PMA Monthly approvals from 4/1/2023 to 4/30/2023

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P210011	04/28/2023	PMAO - PMA Origi	XT CDX	TEMPUS LABS, INC.	Approval for the xT CDx. The device is a qualitative Next Generation Sequencing (NGS)-based in vitro diagnostic device intended for use in the detection of substitutions (single nucleotide variants (SNVs) and multi-nucleotide variants (MNVs)) and insertion and deletion alterations (INDELs) in 648 genes, as well as microsatellite instability (MSI) status, using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens, and DNA isolated from matched normal blood or saliva specimens, from previously diagnosed cancer patients with solid malignant neoplasms. The test is intended as a companion diagnostic (CDx) to identify patients who may benefit from treatment with the targeted therapies listed in the Companion Diagnostic Indications table in accordance with the approved therapeutic product labeling. Additionally, xT CDx is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with previously diagnosed solid malignant neoplasms. Genomic findings other than those listed in the Companion Diagnostic Indications table are not prescriptive or conclusive for labeled use of any specific therapeutic product. xT CDx is a single-site assay performed at Tempus Labs, Inc., Chicago, IL.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P220007	04/25/2023	PMAO - PMA Origi	PRECISION7¿; PRECISION7 ¿ FOR ASTIGMATISM; PRECISION7 ¿ MULTIFOCAL; PRECISION7¿ MULTIFOCAL TORIC (SERAFILCON A) SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Approval for Precision7; Precision7 for Astigmatism; Precision7 Multifocal; Precision7 Multifocal Toric (serafilcon A) Soft Contact Lenses; Precision7 (serafilcon A) spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity. Precision7 for Astigmatism (serafilcon A) toric soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have up to 6.00 diopters (D) of astigmatism, Precision7 Multifocal (serafilcon A) soft contact lenses are indicated for the optical correction of presbyopia with or without refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (D) or less and who may have up to approximately 1.50 diopters of astigmatism that does not interfere with visual acuity Precision7 Multifocal Toric (serafilcon A) soft contact lenses are indicated for the optical correction of presbyopia with or without refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (D) or less and who may have up to 6.00 diopters (D) of astigmatism. The lenses are to be prescribed for extended wear for up to 6 continuous nights with removalfor disposal, or cleaning and disinfection (chemical, not heat) prior to reinsertion, as recommended by the eye care professional. Lenses should be discarded and replaced with a new pair each week, or more often, if recommended by the eye care professional.
P220020	04/04/2023	PMAO - PMA Origi	LAVA LIQUID EMBOLIC SYSTEM (LAVA LES) AND LAVA MIXING KIT	BLACKSWAN VASCULAR, INC.	Approval for the Lava Liquid Embolic System (Lava LES) and Lava Mixing Kit. The device is indicated for embolization of arterial hemorrhage in the peripheral vasculature.

Total: 3

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N17600/S038	04/25/2023	N - Normal 180 Day	AVITENE (MICROFIBRILLAR COLLAGEN HOMOSTAT)	DAVOL, INC., SUB. C.R. BARD, INC.	Approval for the additional milling step of the AviteneTM bulk flour and hydration with sterile saline prior to use.
N970003/S283	04/21/2023	R - Real-Time Proc	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Approval for software and cybersecurity changes for the LATITUDE NXT Release 7.3.
P880086/S326	04/14/2023	R - Real-Time Proc	ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS	ABBOTT MEDICAL	Approval for software changes in the Merlin PCS Model 3330 Software v27.0.1 and Merlint.net MN5000 v8.0.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P890003/S457	04/20/2023	N - Normal 180 Day	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Approval for two new models in the Micra Transcatheter Pacing System family, the Micra VR2 and the Micra AV2.
P910023/S451	04/14/2023	R - Real-Time Proc	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ABBOTT MEDICAL	Approval for software changes in the Merlin PCS Model 3330 Software v27.0.1 and Merlint.net MN5000 v8.0.
P910077/S191	04/21/2023	R - Real-Time Proc	VENTAK(R) PRX (TM) MODEL 1700,1705 PULSE GENERATOR	BOSTON SCIENTIFIC	Approval for software and cybersecurity changes for the LATITUDE NXT Release 7.3.
P930021/S028	04/04/2023	Y - 135 Review Tra	BIORA EMDOGAIN(R)	THE STRAUMANN COMPANY	Approval for the implementation of a new freeze room and a new cold room to increase storage capacity for raw materials, and intermediate and final products.
P950037/S246	04/13/2023	R - Real-Time Proc	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Approval for programmer software versions PSW 2301.U and NEO 2301.U.
P960040/S490	04/21/2023	R - Real-Time Proc	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Approval for software and cybersecurity changes for the LATITUDE NXT Release 7.3.
