PMA Monthly approvals from 6/1/2023 to 6/30/2023

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190033	06/29/2023	PMAO - PMA Origi	AAV5 DETECTCDX	ARUP LABORATORIES	Approval of the AAV5 DetectCDx by ARUP Laboratories. This device is indicated for: The AAV5 Total Antibody Assay for ROCTAVIAN (valoctocogene roxaparvovec-rvox) Eligibility in Hemophilia A (AAV5 TAb Assay), or AAV5 DetectCDx, is a qualitative in vitro diagnostic test by electrochemiluminescence intended for detection of antibodies in human plasma collected in 3.2% sodium citrate that bind to the adeno-associated virus serotype 5 (AAV5). The AAV5 TAb Assay is indicated as an aid in the selection of adult hemophilia A patients for whom ROCTAVIAN treatment is being considered. Patients that are anti-AAV5 antibody positive (result of Detected) are not eligible for treatment with ROCTAVIAN; patients that are anti-AAV5 antibody negative (result of Not Detected) are eligible for treatment with ROCTAVIAN. This assay is for professional use and is a single-site assay performed at ARUP Laboratories.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P200007	06/23/2023	PMAO - PMA Origi	HEARTSYNC MULTIFUNCTION DISPOSABLE SINGLE-USE AED DEFIBRILLATOR PADS	GRAPHIC CONTROLS D.B.A. VERMED	Approval for the HeartSync Multifunctional Defibrillation Electrodes. These devices are indicated for: For Automatic External Defibrillators: (Compatible Model AEDs: Physio Control: LifePak-15, LifePak-20/20e, LifePak -1000; Zoll Medical: R-Series, X-Series; Cardiac Science: PowerHeart AED G3 Plus, PowerHeart AED G3 Pro). When used with an external defibrillator, these electrode pads are for treating patients in cardiopulmonary arrest who are: 1) Unconscious; 2) Not breathing spontaneously; and 3) Without circulation (without a pulse). The pads are single use and intended to be used in conjunction with an external defibrillator to monitor and deliver defibrillation energy to the patient. The pads are used on patients over 8 years of age or greater than 55 pounds. The pads are intended for short term use (less than 8 hours). DO NOT DELAY THERAPY IF YOU ARE NOT SURE OF EXACT AGE OR WEIGHT. For Manual Defibrillators: Manual Defibrillators can be used for monitoring, pacing, cardioversion, as well as defibrillation. When used for defibrillation, these electrode pads are for treating patients in cardiopulmonary arrest who are: 1) Unconscious; 2) Not breathing spontaneously; and 3) Without circulation (without a pulse). The pads are single use and intended to be used in conjunction with an external defibrillator to monitor and deliver defibrillation energy to the patient. The pads are used on patients greater than 10 kg or 22 pounds. The pads are intended for short term use (less than 24 hours). DO NOT DELAY THERAPY IF YOU ARE NOT SURE OF EXACT AGE OR WEIGHT.
P210002	06/29/2023	PMAO - PMA Origi	THERASCREEN PDGFRA RGQ PCR KIT	QIAGEN GMBH	Approval for the therascreen PDGFRA RGQ PCR Kit. The QIAGEN therascreen® PDGFRA RGQ PCR Kit is a real-time qualitative in vitro diagnostic assay for the detection of the D842V somatic mutation in the PDGFRA gene using genomic DNA extracted from Gastrointestinal Stromal Tumor (GIST) patients formalin-fixed paraffin-embedded (FFPE) tumor tissue. The therascreen PDGFRA RGQ PCR Kit is intended for use as a companion diagnostic test, to aid clinicians in identification of patients with GIST who may be eligible for treatment with AYVAKIT (avapritinib) based on a PDGFRA mutation detected result. FFPE tumor specimens are processed using the QIAamp® DSP DNA FFPE Tissue Kit for manual sample preparation and the Rotor-Gene® Q (RGQ) MDx instrument for automated amplification and detection. The therascreen PDGFRA RGQ PCR Kit is to be used by trained personnel in a professional laboratory environment.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P210025	06/16/2023	PMAO - PMA Origi	SURVEIL DRUG-COATED BALLOON	SURMODICS, INC.	Approval for the SurVeil DCB. The device is indicated for use for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo or restenotic lesions (</= 180 mm in length) in femoral and popliteal arteries having reference vessel diameters of 4 mm to 7 mm.
P220002	06/15/2023	PMAO - PMA Origi	TOPS SYSTEM	PREMIA SPINE LTD.	Approval for The TOPS System is a motion-preserving spinal implant that is inserted into the lumbar spine via pedicle screws. The TOPS System is intended to stabilize the spine following a lumbar decompression without rigid fixation. The TOPS System is indicated for patients between 35 and 80 years of age with symptomatic degenerative spondylolisthesis up to Grade I, with moderate to severe lumbar spinal stenosis and either the thickening of the ligamentum flavum and/or of the scarring facet joint capsule at one level from L3 to L5.
P220021	06/07/2023	PMAO - PMA Origi	DETOUR SYSTEM	ENDOLOGIX, LLC	Approval for the DETOUR System for use for percutaneous revascularization in patients with symptomatic femoropopliteal lesions from 200 mm to 460 mm in length with chronic total occlusions (100 mm to 425 mm) or diffuse stenosis >70% who may be considered suboptimal candidates for surgical or alternative endovascular treatments. The DETOUR System, or any of its components, is not for use in the coronary and cerebral vasculature.
P220024	06/02/2023	PMAO - PMA Origi	LIQUIFIX FIX8 HERNIA MESH FIXATION (HMF) DEVICE, LIQUIFIX PRECISION OPEN HERNIA MESH FIXATION DEVICE	ADVANCED MEDICAL SOLUTIONS LIMITED	Approval for The LIQUIFIX FIX8 Hernia Mesh Fixation device is intended for use in laparoscopic surgical repair of groin (inguinal and femoral) hernias, achieved through the fixation of prosthetic polypropylene or polyester mesh to the abdominal wall and the approximation of the peritoneum. The LIQUIFIX Precision Open Hernia Mesh Fixation device is intended for use in open surgical repair of groin (inguinal and femoral) hernias, achieved through the fixation of prosthetic polypropylene or polyester mesh to the abdominal wall.
P220029	06/30/2023	PMAO - PMA Origi	OPTILUME BPH CATHETER SYSTEM	UROTRONIC, INC	Approval for the Optilume BPH Catheter System indicated for the treatment of obstructive urinary symptoms associated with Benign Prostatic Hyperplasia (BPH) in men >= 50 years of age.

Total: 8

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P810025/S044	06/22/2023	Y - 135 Review Tra	AMVISC(R)	BAUSCH & LOMB, INC.	Approval for a change in the rubber plunger stopper component of the primary packaging for the subject devices.
