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

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170023	01/28/2020	PMAO - PMA Origi	BULKAMID URETHRAL BULKING SYSTEM	CONTURA INTERNATIONAL A/S	Approval for the Bulkamid Urethral Bulking System. The device is indicated for urethral injection for the treatment of stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD) in adult women who have SUI or stress predominant mixed incontinence.
P180038	01/02/2020	PMAO - PMA Origi	LIAISON XL MUREX ANTI-HBC, LIAISON MUREX CONTROL ANTI-HBC	DIASORIN INC.	Approval for the LIAISON XL MUREX Anti-HBc assay is an in vitro chemiluminescent immunoassay (CLIA) for the qualitative detection of IgG and IgM (total) antibodies to hepatitis B core antigen (anti-HBc) in human adult and pediatric serum and plasma (lithium and sodium heparin, sodium citrate and K2 EDTA) including separator tubes, on the LIAISON XL Analyzer. 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. The assay is not intended for use in screening blood, plasma or tissue donors. The LIAISON XL MUREX Control Anti-HBc (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON XL MUREX Anti-HBc assay. The performance characteristics of LIAISON XL MUREX Control Anti-HBc have not been established for any other assays or instrument platforms.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190018	01/07/2020	PMAO - PMA Origi	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 the Clareon and Clareon Toric Aspheric Hydrophobic Acrylic Intraocular Lens (IOL). Clareon Aspheric Hydrophobic Acrylic Intraocular Lens (IOL): The Clareon Aspheric Hydrophobic Acrylic Intraocular Lens (IOL) is indicated for primary implantation in the capsular bag in the posterior chamber of the eye for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed. Clareon Toric Aspheric Hydrophobic Acrylic Intraocular Lens (IOL): The Clareon Toric Aspheric Hydrophobic Acrylic Intraocular Lenses (IOLs) are indicated for primary implantation in the capsular bag in the posterior chamber of the eye for visual correction of aphakia and pre-existing corneal astigmatism to reduce residual refractive cylinder and improve uncorrected distance vision in adult patients in whom a cataractous lens has been removed. Clareon Aspheric Hydrophobic Acrylic Intraocular Lens (IOL) with the AutonoMe Pre-loaded Delivery System: The Clareon Aspheric Hydrophobic Acrylic Intraocular Lens (IOL) is indicated for primary implantation in the capsular bag in the posterior chamber of the eye for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed. Clareon Toric Aspheric Hydrophobic Acrylic Intraocular Lens (IOL) with the AutonoMe Pre-loaded Delivery System: The Clareon Toric Aspheric Hydrophobic Acrylic Intraocular Lenses (IOLs) are indicated for primary implantation in the capsular bag in the posterior chamber of the eye for visual correction of aphakia and pre-existing corneal astigmatism to reduce residual refractive cylinder and improve uncorrected distance vision in adult patients in whom a cataractous lens has been removed.

Total: 3

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860004/S351	01/22/2020	S - Special CBE	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval for the removal of the Delrin tool from the manufacturing procedure SynchroMed Infusion System.
P860057/S189	01/15/2020	Y - 135 Review Tra	EDWARDS LIFESCIENCES PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Approval for the use of the dry plant quality laboratory for routine environmental and manufacturing solution monitoring.
P900056/S181	01/30/2020	N - Normal 180 Day	ROTAPRO ROTATIONAL ATHERECTOMY SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for modifications to the RotaPro Advancer, RotaPro (pre-connected burr and advancer), RotaPro Console, and software changes.
P910066/S031	01/23/2020	R - Real-Time Proc	ORTHOLOGIC (TM)1000 BONE GROWTH STIMULATOR	DJO, LLC	Approval for design changes to the microcontroller and associated changes to the printed circuit board of the CMF Bone Growth Stimulator (OL1000, OL1000 SC, and SpinaLogic).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P920048/S013	01/28/2020	N - Normal 180 Day	FETAL FIBRONECTIN ENZYME IMMUNOASSAY KIT (EIK)	HOLOGIC, INC.	Approval for a new supplier of a critical component, A137 ascites, that is used in the manufacture of Rapid fFN for the TLiIQ System and Fetal Fibronectin Enzyme Immunoassay.