P970004/S364	04/12/2023	O - Normal 180 Da	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Approval for an alternate Sterilization site located at Sterigenics S. De R.L. de C.V., James Watt No. 22, Parque Industrial Cuamatla, Cuautitlan Izcalli Mexico, MX CP 54730 Mexico.
P970013/S092	04/14/2023	R - Real-Time Proc	MICRONY PACEMAKERS	ABBOTT MEDICAL	Approval for software changes in the Merlin PCS Model 3330 Software v27.0.1 and Merlint.net MN5000 v8.0.
P970051/S217	04/24/2023	R - Real-Time Proc	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for changes to the material and design of the coil crimp and its joining process used in the CI500 Series & CI600 Series Cochlear Implants and the ABI541 Auditory Brainstem Implant
P000009/S102	04/13/2023	R - Real-Time Proc	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Approval for programmer software versions PSW 2301.U and NEO 2301.U.
P000015/S049	04/24/2023	R - Real-Time Proc	NUCLEUS 24 AUDITORY BRAINSTEM IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for changes to the material and design of the coil crimp and its joining process used in the CI500 Series & CI600 Series Cochlear Implants and the ABI541 Auditory Brainstem Implant
P010012/S567	04/21/2023	R - Real-Time Proc	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Approval for software and cybersecurity changes for the LATITUDE NXT Release 7.3.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010032/S192	04/28/2023	Y - 135 Review Tra	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Approval for a change in cleanroom classification from ISO 8 to ISO 9 in the Controlled Access Environment (CAE) room in Abbott's Arecibo, Puerto Rico (PR) manufacturing site and a diameter nozzle change for the mold release spray. The change is being made to align with the cleanroom classification for the same manufacturing operations and processes in Plano, TX. Abbott is also seeking this higher classification to accommodate for the change in the larger diameter mold release spray.
P020036/S046	04/20/2023	Y - 135 Review Tra	S.M.A.R.T. AND S.M.A.R.T. CONTROL NITINOL STENT SYSTEM	CORDIS US CORPORATIO N	Approval for the removal of an in-process test (pod elongation test), during manufacturing of the POD Subassembly.
P030005/S228	04/21/2023	R - Real-Time Proc	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Approval for software and cybersecurity changes for the LATITUDE NXT Release 7.3.
P030011/S084	04/12/2023	R - Real-Time Proc	SYNCARDIA TEMPORARY CARDIO WEST TOTAL ARTIFICIAL HEART (TAH-T)	SYNCARDIA SYSTEMS, LLC	Approval for a software change to the cardiac output and fill volume calculations of the Freedom Driver.
P030035/S192	04/14/2023	R - Real-Time Proc	ANTHEM AND FRONTIER II CRT-P'S	ABBOTT MEDICAL	Approval for software changes in the Merlin PCS Model 3330 Software v27.0.1 and Merlint.net MN5000 v8.0.
P030050/S039	04/25/2023	P - Panel Track	SCULPTRA AND SCULPTRA AESTHETIC	Q-MED AB	Approval for Sculptra. The device is indicated for correction of fine lines and wrinkles in the cheek region for use in immune-competent subjects.
P030054/S405	04/14/2023	R - Real-Time Proc	ST JUDE MEDICAL EPIC HF SYSTEM	ABBOTT MEDICAL	Approval for software changes in the Merlin PCS Model 3330 Software v27.0.1 and Merlint.net MN5000 v8.0.
P050023/S173	04/13/2023	R - Real-Time Proc	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval for programmer software versions PSW 2301.U and NEO 2301.U.
P070008/S146	04/13/2023	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 programmer software versions PSW 2301.U and NEO 2301.U.
P080025/S259	04/12/2023	O - Normal 180 Da	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODU LATION	Approval for an alternate Sterilization site located at Sterigenics S. De R.L. de C.V., James Watt No. 22, Parque Industrial Cuamatla, Cuautitlan Izcalli Mexico, MX CP 54730 Mexico.
P100010/S131	04/27/2023	Y - 135 Review Tra	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Approval for implementing a parametric release method at Steri-Tech in Salinas, Puerto Rico.
P100045/S065	04/28/2023	S - Special CBE	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ABBOTT MEDICAL	Approval for labeling changes being made to the users manual or system guides with updated electromagnetic compatibility (EMC) information.
P110019/S123	04/05/2023	O - Normal 180 Da	XIENCE SKYPOINT EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Approval for identification of an alternate product trade name for XIENCE Sierra as XIENCE PROS

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110042/S178	04/21/2023	R - Real-Time Proc	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for software and cybersecurity changes for the LATITUDE NXT Release 7.3.
