at Harleigh (Malaysia) SDN. BHD., No. 4, Jalan Tahana, Tampoi Industrial Estate, Johor Bahru, Johor, Malaysia 80350.
P030011/S074	11/26/2019	S - Special CBE	SYNCARDIA TEMPORARY TOTAL ARTIFICIAL HEART (TAH-T) SYSTEM	SYNCARDIA SYSTEMS, LLC	Approval to update labeling in the Freedom Driver System manuals and clinical training slides.
P040024/S109	11/04/2019	N - Normal 180 Day	RESTYLANE INJECTABLE GEL	Q-MED AB	Approval for revisions to the active thumb flexion information and post marketing surveillance data in the clinician and patient labeling.
P040047/S055	11/06/2019	Y - 135 Review Tra	COAPTITE	MERZ NORTH AMERICA, INC	Approval for modifications to the manufacturing equipment for Coaptite Injectable Implant, Radiesse Injectable Implant, and Radiesse (+) Lidocaine Dermal Filler.
P050037/S098	11/06/2019	Y - 135 Review Tra	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Approval for modifications to the manufacturing equipment for Coaptite Injectable Implant, Radiesse Injectable Implant, and Radiesse (+) Lidocaine Dermal Filler.
P050052/S115	11/06/2019	Y - 135 Review Tra	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval for modifications to the manufacturing equipment for Coaptite Injectable Implant, Radiesse Injectable Implant, and Radiesse (+) Lidocaine Dermal Filler.
P060038/S033	11/21/2019	O - Normal 180 Day	MITROFLOW AORTIC PERICARDIAL HEART VALVE	LIVANOVA CANADA CORP.	Approval to terminate NEMO post-approval study.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P060040/S074	11/20/2019	R - Real-Time Proc	HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORP.	Approval for various modifications to the labeling of the HeartMate 3 Left Ventricular Assist System and HeartMate II Left Ventricular Assist System regarding conformances to IEC 60601-1-2:2014 and IEC 60601-4-2:2016 standards.
P070026/S059	11/29/2019	O - Normal 180 Day	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Approval for the addition of manufacturing site for CERAMAX Liner and BIOLOX Delta Head components located at CeramTec GmbH Medical Products Division.
P080004/S025	11/29/2019	R - Real-Time Proc	ISERT PRELOADED SYSTEM/ ISERT MICRO INJECTOR	HOYA SURGICAL OPTICS, INC.	Approval for design modifications to the slider component of the iSert® injectors.
P080012/S061	11/08/2019	R - Real-Time Proc	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Approval for change to extend the shelf life of the Prometra II 20ml Pump component of the Prometra Programmable Infusion Pump System from 6 months to 1 year.
P080025/S179	11/06/2019	Y - 135 Review Tra	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Approval for an alternate supplier for the dimer diamine.
P080025/S194	11/26/2019	R - Real-Time Proc	INTERSTIM THERAPY SYSTEM AND VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Approval for an update to the inner packaging tray that holds the torque wrench.
P100022/S033	11/12/2019	R - Real-Time Proc	ZILVER PTX DRUG-ELUTING PERIPHERAL STENT	COOK MEDICAL INCORPORATED	Approval for an additional active pharmaceutical ingredient supplier.
P100027/S031	11/19/2019	R - Real-Time Proc	INFORM HER2 DUAL ISH DNA PROBE COCKTAIL	VENTANA MEDICAL SYSTEMS, INC.	Approval for minor software and firmware updates for Ventana System Software on the BenchMark ULTRA instruments.
P100047/S131	11/06/2019	N - Normal 180 Day	HEARTWARE HVAD SYSTEM	MEDTRONIC	Approval for design changes to the Outflow Graft.
P110002/S022	11/13/2019	O - Normal 180 Day	MOBI-C CERVICAL DISC PROSTHESIS (ONE-LEVEL INDICATIONS)	LDR SPINE USA	Approval for a new manufacturing site to be used for kitting and shipping of Mobi-C as well as reconditioning and servicing of instruments from the field for reuse.
P110009/S022	11/13/2019	O - Normal 180 Day	MOBI-C CERVICAL DISC PROSTHESIS (FOR TWO-LEVEL)	LDR SPINE USA INC.	Approval for a new manufacturing site to be used for kitting and shipping of Mobi-C as well as reconditioning and servicing of instruments from the field for reuse.
P110023/S028	11/20/2019	O - Normal 180 Day	EVERFLEX SELF-EXPANDING PERIPHERAL STENT SYSTEMS AND EVERFLEX SELF-EXPANDING PERIPHERAL STENT WITH ENTRUST DELIVERY SYSTEMS	MEDTRONIC VASCULAR INC	Approval for labeling updates with the final results of the DURABILITY post-approval study.
P120005/S083	11/01/2019	O - Normal 180 Day	DEXCOM G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Approval for updates to the protocol (PTL901895, V004), including addition of the Dexcom G6 CGM.