P860003/S103	06/16/2023	N - Normal 180 Day	UVAR PHOTOPHERESIS SYSTEM	MALLINCKRODT PHARMACEUTICALS IRELAND LIMITED	Approval for resin changes for the CELLEX® Photopheresis Procedural Kit.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P950037/S244	06/28/2023	N - Normal 180 Day	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Approval for the Amvia and Solvia family of pulse generators and cardiac resynchronization therapy pacekaer devices, as well as for updated programmer software versions PSW 2204.U and NEO 2204.U, updated Home Monitoring Service Center software version 3.55.0, and updates to the CardioMessenger Smart 4G firmware.
P950037/S249	06/28/2023	R - Real-Time Proc	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Approval for the MR Conditional labeling of additional system configurations with partially capped Pamira or Plexa DF4 S DX ICD leads when used under specific scan conditions.
P960043/S118	06/02/2023	P - Panel Track	PROSTAR 9 FR. PERCUTANEOUS VASCULAR SURGICAL (PVS) SYSTEM	ABBOTT VASCULAR INC.	Approval for the Perclose ProStyle Suture-Mediated Closure and Repair System and Perclose ProGlide Suture-Mediated Closure System for closure of multiple access sites in a single femoral vein. The Perclose ProGlide Suture-Mediated Closure System/Perclose ProStyle Suture-Mediated Closure and Repair System is indicated for the percutaneous delivery of suture for closing the common femoral artery and vein access site of patients who have undergone diagnostic or interventional catheterization procedures. The Perclose ProGlide SMC System/Perclose ProStyle SMCR System is indicated for closing the common femoral vein in single or multiple access sites per limb. The Perclose ProGlide SMC System/Perclose ProStyle SMCR System is used without or, if required, with adjunctive manual compression. For access sites in the common femoral artery using 5F to 21F sheaths. For arterial sheath sizes greater than 8F, at least two devices and the pre-close technique are required. For access sites in the common femoral vein using 5F to 24F sheaths. For venous sheath sizes greater than 14F, at least two devices and the pre-close technique are required.
P970051/S218	06/08/2023	O - Normal 180 Day	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval of the PAS protocol for the post-approval study (PAS) protocol.
P980023/S121	06/28/2023	R - Real-Time Proc	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Approval for the MR Conditional labeling of additional system configurations with partially capped Pamira or Plexa DF4 S DX ICD leads when used under specific scan conditions.
P000009/S101	06/28/2023	N - Normal 180 Day	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Approval for the Amvia and Solvia family of pulse generators and cardiac resynchronization therapy pacekaer devices, as well as for updated programmer software versions PSW 2204.U and NEO 2204.U, updated Home Monitoring Service Center software version 3.55.0, and updates to the CardioMessenger Smart 4G firmware.
P010030/S162	06/30/2023	N - Normal 180 Day	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Approval for the new generation model, LifeVest 5100, involving minor software, hardware and labeling changes.
P020012/S045	06/15/2023	S - Special CBE	ARTEFILL, BELLAFILL PMMA COLLAGEN PERMANENT DERMAL FILLER	SUNEVA MEDICAL, INC.	Approval for revisions to the patient labeling as a result of postmarket surveillance data.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P020050/S040	06/02/2023	R - Real-Time Proc	WAVELIGHT ALLEGRETTO WAVE EXCIMER LASER SYSTEM	ALCON LABORATORIES, INC.	Approval for the modification of ESD-Joystick - Adapter on patient bed
P030008/S036	06/02/2023	R - Real-Time Proc	WAVELIGHT ALLEGRETTO WAVE EXCIMER LASER SYSTEM	ALCON LABORATORIES, INC.	Approval for the modification of ESD-Joystick - Adapter on patient bed
P030017/S351	06/06/2023	N - Normal 180 Day	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the addition of an alternate supplier (AUSA Medical Devices Private Limited) for the passing elevator component used with the Precision Spinal Cord Stimulator (SCS) Systems, as well as changes to the manufacturing process (addition of a tumbling process and cleaning step with 70% IPA) and resin material
P030050/S040	06/02/2023	O - Normal 180 Day	SCULPTRA AND SCULPTRA AESTHETIC	Q-MED AB	Approval for updated labeling to include 1) results from the 5-Year Post Approval Study; 2) device-specific use training program information; and 3) information on delayed-onset inflammation at the site of dermal filler injection following viral or bacterial illnesses or infections, vaccinations, or dental procedures.
P030050/S043	06/14/2023	S - Special CBE	SCULPTRA AND SCULPTRA AESTHETIC	Q-MED AB	Approval for revisions to the clinician labeling and patient labeling as a result of postmarket surveillance data.
P030053/S068	06/21/2023	R - Real-Time Proc	MEMORYGEL SILICONE GEL -FILLED BREAST IMPLANTS	MENTOR CORP.	Approval for addition of a new style, Moderate High BOOST Breast Implants to the MemoryGel BOOST product line.
P040024/S137	06/01/2023	S - Special CBE	RESTYLANE INJECTABLE GEL	Q-MED AB	Approval for revisions to the clinician labeling and patient labeling as a result of postmarket surveillance data.
P050023/S171	06/28/2023	N - Normal 180 Day	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval for the Amvia and Solvia family of pulse generators and cardiac resynchronization therapy pacekaer devices, as well as for updated programmer software versions PSW 2204.U and NEO 2204.U, updated Home Monitoring Service Center software version 3.55.0, and updates to the CardioMessenger Smart 4G firmware.
P050023/S175	06/28/2023	R - Real-Time Proc	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval for the MR Conditional labeling of additional system configurations with partially capped Pamira or Plexa DF4 S DX ICD leads when used under specific scan conditions.
P050037/S126	06/08/2023	S - Special CBE	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Approval for revisions to the clinician labeling and patient labeling as a result of postmarket surveillance data.
P050047/S088	06/08/2023	S - Special CBE	JUVEDERM 24HV, JUVEDERM 30 AND JUVEDERM 30HV GEL IMPLANTS	ALLERGAN	Approval for revisions to the clinician labeling and patient labeling as a result of postmarket surveillance data.
P050052/S148	06/08/2023	S - Special CBE	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval for revisions to the clinician labeling and patient labeling as a result of postmarket surveillance data.
P070008/S144	06/28/2023	N - Normal 180 Day	STRATOS LV CRT-P AND STRATOS LV-T CRT-P, COROX OTW BP LEAD AND COROX OTW-S BP LEAD	BIOTRONIK, INC.	Approval for the Amvia and Solvia family of pulse generators and cardiac resynchronization therapy pacekaer devices, as well as for updated programmer software versions PSW 2204.U and NEO 2204.U, updated Home Monitoring Service Center software version 3.55.0, and updates to the CardioMessenger Smart 4G firmware.