P120002/S021	04/20/2023	Y - 135 Review Tra	SMA RT CONTROL AND SMART VASCULAR STENT SYSTEMS	CORDIS US CORPORATION	Approval for the removal of an in-process test (pod elongation test), during manufacturing of the POD Subassembly.
P130008/S095	04/28/2023	R - Real-Time Proc	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval for the change to the Model 2740 Programmer Cable Printed Circuit Board Assembly (PCBA).
P130015/S017	04/18/2023	N - Normal 180 Day	ELECSYS® HBEAG IMMUNOASSAY AND ELECSYS® PRECICONTROL HBEAG	ROCHE DIAGNOSTICS OPERATIONS INC	Approval for the migration of the Elecsys HBeAg Immunoassay and Elecsys PreciControl HBeAg to the cobas e 402 immunoassay analyzer
P130026/S083	04/17/2023	R - Real-Time Proc	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Approval for adding a second source supplier, Sigmatron, of the Interface Printed Circuit Board Assembly used in the TactiSys Quartz Equipment to improve supply chain versatility.
P140003/S110	04/27/2023	O - Normal 180 Da	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval of the revised protocol for the Impella Real-World Surveillance of patients using Sodium Bicarbonate. The PAS protocol has been submitted to comply with the conditions of approval outlined in our approval orders for P140003/S088 and P170011/S035.
P140018/S033	04/03/2023	Y - 135 Review Tra	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Approval for a change to the biological indicator used during the sterilization of the VenaSeal adhesive at the Medtronic Galway facility.
P140020/S027	04/26/2023	N - Normal 180 Day	BRACANALYSIS CDX	MYRIAD GENETIC LABORATORIES	Approval for the change of Zejula® (niraparib) indication from a complementary diagnostic to a companion diagnostic to aid in identifying ovarian cancer patients with deleterious or suspected deleterious germline BRCA1 and BRCA2 mutations, who are or may become eligible for maintenance treatment with Zejula® (niraparib).
P140029/S048	04/12/2023	S - Special CBE	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Approval for revisions to the clinician labeling and patient labeling of Restylane Kysse as a result of postmarket surveillance data.
P140031/S146	04/04/2023	O - Normal 180 Da	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for addition of a new Edwards manufacturing facility located in Limerick, Ireland as an alternate manufacturing site for the Edwards Commander Delivery system sizes 23mm and 26mm.
P140033/S077	04/14/2023	R - Real-Time Proc	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ABBOTT MEDICAL	Approval for software changes in the Merlin PCS Model 3330 Software v27.0.1 and Merlint.net MN5000 v8.0.
P150001/S104	04/18/2023	R - Real-Time Proc	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	Approval for a minor design change to the Next Generation Pumps (NGP) to remove remote bolus functionality, remove remote settings modification, and disable over the air programming. The proposed changes address vulnerabilities in connection with Field Action (FA1272) and will be implemented in the MiniMed 670G and 630G Insulin Pumps.
P150012/S139	04/19/2023	R - Real-Time Proc	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Approval for the replacement of raw material Elasthane 55D MR supplied by DSM with Pellethane 2363 55D supplied by Lubrizol Advanced Materials, Inc for use in the polyurethane outer insulation tubing for the INGEVITY MRI and INGEVITY+ leads.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150012/S140	04/21/2023	R - Real-Time Proc	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Approval for software and cybersecurity changes for the LATITUDE NXT Release 7.3.
P150033/S161	04/20/2023	N - Normal 180 Day	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval for two new models in the Micra Transcatheter Pacing System family, the Micra VR2 and the Micra AV2.
P150035/S004	04/14/2023	R - Real-Time Proc	AVEIR VR LEADLESS SYSTEM	ABBOTT MEDICAL	Approval for software changes in the Merlin PCS Model 3330 Software v27.0.1 and Merlint.net MN5000 v8.0.
P150040/S013	04/13/2023	O - Normal 180 Da	VISUMAX FEMTOSECOND LASER	CARL ZEISS MEDITEC, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P160017/S091	04/21/2023	P - Panel Track	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval of the MiniMed 780G System for modifications to the SmartGuard Technology and for expanding the indications for use to include the Guardian 4 Sensor.
P160017/S093	04/27/2023	R - Real-Time Proc	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval for enabling the firmware over the air (FOTA) update for the MiniMed 770G system and the associated labeling changes.
P160017/S108	04/18/2023	R - Real-Time Proc	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval for a minor design change to the Next Generation Pumps (NGP) to remove remote bolus functionality, remove remote settings modification, and disable over the air programming. The proposed changes address vulnerabilities in connection with Field Action (FA1272) and will be implemented in the MiniMed 670G and 630G Insulin Pumps.
P160019/S014	04/24/2023	N - Normal 180 Day	ELECSYS HBSAG II/ ELECSYS HBSAG CONFIRMATORY TEST/ PRECICONTROL HBSAG II	ROCHE DIAGNOSTICS , INC.	Approval for the migration of Elecsys HBsAg II from the cobas e 601 to the cobas e 402 analyzer.
