PMA Monthly approvals from 12/1/2022 to 12/31/2022

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P210040	12/12/2022	PMAO - PMA Origi	RESOLUTION CTDX FIRST	RESOLUTION BIOSCIENCE, INC.	Approval for the Agilent Resolution ctDx FIRST assay. The device is a qualitative next generation sequencing-based, in vitro diagnostic test that uses targeted hybrid-capture sequencing technology to detect and report single nucleotide variants (SNVs) and deletions in two genes. The Agilent Resolution ctDx FIRST assay utilizes circulating cell-free DNA (cfDNA) isolated from plasma of peripheral whole blood collected in Streck Cell-Free DNA Blood Collection Tubes (BCTs). The test is intended as a companion diagnostic to identify patients with non-small cell lung cancer (NSCLC) who may benefit from treatment with the targeted therapy listed in Table 1, in accordance with the approved therapeutic labeling. Table 1. Companion Diagnostic Indication Indication: Non-small cell lung cancer (NSCLC); Biomarker: KRAS G12C; Therapy: KRAZATI (adagrasib) A negative result from a plasma specimen does not assure that the patient¿s tumor is negative for genomic findings. Patients with NSCLC who are negative for the biomarker listed in Table 1 should be reflexed to tissue biopsy testing for Table 1 biomarker using an FDA-approved tumor tissue test, if feasible. Additionally, the test is intended to provide tumor mutation profiling for SNVs and deletions in the EGFR gene for use by qualified health care professionals in accordance with professional guidelines in oncology for patients with NSCLC. The test is for use with patients previously diagnosed with NSCLC and in conjunction with other laboratory and clinical findings. Genomic findings other than those listed in Table 1 are not prescriptive or conclusive for labeled use of any specific therapeutic product. The Agilent Resolution ctDx FIRST assay is a single-site assay performed at Resolution Bioscience, Inc.

Total: 1

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S277	12/20/2022	N - Normal 180 Day	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Approval for hardware and software changes to the LATITUDE NXT Patient Management System Communicator (Models 6280/6498 and 6290) required for the removal of the telephone modem (POTS plain old telephone service).
N970003/S278	12/12/2022	R - Real-Time Proc	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Approval for a supplier site change and the addition of the antioxidant Butylated Hydroxytoluene to a material used in core assemblies for pulse generators.
N970003/S280	12/12/2022	R - Real-Time Proc	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Approval for modifications to the product labeling for the Accolade family of pacemakers and cardiac resynchronization therapy pacemakers to provide additional clarity.
P830055/S264	12/07/2022	Y - 135 Review Tra	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for the change in coolant/lubricant formulation which is used in the manufacturing process of knee components from the LCS® Total Knee System.
P840024/S093	12/06/2022	R - Real-Time Proc	NUCLEUS MULTICHANNEL IMPLANTABLE HEARING PROSTHESI	COCHLEAR AMERICAS	Approval for the Cochlear Nucleus® MRI Kit, an accessory, together with associated labeling changes, to allow certain Nucleus implant recipients to undergo MRI scans at 1.5 T with the implant magnet in place.
P850048/S057	12/16/2022	R - Real-Time Proc	TANDEM-R PSA IMMUNORADIOMETRIC ASSAY	BECKMAN COULTER, INC.	Approval for a modification to the UniCel DxI Immunoassay system¿s sample probe and reagent probe wash nozzle design using injection molding to reduce production cost.
P890017/S023	12/20/2022	R - Real-Time Proc	PALMAZ BALLOON EXPANDABLE STENT	CORDIS US CORPORATIO N	Approval to remove references to obsoleted accessory devices and add instructions for unaided manual crimping of the stent implant to a stent delivery system (i.e., balloon catheter) in the Instructions For Use (IFU) document.
P890027/S061	12/06/2022	R - Real-Time Proc	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT SYS / CHILDREN	COCHLEAR AMERICAS	Approval for the Cochlear Nucleus® MRI Kit, an accessory, together with associated labeling changes, to allow certain Nucleus implant recipients to undergo MRI scans at 1.5 T with the implant magnet in place.
P910077/S188	12/20/2022	N - Normal 180 Day	VENTAK(R) PRX (TM) MODEL 1700,1705 PULSE GENERATOR	BOSTON SCIENTIFIC	Approval for hardware and software changes to the LATITUDE NXT Patient Management System Communicator (Models 6280/6498 and 6290) required for the removal of the telephone modem (POTS plain old telephone service).
P950037/S240	12/02/2022	R - Real-Time Proc	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Approval for the use of the DataBridge 4G/LTE adapter with the Renamic Programmer.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960030/S077	12/07/2022	R - Real-Time Proc	PASSIVE PLUS DX ENDOCARDIAL STEROID ELUTING, PASSIVE-FIXATION PACING LEADS	ABBOTT MEDICAL	Approval for MR Conditional labeling for IsoFlex pacing leads when combined with the Assurity MRI and Endurity MRI single and dual chamber implantable pulse generators.
P960040/S483	12/20/2022	N - Normal 180 Day	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Approval for hardware and software changes to the LATITUDE NXT Patient Management System Communicator (Models 6280/6498 and 6290) required for the removal of the telephone modem (POTS plain old telephone service).
P960040/S484	12/12/2022	R - Real-Time Proc	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Approval for modifications to the product labeling for the Accolade family of pacemakers and cardiac resynchronization therapy pacemakers to provide additional clarity.
P970038/S045	12/16/2022	R - Real-Time Proc	TANDEM-R FREE PSA IMMUNORADIOMETRIC ASSAY/TANDEM-MP FREE PSA IMMUNOENZYMETRIC ASSAY	BECKMAN COULTER, INC.	Approval for a modification to the UniCel DxI Immunoassay system¿s sample probe and reagent probe wash nozzle design using injection molding to reduce production cost
P970051/S214	12/06/2022	R - Real-Time Proc	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for the Cochlear Nucleus® MRI Kit, an accessory, together with associated labeling changes, to allow certain Nucleus implant recipients to undergo MRI scans at 1.5 T with the implant magnet in place.
P970051/S216	12/15/2022	O - Normal 180 Da	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval of the revised protocol for the post-approval study (PAS) protocol.
P980041/S050	12/16/2022	R - Real-Time Proc	ACCESS AFP IMMUNOASSAY SYSTEM	BECKMAN COULTER, INC.	Approval for a modification to the UniCel DxI Immunoassay systems sample probe and reagent probe wash nozzle design using injection molding to reduce production cost.
P990004/S055	12/21/2022	Y - 135 Review Tra	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Approval for an additional sterilization chamber to be used for Gamma irradiation at the current Gamma sterilization site
P990074/S050	12/29/2022	R - Real-Time Proc	NATRELLE SALINE BREAST IMPLANTS	ALLERGAN	Approval for modifications to Physician and Patient Labeling.
P000015/S048	12/06/2022	R - Real-Time Proc	NUCLEUS 24 AUDITORY BRAINSTEM IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for the Cochlear Nucleus® MRI Kit, an accessory, together with associated labeling changes, to allow certain Nucleus implant recipients to undergo MRI scans at 1.5 T with the implant magnet in place.
P010012/S559	12/20/2022	N - Normal 180 Day	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Approval for hardware and software changes to the LATITUDE NXT Patient Management System Communicator (Models 6280/6498 and 6290) required for the removal of the telephone modem (POTS plain old telephone service).

