PMA Monthly approvals from 2/1/2021 to 2/28/2021

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190005	02/03/2021	PMAO - PMA Origi	ELECSYS ANTI-HBE, PRECICONTROL ANTI-HBE	ROCHE DIAGNOSTICS	Approval for the Elecsys Anti-HBe The device is an immunoassay for the in vitro qualitative detection of total antibodies to hepatitis B e antigen (anti-HBe) in human adult serum or plasma (potassium EDTA, lithium heparin, sodium citrate, sodium heparin) from individuals with symptoms of hepatitis or at risk for hepatitis B virus (HBV) infection. Assay results, in conjunction with other laboratory results and clinical information may be used as an aid in the diagnosis of hepatitis B virus (HBV) infection in patients with symptoms of hepatitis or who may be at risk for HBV infection. A reactive test is presumptive laboratory evidence of HBV seroconversion. Further HBV serological marker testing is required to define the specific disease state. The PreciControl Anti-HBe is used for quality control of the Elecsys Anti-HBe immunoassay on the cobas e 602 immunoassay analyzer. The performance of PreciControl Anti-HBe has not been established with any other anti-HBe assay.
P190013	02/02/2021	PMAO - PMA Origi	AED BATTERY EXCHANGE (MODELS 9146-ABE, G5-ABE, 5070-ABE, FR3-ABE)	AED BATTERY EXCHANGE, LLC	Approval for the AED Battery Exchange (Models 9146-ABE, G5-ABE, 5070-ABE, FR3-ABE). The AED battery supplies power to an AED as required during self maintenance, automated diagnoses, and defibrillation. The 9146-ABE is indicated for use with the Cardiac Science Powerheart G3, models 9390A, 9390E, 9300A, and 9300E. The G5-ABE is indicated for use with the Cardiac Science Powerheart G5, models G5A-80A, G5A-80C, G5S-80A, and G5S-80C. The 5070-ABE is indicated for use with the Philips HeartStart OnSite/Home, models M5066A, M5067A, M5068A, and the FRx, model 861304. The FR3-ABE is indicated for use with the Philips HeartStart FR3, models 861388 and 861389.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190034	02/23/2021	PMAO - PMA Origi	ELECSYS ANTI-HBS II, PRECICONTROL ANTI-HBS, ANTI-HBS CALCHECK	ROCHE DIAGNOSTICS	Approval for the Elecsys Anti-HBs II, PreciControl Anti-HBs, Anti-HBs CalCheck. Elecsys Anti-HBs II Immunoassay for the in vitro quantitative determination of total antibodies to the hepatitis B surface antigen (HBsAg) in human adult, pregnant women, and pediatric (ages 2 to 21 years) serum and plasma (K2-EDTA and K3-EDTA). Assay results may be used as an aid in the determination of susceptibilty to hepatitis B virus (HBV) infection for individuals prior to or following HBV vaccination; or where vaccination status is unknown. Assay results may be used with other HBV serological markers for the laboratory diagnosis of HBV disease associated with HBV infection. A reactive assay result will allow a differential diagnosis in individuals displaying signs and symptons of hepatitis in whom etiology is unknown. The detection of anti-HBs is indicative of laboratory diagnosis of seroconversion from hepatitis B virus (HBV) infection or from vaccination. The electrochemiluminescence immunoassay ECLIA is intended for use on the cobas e 601 immunoassay analyzer. PreciControl Anti-HBs PreciControl Anti-HBs is used for quality control of the Elecsys Anti-HBs immunoassay on the Elecsys and cobas e immunoassay analyzers and of the Elecsys Anti-HBs II immunoassay on the cobas e 601 immunoassay analyzer. The performance of PreciControl Anti-HBs has not been established with any other anti-HBs assay. Anti-HBs CalCheck Anti-HBs CalCheck is an assayed control material for use in the verification of the calibration established by the Elecsys Anti-HBs immunoassay on the cobas e immunoassay analyzers and by the Elecsys Anti-HBs II immunoassay on the cobas e 601 immunoassay analyzer.
P200039	02/12/2021	PMAO - PMA Origi	SHOCKWAVE INTRAVASCULAR LITHOTRIPSY (IVL) SYSTEM WITH SHOCKWAVE C2 CORONARY INTRAVASCULAR LITHOTRIPSY (IVL) CATHETER	SHOCKWAVE MEDICAL, INC.	Approval for the Shockwave Intravascular Lithotripsy (IVL) System with Shockwave C2 Coronary Intravascular Lithotripsy (IVL) Catheter. The Shockwave Intravascular Lithotripsy (IVL) System with Shockwave C2 IVL Coronary Catheter is indicated for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic de novo coronary arteries prior to stenting.