P160029/S019	04/03/2023	R - Real-Time Proc	HEARTSTART ONSITE DEFIBRILLATOR (MODEL M5066A) AND HEARTSTART HOME DEFIBRILLATOR (MODEL M5068A)	PHILIPS MEDICAL SYSTEMS, INC.	Approval for design changes including hardware changes for compliance with international restricted material regulations.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160037/S014	04/12/2023	R - Real-Time Proc	BD ONCLARITY HPV ASSAY	BECTON, DICKINSON AND COMPANY	Approval for The BD Onclarity HPV Assay. The device is indicated as a qualitative in vitro test for the detection of Human Papillomavirus in clinician-collected cervical specimens using an endocervical brush/spatula combination or broom and placed in a BD SurePath vial or placed in ThinPrep Pap Test PreservCyt Solution . The test utilizes amplification of target DNA by the Polymerase Chain Reaction (PCR) and nucleic acid hybridization for the detection of 14 high-risk (HR) HPV types in a single analysis. The test specifically identifies types 16, 18, 31, 45, 51, and 52 while reporting the other HR HPV types in groups (33/58, 35/39/68, and 56/59/66). The BD Onclarity HPV Assay is indicated for use for routine cervical cancer screening as per professional medical guidelines, including triage of ASC-US cytology, co-testing (or adjunctive screen) with cytology, and HPV primary screening of women to assess the risk for cervical precancer and cancer. Patients should be followed-up in accordance with profession medical guidelines, results from prior screening, medical history, and other risk factors. WARNING The BD Onclarity HPV Assay is NOT intended: 1) For use in determining the need for treatment (i.e., excisional or ablative treatment of the cervix) in the absence of high-grade cervical dysplasia. Patients who are HPV 16, 18 and 45 positive should be assessed for the development of high-grade cervical intraepithelial neoplasia according to current practice guidelines; 2) For women who have undergone hysterectomy with removal of the cervix; and 3) For use with samples other than those collected by a clinician using an endocervical brush/spatula combination or broom and placed in the BD SurePath Preservative Fluid Collection Vial or placed in PreservCyt Solution. HPV-negative cancers of the cervix do occur infrequently. In addition, HPV screening is not 100% sensitive for HPV-associated cervical cancer. Use of this device for primary cervical cancer screening should be undertaken after carefully considering the performance characteristics put forth in this label, as well as recommendations of professional guidelines. The use of this test has not been evaluated for the management of women with prior ablative or excisional therapy, or who are pregnant, or below age 21, or for the management of transgender individuals.
P160045/S041	04/07/2023	S - Special CBE	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Approval for the addition of new limitation statements to enhance the safety of use of the Oncomine Dx Target Test.
P170002/S024	04/26/2023	R - Real-Time Proc	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Approval for an additional supplier for the 30G ½ needle.
P170011/S049	04/27/2023	O - Normal 180 Da	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval of the revised protocol for the Impella Real-World Surveillance of patients using Sodium Bicarbonate.
P180011/S052	04/10/2023	O - Normal 180 Da	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval to update the labeling to include the long-term results of the IMPERIAL continued follow-up and REGAL post-approval studies

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180028/S013	04/03/2023	R - Real-Time Proc	HEARTSTART FRX DEFIBRILLATOR	PHILIPS MEDICAL SYSTEMS	Approval for design changes including hardware changes for compliance with international restricted material regulations.
P180032/S012	04/19/2023	R - Real-Time Proc	CERENE® CRYOTHERAPY DEVICE	CHANNEL MEDSYSTEMS, INC.	Approval for re-introduction of an air pump manufactured by another supplier as an alternative for the existing air pump.
P190009/S003	04/21/2023	N - Normal 180 Day	OPRA IMPLANT SYSTEM	INTEGRUM AB	Approval for the use of additional instruments for use with the OPRA system (i.e., the Abutment Installation Kit, the Abutment Extraction Kit, the Fixture Removal Kit, and the Fractured Abutment/ Abutment Screw Kit).
P190017/S009	04/13/2023	N - Normal 180 Day	LIAISON® XL MUREX HBSAG QUAL, LIAISON® MUREX CONTROL HBSAG, AND LIAISON® XL MUREX HBSAG CONFIRMATORY TEST	DIASORIN INC	Approval for removal of repeat testing for samples greater than or equal to 140 s/co by the LIAISON XL MUREX HBsAg Qual assay and removal of testing these samples with LIAISON XL MUREX HBsAg Confirmatory Test.