P070008/S149	06/28/2023	R - Real-Time Proc	STRATOS LV CRT-P AND STRATOS LV-T CRT-P, COROX OTW BP LEAD AND COROX OTW-S BP LEAD	BIOTRONIK, INC.	Approval for the MR Conditional labeling of additional system configurations with partially capped Pamira or Plexa DF4 S DX ICD leads when used under specific scan conditions.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P080004/S045	06/22/2023	O - Normal 180 Da	HOYA ISPHERIC MODEL YA-60BB INTRAOCULAR LENS	HOYA SURGICAL OPTICS, INC.	Approval for a manufacturing site located at HOYA Lamphun Ltd., 725 Moo 4, Tambol Banklang, Amphur Muagn, Lamphun 5100, Thailand. Manufacturing processes will be limited to lathe cutting through primary packaging, shipment to and from sterilizer, Siam Steri Service Co. LTD, secondary packaging, and distribution of intraocular lenses (IOLs) and injector cartridges.
P100003/S008	06/12/2023	O - Normal 180 Day	SECURE-C ARTIFICIAL CERVICAL DISC	GLOBUS MEDICAL INC.	Approval to update labeling for the SECURE®-C to reflect the findings of the Enhanced Surveillance Study (PAS2).
P100042/S034	06/02/2023	N - Normal 180 Day	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Approval for the addition of manual post-cytology (cytology by ThinPrep Genesis Processor) aliquot, pre-cytology aliquot and post-cytology (cytology by ThinPrep Genesis Processor) aliquot removed by the ThinPrep Genesis Processor as acceptable samples for the Aptima HPV Assay and Aptima HPV 16 18/45 Genotype Assay.
P110033/S071	06/08/2023	S - Special CBE	JUVEDERM VOLUMA XC	ALLERGAN	Approval for revisions to the clinician labeling and patient labeling as a result of postmarket surveillance data.
P110033/S073	06/23/2023	S - Special CBE	JUVEDERM VOLUMA XC	ALLERGAN	Approval for additional incoming testing for the phosphate buffer solution used in the manufacture of the Juvéderm injectable gel implants.
P110042/S181	06/15/2023	R - Real-Time Proc	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for software (SW) changes to the EMBLEM subcutaneous implantable cardioverter defibrillator (S-ICD) Programmer SW Application Models 2877 and 3877, and firmware (FW) changes to the EMBLEM Pulse Generator (PG) FW.
P120007/S030	06/02/2023	N - Normal 180 Day	APTIMA HPV 16 18/45 GENOTYPE ASSAY	GEN-PROBE INCORPORATED	Approval for the addition of manual post-cytology (cytology by ThinPrep Genesis Processor) aliquot, pre-cytology aliquot and post-cytology (cytology by ThinPrep Genesis Processor) aliquot removed by the ThinPrep Genesis Processor as acceptable samples for the Aptima HPV Assay and Aptima HPV 16 18/45 Genotype Assay.
P130005/S036	06/01/2023	N - Normal 180 Day	DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM	CARDIOVASCULAR SYSTEMS, INC.	Approval for a design change to the 1.25mm Coronary Crown Orbital Atherectomy Device, a name change from Diamondback 360 Coronary Orbital Atherectomy System to Diamondback 360 Precision, and updates to the Instructions for Use.
P130008/S090	06/08/2023	P - Panel Track	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval to expand the indications for use to OSA patients with an upper limit baseline apnea-hypopnea index (AHI) to 100 (increase from <= 65 to <=100) and increasing the an upper limit body mass index (BMI) warning to 40 (increase from <=32 to <=40).
P130008/S092	06/27/2023	N - Normal 180 Day	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval for the updated SleepSync Programmer (Model 2740) which consists of the Inspire Programming Software Application (Model 2740S) that can be installed on customer owned devices and paired with the Inspire Programmer Cable (Model 2740C).
P130026/S084	06/29/2023	R - Real-Time Proc	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Approval for the implementation of a step in the manufacturing process for the wires within the connectors of the TactiCath Contact Force Ablation Catheter, Sensor Enabled.
P140003/S112	06/27/2023	R - Real-Time Proc	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for changes to the design of the catheter fixation mechanisms on the Impella CP with SmartAssist repositioning unit assembly.
P140003/S113	06/14/2023	S - Special CBE	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval to update the Instructions for Use of Impella Ventricular Support Systems to include a warning and recommendations when using Impella catheters with Transcatheter Aortic Valve Replacement (TAVR) devices.
P140016/S006	06/07/2023	S - Special CBE	ZENITH ALPHA THORACIC ENDOVASCULAR GRAFT	COOK MEDICAL INCORPORATED	Approval for an added incoming inspection step for the introducer sheath.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140026/S024	06/16/2023	N - Normal 180 Day	ENROUTE TRANSCAROTID STENT SYSTEM	SILK ROAD MEDICAL, INC	Approval for the addition of 7 tapered stent sizes.
P140029/S049	06/01/2023	S - Special CBE	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Approval for revisions to the clinician labeling and patient labeling as a result of postmarket surveillance data.
P150003/S093	06/12/2023	R - Real-Time Proc	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for changes to the labeling, device packaging, and addition of the 48 mm device delivery system to allow for alignment of the product matrix to include the 48-mm stent size.
P150033/S166	06/07/2023	R - Real-Time Proc	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval for updating the current labeling of the Micra Transcatheter Pacing System (TPS) to include jugular venous access as an additional or alternate access site.
P150035/S003	06/29/2023	P - Panel Track	AVEIR VR LEADLESS SYSTEM	ABBOTT MEDICAL	Approval for the Aveir DR Leadless System, Aveir Leadless Pacemaker (Right Ventricular), Aveir Leadless Pacemaker (Right Atrial), Aveir Delivery Catheter, Aveir Link Module.
P160013/S013	06/28/2023	O - Normal 180 Da	ORGAN CARE SYSTEM (OCS¿) LUNG SYSTEM	TRANSMEDICS, INC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P160017/S110	06/15/2023	O - Normal 180 Da	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval of the protocol for the post-approval study (PAS)
P160022/S015	06/21/2023	N - Normal 180 Day	X SERIES®, R SERIES®, AED PRO®, AED 3¿ BLS PROFESSIONAL DEFIBRILLATORS, PRO-PADZ RADIOTRANSPARENT ELECTRODE, SUREPOWER ¿ BATTERY PACK, SUREPOWER II¿ BATTERY PACK, AED PRO® NON-RECHARGEABLE LITHIUM BATTERY PACK, AED 3 ¿ BATTERY PACK, SUREPOWER¿ CHARGER, AND SUREPOWER ¿ SINGLE BAY CHARGER	ZOLL MEDICAL CORPORATION	Approval for the following Zoll automated external defibrillator (AED) accessories: 1) Zoll OneStep CPR Cable; 2) R Series OneStep Pacing Cable; 3) X Series OneStep Cable; 4) X Series/Propaq MD Multifunction Therapy Cable; 5) OneStep CPR Complete Electrodes; 6) OneStep CPR Complete Adult-Child Electrodes; 7) OneStep Basic Electrodes; 8) OneStep Pacing Electrodes; 9) OneStep Pediatric Electrodes; 10) OneStep Pediatric CPR Electrodes; 11) OneStep CPR II Electrodes; 12) OneStep CPR A/A (Anterior/Anterior) Electrodes; and 13) OneStep CPR Electrodes.