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P130009/S101	11/04/2019	O - Normal 180 Day	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P130022/S022	11/22/2019	O - Normal 180 Day	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for a manufacturing site located at Integer (dba Greatbatch Medical S. de R.L. de C.V.), Blvd. Hector Teran Teran No. 20120, Ciudad Industrial Tijuana, Baja California, Mexico 22444 for the manufacturing of implantable pulse generators for the Senza Spinal Cord Stimulation (SCS) System.
P130022/S027	11/08/2019	R - Real-Time Proc	SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for mechanical and design changes made to the current charger (CGR1000) for the Senza Spinal Cord Stimulation (SCS) system to improve cosmetics and reduce the size of the charger. The modified patient remote charger will now be offered as model CGR2500.
P140025/S011	11/19/2019	R - Real-Time Proc	VENTANA ALK (D5F3) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for minor software and firmware updates for Ventana System Software on the BenchMark ULTRA instruments.
P150026/S007	11/08/2019	R - Real-Time Proc	HEARTLIGHT ENDOSCOPIC ABLATION SYSTEM	CARDIOFOCUS, INC.	Approval for a material change in a component of the catheter
P150033/S059	11/20/2019	R - Real-Time Proc	MICRA MC1VR01 TRANSCATHETER PACING SYSTEM (TPS)	MEDTRONIC INC.	Approval for the addition of a caution statement to the Micra TPS Instructions for Use.
P160002/S010	11/19/2019	R - Real-Time Proc	VENTANA PD-LL (SP142) ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for minor software and firmware updates for Ventana System Software on the BenchMark ULTRA instruments.
P160014/S013	11/07/2019	R - Real-Time Proc	COBRA PZF NANOCOATED CORONARY STENT SYSTEM	CELONOVA BIOSCIENCES, INC.	Approval for changes to the wall thickness specification for the balloon assembly and to the balloon growth specification for the 3.50 mm device.
P160026/S011	11/25/2019	N - Normal 180 Day	LIFEPAK 20E DEFIBRILLATOR/MONITOR	PHYSIO-CONTROL. INC.	Approval for a new Microcontroller component, which is located on the Power PCBA, and associated supporting subcomponents on the PCBA.
P160036/S001	11/29/2019	O - Normal 180 Day	HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM	DT MEDTECH LLC	Approval for the post-approval study protocols for the two post-approval studies.
P160037/S003	11/22/2019	O - Normal 180 Day	BD ONCLARITY HPV ASSAY	BECTON, DICKINSON AND COMPANY	Approval for a post approval study labeling update.
P160046/S006	11/19/2019	R - Real-Time Proc	VENTANA PD-LL (SP263) ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for minor software and firmware updates for Ventana System Software on the BenchMark ULTRA instruments.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160047/S007	11/04/2019	O - Normal 180 Day	MARA WATER VAPOR ABLATION SYSTEM, MARA WATER VAPOR PROBE PROCEDURE KIT, MARA WATER VAPOR PROBE, MARA SUPPLY AND DRAIN ACCESSORY, MARA WATER VAPOR GENERATOR, AND MARA WATER VAPOR GENERATOR ACCESSORY KIT	AEGEA MEDICAL , INC	Approval to change the trade name of the device from the AEGEA Vapor System to the MARA Water Vapor Ablation System.
P160048/S012	11/25/2019	O - Normal 180 Day	EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM	SENSEONICS, INCORPORATED	Approval of the protocol for the post-approval study (PAS) referenced above. The PAS protocol has been submitted to comply with the conditions of approval outlined in our approval order for P160048/S006
P160054/S022	11/20/2019	R - Real-Time Proc	HEARTMATE 3 LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATION	Approval for various modifications to the labeling of the HeartMate 3 Left Ventricular Assist System and HeartMate II Left Ventricular Assist System regarding conformances to IEC 60601-1-2:2014 and IEC 60601-4-2:2016 standards
P160055/S008	11/22/2019	R - Real-Time Proc	LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Approval for additional qualified coupling agents and UV protective eyewear to be used with the LAL/LDD.
P170002/S004	11/01/2019	Y - 135 Review Tra	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Approval for implementation of the International Council for Harmonization (ICH) elemental impurities guideline and change in the test method and specification to assay aluminum by the raw material supplier for the hyaluronic acid.
P170003/S014	11/26/2019	O - Normal 180 Day	LUTONIX 035 DRUG COATED BALLOON PTA CATHETER, MODEL 9010	LUTONIX	Approval for the revised protocol and informed consent for the New Enrollment PAS Registry.
P170008/S019	11/19/2019	N - Normal 180 Day	ELUNIR RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Approval for the expansion of the EluNIR Ridaforolimus Eluting Coronary Stent System product matrix by adding stent length of 38 mm in diameters 2.75, 3.0, 3.5 and 4.0 mm. This device is indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to de novo lesions <=36mm in length in native coronary arteries with reference diameter of 2.50mm to 4.25mm.
P170019/S012	11/06/2019	S - Special CBE	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval for adding fixed text language to the first page of the patient report indicating for Microsatellite Instability (MSI) results, confirmatory testing using a validated orthogonal method should be performed.
P170030/S002	11/12/2019	O - Normal 180 Day	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P180002/S010	11/13/2019	R - Real-Time Proc	ZEPHYR 5.5 EBV CIRCLE FLANGE VALVE	PULMONX CORPORATION	Approval for the Zephyr 5.5 EBV Circle Flange Valve.