P200015/S029	04/04/2023	O - Normal 180 Da	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Approval for addition of a new Edwards manufacturing facility located in Limerick, Ireland as an alternate manufacturing site for the Edwards Commander Delivery system sizes 23mm and 26mm.
P200035/S008	04/18/2023	O - Normal 180 Da	ORGANOX METRA SYSTEM	ORGANOX LIMITED	Approval for the OrganOx metra®. The New Enrollment PAS is a multi-center, single-arm, unblinded post-approval study designed to compare recipients of PAS NMP livers versus IDE SCS livers with respect to adverse biliary-related events. Recruitment will take place at a minimum of 10 sites which are UNOS member liver transplant centers.
P200044/S002	04/21/2023	S - Special CBE	LUNGFIT PH	BEYOND AIR, INC.	Approval for an update to Pre-Use Guide (20092-01) to include a figure for bagging system connections which is already included in the Operators Manual and included in training.
P210014/S002	04/06/2023	O - Normal 180 Da	SLENDER SIROLIMUS-ELUTING CORONARY STENT INTEGRATED DELIVERY SYSTEM AND DIRECT SIROLIMUS-ELUTING CORONARY STENT RAPID EXCHANGE DELIVERY SYSTEM	SVELTE MEDICAL SYSTEMS, INC.	Approval to terminate of both PAS clinical studies, PAS001 continued follow-up of OPTIMIZE Clinical Study and PAS002 DIRECT IV Study.
P210019/S002	04/28/2023	P - Panel Track	ADVIA CENTAUR ANTI-HBC TOTAL (HBCT2) AND ATELLICA IM ANTI-HBC TOTAL (HBCT2)	SIEMENS HEALTHCARE DIAGNOSTICS, INC.	Approve inclusion of pediatric subjects in the intended use population for the ADVIA Centaur XP/XPT, ADVIA Centaur CP, and Atellica IM Analyzers

Total: 64

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S101	04/04/2023	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Changes related to the addition of two (2) QICPIC particle size analyzers, used in the manufacture of SURGICEL® Powder Absorbable Hemostatic Powder at the ETHICON LLC, San Lorenzo, Puerto Rico manufacturing site.
N16837/S030	04/25/2023	X - 30-Day Notice	ARTEGRAFT{TM} AND REINFORCED ARTEGRAFT {TM}	LEMAITRE VASCULAR, INC.	Addition of two new alternative service suppliers to perform water testing and environmental testing for manufacturing of the Artegraft Collagen Vascular Graft.
P810006/S103	04/18/2023	X - 30-Day Notice	COLLASTAT	INTEGRA LIFESCIENCES CORPORATION	Address a modification to the reporting language of relevant regulatory standard(s). Other than in the reporting units, the proposed change did not stem from or cause a change to any test methods or product release specifications. A 3-year retrospective analysis of the potential effect of the change did not raise any issues related to past product release decisions, and therefore no future product release issues are predicted by the proposed change.
P840001/S539	04/20/2023	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Implement new Laser Solder process parameters for the hybrid and battery connections of the Percept PC (Model B35200) and Pain PC (Model 977005 Sequentia LT and Model 977006 Vanta with AdaptiveStim) Neurostimulator Devices.
P840001/S540	04/20/2023	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Add new Tensile Tester Instron model 34SC-1, update relevant Software, update Test Method Neuro Lead Body Joint Tensile to include Tensile Tester Instron model 34SC-1, reword operation steps, and include visual aids of how to use the new equipment at the Medtronic Danvers manufacturing site.
P840062/S088	04/18/2023	X - 30-Day Notice	COLLACOTE(TM)	INTEGRA LIFESCIENCES CORP.	Endotoxin unit change from EU/ml to EU/device per revised USP<161>
P850010/S106	04/18/2023	X - 30-Day Notice	HELISTAT(TM) ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	INTEGRA LIFESCIENCES CORPORATION	Endotoxin unit change from EU/ml to EU/device per revised USP<161>
P860057/S212	04/27/2023	X - 30-Day Notice	EDWARDS LIFESCIENCES PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Transfer of receiving inspection activities for non-biological pericardial valve components from the Edwards Irvine facility to the Edwards Singapore facility.
P900033/S106	04/18/2023	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Endotoxin unit change from EU/ml to EU/Device per revised USP <161>.
P900056/S205	04/19/2023	X - 30-Day Notice	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Add an additional Pump Seal supplier for Rotablator and ROTAPRO Advancers
P900056/S206	04/27/2023	X - 30-Day Notice	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Use of parametric release and an alternate process challenge device for the BSC2019 ethylene oxide sterilization cycle at the Steris AST Costa Rica Facility.
P920047/S130	04/27/2023	X - 30-Day Notice	EPT-1000 CARDIAC ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Use of parametric release and an alternate process challenge device for the BSC2019 ethylene oxide sterilization cycle at the Steris AST Costa Rica Facility.