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P010012/S560	12/12/2022	R - Real-Time Proc	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Approval for modifications to the product labeling for the Accolade family of pacemakers and cardiac resynchronization therapy pacemakers to provide additional clarity.
P010013/S089	12/01/2022	S - Special CBE	NOVASURE IMPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM	HOLOGIC, INC.	Approval for the inclusion of updated language to a contraindication in the device instructions for use.
P010032/S186	12/16/2022	N - Normal 180 Day	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Approval for approval for commercial distribution of Abbotts Eterna Spinal Cord Stimulation (SCS) System. This system consists of a rechargeable Implantable Pulse Generator (IPG), Charging System, and Clinician Programmer Application and Patient Controller Application. These components are intended to be used with commercially available SCS leads, extensions and accessories.
P020056/S059	12/29/2022	R - Real-Time Proc	NATRELLE SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Approval for modifications to Physician and Patient Labeling.
P030005/S222	12/20/2022	N - Normal 180 Day	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Approval for hardware and software changes to the LATITUDE NXT Patient Management System Communicator (Models 6280/6498 and 6290) required for the removal of the telephone modem (POTS plain old telephone service).
P030005/S223	12/12/2022	R - Real-Time Proc	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Approval for modifications to the product labeling for the Accolade family of pacemakers and cardiac resynchronization therapy pacemakers to provide additional clarity.
P030005/S225	12/12/2022	R - Real-Time Proc	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Approval for modifications to the product labeling for the Accolade family of pacemakers and cardiac resynchronization therapy pacemakers to provide additional clarity.
P040002/S070	12/06/2022	N - Normal 180 Day	ENDOLOGIX POWERLINK SYSTEM	ENDOLOGIX, LLC	Approval for the updates to the AFX2 Endovascular AAA System labeling (i.e., Instructions For Use (IFU), patient guide, and implant card).
P040014/S047	12/16/2022	O - Normal 180 Da	IBI THERAPY CARDIAC ABLATION SYSTEM ERS/ 1500T RF GENERATOR	IRVINE BIOMEDICAL, INC.	Approval for Sterigenics Utah as an alternate EO sterilization vendor for Irvine EP cables.
P040024/S132	12/20/2022	N - Normal 180 Day	RESTYLANE INJECTABLE GEL	Q-MED AB	Approval for the addition of lidocaine hydrochloride from a new manufacturing site of the lidocaine hydrochloride supplier.
P040024/S136	12/23/2022	S - Special CBE	RESTYLANE INJECTABLE GEL	Q-MED AB	Approval for revisions to the clinician labeling and patient labeling of Restylane® Silk Injectable Gel as a result of postmarket surveillance data.

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P040042/S053	12/16/2022	O - Normal 180 Da	THERAPY DUAL 8 CARDIAC ABLATION SYSTEM,THERAM 8MM THERMISTER ABLATION CATHETER SAFIRE TX ABLATION CATHETER	IRVINE BIOMEDICAL,INC.(IBI)	Approval for Sterigenics Utah as an alternate EO sterilization vendor for Irvine EP cables.
P050006/S104	12/15/2022	S - Special CBE	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Approval for minor modifications to the instructions for use and labeling to align with ISO 4971:2019 and to update the device storage conditions.
P090026/S031	12/16/2022	R - Real-Time Proc	ACCESS HYBRITECH P2PSA ON THE ACCESS IMMUNOASSAY SYSTEMS	BECKMAN COULTER, INC.	Approval for a modification to the UniCel DxI Immunoassay system¿s sample probe and reagent probe wash nozzle design using injection molding to reduce production cost.
P100026/S091	12/29/2022	O - Normal 180 Da	NEUROPACE RNS SYSTEM	NEUROPACE INC	Approval to use a second contract sterilizer for the ethylene oxide (EO) sterilization of RNS System products.
P110016/S080	12/14/2022	P - Panel Track	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ABBOTT MEDICAL	Approval for expanding the indications to include the treatment of ventricular tachycardia to the current approved device indication for use.
P110027/S013	12/12/2022	N - Normal 180 Day	THERASCREEN KRAS RGQ PCR KIT	QIAGEN GMBH	Approval for expanding the indication to aid in the identification of non-small cell lung cancer patients whose tumors harbor KRAS G12C mutations and may benefit from treatment with KRAZATI (adagrasib).
P110042/S173	12/20/2022	N - Normal 180 Day	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for hardware and software changes to the LATITUDE NXT Patient Management System Communicator (Models 6280/6498 and 6290) required for the removal of the telephone modem (POTS plain old telephone service).
P110042/S174	12/12/2022	R - Real-Time Proc	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for modifications to the product labeling for the Accolade family of pacemakers and cardiac resynchronization therapy pacemakers to provide additional clarity.
P120020/S029	12/20/2022	R - Real-Time Proc	SUPERA PERIPHERAL STENT SYSTEM	ABBOTT VASCULAR (IDEF TECHNOLOGIES INC)	Approval for modification to the packaging pouch.