P930014/S124	01/09/2020	O - Normal 180 Day	ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Approval for a manufacturing site located at Alcon Laboratories Ireland, Ltd.; Cork Business and Technology Park Model Farm Road Cork Ireland.
P930016/S060	01/28/2020	R - Real-Time Proc	VISX EXCIMER LASER SYSTEM MODELS "B" AND "C"	AMO MANUFACTURING USA, LLC	Approval for four (4) minor software changes to the iDESJGN Refractive Studio.
P960009/S363	01/29/2020	R - Real-Time Proc	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval for labeling updates to the Deep Brain Stimulation (DBS) Therapy System.
P970003/S229	01/13/2020	R - Real-Time Proc	VNS THERAPY SYSTEM	LIVANOVA USA, INC.	Approval for the changes that are being made to the firmware of the Model 1000 Generator (SN >= 100,000) to prevent resetting the microcontroller unit when an uncorrectable FRAM bit error is detected.
P980052/S007	01/10/2020	O - Normal 180 Day	TMJ CONCEPTS PATIENT-FITTED TMJ RECONSTRUCTION PROSTHESIS	TMJ CONCEPTS	Approval for a manufacturing site located at TMJ Concepts, 6059 King Drive, Ventura, California.
P020025/S123	01/27/2020	R - Real-Time Proc	EP TECHNOLOGIES EPT-1000 XP RF ABLATION SYSTEM	BOSTON SCIENTIFIC	Approval for design and associated manufacturing changes to the magnetic tracking sensor found in IntellaNav catheter families.
P030017/S331	01/24/2020	R - Real-Time Proc	PERCISION, PRECISION SPECTRA, SPECTRA WAVEWRITER; PRECISION NOVI, PERCISION MONTAGE AND PERCISION MONTAGE MRI SPINAL CORD STIMULATOR (SCS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Approval for updating the Clinician Programmer (CP) computer to Surface Pro (SP6) with Windows 10 and for minor installation and labeling updates to the Bionic Navigator software used with the Precision, Precision Spectra, Spectra WaveWriter, Precision Novi, Precision Montage, and Precision Montage MRI Spinal Cord Stimulator (SCS) Systems.
P050031/S004	01/10/2020	R - Real-Time Proc	PARAGON Z CRT (TISILFOCON A) RIGID GAS PERMEABLE CONTACT LENSES FOR CONTACT LENS CORNEAL REFRACTIVE THERAPY	PARAGON VISION SCIENCES	Approval for the addition of two new plasma systems, a change to the blocking compound, and a new contact angle specification.
P060040/S073	01/27/2020	N - Normal 180 Day	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORP.	Approval for the HeartMate Touch Communication System.
P080011/S098	01/28/2020	O - Normal 180 Day	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Approval for the addition of a new private label trade name, Pearle Vision Monthly Multifocal, for the CooperVision comfilcon A soft (hydrophilic) extended wear contact lenses.
P080012/S057	01/15/2020	Y - 135 Review Tra	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Approval for change in the sourcing of the lubricant chemical and in the resin tint blends to not include a carrier for two syringes and a stop cock which are components in the Prometra II® Programmable Infusion Pump Accessories the Refill Kit and the Catheter Access Port Kit.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P080012/S064	01/15/2020	S - Special CBE	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Approval for minor software changes (correction of firmware errors) to bring the Prometra II Programmable Pumps (20mL and 40mL) back into specification to match the performance as reflected in the original software requirements.
P090031/S009	01/09/2020	N - Normal 180 Day	MONOVISC	ANIKA THERAPEUTICS, INC.	Approval for inclusion of new clinical evidence in the labeling (Information for Prescribers) for Monovisc.
P100042/S028	01/21/2020	R - Real-Time Proc	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Approval to add an alternate cleaning method for the Sample Shields and Target Capture Reagent (TCR) adapters used on the Panther/Panther Fusion instruments.
P100047/S150	01/27/2020	Y - 135 Review Tra	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for implementation of a new machine for the manufacturing process of the HVAD Outflow Graft component.
P110010/S163	01/03/2020	O - Normal 180 Day	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for revisions to the labeling that incorporate the results of the PROMUS Element Plus Post-Approval Study.
P110010/S164	01/03/2020	O - Normal 180 Day	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for revisions to the labeling that incorporate the results of the PROMUS Element Plus Post-Approval Study.