Total: 4

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N18286/S037	02/24/2021	S - Special CBE	GELFOAM	PFIZER, INC.	Approval for addition of text to the Gelfoam Instructions for Use regarding the unapproved use of absorbable gelatin for embolization

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S259	02/02/2021	R - Real-Time Proc	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Approval for a software maintenance release for the Model 3892 Altrua, Insignia I, and Nexus I software application on the Model 3300 LATITUDE Programming System.
P830063/S013	02/12/2021	R - Real-Time Proc	GAMBRO FIBER PLASMAFILTER	BAXTER INTERNATIONAL, INC.	Approval for a change in the parting line on the blood ports of the support plate of the manufacturing mold.
P840001/S482	02/24/2021	R - Real-Time Proc	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Approval for change in A710 software to version 1.3.130 from version 1.3.80 to correct software code to ensure Model A710 Intellis Clinician Programmer Application (CP App) for Mobile Platform resets invalid data to resolve the memory block validation error.
P890003/S438	02/09/2021	R - Real-Time Proc	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Approval for updates to the MyCareLink Patient Monitor firmware.
P900056/S183	02/05/2021	N - Normal 180 Day	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Approval for a change in the core wire supplier to increase torqueability of the Rotawire guidewires (Floppy and Extra Support), and the associated rebranding of the Rotawire guidewires as the Rotawire Drive guidewires (Floppy and Extra Support).
P910077/S182	02/02/2021	R - Real-Time Proc	VENTAK(R) PRX (TM) MODEL 1700,1705 PULSE GENERATOR	BOSTON SCIENTIFIC	Approval for a software maintenance release for the Model 3892 Altrua, Insignia I, and Nexus I software application on the Model 3300 LATITUDE Programming System.
P930014/S132	02/18/2021	O - Normal 180 Day	ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES	ALCON LABORATORIES, INC.	Approval for a contract sterilization site located at Synergy Health Sterilisation UK Ltd., Unit 1, Alpha Court, Capitol Park, Thorne, Doncaster DN8 5TZ United Kingdom.
P930016/S062	02/26/2021	O - Normal 180 Day	VISX EXCIMER LASER SYSTEM MODELS "B" AND "C"	AMO MANUFACTURING USA, LLC	Approval of several minor clarifications and corrections to either define the original intent of the protocol, or correct mismatched information in the protocol.
P940010/S017	02/24/2021	R - Real-Time Proc	OPTIGUIDE(TM) FIBER OPTIC DIFFUSER	PINNACLE BIOLOGICS, INC.	Approval for the addition of the PB900 series to OPTIGUIDE® Cylindrical Diffuser fiber optics. The change being made (due to addition of the fiber that is equivalent to PB200 and PB700 fibers) is in two quality control procedures to accommodate the smaller diameter of this design.
P960040/S460	02/02/2021	R - Real-Time Proc	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Approval for a software maintenance release for the Model 3892 Altrua, Insignia I, and Nexus I software application on the Model 3300 LATITUDE Programming System.
P970003/S234	02/22/2021	R - Real-Time Proc	VNS THERAPY SYSTEM	LIVANOVA USA, INC.	Approval for changes to the M3000 Programming Software (from M3000 v1.6.1.9 to M3000 v1.6.2.0).
P970004/S322	02/02/2021	R - Real-Time Proc	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Approval for minor labeling changes to the MRI Guidelines for InterStim systems manual for the InterStim Micro and InterStim II systems used for Sacral Neuromodulation (SNM) therapy to treat urinary retention and the symptoms of overactive bladder, and chronic fecal incontinence.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S764	02/09/2021	R - Real-Time Proc	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for updates to the MyCareLink Patient Monitor firmware.
P980035/S663	02/09/2021	R - Real-Time Proc	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Approval for updates to the MyCareLink Patient Monitor firmware.
P980035/S670	02/12/2021	R - Real-Time Proc	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Approval for software application release SmartSync Application Update Version 3.2.4.
P980049/S137	02/18/2021	N - Normal 180 Day	DEFENDER II MODEL 9201 IMPLANTABLE CARDIOVERTER DEFIBRILLATOR	MICROPORT CRM USA INC.	Approval for a modular programming system.
P980053/S018	02/25/2021	O - Normal 180 Day	DURASPHERE INJECTABLE BULKING AGENT	CARBON MEDICAL TECHNOLOGI ES, INC.	Approval for a manufacturing site located at Steris, 9303 West Broadway Ave., Brooklyn Park, MN 55445, a contract sterilizer.
P010012/S529	02/02/2021	R - Real-Time Proc	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Approval for a software maintenance release for the Model 3892 Altrua, Insignia I, and Nexus I software application on the Model 3300 LATITUDE Programming System.