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P130008/S093	12/16/2022	O - Normal 180 Da	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval for the Inspire® Upper Airway Stimulation (UAS). The device is indicated for use to treat a subset of patients with moderate to severe obstructive sleep apnea (OSA) (apnea-hypopnea index [AHI] of greater than or equal to 15 and less than or equal to 65). Inspire® UAS is used in adult patients 22 years of age and older who have been confirmed to fail or cannot tolerate positive airway pressure (PAP) treatments (such as continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BPAP] machines) and who do not have a complete concentric collapse at the soft palate level. PAP failure is defined as an inability to eliminate OSA (AHI of greater than 15 despite PAP usage), and PAP intolerance is defined as: 1) Inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of use per night); or 2) Unwillingness to use PAP (for example, a patient returns the PAP system after attempting to use it). Inspire® UAS is also indicated for use in patients between the ages of 18 and 21with moderate to severe OSA (15 AHI65) who: 1) Do not have complete concentric collapse at the soft palate level; 2) Are contraindicated for, or not effectively treated by, adenotonsillectomy; 3) Have been confirmed to fail, or cannot tolerate, PAP therapy despite attempts to improve compliance; and 4) Have followed standard of care in considering all other alternative/adjunct therapies.
P130012/S010	12/12/2022	Y - 135 Review Tra	MYOPORE SUTURELESS MYOCARDIAL PACING LEAD	GREATBATCH MEDICAL	Approval for a supplier site change and subsequent manufacturing process changes.
P130016/S051	12/06/2022	R - Real-Time Proc	NUCLEUS HYBRID L24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for the Cochlear Nucleus® MRI Kit, an accessory, together with associated labeling changes, to allow certain Nucleus implant recipients to undergo MRI scans at 1.5 T with the implant magnet in place.
P140029/S045	12/20/2022	N - Normal 180 Day	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Approval for the addition of lidocaine hydrochloride from a new manufacturing site of the lidocaine hydrochloride supplier.
P140029/S047	12/23/2022	S - Special CBE	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Approval for revisions to the clinician labeling and patient labeling of Restylane® Refyne Injectable Gel as a result of postmarket surveillance data.
P140033/S076	12/07/2022	R - Real-Time Proc	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ABBOTT MEDICAL	Approval for MR Conditional labeling for IsoFlex pacing leads when combined with the Assurity MRI and Endurity MRI single and dual chamber implantable pulse generators.
P150001/S094	12/16/2022	Y - 135 Review Tra	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	Approval for the addition of Medtronic Puerto Rico Operations Co. as a manufacturing site for the sensor fabrication process for the Guardian Sensor (3). The Guardian Sensor (3) is a component of the MiniMed 670G and 770G Systems, the Guardian Connect System, and the MiniMed 630G System.
P150001/S102	12/16/2022	S - Special CBE	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	Approval for adding supplemental labeling information to the current instructions for use (IFU) for the Medtronic MiniMed 630G, 670G, and 770G Pump Systems.
P150012/S131	12/20/2022	N - Normal 180 Day	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIE NTIFIC	Approval for hardware and software changes to the LATITUDE NXT Patient Management System Communicator (Models 6280/6498 and 6290) required for the removal of the telephone modem (POTS plain old telephone service).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150012/S132	12/12/2022	R - Real-Time Proc	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Approval for modifications to the product labeling for the Accolade family of pacemakers and cardiac resynchronization therapy pacemakers to provide additional clarity.
P150012/S134	12/12/2022	R - Real-Time Proc	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Approval for modifications to the product labeling for the Accolade family of pacemakers and cardiac resynchronization therapy pacemakers to provide additional clarity.
P150038/S022	12/08/2022	N - Normal 180 Day	EXABLATE	INSIGHTEC	Approval for labeling changes to the indications for use of the device in idiopathic Essential tremor patients with medication-refractory tremor.
P150048/S060	12/29/2022	O - Normal 180 Da	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Approval for a manufacturing site located at 35 Changi North Crescent, Changi, Singapore, 499641 for RESILIA/GLX processing and final packaging of the INSPIRIS RESILIA Aortic Valves, as well as an alternate ethylene oxide sterilization site at Sterile Services Singapore, 47 Jaran Buroh Unit #01-01, Singapore South West, Singapore 619491.
P160007/S043	12/16/2022	Y - 135 Review Tra	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Approval for the addition of Medtronic Puerto Rico Operations Co. as a manufacturing site for the sensor fabrication process for the Guardian Sensor (3). The Guardian Sensor (3) is a component of the MiniMed 670G and 770G Systems, the Guardian Connect System, and the MiniMed 630G System.
P160017/S096	12/16/2022	Y - 135 Review Tra	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval for the addition of Medtronic Puerto Rico Operations Co. as a manufacturing site for the sensor fabrication process for the Guardian Sensor (3). The Guardian Sensor (3) is a component of the MiniMed 670G and 770G Systems, the Guardian Connect System, and the MiniMed 630G System.
P160017/S106	12/16/2022	S - Special CBE	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval for adding supplemental labeling information to the current instructions for use (IFU) for the Medtronic MiniMed 630G, 670G, and 770G Pump Systems.
P160022/S014	12/20/2022	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 Cable; 2) ZOLL ® X Series Multifunction Therapy Cable; 3) ZOLL ® Propaq MD Multifunction Cable; 4) ZOLL ® X Series OneStep Cable; 5) ZOLL ® Multifunction Therapy Cable with CPR-D Connector; 6) ZOLL ® Pro-padz ® Sterile Electrodes; 7) ZOLL ® Stat-padz ® Electrodes; 8) ZOLL ® Stat-padz ® Deployment Readiness Pack Electrodes; 9) ZOLL ® Pedi-padz ® Electrodes; 10) ZOLL ® Pedi-padz ® II Electrodes; and 11) ZOLL ® Stat-padz ® II Electrodes.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160022/S016	12/19/2022	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 CORPORATIO N	Approval for the following ZOLL automated external defibrillator (AED) accessories: ZOLL® Pedi-padz® Liquid Gel Electrodes, ZOLL® Adult Liquid Gel Electrodes, ZOLL® Pro-padz® Radiolucent Liquid Gel Electrodes, ZOLL® Pro-padz® Radiolucent Electrodes, ZOLL® Pedi-padz® Radiolucent Electrodes, ZOLL® CPR-D-padz® Electrodes, ZOLL® CPR Stat-padz® Electrodes, ZOLL® CPR Dura-padz® Reusable Electrodes.
P160041/S035	12/14/2022	N - Normal 180 Day	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Approval for the cobas CMV migration from cobas 6800/8800 to the cobas 5800.
P160053/S002	12/06/2022	P - Panel Track	MAGTRACETM AND SENTIMAG(R) MAGNETIC LOCATIZATION SYSTEM	ENDOMAGNE TICS LTD.	Approved to assist in localizing lymph nodes draining a tumor site, as part of a sentinel lymph node biopsy procedure, in patients with breast cancer undergoing a mastectomy or lumpectomy. For patients undergoing lumpectomy, nipple sparing, nipple areolar sparing or skin sparing procedures, Magtrace is indicated to be injected only peritumorally.
P170011/S047	12/05/2022	O - Normal 180 Da	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval for various modifications to the Instructions for Use to add the final results of Post-Approval Study (PAS) #1, Impella RP Real-World Evidence Evaluation and Periodic Reporting, ordered in our September 20, 2017, letter and to update the indications for use statement based on the PAS results.
P170013/S010	12/09/2022	O - Normal 180 Da	LOW-PROFILE VISUALIZED INTRALUMINAL SUPPORT (LVIS) AND LVIS JR.	MICROVENTI ON, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P170041/S006	12/01/2022	N - Normal 180 Day	ABBOTT REALTIME IDH1	ABBOTT MOLECULAR, INC.	Approval to expand the indications for use of the Abbott RealTime IDH1 Assay to include a companion diagnostic indication for the detection of isocitrate dehydrogenase-1 (IDH1) mutations in patients with acute myeloid leukemia (AML) who may benefit from treatment with REZLIDHIA (olutasidenib).
P180035/S012	12/07/2022	O - Normal 180 Da	MISIGHT 1 DAY (OMAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES FOR DAILY WEAR	COOPERVISIO N, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P180036/S013	12/02/2022	N - Normal 180 Day	OPTIMIZER SMART SYSTEM	IMPULSE DYNAMICS (USA), INC.	Approval for changes made to the GUARDIO Charger as well as other related changes to device components to accommodate its use with the OPTIhome system.
P180038/S013	12/21/2022	R - Real-Time Proc	LIAISON XL MUREX ANTI-HBC, LIAISON MUREX CONTROL ANTI-HBC	DIASORIN INC.	Approval for software version 4.2.3.2 on the LIAISON XL analyzer.