P110029/S029	01/07/2020	N - Normal 180 Day	ALINITY I HBSAG QUALITATIVE II, ALINITY I HBSAG QUALITATIVE CONFIRMATORY	ABBOTT LABORATORIES	Approval for migration of the ARCHITECT HBsAg Qualitative, ARCHITECT HBsAg Qualitative Calibrators, ARCHITECT HBsAg Qualitative Confirmatory, and ARCHITECT HBsAg Controls onto the Alinity i Analyzer. The device, as modified, will be marketed under the trade names Alinity i HBsAg Qualitative II Reagent Kit, Alinity i HBsAg Qualitative II Calibrators, Alinity i HBsAg Qualitative II Confirmatory Reagent Kit, and Alinity I HBsAg Qualitative II Controls.
P120007/S026	01/21/2020	R - Real-Time Proc	APTIMA HPV 16 18/45 GENOTYPE ASSAY	GEN-PROBE INCORPORATED	Approval to add an alternate cleaning method for the Sample Shields and Target Capture Reagent (TCR) adapters used on the Panther/Panther Fusion instruments.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P120024/S011	01/31/2020	O - Normal 180 Day	ACTIVL ARTIFICIAL DISC	AESCULAP IMPLANT SYSTEMS, LLC	Approval forfollowing changes to the activL® Artificial Disc Enhanced Safety Surveillance Survey: 1) Section: Pain Management; Question 4: Add N/A checkbox to the column, Using Spike Endplate as now it is possible that a Surgeon implanters experience would exclude the Spike Endplate and only include the Keel Endplate; 2) Section: Spike vs. Keel Endplate Design; Header Remove For Surgeons Outside the US ONLY as now it is possible that a Surgeon implanter within the U.S. will have the option of the Spike Endplate and Keel Endplate. The following change to the Aesculap activL® Artificial Disc Enhanced Safety Surveillance Study as follows: 3) Appendix A Remove previous version of the activL® Artificial Disc Enhanced Safety Surveillance Survey and replaced it with the updated version reflecting the updates detailed above.
P130008/S049	01/16/2020	S - Special CBE	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval for updates to the Inspire System Implant Manual.
P140003/S057	01/30/2020	N - Normal 180 Day	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for a design change for the Automated Impella Controller (AIC) carrier board.
P140003/S066	01/22/2020	S - Special CBE	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for adding a caution to the Impella Instructions for Use label regarding continuing Impella therapy in cardiogenic shock patients where Extra-corporeal Membrane Oxygenation (ECMO) is to be initiated.
P140009/S039	01/02/2020	P - Panel Track	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Approval for expanding the indications to include bilateral stimulation of the internal globus pallidus (GPi) as an adjunctive therapy to reduce some of the symptoms of advanced levodopa-responsive Parkinsons disease that is not adequately controlled by medications.. This device is indicated for: 1) Bilateral stimulation of the subthalamic nucleus (STN) or the internal GPi as an adjunctive therapy to reduce some of the symptoms of advanced levodopa-responsive Parkinsons disease that is not adequately controlled by medications; and 2) Unilateral or bilateral stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the suppression of disabling upper extremity tremor in adult essential tremor patients whose tremor is not adequately controlled by medications and where the tremor constitutes a significant functional.
P140018/S018	01/25/2020	N - Normal 180 Day	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Approval for an update to the instructions for use adding the option to deliver up to 3 aliquots of the device prior to compression.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140030/S009	01/23/2020	Y - 135 Review Tra	ASTRON PERIPHERAL SELF-EXPANDING NITINOL STENT SYSTEM	BIOTRONIK, INC.	Approval for an additional EO sterilizer.
P140032/S048	01/22/2020	S - Special CBE	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Approval for the removal of the Delrin tool from the manufacturing procedure for the Implantable System for Remodulin.
P150033/S061	01/15/2020	N - Normal 180 Day	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval for the Micra AV Transcatheter Pacing System Model MC1AVR1 and Application Software Model SW044.
P150036/S039	01/15/2020	Y - 135 Review Tra	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Approval for the use of the dry plant quality laboratory for routine environmental and manufacturing solution monitoring.
P150048/S034	01/15/2020	Y - 135 Review Tra	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Approval for the use of the dry plant quality laboratory for routine environmental and manufacturing solution monitoring.