P010015/S458	02/09/2021	R - Real-Time Proc	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Approval for updates to the MyCareLink Patient Monitor firmware.
P010015/S464	02/12/2021	R - Real-Time Proc	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Approval for software application release SmartSync Application Update Version 3.2.4. .
P010031/S724	02/09/2021	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for updates to the MyCareLink Patient Monitor firmware.
P010032/S157	02/22/2021	O - Normal 180 Day	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Approval to add Abbott Medical Puerto Rico facility located at Km 67.5 Rd2 Arecibo, Puerto Rico, 00612 as an alternate sterilization and manufacturing site of the Paddle Lead and Internal Lead Extension products.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010032/S169	02/24/2021	Y - 135 Review Tra	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Approval to change the grade in raw materials used in the formulation of the Green Solvent, used for in-process cleaning of leads and pins.
P020050/S037	02/18/2021	S - Special CBE	WAVELIGHT ALLEGRETTO WAVE EXCIMER LASER SYSTEM	ALCON LABORATORIES, INC.	Approval for labeling changes to add and strengthen contraindications.
P030005/S205	02/02/2021	R - Real-Time Proc	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Approval for a software maintenance release for the Model 3892 Altrua, Insignia I, and Nexus I software application on the Model 3300 LATITUDE Programming System.
P030008/S033	02/18/2021	S - Special CBE	WAVELIGHT ALLEGRETTO WAVE EXCIMER LASER SYSTEM	ALCON LABORATORIES, INC.	Approval for labeling changes to add and strengthen contraindications.
P040020/S094	02/18/2021	O - Normal 180 Day	ACRYSOF RESTOR APODIZED DIFFRACTIVE OPTIC POSTERIOR CHAMBER IOL	ALCON RESEARCH, LTD.	Approval for a contract sterilization site located at Synergy Health Sterilisation UK Ltd., Unit 1, Alpha Court, Capitol Park, Thorne, Doncaster DN8 5TZ United Kingdom.
P040029/S016	02/04/2021	O - Normal 180 Day	JSZ ORTHOKERATOLOGY (OPRIFOCON A) CONTACT LENSES FOR OVERNIGHT WEAR	EUCLID SYSTEMS CORPORATION	Approval for model name additions to the Euclid Systems Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear and Euclid Systems Orthokeratology (tisilfocon A) Contact Lenses for Overnight Wear
P080004/S033	02/26/2021	O - Normal 180 Day	HOYA ISPHERIC MODEL YA-60BB INTRAOCULAR LENS	HOYA SURGICAL OPTICS, INC.	approval for a new Ethylene Oxide Contract Sterilizer, SIAM STERI SERVICES CO. LTD., Phan Thong, Chon Buri, 20160 Thailand
P080006/S156	02/09/2021	O - Normal 180 Day	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Approval for a labeling update with the clinical study summary for the Attain Ability Straight Left Ventricular Lead.
P080025/S217	02/02/2021	R - Real-Time Proc	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Approval for minor labeling changes to the MRI Guidelines for InterStim systems manual for the InterStim Micro and InterStim II systems used for Sacral Neuromodulation (SNM) therapy to treat urinary retention and the symptoms of overactive bladder, and chronic fecal incontinence.
P100010/S108	02/11/2021	O - Normal 180 Day	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Approval of the protocol for the post-approval study (PAS) protocol.
P100047/S149	02/12/2021	O - Normal 180 Day	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval of the revised protocol for the PAS protocol.
P110042/S150	02/02/2021	R - Real-Time Proc	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for a software maintenance release for the Model 3892 Altrua, Insignia I, and Nexus I software application on the Model 3300 LATITUDE Programming System.
P120010/S139	02/25/2021	S - Special CBE	MINIMED 530G SYSTEM	MEDTRONIC INC.	Approval for an update to product labeling to warn against a new interference by Hydroxyurea to the continuous glucose monitoring (CGM) component of the system.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130008/S056	02/12/2021	N - Normal 180 Day	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval for: 1) Updated version of the Model 2740 Inspire Programmer System; 2) Minor software changes to the Application Module (AM)/Tablet; 3) Manufacturing process changes to reduce scrap for the new programmer cable; 4) Changes to improve aesthetics of the programmer cable; and 5) Minor software updates regarding non-English languages for the European market and minor bug fixes.
P130013/S041	02/10/2021	S - Special CBE	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Approval to add a precaution statement to the instructions for use.
P130021/S085	02/26/2021	R - Real-Time Proc	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Approval for a modification to the polypropylene resin material formulation used in the packaging lid and retainer assembly.