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P180039/S012	12/21/2022	R - Real-Time Proc	LIAISON® XL MUREX ANTI-HBS, LIAISON® XL MUREX CONTROL ANTI-HBS AND LIAISON® XL MUREX ANTI-HBS VERIFIERS	DIASORIN INC.	Approval for software version 4.2.3.2 on the LIAISON XL analyzer.
P180045/S010	12/21/2022	R - Real-Time Proc	LIAISON® XL MUREX HBC IGM, LIAISON® XL MUREX CONTROL HBC IGM	DIASORIN INC.	Approval for software version 4.2.3.2 on the LIAISON XL analyzer.
P180046/S062	12/19/2022	N - Normal 180 Day	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for updated labeling information
P180047/S020	12/21/2022	R - Real-Time Proc	LIAISON QUANTIFERON - TB GOLD PLUS, LIAISON CONTROL QUANTIFERON - TB GOLD PLUS AND LIAISON QUANTIFERON SOFTWARE	DIASORIN, INC.	Approval for software version 4.2.3.2 on the LIAISON XL analyzer.
P180048/S010	12/21/2022	R - Real-Time Proc	LIAISON® XL MUREX HBEAG, LIAISON® XL MUREX CONTROL HBEAG	DIASORIN INC.	Approval for software version 4.2.3.2 on the LIAISON XL analyzer.
P180049/S010	12/21/2022	R - Real-Time Proc	LIAISON® XL MUREX ANTI-HBE, LIAISON® XL MUREX CONTROL ANTI-HBE	DIASORIN INC.	Approval for software version 4.2.3.2 on the LIAISON XL analyzer.
P190002/S013	12/15/2022	R - Real-Time Proc	SALUDA MEDICAL EVOKE SCS SYSTEM	SALUDA MEDICAL PTY LTD	Approval for design changes to the set screw and set screw block components of the lead extension, including an increase in set screw block inner diameter, increase in thread size of the set screw and set screw block hole, and other minor changes in geometry.
P190002/S015	12/29/2022	R - Real-Time Proc	SALUDA MEDICAL EVOKE SCS SYSTEM	SALUDA MEDICAL PTY LTD	Approval for software and firmware changes to the Clinical Programming Application (CPA) and Clinical Data Viewer (CDV) intended to simplify the clinical software, improve usability and user interface during programming, and improve traceability. Labeling changes were also proposed to modify the instructions for use based on the software and firmware changes.
P190006/S062	12/19/2022	N - Normal 180 Day	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for updated labeling information.
P190016/S006	12/15/2022	R - Real-Time Proc	TULA® SYSTEM	TUSKER MEDICAL, INC.	Approval for a design modification to the firmware of the Iontophoresis Control Unit component of the Tula System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190017/S008	12/21/2022	R - Real-Time Proc	LIAISON® XL MUREX HBSAG QUAL, LIAISON® MUREX CONTROL HBSAG, AND LIAISON® XL MUREX HBSAG CONFIRMATORY TEST	DIASORIN INC	Approval for software version 4.2.3.2 on the LIAISON XL analyzer.
P190032/S004	12/22/2022	P - Panel Track	FOUNDATIONONE LIQUID CDX (F1 LIQUID CDX)	FOUNDATION MEDICINE INC.	Approval to include a companion diagnostic indication for NTRK1, NTRK2, and NTRK3 fusions in patients with solid tumors and for ROS1 fusions in patients with non-small cell lung cancer who may benefit from treatment with ROZLYTREK® (entrectinib).
P190032/S008	12/19/2022	R - Real-Time Proc	FOUNDATIONONE LIQUID CDX (F1 LIQUID CDX)	FOUNDATION MEDICINE INC.	Approval for FoundationOne® Liquid CDx (FILCDx) label expansion to obtain companion diagnostic group labeling claim for patients with non-small cell lung cancer harboring EGFR exon 19 deletions or EGFR exon 21 L858R mutations for treatment with any one of the FDA-approved EGFR Tyrosine Kinase Inhibitors (TKI).
P200002/S004	12/27/2022	N - Normal 180 Day	EPI-SENSE GUIDED COAGULATION SYSTEM	ATRICURE, INC.	Approval for the Multifunctional Ablation Generator (MAG) as part of the EPi-Sense® and EPi-Sense ST Guided Coagulation System (EPi-Sense).
P200013/S011	12/22/2022	S - Special CBE	ALINITY M HBV	ABBOTT MOLECULAR, INC.	Approval for addition to Limitations of the Procedure: Unexpected HBV DNA levels due to carry over may occur. If results are inconsistent with patient history and other diagnostics through patient monitoring, a retest of the sample should be considered by the physician or healthcare provider. Approval is also for the following change to the Specific Performance Characteristic ¿ Carryover section: The carryover rate for Alinity m HBV was determined in two studies. Study 1 evaluated the carryover rate in the Sample Input Rack and Sample Processing Unit by analyzing 360 valid replicates of HBV negative samples processed from alternating positions in the sample input rack with 360 valid replicates of high concentrated HBV positive samples at 100,000,000 IU/mL, across multiple runs. HBV DNA was not detected in any of the HBV negative samples, resulting in a carryover rate of 0% (95% CI: 0.0 to 1.1%). Study 2 evaluated the carryover rate in the AMP tray by evaluating 414 valid replicates of HBV negative samples processed from alternating positions at the AMP Tray with 414 valid replicates of high concentrated HBV positive samples at 100,000,000 IU/mL across multiple runs. HBV DNA was detected in 16 of the HBV negative samples resulting in a carryover rate of 3.9% (95% CI: 2.2 to 6.2%).
P200028/S013	12/13/2022	R - Real-Time Proc	DIAMONDTEMP ABLATION SYSTEM	MEDTRONIC INC.	Approval for the release of a Universal Serial Bus (USB) tool to upgrade commercially distributed Radiofrequency (RF) Generator (CEDTG200) units from software V1.31 to V1.41.
P200029/S004	12/02/2022	O - Normal 180 Da	THERASPHERE	BOSTON SCIENTIFIC CORPORATION	Approval of the revised protocol for the post-approval study (PAS) protocol.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P200039/S008	12/13/2022	R - Real-Time Proc	SHOCKWAVE INTRAVASCULAR LITHOTRIPSY (IVL) SYSTEM WITH SHOCKWAVE C2 CORONARY INTRAVASCULAR LITHOTRIPSY (IVL) CATHETER	SHOCKWAVE MEDICAL, INC.	Approval for the addition of a sterile sleeve and labeling modifications, including an increase in the maximum pulse count from 80 to 120.
P200044/S001	12/28/2022	R - Real-Time Proc	LUNGFIT PH	BEYOND AIR, INC.	Approval for revised labeling to identify additional compatible ventilators
P210005/S003	12/23/2022	R - Real-Time Proc	IC-8 APTHERA INTRAOCULAR LENS (IOL)	ACUFOCUS, INC.	Approval for the extension of the expiration dating on product labeling from 6 months to 12 months, and proposed modifications to the protocols for your respective ongoing accelerated and real-time shelf life studies.
P210005/S004	12/02/2022	O - Normal 180 Da	IC-8 APTHERA INTRAOCULAR LENS (IOL)	ACUFOCUS, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P210019/S001	12/20/2022	N - Normal 180 Day	ADVIA CENTAUR ANTI-HBC TOTAL (HBCT2) AND ATELLICA IM ANTI-HBC TOTAL (HBCT2)	SIEMENS HEALTHCARE DIAGNOSTICS , INC.	Approval for the use of the ADVIA Centaur Anti-HBc Total 2 (HBcT2) assay on the ADVIA Centaur CP.