P160042/S022	06/06/2023	S - Special CBE	REVANESSE ULTRA	PROLLENIUM MEDICAL TECHNOLOGIES INC.	Approval for revisions to the clinician labeling and patient labeling as a result of postmarket surveillance data.
P160047/S030	06/30/2023	R - Real-Time Proc	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	COOPERSURGICAL, INC.	Approval for changes in the software test values (RF test time and Middle Balloon test pressure) for verification and validation tests.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160053/S007	06/29/2023	O - Normal 180 Da	MAGTRACETM AND SENTIMAG(R) MAGNETIC LOCATIZATION SYSTEM	ENDOMAGNETICS LTD.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P160055/S028	06/29/2023	R - Real-Time Proc	LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Approval for updates to LDD user interface, user settings, and diagnostic routings along with minor bug fixes.
P170002/S031	06/12/2023	S - Special CBE	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Approval for revisions to the clinician labeling and patient labeling as a result of postmarket surveillance data.
P170011/S050	06/23/2023	S - Special CBE	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval for updates to the Instructions for Use (IFU) to include warning statements and clinical recommendations related to risk of thrombus formation or deposition in the Impella RP Flex with SmartAssist when indwelling venous lines or cannulas are present.
P180001/S007	06/07/2023	S - Special CBE	ZENITH DISSECTION ENDOVASCULAR SYSTEM	WILLIAM COOK EUROPE APS	Approval for an added incoming inspection step for the introducer sheath.
P180035/S018	06/09/2023	O - Normal 180 Da	MISIGHT 1 DAY (OMAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES FOR DAILY WEAR	COOPERVISION, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P180035/S019	06/09/2023	O - Normal 180 Da	MISIGHT 1 DAY (OMAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES FOR DAILY WEAR	COOPERVISION, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P180036/S017	06/06/2023	R - Real-Time Proc	OPTIMIZER SMART SYSTEM	IMPULSE DYNAMICS (USA), INC.	Approval for modifications of the Optimizer Smart Mini firmware.
P180046/S063	06/13/2023	N - Normal 180 Day	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for changes to the charging device.
P180046/S066	06/02/2023	N - Normal 180 Day	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for labeling updates on compatible medical procedures for the rechargeable model 5101 of the Axonics Sacral Neuromodulation System
P190006/S063	06/13/2023	N - Normal 180 Day	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for changes to the charging device.
P190006/S066	06/02/2023	N - Normal 180 Day	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for labeling updates on compatible medical procedures for the rechargeable model 5101 of the Axonics Sacral Neuromodulation System

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190017/S012	06/07/2023	S - Special CBE	LIAISON® XL MUREX HBSAG QUAL, LIAISON® MUREX CONTROL HBSAG, AND LIAISON® XL MUREX HBSAG CONFIRMATORY TEST	DIASORIN INC	Approved for correction of typographical errors in the package insert of the LIAISON XL MUREX HBsAg Qual Assay.
P190021/S003	06/23/2023	Y - 135 Review Tra	REACTIV8 IMPLANTABLE NEUROSTIMULATION SYSTEM	MAINSTAY MEDICAL LIMITED	Approval for a change in manufacturing layout for the ReActiv8® Implantable Neurostimulation System to introduce improvements in the distribution of the Surface Mount Technology (SMT) manufacturing area and expand capacity to meet increasing volume of business.
P190032/S010	06/08/2023	P - Panel Track	FOUNDATIONONE LIQUID CDX (F1 LIQUID CDX)	FOUNDATION MEDICINE INC.	Approval for the FoundationOne Liquid CDx (F1 Liquid CDx). The device expands the indications for use to include a companion diagnostic indication for the detection of BRAF V600E alteration in patients with metastatic colorectal cancer (CRC) who may benefit from treatment with BRAFTOVI® (encorafenib) in combination with cetuximab.
P190034/S002	06/13/2023	N - Normal 180 Day	ELECSYS ANTI-HBS II, PRECICONTROL ANTI-HBS, ANTI-HBS CALCHECK	ROCHE DIAGNOSTICS	Approval for the migration of Elecsys Anti-HBs II assay on the cobas e 602 immunoanalyzer.
P200013/S014	06/16/2023	R - Real-Time Proc	ALINITY M HBV	ABBOTT MOLECULAR, INC.	Approval to add a sheet metal shroud around the Alinity m System Tip Chute Assembly.
P200028/S018	06/21/2023	R - Real-Time Proc	DIAMONDTEMP ABLATION SYSTEM	MEDTRONIC INC.	Approval for the addition of a 3-way stopcock component to the tubing set packaging pouch prior to sterilization.
P200036/S006	06/12/2023	R - Real-Time Proc	ECOIN PERIPHERAL NEUROSTIMULATOR	VALENCIA TECHNOLOGIES CORPORATION	Approval for an additional battery supplier for the eCoin implanted tibial stimulator
P200039/S012	06/15/2023	R - Real-Time Proc	SHOCKWAVE INTRAVASCULAR LITHOTRIPSY (IVL) SYSTEM WITH SHOCKWAVE C2 CORONARY INTRAVASCULAR LITHOTRIPSY (IVL) CATHETER	SHOCKWAVE MEDICAL, INC.	Approval for a minor formulation change to the inner member.
P210022/S005	06/16/2023	R - Real-Time Proc	ALINITY M CMV	ABBOTT MOLECULAR, INC.	Approval to add a sheet metal shroud around the Alinity m System Tip Chute Assembly.

Total: 69

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S103	06/26/2023	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Replacement of the obsolete model VAPOR-FLO IV with the new model VAPOR-FLO VI used in the manufacture of SURGICEL® Powder Absorbable Hemostatic Powder.
N16837/S031	06/29/2023	X - 30-Day Notice	ARTEGRAFT{TM} AND REINFORCED ARTEGRAFT {TM}	LEMAITRE VASCULAR, INC.	Implementation of changes to the purified water testing protocol for manufacturing of the Artegraft Collagen Vascular Graft.
N970012/S198	06/28/2023	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Change to the colorant used in a manufacturing aid during InhibiZone impregnation.
P830061/S216	06/14/2023	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of an automated pressure monitoring system.
P840001/S542	06/02/2023	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Implementation of a new workflow for assembly of labeling materials for the INS products.