P160003/S007	01/23/2020	Y - 135 Review Tra	PRO-KINETIC ENERGY COBALT CHROMIUM (COCR) CORONARY STENT SYSTEM	BIOTRONIK, INC.	Approval for an additional EO sterilizer.
P160023/S016	01/21/2020	R - Real-Time Proc	APTIMA HCV QUANT DX ASSAY	HOLOGIC, INC.	Approval to add an alternate cleaning method for the Sample Shields and Target Capture Reagent (TCR) adapters used on the Panther/Panther Fusion instruments.
P160025/S007	01/23/2020	Y - 135 Review Tra	ASTRON PULSAR STENT SYSTEM, PULSAR-18 STENT SYSTEM	BIOTRONIK, INC.	Approval for an additional EO sterilizer.
P160026/S013	01/17/2020	R - Real-Time Proc	LIFEPAK 1000 DEFIBRILLATOR, LIFEPAK 20 DEFIBRILLATOR/ MONITOR, LIFEPAK 20E DEFIBRILLATOR/ MONITOR, LIFEPAK 15 MONITOR/DEFIBRILLATOR, LIFEPAK 12 DEFIBRILLATOR/ MONITOR	PHYSIO-CONTROL. INC.	Approval for a material change for two PCBAs in the LifePak Automated External Defibrillators (AEDs).
P160047/S005	01/08/2020	N - Normal 180 Day	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	AEGEA MEDICAL , INC	Approval of changes to the instructions for use and patient labeling to include the results of the Post-Ablation Cavity Evaluation (PACE) study, which evaluated the ability to assess the uterine cavity more than three-years post endometrial ablation with the MARA Water Vapor System

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160047/S006	01/16/2020	N - Normal 180 Day	AEGEA VAPOR SYSTEM	AEGEA MEDICAL , INC	Approval for a change in device design to change the location and method of vapor generation. These include changes in the fluid source for vapor generation from water to saline, modification of the vapor probe to generate vapor within the handle, modification of the console to control saline delivery without directly contacting the saline, changes in the feedback controls associated with the change in vapor generation, and changes in packaging, sterilization, and reprocessing associated with changes in the patient contact status of the console. In addition, this supplement includes changes in the location in which AEGEA Medical Inc. will manufacture the vapor probe to Menlo Park, CA, establishment of contract manufacturing of the console by Nextern, Inc. in White Bear Leak, MN, and change in the supplier of sterilization of the vapor probe to Sterigenics in Los Angeles, California.
P160054/S021	01/27/2020	N - Normal 180 Day	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATION	Approval for the HeartMate Touch Communication System.
P170002/S006	01/30/2020	Y - 135 Review Tra	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Approval for a transfer of the lidocaine assay and 2,6-DMA limit test from a contract laboratory to an in-house laboratory.
P170011/S015	01/30/2020	N - Normal 180 Day	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval for a design change for the Automated Impella Controller (AIC) carrier board.
P170025/S014	01/21/2020	R - Real-Time Proc	APTIMA HBV QUANT ASSAY	HOLOGIC, INC	Approval to add an alternate cleaning method for the Sample Shields and Target Capture Reagent (TCR) adapters used on the Panther/Panther Fusion instruments.
P170030/S001	01/23/2020	Y - 135 Review Tra	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Approval for an additional EO sterilizer.
P170034/S004	01/23/2020	O - Normal 180 Day	HYDRUS MICROSTENT	IVANTIS, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P180025/S006	01/23/2020	R - Real-Time Proc	MANTA VASCULAR CLOSURE DEVICE	ESSENTIAL MEDICAL, INC.	Approval to individually package the 8F Depth Locator.
P180031/S002	01/18/2020	O - Normal 180 Day	NEUROFORM ATLAS® STENT SYSTEM	STRYKER NEUROVASCULAR	Approval of the revised protocol for the post-approval study (PAS) protocol.
P180034/S001	01/28/2020	N - Normal 180 Day	TACK ENDOVASCULAR SYSTEM (6F)	INTACT VASCULAR, INC.	Approval for the Tack Endovascular System® (6F, 4.0-8.0mm) for use in the superficial femoral and proximal popliteal arteries ranging in diameter from 4.0mm to 8.0mm for the repair of post percutaneous transluminal balloon angioplasty dissection(s).