P130022/S035	02/26/2021	O - Normal 180 Day	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for a new Nordson Medical¿s manufacturing site of the Implantable Pulse Generators (IPGs) of the Senza neuromodulation system located at 105 E Tasman Dr. San Jose, CA, 95134. Pro-Tech will continue to perform final packaging and sterilization.
P130022/S038	02/05/2021	R - Real-Time Proc	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for minor software changes, including the addition of a mechanism for Health Care Providers to conduct an impedance check of the implanted system, as well as expanding the number of available programs.
P140009/S053	02/22/2021	O - Normal 180 Day	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Approval to add Abbott Medical Puerto Rico facility located at Km 67.5 Rd2 Arecibo, Puerto Rico, 00612 as an alternate sterilization and manufacturing site of the Paddle Lead and Internal Lead Extension products.
P140009/S065	02/24/2021	Y - 135 Review Tra	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Approval to change the grade in raw materials used in the formulation of the Green Solvent, used for in-process cleaning of leads and pins.
P140013/S012	02/17/2021	R - Real-Time Proc	MINERVA ENDOMETRIAL ABLATION SYSTEM	MINERVA SURGICAL	Approval for a design change to the Check Valve located on the Disposable Handpiece.
P140031/S126	02/17/2021	R - Real-Time Proc	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for the shelf life extension from 2 to 3 years.
P150001/S090	02/25/2021	S - Special CBE	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	Approval for an update to product labeling to warn against a new interference by Hydroxyurea to the continuous glucose monitoring (CGM) component of the system.
P150012/S104	02/02/2021	R - Real-Time Proc	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Approval for a software maintenance release for the Model 3892 Altrua, Insignia I, and Nexus I software application on the Model 3300 LATITUDE Programming System.
P150013/S021	02/22/2021	N - Normal 180 Day	PD-L1 IHC 22C3 PHARMDX	AGILENT TECHNOLOGIES, INC.	Approval for the PD-L1 IHC 22C3 pharmDX as a companion diagnostic device to detect PD-L1 protein (Tumor Proportion Score ?50%) in patients with non-small cell lung cancer (NSCLC) for treatment with LIBTAYO.
P150019/S063	02/25/2021	S - Special CBE	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Approval for an update to product labeling to warn against a new interference by Hydroxyurea to the continuous glucose monitoring (CGM) component of the system.
P150029/S036	02/25/2021	S - Special CBE	IPRO2 CGM SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Approval for an update to product labeling to warn against a new interference by Hydroxyurea to the continuous glucose monitoring (CGM) component of the system.
P150033/S088	02/09/2021	R - Real-Time Proc	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval for updates to the MyCareLink Patient Monitor firmware.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150040/S008	02/19/2021	N - Normal 180 Day	VISUMAX FEMTOSECOND LASER	CARL ZEISS MEDITEC, INC.	Approval of obsolescence and life-cycle changes of hardware, software, and electronics.
P160007/S040	02/25/2021	S - Special CBE	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Approval for an update to product labeling to warn against a new interference by Hydroxyurea to the continuous glucose monitoring (CGM) component of the system.
P160017/S090	02/25/2021	S - Special CBE	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval for an update to product labeling to warn against a new interference by Hydroxyurea to the continuous glucose monitoring (CGM) component of the system.
P160032/S002	02/25/2021	N - Normal 180 Day	LIFELINE/REVIVER DDU-100, LIFELINE/ REVIVER AUTO DDU-120, LIFELINE/REVIVER VIEW DDU-2300, LIFELINE/ REVIVER VIEW AUTO DDU-2200, LIFELINE/ REVIVER ECG DDU-2450, AND LIFELINE/REVIVER ECG+ DDU-2475 AUTOMATED EXTERNAL DEFIBRILLATORS	DEFIBTECH, LLC	Approval for software changes and minor production software updates to the DDU-100 Series AEDs, as well as changes in specifications used during design validation for the DDU-100 Series AEDs, the DDU-2200, DDU-2300, DDU-2450, and DDU-2475 AEDs.
P160035/S016	02/17/2021	O - Normal 180 Day	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Approval for updates to the Instructions for Use based on the post-approval study results.
P160043/S039	02/18/2021	R - Real-Time Proc	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for an extended shelf life of 36 months.
P160055/S016	02/19/2021	R - Real-Time Proc	LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Approval for modifications of the Professional Use labeling to include the RxSight Insertion Device as a method for introducing the Light Absorbable Lens (LAL) into the eye, along with other minor changes.
P170002/S010	02/10/2021	Y - 135 Review Tra	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Approval for an alternate analytical laboratory for the determination of residual 1,4-butanediol diglycidyl ether (BDDE) as part of batch release testing.