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Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S096	12/20/2022	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Changes related to improvements to the splice detection, vision system, and reject mechanism of the Automated Foil Sealer Equipment (SL1099) used to seal the foil pouches at the ETHICON LLC, San Lorenzo, Puerto Rico manufacturing site.
N18033/S110	12/16/2022	X - 30-Day Notice	ACUVUE CONTACT LENS	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Alternate supplier for a raw material used in the production of lens molds for the manufacturing process of VISTAKON (etafilcon A) Brand Contact Lenses.

N970003/S281	12/14/2022	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Add a new cleanroom to the BSC-Clonmel manufacturing facility.
N970003/S282	12/20/2022	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Manufacture the accelerometer cover component of pulse generator devices.
Submission Number	**Date Final Decision**	**Review Track**	**Trade Name**	**Appl/Spr Name**	**Approval Order Statement**
P810006/S101	12/19/2022	X - 30-Day Notice	COLLASTAT	INTEGRA LIFESCIENCES CORPORATION	For the Environmental Monitoring Process Qualification of Room 307, at the Collagen Manufacturing Center (CMC) located at 105 Morgan Lane, Plainsboro, NJ 08536.
P840001/S534	12/08/2022	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Implementation of a validated test method for the incoming inspection of a component used at the Medtronic Energy and Component Center (MECC).
P850010/S104	12/19/2022	X - 30-Day Notice	HELISTAT(TM) ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	INTEGRA LIFESCIENCES CORPORATION	For the Environmental Monitoring Process Qualification of Room 307, at the Collagen Manufacturing Center (CMC) located at 105 Morgan Lane, Plainsboro, NJ 08536.
P860004/S402	12/02/2022	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Implement a new inspection method (Vision System) for the identification of laser welds.
P860004/S403	12/08/2022	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Implementation of a validated test method for the incoming inspection of a component used at the Medtronic Energy and Component Center (MECC).
P880047/S052	12/20/2022	X - 30-Day Notice	INTERCEED TC7 ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Changes related to improvements to the splice detection, vision system, and reject mechanism of the Automated Foil Sealer Equipment (SL1099) used to seal the foil pouches at the ETHICON LLC, San Lorenzo, Puerto Rico manufacturing site.
P880081/S047	12/06/2022	X - 30-Day Notice	UV ABSORBING SILICONE POSTERIOR CHAMBER INTRAOCULAR LENSES	JOHNSON & JOHNSON SURGICAL VISION, INC.	Adding an alternative supplier for the lens case assembly (LCA).
P900033/S103	12/07/2022	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Change to the Water for Injection distribution System located at the Collagen Manufacturing Center.
P910077/S190	12/14/2022	X - 30-Day Notice	VENTAK(R) PRX (TM) MODEL 1700,1705 PULSE GENERATOR	BOSTON SCIENTIFIC	Add an equivalent manufacturing line used for printed circuit assemblies for the LATITUDE Wave Communicator Model 6290.
P930014/S144	12/20/2022	X - 30-Day Notice	ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES	ALCON LABORATORIES, INC.	Change from two fixtures to a single fixture used for lens cleaning, extraction, vacuum drying and plasma treatment processes.

P950020/S132	12/07/2022	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Relocate manufacturing equipment from one cleanroom to another at the same manufacturing facility.
P950034/S055	12/22/2022	X - 30-Day Notice	SEPRAFILM(TM) (HAL-F (TM)) BIORESORBABLE MEMBRANE	BAXTER HEALTHCARE CORPORATION	Removal of an In-Process Control as part of the Seprafilm packaging process of counting films
P950037/S241	12/07/2022	X - 30-Day Notice	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Introduce an automatic optical inspection of the blister packaging for IPGs and ICDs.
Submission Number	**Date Final Decision**	**Review Track**	**Trade Name**	**Appl/Spr Name**	**Approval Order Statement**
P950037/S243	12/16/2022	X - 30-Day Notice	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Modify the process monitoring select ICD lead families to increase efficiency in the lead manufacturing process.
P960009/S444	12/08/2022	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Implementation of a validated test method for the incoming inspection of a component used at the Medtronic Energy and Component Center (MECC).
P960016/S089	12/08/2022	X - 30-Day Notice	LIVEWIRE(R) CARDIAC ABLATION SYSTEM	ST. JUDE MEDICAL	Alternate tier 3 supplier of resin for the FlexAbility/FlexAbility SE Ablation Catheters, TactiCath SE Ablation Catheter, Livewire TC Ablation Catheter, and Safire Ablation Catheter.
P960040/S488	12/14/2022	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Add a new cleanroom to the BSC-Clonmel manufacturing facility.
P960040/S489	12/20/2022	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Manufacture the accelerometer cover component of pulse generator devices.
P960043/S119	12/16/2022	X - 30-Day Notice	PROSTAR 9 FR. PERCUTANEOUS VASCULAR SURGICAL (PVS) SYSTEM	ABBOTT VASCULAR INC.	Implementation of a sustainable ethylene oxide (SEO) sterilization cycle ("soft" cycle) at the Synergy Health Ireland facility.
P970004/S378	12/08/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Implementation of a validated test method for the incoming inspection of a component used at the Medtronic Energy and Component Center (MECC).
P970051/S215	12/06/2022	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Additional printed circuit board (PCB) supplier.
P980023/S116	12/07/2022	X - 30-Day Notice	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Introduce an automatic optical inspection of the blister packaging for IPGs and ICDs.