P930021/S031	04/18/2023	X - 30-Day Notice	BIORA EMDOGAIN(R)	THE STRAUMANN COMPANY	Addition of a new washer disinfector for production.

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P950008/S018	04/20/2023	X - 30-Day Notice	SILIKON 1000	ALCON	Change to the endotoxin test method on finished Silikon 1000 product and the respective releasing specifications.
P950020/S137	04/26/2023	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Introduce additional manufacturing equipment.
P950037/S248	04/04/2023	X - 30-Day Notice	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Introduction of an automatic optical inspection for the blister packaging of ICD lead families and updates to visual inspection criteria.
P960009/S450	04/20/2023	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Implement new Laser Solder process parameters for the hybrid and battery connections of the Percept PC (Model B35200) and Pain PC (Model 977005 Sequentia LT and Model 977006 Vanta with AdaptiveStim) Neurostimulator Devices.
P970004/S379	04/04/2023	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	an update to the inspection test method of a component from an external supplier
P980003/S095	04/27/2023	X - 30-Day Notice	CHILLI COOLED RF ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Use of parametric release and an alternate process challenge device for the BSC2019 ethylene oxide sterilization cycle at the Steris AST Costa Rica Facility.
P980016/S850	04/12/2023	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Use a drop in replacement Hall sensor integrated circuit.
P980016/S853	04/12/2023	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement an optical vision measurement system at a supplier of shield assembly components.
P980023/S120	04/04/2023	X - 30-Day Notice	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Introduction of an automatic optical inspection for the blister packaging of ICD lead families and updates to visual inspection criteria.
P980035/S743	04/12/2023	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implement an automated process monitoring station for the burn-in test system used during medium rate battery manufacturing at MECC.
P980035/S744	04/26/2023	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Modify the tooling and associated recipe software for the optical measurement system, which is used to verify that dimensions are within specification during printed circuit board (PCB) manufacturing.
P980040/S158	04/20/2023	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Use an alternate supplier for the handpiece of the TECNIS Simplicity Delivery System.

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P990004/S057	04/26/2023	X - 30-Day Notice	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Bioburden sample size reduction and the introduction of an upper control limit for in-process bioburden testing.
P010014/S104	04/06/2023	X - 30-Day Notice	OXFORD(TM) MENISCAL UNICOMPARTMENTAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Introduction of alternative manufacturing materials that are used in Non-Destructive Testing (NDT), specifically the Fluorescent Penetrant Inspection (FPI) on the castings of Oxford Partial Knee tibial tray and twin peg femoral components.
P010015/S516	04/07/2023	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implement a new test method to make the ICR/Nail Head Pin (FALW) weld rework criterion measurable and to update the WI for clarification.
P010015/S517	04/12/2023	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implement an automated process monitoring station for the burn-in test system used during medium rate battery manufacturing at MECC.
P010029/S032	04/25/2023	X - 30-Day Notice	EUFLEXXA (1% SODIUM HYALURONATE)	FERRING PHARMACEUTICALS, INC.	Alternative pressure set point during the fermentation process.
P010029/S033	04/26/2023	X - 30-Day Notice	EUFLEXXA (1% SODIUM HYALURONATE)	FERRING PHARMACEUTICALS, INC.	Modifications to the ultrafiltration system in the manufacturing process.
P010031/S817	04/12/2023	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Use a drop in replacement Hall sensor integrated circuit.
P010031/S819	04/12/2023	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement an optical vision measurement system at a supplier of shield assembly components.
P010032/S196	04/07/2023	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Utilize alternate suppliers for the resistor and capacitor components used in the Orion family of Implantable Pulse Generators.
P020025/S138	04/27/2023	X - 30-Day Notice	EP TECHNOLOGIES EPT-1000 XP RF ABLATION SYSTEM	BOSTON SCIENTIFIC	Use of parametric release and an alternate process challenge device for the BSC2019 ethylene oxide sterilization cycle at the Steris AST Costa Rica Facility.
P050037/S123	04/26/2023	X - 30-Day Notice	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Change in Autoclave Rack Design for Sterilization of Merz North America Medical Devices
P050052/S145	04/26/2023	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Change in Autoclave Rack Design for Sterilization of Merz North America Medical Devices
P060037/S083	04/06/2023	X - 30-Day Notice	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Additional supplier of compression molded UHMWPE (conventional Ultra High Molecular Weight Polyethylene (UHMWPE) or Prolong® crosslinked UHMWPE) bar stock and removal of morphology test from receiving inspection of the bar stock.

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P060040/S092	04/29/2023	X - 30-Day Notice	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Implement a supplier facility relocation for the User Interface (UI) Membrane component of the HeartMate II System Controller and HeartMate 3 System Controller.