Total: 58

30-Day Notice

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N12159/S066	11/19/2019	X - 30-Day Notice	SURGICEL POWDER	ETHICON, INC.	Add a duplicate Analyzer which has the same functionality and will operate within the same specifications as the existing Analyzer that is already in use for the manufacture of Surgicel Powder.
N970003/S245	11/27/2019	X - 30-Day Notice	ESSENTIO SR/DR SL, ESSENTIO DR EL, PROPONENT SR/DR SL, PROPONENT DR EL, ACCOLADE SR/DR SL, ACCOLADE DR EL, ALTRUA 2 SR/DR SL, AND ALTRUA 2 DR EL	BOSTON SCIENTIFIC CORP.	Replace the current Automated Optical Inspection equipment system and to update the inspection process.
N970012/S168	11/27/2019	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE/ INFLATABLE PENILE PROSTHESIS (IPP) WITH AND WITHOUT INHIBIZONE TREATMENT	BOSTON SCIENTIFIC CORP.	Process change to add the Boston Scientific St. Paul facility as an alternate manufacturing site for silicone molded components.
N970012/S169	11/27/2019	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE/INFLATABLE PENILE PROSTHESIS (IPP) WITH AND WITHOUT INHIBIZONE TREATMENT	BOSTON SCIENTIFIC CORP.	Process change to add the Boston Scientific St. Paul facility as an alternate manufacturing site for the coating process for the reservoir and cylinder components.
P830055/S237	11/14/2019	X - 30-Day Notice	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Addition of an alternate casting site for the ATTUNE Revision Femoral Component material casting process. This change will add the DePuy Synthes Raynham, MA facility in addition to Orchid Orthopedic Solutions, the current external supplier.
P830061/S178	11/27/2019	X - 30-Day Notice	CAPSURE SENSE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Minor changes to the Final Device Acceptance-Functional Test for leads.
P850064/S041	11/22/2019	X - 30-Day Notice	LIFEPULSE HIGH FREQUENCY VENTILATOR	BUNNELL, INC.	For the LifePulse High Frequency Ventilator (HFV), to notify of a change to the manufacturing process and manufacturer of the priority alarm cover. The priority alarm cover is specific to the HFV 204.
P850079/S085	11/14/2019	X - 30-Day Notice	METHAFILCON B SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION, INC.	Installation and validation of two new sterilizers at the CooperVision, Inc., manufacturing facility in Scottsville, New York.

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P860057/S193	11/18/2019	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT THEON PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, THEON RSR PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, MAGNA EASE PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, AND MAGNA MITRAL EASE PERICARDIAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS	EDWARDS LIFESCIENCES, LLC.	Supplier Southington Tool and Manufacturing Corporation (STMC) to perform wireform crimping and tensile test verification.
P860057/S194	11/24/2019	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT THEON PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, THEON RSR PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, MAGNA EASE PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, THEON PERICARDIAL MITRAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, AND MAGNA MITRAL EASE PERICARDIAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS	EDWARDS LIFESCIENCES, LLC.	Several modifications to the final assembly cleanroom and down classification of gowning room 129 from ISO Class 7 to ISO Class 8 at the Irvine facility.
P860057/S195	11/26/2019	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT AORTIC BIOPROSTHESES AND CARPENTIER-EDWARDS PERIMOUNT MITRAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Implementation of a new cleanroom for receiving inspection processes.

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P890003/S420	11/12/2019	X - 30-Day Notice	CARELINK SMARTSYNC DEVICE MANAGER AND MYCARELINK PATIENT MONITOR	MEDTRONIC, INC.	Update electrical current inspection test limits used for manufacturing RF Head assemblies.
P890023/S039	11/14/2019	X - 30-Day Notice	OCUFILCON D SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	THE COOPER COMPANIES	Installation and validation of two new sterilizers at the CooperVision, Inc., manufacturing facility in Scottsville, New York.
P900056/S179	11/07/2019	X - 30-Day Notice	ROTABLATOR ROTATIONAL ANGIOPLASTY SYSTEM GUIDEWIRE WITH WIRECLIP TORQUER	BOSTON SCIENTIFIC CORP.	Reduce the Ethylene Oxide gas concentration and qualify additional process challenge devices used in the BSC2000-2 sterilization cycle.
P900056/S180	11/21/2019	X - 30-Day Notice	ROTABLATOR (ROTABLATOR ROTALINK PLUS, ROTALINK BURR)/ ROTAPRO ROTATIONAL ATHERECTOMY SYSTEM (ROTAPRO PLUS)	BOSTON SCIENTIFIC CORP.	Replacement of a curing oven and automating some of its processes.
P910023/S421	11/14/2019	X - 30-Day Notice	ELLIPSE ICD DEVICES	ST. JUDE MEDICAL	Automate stacking HV capacitor components.
P910077/S175	11/26/2019	X - 30-Day Notice	LATITUDE PROGRAMMING SYSTEM	BOSTON SCIENTIFIC	Add a new functional tester to the Model 3300 LATITUDE Programming Sytem manufacturing line.