P980023/S117	12/16/2022	X - 30-Day Notice	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Modify the process monitoring select ICD lead families to increase efficiency in the lead manufacturing process.
P980037/S089	12/07/2022	X - 30-Day Notice	ANGIOJET RHEOLYTIC THROMBECTOMY LF140 CATHETER	BOSTON SCIENTIFIC CORP.	Adding a new component supplier and changes to the existing incoming inspection method and criteria.
P980040/S153	12/06/2022	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Adding an alternative supplier for the lens case assembly (LCA).
Submission Number	**Date Final Decision**	**Review Track**	**Trade Name**	**Appl/Spr Name**	**Approval Order Statement**
P980040/S154	12/15/2022	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Changes to the torque testing of the preloaded IOL delivery systems of soft acrylic one-piece IOLs manufactured in Puerto Rico.
P980040/S155	12/12/2022	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Adding an alternate manufacturing and sterilization site at AMO Groningen B.V., Van Swietenlaan 5, Groningen, The Netherlands 9728NX for TECNIS Eyhance IOL with TECNIS Simplicity Delivery System, Model DIB00, and TECNIS Eyhance Toric II IOLs with TECNIS Simplicity Delivery System, Models DIU150-600.
P990080/S056	12/06/2022	X - 30-Day Notice	CEEON EDGE FOLDABLE ULTRAVIOLET LIGHT-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS, MODEL 911A	JOHNSON & JOHNSON SURGICAL VISION, INC.	Adding an alternative supplier for the lens case assembly (LCA).
P000006/S063	12/01/2022	X - 30-Day Notice	TITAN INFLATABLE PENILE PROSTHESIS	COLOPLAST CORP.	Manufacturing change to the cylinder bladder dipping and drying process.
P000009/S099	12/07/2022	X - 30-Day Notice	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Introduce an automatic optical inspection of the blister packaging for IPGs and ICDs.
P010012/S565	12/14/2022	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Add a new cleanroom to the BSC-Clonmel manufacturing facility.
P010012/S566	12/20/2022	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Manufacture the accelerometer cover component of pulse generator devices.
P020036/S047	12/07/2022	X - 30-Day Notice	S.M.A.R.T. AND S.M.A.R.T. CONTROL NITINOL STENT SYSTEM	CORDIS US CORPORATIO N	New polyimide supplier.

P020036/S048	12/16/2022	X - 30-Day Notice	S.M.A.R.T. AND S.M.A.R.T. CONTROL NITINOL STENT SYSTEM	CORDIS US CORPORATIO N	In-source polytetrafluorethylene (PTFE) component manufacturing.
P030005/S226	12/14/2022	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Add a new cleanroom to the BSC-Clonmel manufacturing facility.
P030005/S227	12/20/2022	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Manufacture the accelerometer cover component of pulse generator devices.
Submission Number	**Date Final Decision**	**Review Track**	**Trade Name**	**Appl/Spr Name**	**Approval Order Statement**
P030017/S353	12/19/2022	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Add two alternative Laser Welders, FiberStar (Model 7600), at the Boston Scientific Puerto Rico manufacturing site.
P030017/S355	12/17/2022	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Introduce an optional weld cycle (reweld) to the Weld Case and Feedthru Laser Weld Implantable Pulse Generators process step at your Clonmel Ireland manufacturing facility.
P030047/S045	12/07/2022	X - 30-Day Notice	CORDIS PRECISE NITINOL STENT SYSTEM	CORDIS US CORPORATIO N	New polyimide supplier.
P030047/S046	12/16/2022	X - 30-Day Notice	CORDIS PRECISE NITINOL STENT SYSTEM	CORDIS US CORPORATIO N	In-source polytetrafluorethylene (PTFE) component manufacturing.
P040020/S104	12/20/2022	X - 30-Day Notice	ACRYSOF RESTOR APODIZED DIFFRACTIVE OPTIC POSTERIOR CHAMBER IOL	ALCON RESEARCH, LTD.	Change from two fixtures to a single fixture used for lens cleaning, extraction, vacuum drying and plasma treatment processes.
P040021/S051	12/14/2022	X - 30-Day Notice	SJM BIOCOR VALVE / SJM BIOCOR SUPRA VALVE	ABBOTT MEDICAL	Modification to the test method used to verify sterilant, storage, and fixation solution concentrations.
P040037/S155	12/21/2022	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,I NC	Implementation of a new water purification system at the Kendrick Peak facility.
P040042/S054	12/08/2022	X - 30-Day Notice	THERAPY DUAL 8 CARDIAC ABLATION SYSTEM,THERAM 8MM THERMISTER ABLATION CATHETER SAFIRE TX ABLATION CATHETER	IRVINE BIOMEDICAL,I NC.(IBI)	Alternate tier 3 supplier of resin for the FlexAbility/FlexAbility SE Ablation Catheters, TactiCath SE Ablation Catheter, Livewire TC Ablation Catheter, and Safire Ablation Catheter.
P040045/S129	12/19/2022	X - 30-Day Notice	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Qualification of an additional flexible re-cartoning line used to repackage VISTAKON® (senofilcon A) Brand Contact Lenses.
P040047/S068	12/15/2022	X - 30-Day Notice	COAPTITE	MERZ NORTH AMERICA, INC	Update to Merz's cleaning procedure for washing cleanroom related items only.