P170013/S003	02/25/2021	O - Normal 180 Day	LOW-PROFILE VISUALIZED INTRALUMINAL SUPPORT (LVIS) AND LVIS JR.	MICROVENTION, INC.	Approval for a manufacturing site located at MicroVention, Inc., 35 Enterprise, Aliso Viejo, California 92656.
P170018/S012	02/16/2021	S - Special CBE	LIFEPAK® CR2 DEFIBRILLATOR	PHYSIO-CONTROL, INC	Approval for a new warning associated with premature battery depletion of the LIFEPAK CR2 lithium battery.
P180013/S006	02/11/2021	O - Normal 180 Day	VICI VENOUS STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for the transfer of the finished device manufacturing site from Fremont, California to Galway, Ireland, the addition of new sterilization sites and cycles, and a change in legal manufacturer from Veniti, Inc. to Boston Scientific Corporation.
P180032/S003	02/25/2021	O - Normal 180 Day	CERENE® CRYOTHERAPY DEVICE	CHANNEL MEDSYSTEMS, INC.	Approval for the addition of information from the post-approval study to the patient labeling and instructions for use

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180046/S026	02/03/2021	R - Real-Time Proc	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for an update to the software and associated labeling for the Model 1101 implantable neurostimulator and Model 2501 clinician programmer to support the use of two therapy programs.
P190006/S026	02/03/2021	R - Real-Time Proc	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for an update to the software and associated labeling for the Model 1101 implantable neurostimulator and Model 2501 clinician programmer to support the use of two therapy programs.
P190008/S010	02/18/2021	O - Normal 180 Day	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Approval of the revised study inclusion and exclusion criteria, revised study milestone, and clarification-based updates to the base protocol.
P190009/S001	02/12/2021	O - Normal 180 Day	OPRA IMPLANT SYSTEM	INTEGRUM AB	Approval of the protocol for the post-approval study (PAS) protocol.
P190009/S002	02/12/2021	O - Normal 180 Day	OPRA IMPLANT SYSTEM	INTEGRUM AB	Approval of the protocol for the post-approval study (PAS) protocol
P190018/S005	02/18/2021	O - Normal 180 Day	CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM, CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM	ALCON RESEARCH, LTD.	Approval for a contract sterilization site located at Synergy Health Sterilisation UK Ltd., Unit 1, Alpha Court, Capitol Park, Thorne, Doncaster DN8 5TZ United Kingdom.
P190019/S003	02/10/2021	R - Real-Time Proc	RANGER¿ PACLITAXEL-COATED PTA BALLOON CATHETER	BOSTON SCIENTIFIC CORPORATION	Approval for a 24 month shelf life for the Ranger Paclitaxel-Coated PTA Balloon Catheter.
P200015/S005	02/17/2021	R - Real-Time Proc	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Approval for the shelf life extension from 2 to 3 years.

Total: 71

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N17600/S035	02/17/2021	X - 30-Day Notice	AVITENE (MICROFIBRILLAR COLLAGEN HOMOSTAT)	DAVOL, INC., SUB. C.R. BARD, INC.	Changes to the secondary pouch material and supplier facility for Avitene Microfibrillar Collagen Hemostat.
P790005/S067	02/17/2021	X - 30-Day Notice	OSTEOSTIM(R)	EBI, LLC	Qualify and approve an alternate, proposed supplier to provide thermoformed PETG packaging trays and lids utilized in the final sterile pack assembly of EBI OsteoGen Surgically Implantable Bone Growth Stimulators and SpF Implantable Spinal Fusion Stimulators.
P800002/S028	02/17/2021	X - 30-Day Notice	AVITENE MICROFIBRILLAR COLLAGEN HEMOSTAT NON-WOVEN WEB	C.R. BARD, INC.	Changes to the secondary pouch material and supplier facility for Avitene Microfibrillar Collagen Hemostat.
P810006/S093	02/04/2021	X - 30-Day Notice	COLLASTAT	INTEGRA LIFESCIENCES CORPORATION	Add an additional sealer and sealing tool for the packaging of the Helistat and OraFoam ½ inch x 1.0 inch product configuration.
P810006/S094	02/26/2021	X - 30-Day Notice	COLLASTAT	INTEGRA LIFESCIENCES CORPORATION	Modification to the cleaning process at the Collagen Manufacturing Center of Integra.
P830055/S262	02/19/2021	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Rework process for the removal of micro scratches which occurs during the manufacture of components of the LCS® Total Knee System that are manufactured at the DePuy Raynham, MA manufacturing facility.
P830061/S192	02/09/2021	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add an alternate supplier for the specified connector component.