P920047/S118	11/07/2019	X - 30-Day Notice	BLAZER II CARDIAC ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC CORP.	Reduce the Ethylene Oxide gas concentration and qualify additional process challenge devices used in the BSC2000-2 sterilization cycle.
P930039/S208	11/27/2019	X - 30-Day Notice	CAPSUREFIX NOVUS LEAD	MEDTRONIC, INC.	Minor changes to the Final Device Acceptance-Functional Test for leads.
P950020/S099	11/07/2019	X - 30-Day Notice	WOLVERINE CORONARY CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Reduce the Ethylene Oxide gas concentration and qualify additional process challenge devices used in the BSC2000-2 sterilization cycle.
P960040/S444	11/15/2019	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Remove a redundant process monitor inspection on the Tachy battery stack's discrete separator.
P980003/S091	11/07/2019	X - 30-Day Notice	CHILLI II COOLED ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC CORP.	Reduce the Ethylene Oxide gas concentration and qualify additional process challenge devices used in the BSC2000-2 sterilization cycle.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S721	11/01/2019	X - 30-Day Notice	EVERA MRI DF-1 ICD, EVERA MRI ICD, EVERA S DR/VR ICD, EVERA XT DR/ VR ICD, MIRRO 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 MANAGEMEN T	Update the Dadet manufacturing process and implement associated new equipment at the Switzerland Operations facility.
P980035/S606	11/01/2019	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ADVISA DR IPG, ADVISA DR/SR MRI IPG, ASTRA S DR/SR MRI IPG, ASTRA XT DR/SR MRI IPG, AZURE S DR/SR MRI IPG, AZURE XR DR/SR MRI IPG AND RELIA IPG	MEDTRONIC INC.	Update the Dadet manufacturing process and implement associated new equipment at the Switzerland Operations facility.
P980040/S110	11/22/2019	X - 30-Day Notice	SENSAR/TECNIS 1-PIECE IOL WITH SMARTLOAD DELIVERY TECHNOLOGY, TECNIS OPTIBLUE 1-PIECE IOL WITH SMARTLOAD DELIVERY TECHNOLOGY, TECNIS 1-PIECE IOL WITH TECNIS SIMPLICITY DELIVERY SYSTEM, TECNIS 1-PIECE OPTIBLUE IOL WITH TECNIS SIMPLICITY DELIVERY SYSTEM, TECNIS MULTIFOCAL 1-PIECE IOL WITH TECNIS SIMPLICITY DELIVERY SYSTEM, TECNIS TORIC 1-PIECE IOL WITH TECNIS SIMPLICITY DELIVERY SYSTEM, TECNIS SYMFONY EXTENDED RANGE OF VISION IOL WITH TECNIS SIMPLICITY DELIVERY SYSTEM, TECNIS SYMFONY TORIC EXTENDED RANGE OF VISION IOL WITH TECNIS SIMPLICITY DELIVERY SYSTEM	JOHNSON & JOHNSON SURGICAL VISION, INC.	Consolidation of the cosmetic inspection for the one-piece intraocular lenses packaged in the SmartLOAD Delivery Technology and TECNIS Simplicity Delivery System manufactured at the AMO Puerto Rico facility.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P990075/S046	11/19/2019	X - 30-Day Notice	SALINE-FILLED AND SPECTRUM BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Qualification of new manufacturing equipment related to the removal of foreign debris from packaging used for Saline-Filled and Spectrum Breast Implants.
P000053/S108	11/27/2019	X - 30-Day Notice	AMS 800 SERIES PRODUCT LINE/ ARTIFICIAL URINARY SPHINCTER WITH AND WITHOUT INHIBIZONE TREATMENT	BOSTON SCIENTIFIC CORP.	Process change to add the Boston Scientific St. Paul facility as an alternate manufacturing site for silicone molded components.
P000054/S056	11/01/2019	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Implementation of new instruments to assess percent solids in a collagen dispersion used in the manufacturing of INFUSE Bone Graft.
P000054/S057	11/29/2019	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Modifications to the post-approval stability protocol for the drug component of INFUSE Bone Graft.
P000058/S075	11/01/2019	X - 30-Day Notice	INFUSE BONE GRAFT/ MEDTRONIC INTERBODY FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Implementation of new instruments to assess percent solids in a collagen dispersion used in the manufacturing of INFUSE Bone Graft.
P000058/S076	11/29/2019	X - 30-Day Notice	INFUSE BONE GRAFT/ MEDTRONIC INTERBODY FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Modifications to the post-approval stability protocol for the drug component of INFUSE Bone Graft.
P010012/S511	11/15/2019	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Remove a redundant process monitor inspection on the Tachy battery stack's discrete separator.
P010015/S420	11/01/2019	X - 30-Day Notice	CONSULTA CRT-P, PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P, SOLARA BIPOLAR CRT-P, SOLARA QUADRIPOLAR CRT-P, SYNCRA CRT-P AND VIVA CRT-P	MEDTRONIC INC.	Update the Dadet manufacturing process and implement associated new equipment at the Switzerland Operations facility.