P050006/S105	12/21/2022	X - 30-Day Notice	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Implementation of a new water purification system at the Kendrick Peak facility.
P050007/S042	12/16/2022	X - 30-Day Notice	STARCLOSE VASCULAR CLOSURE SYSTEM	ABBOTT VASCULAR DEVICES	Implementation of a sustainable ethylene oxide (SEO) sterilization cycle ("soft" cycle) at the Synergy Health Ireland facility.
P050023/S168	12/07/2022	X - 30-Day Notice	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Introduce an automatic optical inspection of the blister packaging for IPGs and ICDs.
P050037/S120	12/15/2022	X - 30-Day Notice	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Update to cleaning procedure for washing cleanroom related items.
Submission Number	**Date Final Decision**	**Review Track**	**Trade Name**	**Appl/Spr Name**	**Approval Order Statement**
P050051/S048	12/07/2022	X - 30-Day Notice	ABBOTT ARCHITECT AUSAB	ABBOTT LABORATORIES INC	Replacement of a current testing assay with a new equivalent assay.
P050052/S141	12/15/2022	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Update to cleaning procedure for washing cleanroom related items.
P060001/S035	12/15/2022	X - 30-Day Notice	PROTEGE GPS AND PROTEGE RX CAROTID STENT SYSTEMS	MEDTRONIC VASCULAR INC	Addition of a new electropolishing station to the manufacturing process.
P070008/S142	12/07/2022	X - 30-Day Notice	STRATOS LV CRT-P AND STRATOS LV-T CRT-P, COROX OTW BP LEAD AND COROX OTW-S BP LEAD	BIOTRONIK, INC.	Introduce an automatic optical inspection of the blister packaging for IPGs and ICDs.
P070026/S103	12/08/2022	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Changing the frequency of the chemistry test from each furnace cycle to bi-weekly and consequential procedural update.
P080010/S021	12/06/2022	X - 30-Day Notice	TECNIS MULTIFOCAL FOLDABLE POSTERIOR CHAMBER INTRAOCULAR LENS (IOL)	JOHNSON & JOHNSON SURGICAL VISION, INC.	Adding an alternative supplier for the lens case assembly (LCA).
P080011/S151	12/07/2022	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Method Validation for Analysis of Polymerization Mixture by GC at the CooperVision manufacturing Puerto Rico LLC., at Juana Diaz facility.
P080011/S152	12/21/2022	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Software update to the Biofinity made to order line at the CooperVision Manufacturing, Ltd. facility in Hamble, United Kingdom.
P080025/S273	12/08/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Implementation of a validated test method for the incoming inspection of a component used at the Medtronic Energy and Component Center (MECC).
P100009/S050	12/15/2022	X - 30-Day Notice	MITRACLIP DELIVERY SYSTEM	ABBOTT MEDICAL	Changes to adhesives used in the MitraClip Clip Delivery System.
P100010/S133	12/07/2022	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Manufacturing changes for improvements in the Cell Operating System (COS) workstream.

P100021/S111	12/01/2022	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Implement an alternative bacterial water testing method.
P100029/S048	12/06/2022	X - 30-Day Notice	ST JUDE MEDICAL TRIFECTA VALVE	ABBOTT MEDICAL	Implementation of a continuous airflow monitoring system.
P100029/S049	12/14/2022	X - 30-Day Notice	ST JUDE MEDICAL TRIFECTA VALVE	ABBOTT MEDICAL	Modification to the test method used to verify sterilant, storage, and fixation solution concentrations.
P100040/S055	12/01/2022	X - 30-Day Notice	VALIANT THORACIC STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Implement an alternative bacterial water testing method.
P100044/S051	12/22/2022	X - 30-Day Notice	PROPEL	INTERSECT ENT	Implementation of a new software system used to document, process, and store data for the spray coating manufacturing process for the Propel Sinus Implants.
Submission Number	**Date Final Decision**	**Review Track**	**Trade Name**	**Appl/Spr Name**	**Approval Order Statement**
P110016/S081	12/08/2022	X - 30-Day Notice	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ABBOTT MEDICAL	Alternate tier 3 supplier of resin for the FlexAbility/FlexAbility SE Ablation Catheters, TactiCath SE Ablation Catheter, Livewire TC Ablation Catheter, and Safire Ablation Catheter.
P110023/S036	12/15/2022	X - 30-Day Notice	EVERFLEX SELF-EXPANDING PERIPHERAL STENT SYSTEM (EVERFLEX)	MEDTRONIC VASCULAR INC	Addition of a new electropolishing station to the manufacturing process.
P110029/S040	12/07/2022	X - 30-Day Notice	ARCHITECT HBSAG QUALITATIVE, QUALITATIVE CONFIRMATORY, CONFIRMATORY MANUAL DILUENT, CALIBRATORS, AND CONTROLS	ABBOTT LABORATORIES	Replacement of a current testing assay with a new equivalent assay.
P110042/S176	12/07/2022	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Modification of electrical test software to ensure that the correct date and time stamp are loaded at Final Pack of the EMBLEM S-ICD pulse generators.
P110042/S177	12/14/2022	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Add a new cleanroom to the BSC-Clonmel manufacturing facility.
P120002/S022	12/07/2022	X - 30-Day Notice	SMA RT CONTROL AND SMART VASCULAR STENT SYSTEMS	CORDIS US CORPORATION	New polyimide supplier.
P120002/S023	12/16/2022	X - 30-Day Notice	SMA RT CONTROL AND SMART VASCULAR STENT SYSTEMS	CORDIS US CORPORATION	In-source polytetrafluorethylene (PTFE) component manufacturing.
P120006/S041	12/22/2022	X - 30-Day Notice	OVATION ABDOMINAL STENT GRAFT SYSTEM	ENDOLOGIX, LLC	Implementation of a supplier change for the guide wire lumen component of the Ovation iX Iliac Limb Delivery Catheter and Ovation iX Iliac Extension Delivery Catheter.

P120010/S142	12/08/2022	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Addition of a new supplier for the thermoformed packaging tray for the Enlite sensor and the Guardian Sensor (3). The Enlite sensor is a components of the MiniMed 530G, 630G, Paradigm Real-Time Revel, and iPro2 CGM systems. The Guardian Sensor (3) is a component of the MiniMed 630G, Guardian Connect, 670G and 770G systems.
P130006/S094	12/21/2022	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Implementation of a new water purification system at the Kendrick Peak facility.
P130021/S128	12/01/2022	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Implement an alternative bacterial water testing method.
P130021/S129	12/01/2022	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Modifications to final inspection test equipment and methods to evaluate torque and tensile force performance.
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P130022/S047	12/23/2022	X - 30-Day Notice	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Add an alternate manufacturing site, the NevroCosta Rica (CR) facility, for the HFX Trial Stimulator (TSM3500) and to add an alternate Printed Circuit Board Assembly (PCBA) supplier, Micro Systems Engineering, Inc. (MSEI), for the HFX Trial Stimulator (TSM3500).
P130026/S081	12/08/2022	X - 30-Day Notice	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Alternate tier 3 supplier of resin for the FlexAbility/FlexAbility SE Ablation Catheters, TactiCath SE Ablation Catheter, Livewire TC Ablation Catheter, and Safire Ablation Catheter.
P130026/S082	12/15/2022	X - 30-Day Notice	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Supplier manufacturing process change to strengthen the connector components.
P140010/S071	12/01/2022	X - 30-Day Notice	IN.PACT ADMIRAL PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) BALLOON CATHETER AND IN.PACT 018 PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) BALLOON CATHETER	MEDTRONIC INC.	Implement an alternative bacterial water testing method.
P140018/S036	12/01/2022	X - 30-Day Notice	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Implement an alternative bacterial water testing method.
P140026/S025	12/16/2022	X - 30-Day Notice	ENROUTE TRANSCAROTID STENT SYSTEM	SILK ROAD MEDICAL, INC	In-source polytetrafluorethylene (PTFE) component manufacturing.
P140026/S026	12/16/2022	X - 30-Day Notice	ENROUTE TRANSCAROTID STENT SYSTEM	SILK ROAD MEDICAL, INC	New polyimide supplier.
P140031/S150	12/12/2022	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Implement in-house injection molding processes for Crimper subassemblies.
P150001/S101	12/08/2022	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	Addition of a new supplier for the thermoformed packaging tray for the Enlite sensor and the Guardian Sensor (3). The Enlite sensor is a components of the MiniMed 530G, 630G, Paradigm Real-Time Revel, and iPro2 CGM systems. The Guardian Sensor (3) is a component of the MiniMed 630G, Guardian Connect, 670G and 770G systems.