P190006/S001	01/14/2020	R - Real-Time Proc	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for an updated software for the Axonics Clinician Programmer (CP), model 2501 (Software Version 416).

Total: 51

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S248	01/28/2020	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Reduce the burn-in process temperature setting used during manufacturing of the Integrated Circuit modules of the NG3/NG4 and Accolade Pulse Generator product families.
P830055/S242	01/02/2020	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Manufacturing process change to increase the amount of reclaimed material.
P840001/S451	01/09/2020	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Changes to the manufacturing process (i.e., copper plating, additional solder mask developing line) for the printed wiring board (PWB) provided from an external supplier.
P840001/S452	01/09/2020	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Increase the battery manufacturing capacity at the Medtronic Energy and Component Center (MECC).
P860004/S349	01/09/2020	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Changes to the manufacturing process (i.e., copper plating, additional solder mask developing line) for the printed wiring board (PWB) provided from an external supplier.
P860004/S350	01/09/2020	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Increase the battery manufacturing capacity at the Medtronic Energy and Component Center (MECC).
P880047/S034	01/30/2020	X - 30-Day Notice	INTERCEED TC7 ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Addition of GYNECARE INTERCEED Absorbable Adhesion Barrier medium size foil pouches to the upgraded Final Vision System on the automated Foiling Line (G11719) at the Ethicon SARL, Switzerland site for the inspection of hermetically sealed foil pouches.
P880086/S310	01/06/2020	X - 30-Day Notice	ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS	ST. JUDE MEDICAL, INC.	Implement two new inspection processes.
P880086/S311	01/06/2020	X - 30-Day Notice	ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS	ST. JUDE MEDICAL, INC.	Qualify a vendor for ceramic material used to in the Scalable Brady Pacers Filtered Feedthroughs.
P910023/S424	01/06/2020	X - 30-Day Notice	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ST. JUDE MEDICAL	Implement two new inspection processes.
P910056/S040	01/16/2020	X - 30-Day Notice	SOFLEX UV-ABSORBING SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS	BAUSCH & LOMB, INC.	Alternate milling process and an optional cleaning/drying step prior to batch milling for the enVista Hydrophobic Acrylic Intraocular Lenses, Models MX60, MX60E, MX60T, MX60ET and MX60PL.
P910056/S041	01/21/2020	X - 30-Day Notice	SOFLEX UV-ABSORBING SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS	BAUSCH & LOMB, INC.	Adding an alternative site for spectrometer testing of buttons.
P920015/S240	01/10/2020	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Add new inspections of the Packaging Tray assembly process for SelectSecure, Transvene CS/SVC and Sprint Quattro leads.
P920015/S241	01/28/2020	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Implementation of two new Scion Coil Auto-Winder machines.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P940015/S045	01/16/2020	X - 30-Day Notice	SYNVISC ONE	SANOFI GENZYME CORP.	Modifications to the washing process of a component used to manufacture Synvisc and Synvisc-One.
P950020/S100	01/09/2020	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Implement a new laser corewire welder for increased manufacturing capacity.
P950037/S209	01/29/2020	X - 30-Day Notice	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Introduce three new sterilization chambers.
P960009/S366	01/09/2020	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Changes to the manufacturing process (i.e., copper plating, additional solder mask developing line) for the printed wiring board (PWB) provided from an external supplier.
P960009/S367	01/09/2020	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Increase the battery manufacturing capacity at the Medtronic Energy and Component Center (MECC).
P960040/S447	01/28/2020	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Reduce the burn-in process temperature setting used during manufacturing of the Integrated Circuit modules of the NG3/NG4 and Accolade Pulse Generator product families.
P960058/S147	01/17/2020	X - 30-Day Notice	CLARION MULTI-STRATEGY COCHLEAR IMPLANT	ADVANCED BIONICS	Supplier facility move for the manufacturing of implant capacitors.
P970003/S228	01/31/2020	X - 30-Day Notice	VNS THERAPY SYSTEM	LIVANOVA USA, INC.	Make updates to the Electrical Test System used during the production of the Model 2000 Programming Wand.
P970003/S230	01/29/2020	X - 30-Day Notice	VNS THERAPY SYSTEM	LIVANOVA USA, INC.	Incorporate a temporary manufacturing software screening test that detects devices susceptible to GC5 errata.