P010030/S128	11/19/2019	X - 30-Day Notice	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Updates to the incoming inspection and returned goods evaluation instructions for the LifeVest 4000/HWD 1000 Battery packs.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S682	11/01/2019	X - 30-Day Notice	AMPLIA MRI CRT-D, AMPLIA MRI QUAD CRT-D, BRAVA CRT-D, BRAVA QUAD CRT-D, CLARIA MRI CRT-D, CLARIA MRI QUAD CRT-D, COMPIA MRI CRT-D, COMPIA MRI QUAD CRT-D, CONSULTA CRT-D, PROTECTA CRT-D, PROTECTA XT CRT-D, VIVA QUAD S/XT CRT-D AND VIVA S/XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the Dadet manufacturing process and implement associated new equipment at the Switzerland Operations facility.
P010032/S155	11/19/2019	X - 30-Day Notice	GENESIS NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Changes in the viable air sampling method and a corresponding change to the action and alert limits for the airborne microbes in the controlled access environments (CAE).
P020025/S122	11/07/2019	X - 30-Day Notice	BLAZER II XP CARDIAC ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC	Reduce the Ethylene Oxide gas concentration and qualify additional process challenge devices used in the BSC2000-2 sterilization cycle.
P030005/S191	11/27/2019	X - 30-Day Notice	VALITUDE CRT-P IS1/IS4 EL, VISIONIST CRT-P IS1 EL AND VISIONIST CRT-P LV1 EL	GUIDANT CORP.	Replace the current Automated Optical Inspection equipment system and to update the inspection process.
P030053/S054	11/19/2019	X - 30-Day Notice	MEMORYGEL SILICONE GEL-FILLED BREAST IMPLANTS	MENTOR CORP.	Qualification of new manufacturing equipment related to the removal of foreign debris from packaging used for MemoryGel Silicone Gel-Filled Breast Implants.
P050006/S081	11/19/2019	X - 30-Day Notice	GORE CARDIOFORM ASD OCCLUDER	W.L. GORE & ASSOCIATES,INC	Removal of an in-process inspection of the film used to manufacture the Occluder leaflet bag.
P050028/S080	11/05/2019	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HBV TEST, V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Change of a supplier's manufacturing site for critical components.
P050038/S034	11/19/2019	X - 30-Day Notice	ARISTA AH ABSORBABLE HEMOSTAT	C.R. BARD, INC.	Qualification of a new production line identical to the first, extended holding time in the hoppers, and reduction in labeling (no content changes).
P050053/S047	11/01/2019	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC INC.	Implementation of new instruments to assess percent solids in a collagen dispersion used in the manufacturing of INFUSE Bone Graft.
P050053/S048	11/29/2019	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC INC.	Modifications to the post-approval stability protocol for the drug component of INFUSE Bone Graft.
P060006/S098	11/07/2019	X - 30-Day Notice	EXPRESS SD MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Reduce the Ethylene Oxide gas concentration and qualify additional process challenge devices used in the BSC2000-2 sterilization cycle.
P060028/S034	11/19/2019	X - 30-Day Notice	MEMORYSHAPE SILICONE GEL-FILLED BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Qualification of new manufacturing equipment related to the removal of foreign debris from packaging used for MemoreShape Silicone Gel-Filled Breast Implants.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P060030/S081	11/05/2019	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Change of a supplier's manufacturing site for critical components.
P070004/S024	11/06/2019	X - 30-Day Notice	SIENTRA OPUS SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Change to increase the capacity of the shell dipping hoods and curing ovens in the manufacturing of Sientra OPUS® Silicone Gel Breast Implants.
P070004/S025	11/06/2019	X - 30-Day Notice	SIENTRA OPUS SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Addition of two new 30-gallon mixing vessels into production.
P070004/S026	11/06/2019	X - 30-Day Notice	SIENTRA OPUS SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Addition of a new vacuum pump to shell and gel processing.
P070004/S028	11/21/2019	X - 30-Day Notice	SIENTRA OPUS SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Addition of four laminar flow hoods.
P070026/S069	11/07/2019	X - 30-Day Notice	CERAMAX CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Addition of polishing machine used for polishing the intake and polishing the inner sphere of the ceramic inserts of the Ceramax Ceramic Total Hip System.
P090013/S304	11/27/2019	X - 30-Day Notice	CAPSUREFIX MRI LEAD	MEDTRONIC, INC	Minor changes to the Final Device Acceptance-Functional Test for leads.
P100026/S076	11/05/2019	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Manufacturing process changes to printed circuit assembly, interlay, and top can barrier tape for the RNS Neurostimulator, Model 320.
P110004/S034	11/07/2019	X - 30-Day Notice	NIRXCELL COCR CORONARY STENT ON RX SYSTEM	MEDINOL LTD.	Change from a manual inspection system to a semi-autonomous system for labels.
P110010/S170	11/01/2019	X - 30-Day Notice	PROMUS PREMIER AND PROMUS ELITE EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Reduction in the number of samples used for batch release and annual stability testing.