P070008/S148	04/04/2023	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.	Introduction of an automatic optical inspection for the blister packaging of ICD lead families and updates to visual inspection criteria.
P080025/S274	04/04/2023	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Update to the inspection test method of a component from an external supplier.
P100030/S017	04/28/2023	X - 30-Day Notice	ARTERX SURGICAL SEALANT	BAXTER HEALTHCARE CORPORATION	Alternative bacterial endotoxin testing methods for the Preveleak Surgical Sealant.
P100047/S209	04/26/2023	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Move the charging process and storage of the HVAD Monitors from Arrow Electronics to Medtronics Miami Lakes Facility. The address of the facility is the current approved location: HeartWare, Inc. 14400 NW 60th Ave. Miami Lakes, FL33014
P110010/S210	04/10/2023	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Additional manufacturing line to increase production of a piece that protects the final finished device during shipping and handling prior to use.
P120006/S042	04/07/2023	X - 30-Day Notice	OVATION ABDOMINAL STENT GRAFT SYSTEM	ENDOLOGIX, LLC	Implementation of upgraded sterilization equipment, CR2 manufactured by Mevex, for sterilization of the Autoinjector 2 component of the Alto Abdominal Stent Graft System.
P130014/S017	04/05/2023	X - 30-Day Notice	ADHERUS AUTOSPRAY DURAL SEALANT	HYPERBRANCH MEDICAL TECHNOLOGY, INC.	Removal of tetrahydrofuran (THF) as a processing aid during the first synthetic step of Polyethylene glycol3400 succinimidyl sebacate (PEG SB-1).
P130021/S133	04/26/2023	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Change to a sub-tier supplier for the EnVeo PRO, Evolut PRO+, and Evolut FX Loading Systems.
P130021/S134	04/25/2023	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Introduce an alternative injection molder in the manufacturing process of the Evolut FX Stability Member subassembly of the Delivery Catheter System (DCS).
P130021/S135	04/13/2023	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Introduce testing in anaerobic conditions to the bioburden testing conducted prior to sterilization.
P130021/S136	04/19/2023	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Alternative supplier of a raw material used in the manufacture of the tip on the inner member to middle member shaft sub-assembly.
P130021/S137	04/28/2023	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Implement the use of the Transcatheter Aortic Valve Implantation Solutions Display system for tracking of solution expiration dates.
P140002/S024	04/13/2023	X - 30-Day Notice	MISAGO PERIPHERAL SELF-EXPANDING STENT SYSTEM	TERUMO MEDICAL CORPORATION	Addition of an alternate facility for a nitinol tubing supplier.

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P140002/S025	04/07/2023	X - 30-Day Notice	MISAGO PERIPHERAL SELF-EXPANDING STENT SYSTEM	TERUMO MEDICAL CORPORATION	Change in drying method during the manufacturing of the stent.
P140003/S109	04/13/2023	X - 30-Day Notice	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Implement an updated supply chain for the motor assembly magnet of Impella CP with SmartAssist.
P140009/S082	04/07/2023	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Utilize alternate suppliers for the resistor and capacitor components used in the Orion family of Implantable Pulse Generators.
P140019/S008	04/26/2023	X - 30-Day Notice	I-FACTOR PEPTIDE ENHANCED BONE GRAFT	CERAPEDICS, LLC	Change to the manufacturing process for i-FACTOR® Bone Graft to allow for in-house limulus amebocyte lysate (LAL) testing.
P140031/S155	04/26/2023	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Reduction of EO residual aeration time for the Commander delivery system.
P150003/S094	04/10/2023	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Additional manufacturing line to increase production of a piece that protects the final finished device during shipping and handling prior to use.
P150004/S059	04/07/2023	X - 30-Day Notice	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Utilize alternate suppliers for the resistor and capacitor components used in the Orion family of Implantable Pulse Generators.
P150005/S075	04/27/2023	X - 30-Day Notice	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Use of parametric release and an alternate process challenge device for the BSC2019 ethylene oxide sterilization cycle at the Steris AST Costa Rica Facility.
P150033/S167	04/12/2023	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Implement an automated process monitoring station for the burn-in test system used during medium rate battery manufacturing at MECC.
P150036/S069	04/27/2023	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Transfer of receiving inspection activities for non-biological pericardial valve components from the Edwards Irvine facility to the Edwards Singapore facility.
P150048/S071	04/27/2023	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Transfer of receiving inspection activities for non-biological pericardial valve components from the Edwards Irvine facility to the Edwards Singapore facility.
P160012/S007	04/18/2023	X - 30-Day Notice	LIFEPAK CR® PLUS DEFIBRILLATOR, LIFEPAK EXPRESS® DEFIBRILLATOR, AND CHARGE-PAK® BATTERY CHARGER	PHYSIO-CONTROL. INC.	Temperature monitoring controls and a reaction plan when storage temperatures are out of specification.