P970004/S305	01/09/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Changes to the manufacturing process (i.e., copper plating, additional solder mask developing line) for the printed wiring board (PWB) provided from an external supplier.
P970004/S306	01/09/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Increase the battery manufacturing capacity at the Medtronic Energy and Component Center (MECC).
P980016/S725	01/07/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modify the Laser Ribbon Bonder inspection criteria for CRT-P, CRT-D, ICD, and IPG devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S726	01/09/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Minor changes to the manufacturing of Printed Wiring Boards at a Medtronic supplier.
P980016/S727	01/16/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Modify the destructive analysis inspection monitoring frequency for certain header welds in CRT-D, ICD, and IPG families.
P980023/S097	01/29/2020	X - 30-Day Notice	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Introduce three new sterilization chambers.
P980035/S611	01/07/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Modify the Laser Ribbon Bonder inspection criteria for CRT-P, CRT-D, ICD, and IPG devices.
P980035/S612	01/09/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Minor changes to the manufacturing of Printed Wiring Boards at a Medtronic supplier.
P980035/S613	01/16/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Modify the destructive analysis inspection monitoring frequency for certain header welds in CRT-D, ICD, and IPG families.
P980050/S125	01/10/2020	X - 30-Day Notice	MEDTRONIC(R) JEWEL(R) AF 7250 DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATOR, MODEL 9961 PROGRAMMER APPLICATION SOF	MEDTRONIC INC.	Add new inspections of the Packaging Tray assembly process for SelectSecure, Transvene CS/SVC and Sprint Quattro leads.
P010001/S022	01/22/2020	X - 30-Day Notice	CERAMIC TRANSCEND HIP ARTICULATION SYSTEM	CERAMTEC GMBH	Firm requests to change the corrosion protection oil for the proof-test machine.
P010012/S515	01/28/2020	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Reduce the burn-in process temperature setting used during manufacturing of the Integrated Circuit modules of the NG3/NG4 and Accolade Pulse Generator product families.
P010015/S424	01/07/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Modify the Laser Ribbon Bonder inspection criteria for CRT-P, CRT-D, ICD, and IPG devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S425	01/09/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Minor changes to the manufacturing of Printed Wiring Boards at a Medtronic supplier.
P010019/S075	01/22/2020	X - 30-Day Notice	FOCUS NIGHT AND DAY (LOTRAFILCON A) SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Addition of an alternate raw material supplier for the polypropylene resin used in the fabrication of molds for producing class III lotrafilcon A and B soft contact lenses for extended wear.
P010029/S029	01/02/2020	X - 30-Day Notice	EUFLEXXA (1% SODIUM HYALURONATE)	FERRING PHARMACEUTICALS, INC.	Elimination of syringeability testing from finished product testing, and the elimination of the syringeability test parameter from EUFLEXXA release and stability test parameters.
P010030/S131	01/03/2020	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Location change of the supplier's production facility for components of the front response button and rear response button used in the LifeVest 4000 Monitor and the HWD 1000 Monitor.
P010031/S686	01/07/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modify the Laser Ribbon Bonder inspection criteria for CRT-P, CRT-D, ICD, and IPG devices.
P010031/S687	01/09/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Minor changes to the manufacturing of Printed Wiring Boards at a Medtronic supplier.
P010031/S688	01/16/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modify the destructive analysis inspection monitoring frequency for certain header welds in CRT-D, ICD, and IPG families.
P010032/S158	01/10/2020	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Addition of an alternate Tier II supplier of the crystal used in the Orion family IPG devices.
P030005/S194	01/28/2020	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Reduce the burn-in process temperature setting used during manufacturing of the Integrated Circuit modules of the NG3/NG4 and Accolade Pulse Generator product families.
P030011/S076	01/22/2020	X - 30-Day Notice	SYNCARDIA TEMPORARY CARDIO WEST TOTAL ARTIFICIAL HEART (TAH-T)	SYNCARDIA SYSTEMS, LLC	Change of location for a component supplier with additional minor capacitor changes on PCBAs for the Companion 2 Hospital Cart and Driver Caddy.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030035/S179	01/06/2020	X - 30-Day Notice	ANTHEM AND FRONTIER II CRT-P'S	ST. JUDE MEDICAL, INC.	Implement two new inspection processes.
P030036/S116	01/10/2020	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add new inspections of the Packaging Tray assembly process for SelectSecure, Transvene CS/SVC and Sprint Quattro leads.