P110010/S171	11/07/2019	X - 30-Day Notice	PROMUS ELEMENT PLUS AND PROMUS PREMIER AND PROMUS ELITE EVEROLIMUS-ELUTING STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Reduce the Ethylene Oxide gas concentration and qualify additional process challenge devices used in the BSC2000-2 sterilization cycle.
P110010/S172	11/26/2019	X - 30-Day Notice	PROMUS PREMIER EVEROLIMUS-ELUTING CHROMIUM CORONARY STENT SYSTEM (MONORAIL AND OVER THE WIRE) AND PROMUS ELITE EVEROLIMUS-ELUTING CHROMIUM CORONARY STEN SYSTEM (MONORAIL)	BOSTON SCIENTIFIC CORP.	Change to the annealing process of the corewire component of the delivery system.
P110015/S006	11/25/2019	X - 30-Day Notice	13C-SPIRULINA GASTRIC EMPTYING BREATH TEST (GEBT)	ADVANCED BREATH DIAGNOSTICS	Qualification of water activity meter used to analyze solid samples for the 13C-Spirulina gastric emptying breath test (GEBT).

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P110037/S051	11/05/2019	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN CMV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Change of a supplier's manufacturing site for critical components.
P120010/S134	11/22/2019	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Addition of an automated needle hub assembly line for the construction of the Enlite and the Guardian (3) sensors. The Enlite and Guardian (3) sensors are a component of the Minimed, Paradigm, and Ipro2 systems.
P120010/S135	11/04/2019	X - 30-Day Notice	MEDTRONIC MINIMED 530G SYSTEM	MEDTRONIC INC.	Packaging, labeling, and final release activities of the One-Press Serter conducted at Medtronic, Inc. to be moved to contract manufacturer facility. The One-Press Serter is a component of the 530G System, the 630G System, the 670G System, and the Guardian Connect System.
P120010/S136	11/15/2019	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Supplier of the Glucose Oxidase used in the fabrication of the Enlite Sensor and Guardian Sensor (3) moved their manufacturing facility from one location to another within the United Kingdom.
P130009/S104	11/24/2019	X - 30-Day Notice	SAPIEN XT TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Several modifications to the final assembly cleanroom and down classification of gowning room 129 from ISO Class 7 to ISO Class 8 at the Irvine facility.
P130021/S067	11/13/2019	X - 30-Day Notice	ENVEO RAND ENVEO PRO DELIVERY CATHETER SYSTEM OF THE COREVALVE	MEDTRONIC COREVALVE LLC	Packaging and labeling rework for EnVeo R and EnVeo PRO Delivery Catheter Systems (DCS) to be performed at the Brooklyn Park North facility.
P130021/S068	11/07/2019	X - 30-Day Notice	COREVALVE EVOLUT R SYSTEM, COREVALVE EVOLUT PRO SYSTEM, AND COREVALVE EVOLUT PRO + SYSTEM	MEDTRONIC COREVALVE LLC	Increase in the timeframe for receipt of porcine pericardial tissue from abattoirs and initiation of tissue fixation.
P130030/S062	11/07/2019	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Reduce the Ethylene Oxide gas concentration and qualify additional process challenge devices used in the BSC2000-2 sterilization cycle.
P130030/S063	11/26/2019	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM (MONORAIL AND OVER-THE-WIRE)	BOSTON SCIENTIFIC CORP.	Change to the annealing process of the corewire component of the delivery system.
P140003/S062	11/20/2019	X - 30-Day Notice	IMPELLA 2.5, IMPELLA CP, IMPELLA CP WITH SMARTASSIST, IMPELLA 5.0, IMPELLA 5.5 WITH SMARTASSIST AND IMPELLA LD	ABIOMED, INC.	Add an alternative ultrasonic bonding workstation for a wire bonding process used in the manufacturing of the Impella 5.0 System, Impella LD System, and Impella RP System.
P140003/S063	11/25/2019	X - 30-Day Notice	IMPELLA 2.5, IMPELLA CP, IMPELLA CP WITH SMARTASSIST, IMPELLA 5.0, IMPELLA 5.5 WITH SMARTASSIST AND IMPELLA LD	ABIOMED, INC.	Use an additional sterilization chamber at the current sterilization facility for the ethelene oxide sterilization of Impella products.

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P140003/S064	11/28/2019	X - 30-Day Notice	IMPELLA 5.5 WITH SMARTASSIST	ABIOMED, INC.	Add a second supplier for the stainless-steel Impella 5.5 Inflow Cage.
P140009/S051	11/19/2019	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Changes in the viable air sampling method and a corresponding change to the action and alert limits for the airborne microbes in the controlled access environments (CAE).
P140031/S100	11/24/2019	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ULTRA TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Several modifications to the final assembly cleanroom and down classification of gowning room 129 from ISO Class 7 to ISO Class 8 at the Irvine facility.
P140031/S101	11/26/2019	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE, SAPIEN 3 ULTRA TRANSCATHETER HEART VALVE, COMMANDER DELIVERY SYSTEM, EDWARDS ESHEATH INTRODUCER SHEATH, CERTITUDE DELIVERY SYSTEM, CERTITUDE INTRODUCER SHEATH, AND CRIMPER	EDWARDS LIFESCIENCES, LLC.	Implementation of a new cleanroom for receiving inspection processes.