P840001/S543	06/21/2023	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Update the Resistance Spot Welding process for Medium Rate batteries.
P850089/S165	06/14/2023	X - 30-Day Notice	CAPSURE SP, CAPSURE, CAPSURE 2 LEADS, EXCELLENCE S, IMPULSE, IMPLUSE II EXCELLENCE SS, LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of an automated pressure monitoring system.
P860004/S409	06/02/2023	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Implementation of a new workflow for assembly of labeling materials for the INS products.
P860004/S410	06/07/2023	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Surrogate parts to be utilized for laser weld monitoring of pumphead and motor.
P860004/S411	06/07/2023	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Supplier changes to a) use a new surfactant in the raw material manufacturing process; and b) to increase supplier production capacity in the filter manufacturing process for the SynchroMed Infusion System.
P860004/S412	06/21/2023	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Update the Resistance Spot Welding process for Medium Rate batteries.
P890003/S461	06/14/2023	X - 30-Day Notice	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Implementation of an automated pressure monitoring system.
P900033/S107	06/07/2023	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Updates to autoclave software and firmware to ensure accurate records for sterilization cycle information.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P900061/S170	06/14/2023	X - 30-Day Notice	MEDTRONIC PCD TACHYARRHYTHMIA CONTROL SYSTEM	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of an automated pressure monitoring system.
P910007/S061	06/22/2023	X - 30-Day Notice	AXSYM TOTAL PSA & ARCHITECT TOTAL PSA	ABBOTT LABORATORIES	Addition of a new fill line in existing manufacturing space.
P910023/S454	06/15/2023	X - 30-Day Notice	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ABBOTT MEDICAL	Implement an alternate supplier of the MAG1 component used in hybrids for ICD and CRT-D devices.
P920015/S278	06/14/2023	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Implementation of an automated pressure monitoring system.
P930014/S145	06/13/2023	X - 30-Day Notice	ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES	ALCON LABORATORIES, INC.	Adding an alternative supplier for Basic Alumina.
P930021/S032	06/21/2023	X - 30-Day Notice	BIORA EMDOGAIN(R)	THE STRAUMANN COMPANY	Relocation of Visual Inspection and Blistering activities to new cleanrooms in house K to release space for manufacturing of other products in the clean room areas but will also be beneficial for the Emdogain process since it will lead to a better material flow between clean room areas and warehouse.
P930031/S072	06/14/2023	X - 30-Day Notice	WALLSTENT(R) TIPS ENDOPROSTHESIS WITH UNISTEP PLUS DELIVERY SYSTEM	BOSTON SCIENTIFIC CORP.	Upgrading the control system for the furnace system at the Boston Scientific Corporation (BSC) Galway facility.
P930039/S252	06/14/2023	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Implementation of an automated pressure monitoring system.
P940019/S063	06/14/2023	X - 30-Day Notice	WALLSTENT(R) ILIAC ENDOPROSTHESIS	BOSTON SCIENTIFIC SCIMED, INC.	Upgrading the control system for the furnace system at the Boston Scientific Corporation (BSC) Galway facility.
P950005/S086	06/12/2023	X - 30-Day Notice	WEBSTER DIAG./ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC	Implementation of a new ethylene oxide sterilization cycle at the Sterigenics, Santa Teresa, NM facility.
P950008/S021	06/26/2023	X - 30-Day Notice	SILIKON 1000	ALCON	Change to the diaphragm valve material.
P950024/S106	06/14/2023	X - 30-Day Notice	MEDTRONIC(R) CAPSURE (R) EPI PACING LEAD MODEL 4695	MEDTRONIC INC.	Implementation of an automated pressure monitoring system.
P960004/S102	06/29/2023	X - 30-Day Notice	THINLINE ENDOCARDIAL PACING LEADS	BOSTON SCIENTIFIC	Changes to J-Tip stylet forming equipment, method and associated processes.
P960009/S452	06/02/2023	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Implementation of a new workflow for assembly of labeling materials for the INS products.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960009/S453	06/21/2023	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Update the Resistance Spot Welding process for Medium Rate batteries.
P960058/S158	06/02/2023	X - 30-Day Notice	CLARION MULTI-STRATEGY COCHLEAR IMPLANT	ADVANCED BIONICS	Increase in the load capacity of the vacuum bake oven used for the Ultra/Ultra 3D Cochlear Implants.
P960058/S160	06/29/2023	X - 30-Day Notice	CLARION MULTI-STRATEGY COCHLEAR IMPLANT	ADVANCED BIONICS	Addition of an alternate supplier of electrode protective tubes used in the packaging of Advanced Bionics implants.
P960058/S161	06/27/2023	X - 30-Day Notice	CLARION MULTI-STRATEGY COCHLEAR IMPLANT	ADVANCED BIONICS	Material change for implant capacitors on printed circuit board assemblies (PCBAs) supplied for HiRes Ultra and HiRes Ultra 3D Cochlear Implant.
P970004/S382	06/02/2023	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Implementation of a new workflow for assembly of labeling materials for the INS products.
P970004/S383	06/14/2023	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Update to the InterStim X Post Sterilization Test software.
P970004/S384	06/21/2023	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Update the Resistance Spot Welding process for Medium Rate batteries.
P980007/S050	06/22/2023	X - 30-Day Notice	AXSYM FREE PSA	ABBOTT LABORATORIES	Addition of a new fill line in existing manufacturing space.
P980016/S856	06/06/2023	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates to the distribution center sorter tool.
P980016/S857	06/13/2023	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to the device shield inspection processes.
P980016/S859	06/09/2023	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modifications to some battery rework processes at MECC.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S860	06/14/2023	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Implementation of an automated pressure monitoring system.
P980033/S062	06/14/2023	X - 30-Day Notice	WALLSTENT ENDOPROSTHESIS	BOSTON SCIENTIFIC CORPORATIO N	Upgrading the control system for the furnace system at the Boston Scientific Corporation (BSC) Galway facility.
P980035/S747	06/12/2023	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Updates to the battery manufacturing and inspection processes.
P980035/S748	06/13/2023	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Changes to the device shield inspection processes.
P980035/S749	06/20/2023	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Qualify equipment to perform Epoxy Dispense and Cure for implantable pulse generator (IPG) devices.
P980035/S750	06/09/2023	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Modifications to some battery rework processes at MECC.
P980035/S751	06/14/2023	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implementation of an automated pressure monitoring system.
P980050/S140	06/14/2023	X - 30-Day Notice	MEDTRONIC(R) JEWEL(R) AF 7250 DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATOR, MODEL 9961 PROGRAMMER APPLICATION SOF	MEDTRONIC INC.	Implementation of an automated pressure monitoring system.