P160021/S038	04/24/2023	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Expansion of manufacturing space for the endoprosthesis at the Kendrick Peak facility.

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P160026/S038	04/18/2023	X - 30-Day Notice	LIFEPAK 1000 DEFIBRILLATOR, LIFEPAK 20 DEFIBRILLATOR/ MONITOR, LIFEPAK 20E DEFIBRILLATOR/ MONITOR, LIFEPAK 15 MONITOR/DEFIBRILLATOR, LIFEPAK 12 DEFIBRILLATOR/ MONITOR	PHYSIO-CONTROL. INC.	Temperature monitoring controls and a reaction plan when storage temperatures are out of specification.
P160043/S067	04/18/2023	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Additional method used in the UPLC testing of BHT.
P160054/S054	04/29/2023	X - 30-Day Notice	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Implement a supplier facility relocation for the User Interface (UI) Membrane component of the HeartMate II System Controller and HeartMate 3 System Controller.
P170002/S027	04/27/2023	X - 30-Day Notice	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Implementation of new UV spectrophotometer to improve the manufacturing processes for the RHA® Redensity, RHA®2, RHA®3, RHA®4 Dermal Fillers.
P170002/S028	04/27/2023	X - 30-Day Notice	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Addition of activated carbon filters to improve the manufacturing processes for the RHA® Redensity¿, RHA®2, RHA®3, and RHA®4 Dermal Fillers
P170002/S029	04/14/2023	X - 30-Day Notice	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Changes to the manufacturing process to support increased batch production.
P170023/S014	04/19/2023	X - 30-Day Notice	BULKAMID URETHRAL BULKING SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Manufacturing change to the Bulkamid needle hub component by a secondary supplier.
P170034/S009	04/26/2023	X - 30-Day Notice	HYDRUS MICROSTENT	IVANTIS, INC. WHOLLY-OWNED SUBSIDIARY OF ALCON RESEARCH, LLC	Modified in-process cleaning procedures for the Side Interlock Rack Subassembly, Alignment Tube, and Cannula Hub Assembly components of the delivery system.
P180035/S017	04/24/2023	X - 30-Day Notice	MISIGHT 1 DAY (OMAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES FOR DAILY WEAR	COOPERVISION, INC.	Manufacture of MiSight 1 Day (omafilcon A) product on Dry Line HF and Wet Line HVF at the Warrior Close manufacturing facility in Chandlers Ford, Eastleigh, UK.
P180046/S067	04/04/2023	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Change in inspection process of the Axonics IPG (models 1101 and 5101) to remove the weight inspection from the current inspection process.
P190002/S016	04/04/2023	X - 30-Day Notice	SALUDA MEDICAL EVOKE SCS SYSTEM	SALUDA MEDICAL PTY LTD	Move a Printed Circuit Board (PCB) reflow process used to manufacture the Evoke Intraoperative Cable and Lead Adapter from the Artarmon facility to the Macquarie Park facility and to change the legal address on all labeling from Artarmon to Macquarie Park.

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P190006/S067	04/04/2023	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Change in inspection process of the Axonics IPG (models 1101 and 5101) to remove the weight inspection from the current inspection process.
P190019/S019	04/10/2023	X - 30-Day Notice	RANGER¿ PACLITAXEL-COATED PTA BALLOON CATHETER	BOSTON SCIENTIFIC CORPORATION	Additional manufacturing line to increase production of a piece that protects the final finished device during shipping and handling prior to use.
P190019/S020	04/18/2023	X - 30-Day Notice	RANGER¿ PACLITAXEL-COATED PTA BALLOON CATHETER	BOSTON SCIENTIFIC CORPORATION	Expansion of an existing cleanroom at the Hemoteq AG contract manufacturing facility.
P190023/S014	04/26/2023	X - 30-Day Notice	PORTICO TRANSCATHETER AORTIC VALVE IMPLANTATION SYSTEM	ABBOTT MEDICAL	Layout and capacity changes to several Controlled Access Environments (CAEs) to support increased production processes.
P200015/S037	04/26/2023	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Reduction of EO residual aeration time for the Commander delivery system.
P200023/S005	04/10/2023	X - 30-Day Notice	ZILVER VENA VENOUS SELF-EXPANDING STENT	COOK IRELAND LTD.	Update the stent cleaning and electropolishing workstation and cleaning agent.
P210020/S008	04/25/2023	X - 30-Day Notice	OPTILUME URETHRAL DRUG COATED BALLOON	UROTRONIC, INC.	Changes to balloon catheter hub bonding process, acceptable quality level for receiving inspection, and leak test maximum delivered pressure.

Total: 83