P150001/S074	11/22/2019	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED	Addition of an automated needle hub assembly line for the construction of the Enlite and the Guardian (3) sensors. The Enlite and Guardian (3) sensors are a component of the Minimed, Paradigm, and Ipro2 systems.
P150001/S076	11/04/2019	X - 30-Day Notice	MEDTRONIC MINIMED 630G SYSTEM	MEDTRONIC MINIMED	Packaging, labeling, and final release activities of the One-Press Serter conducted at Medtronic, Inc. to be moved to contract manufacturer facility. The One-Press Serter is a component of the 530G System, the 630G System, the 670G System, and the Guardian Connect System.
P150001/S077	11/15/2019	X - 30-Day Notice	MINIMED 630G SYSTEM	MEDTRONIC MINIMED	Supplier of the Glucose Oxidase used in the fabrication of the Enlite Sensor and Guardian Sensor (3) moved their manufacturing facility from one location to another within the United Kingdom.
P150003/S057	11/26/2019	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM (MONORAIL AND OVER-THE-WIRE)	BOSTON SCIENTIFIC CORPORATION	Changes to the electrolytic etch process time and number of switches for the SYNERGY SV and LV stent components.
P150004/S032	11/19/2019	X - 30-Day Notice	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Changes in the viable air sampling method and a corresponding change to the action and alert limits for the airborne microbes in the controlled access environments (CAE).
P150005/S050	11/07/2019	X - 30-Day Notice	BLAZER OPEN IRRIGATED TEMPERATURE ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Reduce the Ethylene Oxide gas concentration and qualify additional process challenge devices used in the BSC2000-2 sterilization cycle.

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P150012/S086	11/27/2019	X - 30-Day Notice	ESSENTIO MRI SR/DR SL, ESSENTIO MRI DR EL, PROPONENT MRI SR/DR SL, PROPONENT MRI DR EL, ACCOLADE MRI SR/DR SL AND ACCOLADE MRI DR EL	BOSTONSCIENTIFIC	Replace the current Automated Optical Inspection equipment system and to update the inspection process.
P150017/S014	11/26/2019	X - 30-Day Notice	CARTIVA SYNTHETIC CARTILAGE IMPLANT	CARTIVA, INC	Expansion of the release criteria of final, finished devices to accept those that have a homogenously opaque appearance.
P150019/S059	11/22/2019	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Addition of an automated needle hub assembly line for the construction of the Enlite and the Guardian (3) sensors. The Enlite and Guardian (3) sensors are a component of the Minimed, Paradigm, and Ipro2 systems.
P150019/S060	11/15/2019	X - 30-Day Notice	PARADIGM REAL-TME REVEL SYSTEM	MEDTRONIC MINIMED	Supplier of the Glucose Oxidase used in the fabrication of the Enlite Sensor and Guardian Sensor (3) moved their manufacturing facility from one location to another within the United Kingdom.
P150029/S032	11/22/2019	X - 30-Day Notice	IPRO2 CGM SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Addition of an automated needle hub assembly line for the construction of the Enlite and the Guardian (3) sensors. The Enlite and Guardian (3) sensors are a component of the Minimed, Paradigm, and Ipro2 systems.
P150029/S033	11/15/2019	X - 30-Day Notice	IPRO2 CGM SYSTEM	MEDTRONIC MINIMED	Supplier of the Glucose Oxidase used in the fabrication of the Enlite Sensor and Guardian Sensor (3) moved their manufacturing facility from one location to another within the United Kingdom.
P150033/S060	11/21/2019	X - 30-Day Notice	MICRA TRANSCATHETER PACING SYSTEM	MEDTRONIC INC.	Add Medtronic Ireland as an alternative site for completing the finished device analytical lot release testing.
P150036/S042	11/07/2019	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Transfer the INTUITY Elite Valve cloth-covered frame (CCF) manufacturing to the Edwards Changi Singapore site.
P150036/S044	11/18/2019	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Supplier Southington Tool and Manufacturing Corporation (STMC) to perform wireform crimping and tensile test verification.
P150036/S045	11/24/2019	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Several modifications to the final assembly cleanroom and down classification of gowning room 129 from ISO Class 7 to ISO Class 8 at the Irvine facility.
P150036/S046	11/14/2019	X - 30-Day Notice	EDWARDS INTUITY ELITE DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC.	Addition of the Draper, UT site for delivery system manufacturing.
P150036/S047	11/26/2019	X - 30-Day Notice	EDWARDS INTUITY VALVES AND DELIVERY SYSTEMS	EDWARDS LIFESCIENCES, LLC.	Implementation of a new cleanroom for receiving inspection processes.
P150048/S040	11/18/2019	X - 30-Day Notice	EDWARDS INSPIRIS RESILIA AORTIC VALVE	EDWARDS LIFESCIENCES, LLC.	Supplier Southington Tool and Manufacturing Corporation (STMC) to perform wireform crimping and tensile test verification.