P990004/S058	06/14/2023	X - 30-Day Notice	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Change to the detergent used in the existing washing machine and to optimize the washing process of the washing machine used in the manufacturing of the SURGIFOAM® Powder and the SURGIFLO® Hemostatic Matrix products.
P990004/S059	06/29/2023	X - 30-Day Notice	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Alternative packaging pattern of SURGIFLO Intermediates for sterilization in the manufacturing of the SURGIFLO® Haemostatic Matrix and the SURGIFLO® Haemostatic Matrix Kit with Thrombin.
P990004/S060	06/29/2023	X - 30-Day Notice	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Additional use of dry heat Oven 3 for crosslinking of SURGIFOAM® Oral Sponge and Hemorrhoidectomy Sponge products.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P990018/S010	06/16/2023	X - 30-Day Notice	MENICON Z RIGID GAS PERMEABLE CONTACT LENS	MENICON CO. LTD.	Changing the manufacturing site for the lens blank material.
P990025/S071	06/12/2023	X - 30-Day Notice	NAVI-STAR DIAGNOSTIC/ ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC.	Implementation of a new ethylene oxide sterilization cycle at the Sterigenics, Santa Teresa, NM facility.
P990071/S057	06/12/2023	X - 30-Day Notice	STOCKERT 70 RADIOFREQUENCY ABLATION GENERATOR	BIOSENSE WEBSTER, INC.	Implementation of a new ethylene oxide sterilization cycle at the Sterigenics, Santa Teresa, NM facility.
P990075/S057	06/02/2023	X - 30-Day Notice	MENTOR CORPORATION SALINE-FILLED AND SPECTRUM (R) MAMMARY PROSTHESES	MENTOR WORLDWIDE LLC	Change to the Thermoform mold for an increase in cavitation from 4 to 6 cavity molds.
P990075/S058	06/02/2023	X - 30-Day Notice	MENTOR CORPORATION SALINE-FILLED AND SPECTRUM (R) MAMMARY PROSTHESES	MENTOR WORLDWIDE LLC	Changes to the production of the Body Diaphragm Valve
P000053/S131	06/28/2023	X - 30-Day Notice	AMS SPHINCTER 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Change to the colorant used in a manufacturing aid during InhibiZone impregnation.
P010015/S518	06/12/2023	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Updates to the battery manufacturing and inspection processes.
P010015/S519	06/13/2023	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Changes to the device shield inspection processes.
P010015/S520	06/09/2023	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Modifications to some battery rework processes at MECC.
P010015/S521	06/14/2023	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implementation of an automated pressure monitoring system.
P010029/S035	06/27/2023	X - 30-Day Notice	EUFLEXXA (1% SODIUM HYALURONATE)	FERRING PHARMACEUTICALS, INC.	Replacement of the first dissolution vessel agitator.
P010030/S166	06/20/2023	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Alternate Tier I suppliers for sourcing of two monitor cables.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S822	06/06/2023	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Updates to the distribution center sorter tool.
P010031/S823	06/13/2023	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Changes to the device shield inspection processes.
P010031/S825	06/09/2023	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Modifications to some battery rework processes at MECC.
P010031/S826	06/14/2023	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Implementation of an automated pressure monitoring system.
P010032/S198	06/02/2023	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Qualify an alternate, in-house facility for the titanium battery case annealing process.
P010068/S071	06/12/2023	X - 30-Day Notice	NAVISTAR/CELSIUS DS DIAGNOSTIC/ABLATION DEFLECTABLE 8MM TIP CATHETER	BIOSENSE WEBSTER, INC.	Implementation of a new ethylene oxide sterilization cycle at the Sterigenics, Santa Teresa, NM facility.
P020047/S076	06/14/2023	X - 30-Day Notice	MULTI-LINK VISION/MINI/8 CORONARY STENT SYSTEMS	ABBOTT VASCULAR	Alternative sourcing of raw materials for one of the adhesives.
P020047/S077	06/12/2023	X - 30-Day Notice	MULTI-LINK VISION/MINI/8 CORONARY STENT SYSTEMS	ABBOTT VASCULAR	Implementing a new test method and test location for the resin proximal shaft raw material.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030017/S364	06/30/2023	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	New manufacturing site for current supplier Meier Tool & Engineering, Inc. (Meier). Meier manufactures the tacked back-up band, Bluetooth antenna, positive and negative battery contacts, and Printed Circuit Board (PCB) metal spacer components for Boston Scientific Neuromodulation Corporation (BSN) Implantable Pulse Generators (IPGs) and External Trial Stimulators (ETS). These parts are non-patient-contacting components used within the Spinal Cord Stimulator (SCS) and Deep Brain Stimulation (DBS). Meiers proposed facility move to Brooklyn Park, MN was approved for the Paddle Lead Disc Electrodes and Slotted Paddle Disc Electrodes used in SCS Leads.
P030031/S133	06/12/2023	X - 30-Day Notice	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Implementation of a new ethylene oxide sterilization cycle at the Sterigenics, Santa Teresa, NM facility.
P030036/S143	06/14/2023	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of an automated pressure monitoring system.
P030054/S407	06/15/2023	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ABBOTT MEDICAL	Implement an alternate supplier of the MAG1 component used in hybrids for ICD and CRT-D devices.
P040020/S105	06/13/2023	X - 30-Day Notice	ACRYSOF RESTOR APODIZED DIFFRACTIVE OPTIC POSTERIOR CHAMBER IOL	ALCON RESEARCH, LTD.	Adding an alternative supplier for Basic Alumina.
P040036/S095	06/12/2023	X - 30-Day Notice	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Implementation of a new ethylene oxide sterilization cycle at the Sterigenics, Santa Teresa, NM facility.
P040038/S042	06/14/2023	X - 30-Day Notice	XACT CAROTID STENT SYSTEM	ABBOTT VASCULAR INC.	Alternative sourcing of raw materials for one of the adhesives.
P040043/S135	06/20/2023	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Modify the supplier of the Tuohy-Borst End Cap component and to introduce modifications to the luer connector for compliance to BS EN ISO 80369-7.
P050007/S044	06/14/2023	X - 30-Day Notice	STARCLOSE VASCULAR CLOSURE SYSTEM	ABBOTT VASCULAR DEVICES	Alternative sourcing of raw materials for one of the adhesives.
P050019/S038	06/14/2023	X - 30-Day Notice	CAROTID WALLSTENT MONORAIL ENDOPROSTHESIS	BOSTON SCIENTIFIC CORP.	Upgrading the control system for the furnace system at the Boston Scientific Corporation (BSC) Galway facility.
P050037/S127	06/28/2023	X - 30-Day Notice	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Qualification of alternate wash cycle process for CaHA particles.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P050051/S052	06/22/2023	X - 30-Day Notice	ABBOTT ARCHITECT AUSAB	ABBOTT LABORATORIES INC	Addition of a new fill line in existing manufacturing space.