P840001/S483	02/10/2021	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Manufacturing location change of polymer resin for an external supplier, AGC Chemicals, and change in a processing aid used in the production of ETFE due to the environmental regulations.
P840062/S079	02/26/2021	X - 30-Day Notice	COLLACOTE(TM)	INTEGRA LIFESCIENCES CORP.	Modification to the cleaning process at the Collagen Manufacturing Center of Integra.
P850010/S093	02/04/2021	X - 30-Day Notice	HELISTAT(TM) ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	INTEGRA LIFESCIENCES CORPORATION	Add an additional sealer and sealing tool for the packaging of the Helistat and OraFoam ½ inch x 1.0 inch product configuration.
P850010/S094	02/26/2021	X - 30-Day Notice	HELISTAT(TM) ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	INTEGRA LIFESCIENCES CORPORATION	Modification to the cleaning process at the Collagen Manufacturing Center of Integra.

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P850035/S056	02/17/2021	X - 30-Day Notice	EBI SPF IMPLANTABLE SPINAL FUSION STIMULATOR	EBI, LLC	Qualify and approve an alternate, proposed supplier to provide thermoformed PETG packaging trays and lids utilized in the final sterile pack assembly of EBI OsteoGen Surgically Implantable Bone Growth Stimulators and SpF Implantable Spinal Fusion Stimulators.
P850064/S044	02/24/2021	X - 30-Day Notice	MODEL 203 LIFE PULSE HIGH FREQUENCY VENTILATOR	BUNNELL, INC.	Change to the test equipment used for electrical safety testing during in-house servicing of the Life Pulse High Frequency Ventilator Model 203.
P850089/S153	02/09/2021	X - 30-Day Notice	CAPSURE SP, CAPSURE, CAPSURE 2 LEADS, EXCELLENCE S, IMPULSE, IMPLUSE II EXCELLENCE SS, LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add an alternate supplier for the specified connector component.
P900033/S093	02/26/2021	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Modification to the cleaning process at the Collagen Manufacturing Center of Integra.
P930021/S027	02/22/2021	X - 30-Day Notice	BIORA EMDOGAIN(R)	THE STRAUMANN COMPANY	Replacement of the current centrifuge used in the manufacture of Emdogain with a new centrifuge.
P950005/S076	02/02/2021	X - 30-Day Notice	WEBSTER DIAG./ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC	Implementation of an automated dimensional inspection process for the ring spacing, tip length, and shaft outer diameter.
P950008/S015	02/15/2021	X - 30-Day Notice	SILIKON 1000	ALCON	Implementation of an alternate indicator for demonstrating successful terminal sterilization for Silikon 1000.
P960009/S395	02/10/2021	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Manufacturing location change of polymer resin for an external supplier, AGC Chemicals, and change in a processing aid used in the production of ETFE due to the environmental regulations.
P960043/S111	02/26/2021	X - 30-Day Notice	PROSTAR 9 FR. PERCUTANEOUS VASCULAR SURGICAL (PVS) SYSTEM	ABBOTT VASCULAR INC.	Implementation of a post-cure process step for a component of the Perclose Suture Trimmer accessory.
P970018/S037	02/16/2021	X - 30-Day Notice	BD PREPSTAIN SYSTEM	BD DIAGNOSTIC SYSTEMS	Change in manufacturing process for BD SurePath Precoat Slides.
P980016/S767	02/03/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Manufacturing location change and processing aid at a raw material supplier.
P980035/S673	02/17/2021	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Add a second manufacturing line for shield assemblies.

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P980040/S130	02/22/2021	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Qualify expansion of manufacturing area to Building 3 of AMO Puerto Rico facility for SmartLoad Delivery Technology and TECNIS Simplicity Delivery System devices that are approved and manufactured in Building 1 of this facility.
P990025/S061	02/02/2021	X - 30-Day Notice	NAVI-STAR DIAGNOSTIC/ ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC.	Implementation of an automated dimensional inspection process for the ring spacing, tip length, and shaft outer diameter.
P000054/S064	02/05/2021	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Change to the process for printing and inspecting labels.
P000058/S083	02/05/2021	X - 30-Day Notice	INFUSE BONE GRAFT/LT-CAGE LUMBAR TAPERED FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Change to the process for printing and inspecting labels.
P010012/S532	02/24/2021	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Molding fixture update for the Acuity X4 E24 molding process.
P010015/S465	02/09/2021	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Add an alternate supplier for the specified connector component.
P010031/S729	02/03/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Manufacturing location change and processing aid at a raw material supplier.
P010032/S170	02/03/2021	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Use of an alternate component supplier Deringer-Ney Inc (DNI) for the electrodes used in Penta Lamitrode Leads, Models 3227, 3228, & 3229. DNI, will stamp the electrodes instead of machine the electrodes to tighter tolerance values.