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P150048/S041	11/24/2019	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS, PERICARDIAL MITRAL BIOPROSTHESIS, AND INSPIRIS RESILIA AORTIC VALVE	EDWARDS LIFESCIENCES, LLC.	Several modifications to the final assembly cleanroom and down classification of gowning room 129 from ISO Class 7 to ISO Class 8 at the Irvine facility.
P150048/S042	11/26/2019	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESES AND EDWARDS INSPIRIS RESILIA AORTIC VALVE	EDWARDS LIFESCIENCES, LLC.	Implementation of a new cleanroom for receiving inspection processes.
P160007/S026	11/22/2019	X - 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Addition of an automated needle hub assembly line for the construction of the Enlite and the Guardian (3) sensors. The Enlite and Guardian (3) sensors are a component of the Minimed, Paradigm, and Ipro2 systems.
P160007/S027	11/04/2019	X - 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Packaging, labeling, and final release activities of the One-Press Serter conducted at Medtronic, Inc. to be moved to contract manufacturer facility. The One-Press Serter is a component of the 530G System, the 630G System, the 670G System, and the Guardian Connect System.
P160007/S028	11/15/2019	X - 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Supplier of the Glucose Oxidase used in the fabrication of the Enlite Sensor and Guardian Sensor (3) moved their manufacturing facility from one location to another within the United Kingdom.
P160008/S007	11/19/2019	X - 30-Day Notice	HEARTSINE¿S SAMARITAN PUBLIC ACCESS AUTOMATED EXTERNAL DEFIBRILLATORS AND ACCESSORIES	HEARTSINE TECHNOLOGIES, LTD.	Change of supplier for cable assemblies.
P160017/S072	11/22/2019	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Addition of an automated needle hub assembly line for the construction of the Enlite and the Guardian (3) sensors. The Enlite and Guardian (3) sensors are a component of the Minimed, Paradigm, and Ipro2 systems.
P160017/S074	11/04/2019	X - 30-Day Notice	MEDTRONIC MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Packaging, labeling, and final release activities of the One-Press Serter conducted at Medtronic, Inc. to be moved to contract manufacturer facility. The One-Press Serter is a component of the 530G System, the 630G System, the 670G System, and the Guardian Connect System.
P160017/S075	11/15/2019	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Supplier of the Glucose Oxidase used in the fabrication of the Enlite Sensor and Guardian Sensor (3) moved their manufacturing facility from one location to another within the United Kingdom.
P160029/S002	11/26/2019	X - 30-Day Notice	HEARTSTART ONSITE DEFIBRILLATOR AND HEARTSTART HOME DEFIBRILLATOR	PHILIPS MEDICAL SYSTEMS, INC.	Updates to the assembly process for the HeartStart OnSite and Home Defibrillators.
P160035/S011	11/03/2019	X - 30-Day Notice	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Change to the routine monitoring of the package sealing process.
P160035/S012	11/03/2019	X - 30-Day Notice	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Raise the comparator threshold value for buzzer board for IKUS driver.

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P160038/S014	11/04/2019	X - 30-Day Notice	PRAXIS EXTENDED RAS PANEL	ILLUMINA, INC.	Replacement of an assembly sub-component.
P160045/S018	11/13/2019	X - 30-Day Notice	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	New PCR tube is provided with the kit.
P170008/S022	11/07/2019	X - 30-Day Notice	ELUNIR RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Change from a manual inspection system to a semi-autonomous system for labels.
P170011/S018	11/20/2019	X - 30-Day Notice	IMPELLA RP	ABIOMED, INC.	Add an alternative ultrasonic bonding workstation for a wire bonding process used in the manufacturing of the Impella 5.0 System, Impella LD System, and Impella RP System.
P170011/S019	11/25/2019	X - 30-Day Notice	IMPELLA RP SYSTEM	ABIOMED, INC.	Use an additional sterilization chamber at the current sterilization facility for the ethelene oxide sterilization of Impella products.
P170012/S020	11/07/2019	X - 30-Day Notice	HEMOBLAST BELLOWS	BIOM'UP SA	Changes involving reorganization of the workflow in the HEMOBLAST Bellows manufacturing facility (St-Priest, France), mainly for the purpose of efficiently utilizing the fixed space in the facility.
P170041/S002	11/12/2019	X - 30-Day Notice	ABBOTT REALTIME IDH1 ASSAY	ABBOTT MOLECULAR, INC.	Update of Quality Procedures for Amplification Reagent Kit and Control Kit.
P180002/S012	11/21/2019	X - 30-Day Notice	ZEPHYR ENDOBRONCHIAL VALVE (EBV) SYSTEM	PULMONX CORPORATION	Changes to the to sterilization parameters for the Endobronchial Valve (EBV) System.
P180002/S013	11/21/2019	X - 30-Day Notice	ZEPHYR ENDOBRONCHIAL VALVE (EBV) SYSTEM	PULMONX CORPORATION	Manufacturing changes to the Endobronchial Valve (EBV) System.
P180029/S016	11/12/2019	X - 30-Day Notice	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	Use of a second electron beam sterilizer in Tullamore Ireland for sterilization of the LOTUS Edge Valve System.
P180029/S017	11/21/2019	X - 30-Day Notice	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	Use of a new water purification system at the Malaysia manufacturing facility.

Total: 116