P050052/S149	06/28/2023	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Qualification of alternate wash cycle process for CaHA particles.
P070026/S108	06/22/2023	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Introduction of a new PROOFTEST SYSTEM to replace the current equipment asset used in the manufacturing process.
P080006/S176	06/14/2023	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Implementation of an automated pressure monitoring system.
P080025/S277	06/02/2023	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Implementation of a new workflow for assembly of labeling materials for the INS products.
P080025/S278	06/14/2023	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Update to the InterStim X Post Sterilization Test software.
P080025/S279	06/21/2023	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Update the Resistance Spot Welding process for Medium Rate batteries.
P090013/S327	06/14/2023	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Implementation of an automated pressure monitoring system.
P090016/S054	06/12/2023	X - 30-Day Notice	BELOTERO BALANCE	MERZ NORTH AMERICA, INC	Change in Storage Site for Raw Materials and Components used in Manufacturing Merz Belotero Balance and Belotero Balance (+) Lidocaine Products: Addition of External Galliker Warehouse
P100009/S056	06/29/2023	X - 30-Day Notice	MITRACLIP DELIVERY SYSTEM	ABBOTT MEDICAL	Increase the personnel occupancy limit for the NorthPoint manufacturing site cleanroom suite.
P100010/S138	06/01/2023	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATHLP	New supplier for the Y-Block, Service Loop Top, and Service Loop Bottom components of the Arctic Front Advance and Arctic Front Advance Pro cryoablation catheters. Additionally, there are also minor updates to the molds and dimension of the components due to the new molding processes.
P100021/S114	06/06/2023	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Addition of alternate suppliers to perform the EtO bioburden reduction process for the Endurant, Endurant II and Endurant IIs Stent Graft System and the Valiant Thoracic Stent Graft with the Captivia Delivery System.
P100021/S115	06/02/2023	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Transfer of component extrusion operations lines 5, 9, and 13 from the Medtronic Santa Rosa site to the Medtronic Danvers site.
P100040/S057	06/06/2023	X - 30-Day Notice	VALIANT THORACIC STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Addition of alternate suppliers to perform the EtO bioburden reduction process for the Endurant, Endurant II and Endurant IIs Stent Graft System and the Valiant Thoracic Stent Graft with the Captivia Delivery System.
P100040/S058	06/02/2023	X - 30-Day Notice	VALIANT THORACIC STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Transfer of component extrusion operations lines 5, 9, and 13 from the Medtronic Santa Rosa site to the Medtronic Danvers site.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100047/S210	06/21/2023	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Implementation of an in-process visual inspection to detect battery weld defects.
P110001/S020	06/14/2023	X - 30-Day Notice	RX HERCULINK ELITE RENAL STENT SYSTEM	ABBOTT VASCULAR	Alternative sourcing of raw materials for one of the adhesives.
P110019/S126	06/14/2023	X - 30-Day Notice	XIENCE SKYPOINT EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Alternative sourcing of raw materials for one of the adhesives.
P110023/S037	06/02/2023	X - 30-Day Notice	EVERFLEX SELF-EXPANDING PERIPHERAL STENT SYSTEM (EVERFLEX)	MEDTRONIC VASCULAR INC	Alternate laser cutting system for the stent manufacturing line.
P110029/S043	06/23/2023	X - 30-Day Notice	ARCHITECT HBSAG QUALITATIVE, QUALITATIVE CONFIRMATORY, CONFIRMATORY MANUAL DILUENT, CALIBRATORS, AND CONTROLS	ABBOTT LABORATORIES	Change of equipment and modification of a manufacturing process.
P110029/S044	06/22/2023	X - 30-Day Notice	ARCHITECT HBSAG QUALITATIVE, QUALITATIVE CONFIRMATORY, CONFIRMATORY MANUAL DILUENT, CALIBRATORS, AND CONTROLS	ABBOTT LABORATORIES	Addition of a new fill line in existing manufacturing space.
P110033/S074	06/29/2023	X - 30-Day Notice	JUVEDERM VOLUMA XC	ALLERGAN	Use of additional cleanrooms and automatic visual inspection equipment for the manufacture of Skinvive by Juvéderm® (Skinvive).
P120008/S023	06/22/2023	X - 30-Day Notice	ABBOTT ARCHITECT AFP ASSAY	ABBOTT LABORATORIES	Addition of a new fill line in existing manufacturing space.
P120017/S032	06/14/2023	X - 30-Day Notice	MODEL 5071 LEAD	MEDTRONIC INC.	Implementation of an automated pressure monitoring system.
P130008/S097	06/20/2023	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Change in manufacturing location for three injection-molded components of the device.
P130021/S138	06/02/2023	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Transfer of component extrusion operations lines 5, 9, and 13 from the Medtronic Santa Rosa site to the Medtronic Danvers site.
P130021/S139	06/13/2023	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	New software to allow tissue cut drawings to be automatically downloaded directly to the laser cutter equipment via the scan of a QR code.
P140005/S005	06/22/2023	X - 30-Day Notice	GENVISC 850	ORTHOGENRX,INC	Moving the manufacturing and sterilization site of the glass syringes (i.e., barrels) from BD Columbus, USA to BD Cuautitlán, Mexico.
P140009/S083	06/02/2023	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Qualify an alternate, in-house facility for the titanium battery case annealing process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140031/S157	06/02/2023	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Manufacture the 29 mm Commander Delivery System at the Limerick, Ireland facility.
P140031/S158	06/13/2023	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Addition of a Receiving Inspection process for the delivery system components/materials at the Edwards Limerick Ireland facility.
P150004/S061	06/02/2023	X - 30-Day Notice	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Qualify an alternate, in-house facility for the titanium battery case annealing process.
P150012/S146	06/29/2023	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Changes to J-Tip stylet forming equipment, method and associated processes.
P150021/S058	06/30/2023	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Introduction of a secondary supplier for components of the Sensor Applicator and the Sensor Pack for the Freestyle Libre 14 Day and Freestyle Libre Pro glucose monitoring systems.
P150030/S033	06/20/2023	X - 30-Day Notice	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Introduction of a new binder used for the porous coating process for R3 Stiktite Coated Acetabular Shells at Orchid Orthopedic Solutions.
P150031/S059	06/30/2023	X - 30-Day Notice	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	New manufacturing site for current supplier Meier Tool & Engineering, Inc. (Meier). Meier manufactures the tacked back-up band, Bluetooth antenna, positive and negative battery contacts, and Printed Circuit Board (PCB) metal spacer components for Boston Scientific Neuromodulation Corporation (BSN) Implantable Pulse Generators (IPGs) and External Trial Stimulators (ETS). These parts are non-patient-contacting components used within the Spinal Cord Stimulator (SCS) and Deep Brain Stimulation (DBS). Meiers proposed facility move to Brooklyn Park, MN was approved for the Paddle Lead Disc Electrodes and Slotted Paddle Disc Electrodes used in SCS Leads.