P030054/S375	01/06/2020	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ST. JUDE MEDICAL	Implement two new inspection processes.
P040027/S077	01/29/2020	X - 30-Day Notice	GORE VIATORR TIPS	W. L. GORE & ASSOCIATES, INC.	Expansion of manufacturing to a newly constructed cleanroom within the same Phoenix facility.
P040037/S135	01/23/2020	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Changing an analytical testing laboratory site.
P050023/S141	01/29/2020	X - 30-Day Notice	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Introduce three new sterilization chambers.
P060022/S025	01/21/2020	X - 30-Day Notice	AKREOS POSTERIOR CHAMBER INTRAOCULAR LENS,MODEL ADAPT	BAUSCH & LOMB, INC.	Adding an alternative site for spectrometer testing of buttons.
P070008/S111	01/29/2020	X - 30-Day Notice	STRATOS LV CRT-P AND STRATOS LV-T CRT-P, COROX OTW BP LEAD AND COROX OTW-S BP LEAD	BIOTRONIK, INC.	Introduce three new sterilization chambers.
P080025/S200	01/09/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Changes to the manufacturing process (i.e., copper plating, additional solder mask developing line) for the printed wiring board (PWB) provided from an external supplier.
P080025/S201	01/09/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Increase the battery manufacturing capacity at the Medtronic Energy and Component Center (MECC).
P090015/S010	01/02/2020	X - 30-Day Notice	BOND ORACLE HER2 IHC SYSTEM	LEICA BIOSYSTEMS	Addition of an item to the list of 'equipment required but not supplied.
P100010/S100	01/17/2020	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATHLP	Update to the supplier process for sanding the distal inside neck of the inner balloon used in the catheter.
P100021/S079	01/09/2020	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Changes to a supplier's manufacturing site, tools, and aids used in the manufacturing of a delivery system component used in the Endurant, Endurant II, and Endurant IIs.
P100026/S078	01/22/2020	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Modify the PXI Vader automated test equipment (ATE) software, hardware, and test database to improve yield of the components used to manufacture the RNS® Neurostimulator (model RNS-320).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P120005/S086	01/08/2020	X - 30-Day Notice	DEXCOM G4 PLATINUM CONTIUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Addition of a Clean Environment Room and associated support rooms to the existing manufacturing space for manufacturing sensors of the G4 PLATINUM/G5 Mobile Continuous Glucose Monitoring (CGM) System.
P130006/S074	01/23/2020	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Changing an analytical testing laboratory site.
P130008/S048	01/10/2020	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Updated molding process for the clamping rod of tunneling tool, which is used to tunnel the lead connector from the point of implantation to the IPG pocket.
P130026/S055	01/14/2020	X - 30-Day Notice	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Additional subcomponent supplier for the titanium deformable body.
P130030/S065	01/09/2020	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL	BOSTON SCIENTIFIC CORP.	Implement a new laser corewire welder for increased manufacturing capacity.
P140009/S054	01/10/2020	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Addition of an alternate Tier II supplier of the crystal used in the Orion family IPG devices.
P140031/S105	01/16/2020	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Use of the dry plant quality laboratory for routine environmental and manufacturing solution monitoring.
P140032/S045	01/09/2020	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Changes to the manufacturing process (i.e., copper plating, additional solder mask developing line) for the printed wiring board (PWB) provided from an external supplier.
P140032/S046	01/09/2020	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Increase the battery manufacturing capacity at the Medtronic Energy and Component Center (MECC).
P140033/S052	01/06/2020	X - 30-Day Notice	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ST. JUDE MEDICAL, INC.	Implement two new inspection processes.
P140033/S053	01/06/2020	X - 30-Day Notice	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ST. JUDE MEDICAL, INC.	Qualify a vendor for ceramic material used to in the Scalable Brady Pacers Filtered Feedthroughs.
P150001/S081	01/22/2020	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	Modification to an existing harvest/reclaim process for construction of refurbished and loaner 630G and 670G insulin pumps. The 630G and 670G Pumps are components of the MiniMed 630G and MiniMed 670G Systems.