P010047/S064	02/11/2021	X - 30-Day Notice	PROGEL PLEURAL AIR LEAK SEALANT	NEOMEND, INC.	Addition of an equivalent piece of testing equipment utilized in a lot release test.
P010068/S061	02/02/2021	X - 30-Day Notice	NAVISTAR/CELSIUS DS DIAGNOSTIC/ABLATION DEFLECTABLE 8MM TIP CATHETER	BIOSENSE WEBSTER, INC.	Implementation of an automated dimensional inspection process for the ring spacing, tip length, and shaft outer diameter.
P030009/S099	02/23/2021	X - 30-Day Notice	DRIVER OVER-THE-WIRE, RAPID EXCHANGE, AND MULTI-EXCHANGE CORONARY STENT SYSTEMS	MEDTRONIC IRELAND	Alternate supplier for the protective sheath component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030031/S112	02/02/2021	X - 30-Day Notice	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Implementation of an automated dimensional inspection process for the ring spacing, tip length, and shaft outer diameter.
P030036/S129	02/09/2021	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Add an alternate supplier for the specified connector component.
P040029/S019	02/08/2021	X - 30-Day Notice	JSZ ORTHOKERATOLOGY (OPRIFOCON A) CONTACT LENSES FOR OVERNIGHT WEAR	EUCLID SYSTEMS CORPORATIO N	Addition of manufacturing alternatives for the Euclid Systems Orthokeratology (oprifocon A) Toric Contact Lenses for Overnight Wear and Euclid Systems Orthokeratology (tisilfocon A) Toric Contact Lenses for Overnight Wear.
P040036/S077	02/02/2021	X - 30-Day Notice	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Implementation of an automated dimensional inspection process for the ring spacing, tip length, and shaft outer diameter.
P050053/S055	02/08/2021	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC INC.	Change to the process for printing and inspecting labels.
P070001/S020	02/23/2021	X - 30-Day Notice	PRODISC TM-C TOTAL DISC REPLACEMENT	CENTINEL SPINE, LLC	Change to eliminate redundant quality control method regarding endplate coating thickness.
P080006/S157	02/09/2021	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Add an alternate supplier for the specified connector component.
P080027/S038	02/25/2021	X - 30-Day Notice	ORAQUICK HCV RAPID ANTIBODY TEST	ORASURE TECHNOLOGI ES INC.	Share manufacturing equipment and production areas for multiple analyte devices having the same platform.
P100009/S038	02/22/2021	X - 30-Day Notice	MITRACLIP DELIVERY SYSTEM	ABBOTT VASCULAR INC.	Minor manufacturing changes to the gripper line of the Clip Delivery System.
P100018/S031	02/26/2021	X - 30-Day Notice	PIPELINE EMBOLIZATION DEVICE	MICRO THERAPEUTI CS, INC. D/B/A EV3 NEUROVASC ULAR	Addition of an alternate sub-tier supplier to provide raw material used in the manufacturing of the Pipeline Flex Embolization Device.
P110002/S029	02/17/2021	X - 30-Day Notice	MOBI-C CERVICAL DISC PROSTHESIS (ONE-LEVEL INDICATION)	ZIMMER BIOMET SPINE, INC.	Qualify an existing manufacturing site as an alternate supplier to perform the titanium (Ti) and hydroxyapatite (HA) coating operations for the Mobi-C® implant endplates.
P110009/S029	02/17/2021	X - 30-Day Notice	MOBI-C CERVICAL DISC PROSTHESIS (TWO-LEVEL INDICATION)	ZIMMER BIOMET SPINE, INC.	Qualify an existing manufacturing site as an alternate supplier to perform the titanium (Ti) and hydroxyapatite (HA) coating operations for the Mobi-C® implant endplates.

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P110010/S187	02/05/2021	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Introduction of the PROMUS family into the reduced Ethylene Oxide gas concentration sterilization cycle.
P110010/S188	02/24/2021	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Adoption of the Ranger Paclitaxel-Coated PTA Balloon Catheter and Promus Everolimus-Eluting Coronary Stent System into the reduced EO gas concentration version of the BSC2000-2 sterilization cycle previously approved to sterilize other Boston Scientific Corporation (BSC) products.
P110013/S106	02/04/2021	X - 30-Day Notice	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Alternative storage facility for stability samples.
P110013/S107	02/23/2021	X - 30-Day Notice	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Alternate supplier for the protective sheath component.
P140003/S079	02/17/2021	X - 30-Day Notice	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	New environmentally controlled manufacturing room for the Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, Impella 5.5 with SmartAssist, and Impella LD.