P150033/S172	06/13/2023	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Changes to the device shield inspection processes.
P150033/S173	06/09/2023	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Updates to the work instructions in the feedthrough potting, curing, and inspection process at SMO.
P150033/S174	06/14/2023	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Implementation of an automated pressure monitoring system.
P160013/S014	06/28/2023	X - 30-Day Notice	ORGAN CARE SYSTEM (OCS) LUNG SYSTEM	TRANSMEDICS, INC	Change the supplier for the vented bag component of the OCS Perfusion module.
P160030/S053	06/30/2023	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Introduction of a secondary supplier for components of the Sensor Applicator and the Sensor Pack for the Freestyle Libre 14 Day and Freestyle Libre Pro glucose monitoring systems.
P160035/S033	06/30/2023	X - 30-Day Notice	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Change in the manufacturing process of the reducer section of the P10P-001 (10 ml) EXCOR Blood pump.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160043/S069	06/02/2023	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Transfer of component extrusion operations lines 5, 9, and 13 from the Medtronic Santa Rosa site to the Medtronic Danvers site.
P160043/S070	06/15/2023	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Implementation of an alternative processing aid for use during the annealing procedure.
P160048/S025	06/09/2023	X - 30-Day Notice	EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM	SENSEONICS, INCORPORATED	Scale-up of a Sensor subassembly manufacturing process and the addition of a new supplier for a critical component of the Eversense E3 Continuous Glucose Monitoring System.
P160054/S055	06/22/2023	X - 30-Day Notice	HEARTMATE 3 LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Add an alternate sub-tier supplier of the silver component used in the percutaneous cable of the HeartMate 3 Left Ventricular Assist System (LVAS).
P160057/S002	06/22/2023	X - 30-Day Notice	TRIVISC	ORTHOGENRX,INC	Moving the manufacturing and sterilization site of the glass syringes (i.e., barrels) from BD Columbus, USA to BD Cuautitlán, Mexico.
P170030/S029	06/15/2023	X - 30-Day Notice	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Implementation of an automated weighing machine for uncoated stent measurements.
P170036/S013	06/14/2023	X - 30-Day Notice	M6-C ARTIFICIAL CERVICAL DISC	SPINAL KINETICS LLC	Addition of a packaging seal test unit identical to the existing unit in operation (BT Integra Pack Tester).
P180046/S069	06/21/2023	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Additional tray sealer to seal the IPG (Model 1101, 5101) trays to the Tyvek lids at Cirtec Medical.
P180051/S004	06/28/2023	X - 30-Day Notice	ORGAN CARE SYSTEM (OCS) HEART SYSTEM	TRANSMEDICS, INC.	Change the supplier for the vented bag component of the OCS Perfusion module.
P190006/S069	06/21/2023	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Additional tray sealer to seal the IPG (Model 1101, 5101) trays to the Tyvek lids at Cirtec Medical.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190018/S025	06/13/2023	X - 30-Day Notice	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 LABORATORIES, LLC	Adding an alternative supplier for Basic Alumina.
P190026/S001	06/27/2023	X - 30-Day Notice	THERASCREEN BRAF V600E RGQ PCR KIT	QIAGEN GMBH	Modify the manufacturing process of the device.
P200010/S015	06/20/2023	X - 30-Day Notice	GUARDANT360 CDX	GUARDANT HEALTH, INC.	New QC materials used for acceptance testing of device components.
P200015/S040	06/02/2023	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Manufacture the 29 mm Commander Delivery System at the Limerick, Ireland facility.
P200015/S041	06/13/2023	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Addition of a Receiving Inspection process for the delivery system components/materials at the Edwards Limerick Ireland facility.
P200022/S011	06/09/2023	X - 30-Day Notice	SIMPLIFY® CERVICAL ARTIFICIAL DISC	NUVASIVE, INC.	Change (addition) of a supplier for manufacturing of the PEEK endplate components.
P200030/S012	06/20/2023	X - 30-Day Notice	GORE EXCLUDER CONFORMABLE AAA ENDOPROSTHESIS (CEXC)	W. L. GORE AND ASSOCIATES, INC.	Modify the supplier of the Tuohy-Borst End Cap component and to introduce modifications to the luer connector for compliance to BS EN ISO 80369-7.
P200031/S004	06/28/2023	X - 30-Day Notice	ORGAN CARE SYSTEM (OCS) LIVER	TRANSMEDICS, INC.	Change the supplier for the vented bag component of the OCS Perfusion module.
P200041/S001	06/29/2023	X - 30-Day Notice	SCOREFLEX NC SCORING PTCA CATHETER	ORBUSNEICH MEDICAL (SHENZHEN) CO., LTD.	Addition of a new manufacturing location for the manufacture of select components of the final Scroreflex NC device.
P200046/S017	06/13/2023	X - 30-Day Notice	HARMONY¿ TPV SYSTEM	MEDTRONIC, INC.	New software to allow tissue cut drawings to be automatically downloaded directly to the laser cutter equipment via the scan of a QR code.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P210011/S001	06/07/2023	X - 30-Day Notice	XT CDX	TEMPUS LABS, INC.	Addition of an alternate specimen collection kit assembly and distribution supplier.
P210027/S003	06/12/2023	X - 30-Day Notice	QDOT MICRO SYSTEM	BIOSENSE WEBSTER, INC.	Implementation of a new ethylene oxide sterilization cycle at the Sterigenics, Santa Teresa, NM facility.
P210032/S009	06/20/2023	X - 30-Day Notice	GORE TAG THORACIC BRANCH ENDOPROSTHESIS (TBE DEVICE)	W. L. GORE & ASSOCIATES, INC.	Modify the supplier of the Tuohy-Borst End Cap component and to introduce modifications to the luer connector for compliance to BS EN ISO 80369-7.
P220003/S011	06/01/2023	X - 30-Day Notice	PASCAL PRECISION TRANSCATHETER VALVE REPAIR SYSTEM	EDWARDS LIFESCIENCES LLC	New in-house supplier of a nitinol paddle component.
P220003/S012	06/22/2023	X - 30-Day Notice	PASCAL PRECISION TRANSCATHETER VALVE REPAIR SYSTEM	EDWARDS LIFESCIENCES LLC	Implement process improvements to the attachment finger bond on the implant catheter (IC) shaft used in PASCAL Precision Implant System.
P220007/S001	06/21/2023	X - 30-Day Notice	PRECISION7; PRECISION7 FOR ASTIGMATISM; PRECISION7 MULTIFOCAL; PRECISION7 MULTIFOCAL TORIC (SERAFILCON A) SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Qualification of an alternate instrument for use in quality control lens power measurement of serafilcon A contact lenses.

Total: 148