P150001/S082	01/31/2020	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	New sterilization site for the sterilization of the Guardian Sensor (3) continuous glucose monitoring sensors that are manufactured at Medtronic Puerto Rico Operations Company. The Guardian Sensor (3) is a component of the MiniMed 630G system, the Guardian Connect system, and the MiniMed 670G system.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150004/S034	01/10/2020	X - 30-Day Notice	PROCLAIM SCS IPG, INFINITY DBS IPG, PROCLAIM DRG IPG.	ABBOTT MEDICAL	Addition of an alternate Tier II supplier of the crystal used in the Orion family IPG devices.
P150012/S089	01/28/2020	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Reduce the burn-in process temperature setting used during manufacturing of the Integrated Circuit modules of the NG3/NG4 and Accolade Pulse Generator product families.
P150026/S009	01/16/2020	X - 30-Day Notice	HEARTLIGHT ENDOSCOPIC ABLATION SYSTEM	CARDIOFOCUS, INC.	Increase the load size in the existing sterilization process.
P150033/S064	01/09/2020	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Minor changes to the manufacturing of Printed Wiring Boards at a Medtronic supplier.
P160004/S029	01/23/2020	X - 30-Day Notice	GORE TIGRIS VASCULAR STENT	W. L. GORE & ASSOCIATES, INC.	Changing an analytical testing laboratory site.
P160007/S034	01/31/2020	X - 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	New sterilization site for the sterilization of the Guardian Sensor (3) continuous glucose monitoring sensors that are manufactured at Medtronic Puerto Rico Operations Company. The Guardian Sensor (3) is a component of the MiniMed 630G system, the Guardian Connect system, and the MiniMed 670G system.
P160008/S008	01/09/2020	X - 30-Day Notice	HEARTSINE TECHNOLOGIES LLC'S SAMARITAN PUBLIC ACCESS AUTOMATED EXTERNAL DEFIBRILLATORS (SAM 350P, SAM 360P AND SAM 450P) AND ACCESSORIES	HEARTSINE TECHNOLOGIES, LTD.	Addition of new automated test equipment used in the manufacture of the Pad-Paks (combined battery and electrode packs).
P160015/S003	01/24/2020	X - 30-Day Notice	AED PLUS AND FULLY AUTOMATIC AED PLUS	ZOLL MEDICAL CORPORATION	Additional rework process on the replacement of the surface mount capacitors utilized on the AED Plus Device Printed Circuit Board Assembly (PCBA).
P160017/S080	01/22/2020	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Modification to an existing harvest/reclaim process for construction of refurbished and loaner 630G and 670G insulin pumps. The 630G and 670G Pumps are components of the MiniMed 630G and MiniMed 670G Systems.
P160017/S081	01/31/2020	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	New sterilization site for the sterilization of the Guardian Sensor (3) continuous glucose monitoring sensors that are manufactured at Medtronic Puerto Rico Operations Company. The Guardian Sensor (3) is a component of the MiniMed 630G system, the Guardian Connect system, and the MiniMed 670G system.
P160021/S025	01/23/2020	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Changing an analytical testing laboratory site.
P160038/S015	01/24/2020	X - 30-Day Notice	PRAXIS EXTENDED RAS PANEL	ILLUMINA, INC.	Manufacturing and Quality Control (QC) process changes.
P170011/S020	01/24/2020	X - 30-Day Notice	IMPELLA RP SYSTEM	ABIOMED, INC.	Implement a manufacturing update at the current supplier for the 11 Fr Contamination Protection Sleeve component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170012/S021	01/24/2020	X - 30-Day Notice	HEMOBLAST¿ BELLOWS	BIOM'UP FRANCE SAS	Changes to the cryogrinding equipment for the processing of the collagen powder component.
P170032/S005	01/23/2020	X - 30-Day Notice	WOVEN ENDOBRIDGE (WEB) ANEURYSM EMBOLIZATION SYSTEM	MICROVENTION, INC.	Change in supplier for a microchip used in the WEB Detachment Controller that is used with the WEB Aneurysm Embolization System.
P170036/S004	01/31/2020	X - 30-Day Notice	M6-C ARTIFICIAL CERVICAL DISC	SPINAL KINETICS LLC	Add a new Cervical Flexural Resistance (CER-FR) tester, EQ 0152-01.
P180046/S003	01/30/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Qualification of an additional sterilization chamber.
P190006/S003	01/28/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Qualification of an additional sterilization chamber.

Total: 91