P140010/S055	02/04/2021	X - 30-Day Notice	IN PACT ADMIRAL PACLITAXEL-ELUTING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Alternative storage facility for stability samples.
P150009/S005	02/17/2021	X - 30-Day Notice	ANGELMED GUARDIAN SYSTEM	ANGEL MEDICAL SYSTEMS INC.	New component manufacturer for the external patient electronics system.
P150016/S020	02/11/2021	X - 30-Day Notice	TRIDYNE VASCULAR SEALANT	NEOMEND, INC.	Addition of an equivalent piece of testing equipment utilized in a lot release test.
P150033/S092	02/18/2021	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Change the order of an integrated circuit manufacturing process at a supplier.
P150033/S094	02/16/2021	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Updates to the endotoxin testing process for the tether component.
P150040/S009	02/24/2021	X - 30-Day Notice	VISUMAX FEMTOSECOND LASER	CARL ZEISS MEDITEC, INC.	Alternate contract sterilizer for the Treatment Pack accessory.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160029/S009	02/12/2021	X - 30-Day Notice	HEARTSTART ONSITE DEFIBRILLATOR (MODEL M5066A) AND HEARTSTART HOME DEFIBRILLATOR (MODEL M5068A)	PHILIPS MEDICAL SYSTEMS, INC.	Inspection procedure changes for components and sub-assemblies used in the manufacture of the HeartStart OnSite Defibrillator (Model M5066A), HeartStart Home Defibrillator (Model M5068A) and HeartStart FRx Defibrillator (Model 861304).
P160033/S005	02/02/2021	X - 30-Day Notice	POWERHEART® G5 AED, POWERHEART® AED G3 PLUS, AND POWERHEART® AED G3	ZOLL MEDICAL CORPORATION	New manufacturing equipment and alternate material for printed circuit boards.
P160043/S042	02/04/2021	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Alternative storage facility for stability samples.
P160043/S043	02/23/2021	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Alternate supplier for the protective sheath component.
P160049/S011	02/19/2021	X - 30-Day Notice	STELLAREX 0.035 OTW DRUG-COATED ANGIOPLASTY BALLOON	THE SPECTRANETICS CORP.	Addition of sterilization chamber 4 in the Los Angeles, CA sterilization facility.
P170012/S025	02/25/2021	X - 30-Day Notice	HEMOBLAST¿ BELLOWS	BIOM'UP FRANCE SAS	Changes to the HEMOBLAST¿ Bellows manufacturing facility, located in in St-Priest, France.
P170030/S014	02/17/2021	X - 30-Day Notice	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Modifications to in-process acceptance criteria and final in-process acceptance criteria.
P180028/S006	02/12/2021	X - 30-Day Notice	HEARTSTART FRX DEFIBRILLATOR	PHILIPS MEDICAL SYSTEMS	Inspection procedure changes for components and sub-assemblies used in the manufacture of the HeartStart OnSite Defibrillator (Model M5066A), HeartStart Home Defibrillator (Model M5068A) and HeartStart FRx Defibrillator (Model 861304).
P180032/S004	02/23/2021	X - 30-Day Notice	CERENE® CRYOTHERAPY DEVICE	CHANNEL MEDSYSTEMS, INC.	Change in facility within the same establishment.
P180046/S029	02/24/2021	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Replacement of a transformer component of the Charging Device due to component obsolescence.
P190006/S029	02/23/2021	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Replacement of a transformer component of the Charging Device due to component obsolescence.
P190008/S009	02/04/2021	X - 30-Day Notice	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Alternative storage facility for stability samples.

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P190019/S006	02/24/2021	X - 30-Day Notice	RANGER¿ PACLITAXEL-COATED PTA BALLOON CATHETER	BOSTON SCIENTIFIC CORPORATION	Adoption of the Ranger Paclitaxel-Coated PTA Balloon Catheter and Promus Everolimus-Eluting Coronary Stent System into the reduced EO gas concentration version of the BSC2000-2 sterilization cycle previously approved to sterilize other Boston Scientific Corporation (BSC) products.
P200022/S004	02/10/2021	X - 30-Day Notice	SIMPLIFY® CERVICAL ARTIFICIAL DISC	SIMPLIFY MEDICAL, INC.	Changes to the Simplify Clip, a packaging component of the Simplify Disc.
P200030/S001	02/01/2021	X - 30-Day Notice	GORE EXCLUDER CONFORMABLE AAA ENDOPROSTHESIS (CEXC)	W. L. GORE AND ASSOCIATES, INC.	Implementation of the use of an alternate polytetrafluoroethylene (PTFE) aqueous-based formulation for coating the processing mandrels used as manufacturing aids during the manufacturing of Gore CEXC components.

Total: 72