P150012/S136	12/14/2022	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Add a new cleanroom to the BSC-Clonmel manufacturing facility.
P150012/S137	12/15/2022	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Update a manufacturing inspection process and add a new manufacturing traceability system.
P150012/S138	12/20/2022	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Manufacture the accelerometer cover component of pulse generator devices.
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P150031/S053	12/17/2022	X - 30-Day Notice	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Introduce an optional weld cycle (reweld) to the Weld Case and Feedthru Laser Weld Implantable Pulse Generators process step at its Clonmel Ireland manufacturing facility.
P150033/S164	12/12/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Implement endotoxin testing of the Micra Transcatheter Pacing System for operational improvement.
P150040/S011	12/21/2022	X - 30-Day Notice	VISUMAX FEMTOSECOND LASER	CARL ZEISS MEDITEC, INC.	Qualify an additional manufacturing site for the supplier of the Contact Glass used in the Treatment Pack accessory.
P160007/S046	12/08/2022	X - 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Addition of a new supplier for the thermoformed packaging tray for the Enlite sensor and the Guardian Sensor (3). The Enlite sensor is a components of the MiniMed 530G, 630G, Paradigm Real-Time Revel, and iPro2 CGM systems. The Guardian Sensor (3) is a component of the MiniMed 630G, Guardian Connect, 670G and 770G systems.
P160017/S105	12/08/2022	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Addition of a new supplier for the thermoformed packaging tray for the Enlite sensor and the Guardian Sensor (3). The Enlite sensor is a components of the MiniMed 530G, 630G, Paradigm Real-Time Revel, and iPro2 CGM systems. The Guardian Sensor (3) is a component of the MiniMed 630G, Guardian Connect, 670G and 770G systems.
P160021/S036	12/21/2022	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implementation of a new water purification system at the Kendrick Peak facility.
P160026/S036	12/12/2022	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.	Manufacturing site location change of the supplier for several critical components in the LIFEPAK 15 monitor/defibrillator.
P160037/S013	12/07/2022	X - 30-Day Notice	BD ONCLARITY HPV ASSAY	BECTON, DICKINSON AND COMPANY	Add an alternative supplier of a critical component.

P160043/S064	12/01/2022	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Implement an alternative bacterial water testing method.
P160047/S027	12/12/2022	X - 30-Day Notice	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	COOPERSURGICAL, INC.	Change to the manufacturing of the vapor block assembly component to improve the fit of the upper and lower components.
P180038/S014	12/08/2022	X - 30-Day Notice	LIAISON XL MUREX ANTI-HBC, LIAISON MUREX CONTROL ANTI-HBC	DIASORIN INC.	Elimination of a manufacturing step for kit component.
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P180039/S013	12/08/2022	X - 30-Day Notice	LIAISON® XL MUREX ANTI-HBS, LIAISON® XL MUREX CONTROL ANTI-HBS AND LIAISON® XL MUREX ANTI-HBS VERIFIERS	DIASORIN INC.	Elimination of a manufacturing step for kit component.
P180045/S011	12/08/2022	X - 30-Day Notice	LIAISON® XL MUREX HBC IGM, LIAISON® XL MUREX CONTROL HBC IGM	DIASORIN INC.	Elimination of a manufacturing step for kit component.
P180047/S022	12/08/2022	X - 30-Day Notice	LIAISON QUANTIFERON - TB GOLD PLUS, LIAISON CONTROL QUANTIFERON - TB GOLD PLUS AND LIAISON QUANTIFERON SOFTWARE	DIASORIN, INC.	Elimination of a manufacturing step for kit component.
P180048/S011	12/08/2022	X - 30-Day Notice	LIAISON® XL MUREX HBEAG, LIAISON® XL MUREX CONTROL HBEAG	DIASORIN INC.	Elimination of a manufacturing step for kit component.
P180049/S011	12/08/2022	X - 30-Day Notice	LIAISON® XL MUREX ANTI-HBE, LIAISON® XL MUREX CONTROL ANTI-HBE	DIASORIN INC.	Elimination of a manufacturing step for kit component.
P190008/S022	12/01/2022	X - 30-Day Notice	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Implement an alternative bacterial water testing method.
P190017/S010	12/08/2022	X - 30-Day Notice	LIAISON® XL MUREX HBSAG QUAL, LIAISON® MUREX CONTROL HBSAG, AND LIAISON® XL MUREX HBSAG CONFIRMATORY TEST	DIASORIN INC	Elimination of a manufacturing step for kit component.

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P190018/S021	12/20/2022	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	Change from two fixtures to a single fixture used for lens cleaning, extraction, vacuum drying and plasma treatment processes.
P190023/S011	12/14/2022	X - 30-Day Notice	PORTICO TRANSCATHETER AORTIC VALVE IMPLANTATION SYSTEM	ABBOTT MEDICAL	Modification to the test method used to verify sterilant, storage, and fixation solution concentrations.
P200015/S032	12/12/2022	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Implement in-house injection molding processes for Crimper subassemblies.
P200046/S013	12/01/2022	X - 30-Day Notice	HARMONY¿ TPV SYSTEM	MEDTRONIC, INC.	Implement an alternative bacterial water testing method.
P210003/S003	12/07/2022	X - 30-Day Notice	ARCHITECT HBSAG NEXT QUALITATIVE REAGENT KIT, ARCHITECT HBSAG NEXT CONFIRMATORY REAGENT KIT, ARCHITECT HBSAG NEXT QUALITATIVE CALIBRATORS,	ABBOTT LABORATORIES	Replacement of a current testing assay with a new equivalent assay.
P210032/S005	12/21/2022	X - 30-Day Notice	GORE TAG THORACIC BRANCH ENDOPROSTHESIS (TBE DEVICE)	W. L. GORE & ASSOCIATES, INC.	Implementation of a new water purification system at the Kendrick Peak facility.
P220003/S003	12/07/2022	X - 30-Day Notice	PASCAL PRECISION TRANSCATHETER VALVE REPAIR SYSTEM	EDWARDS LIFESCIENCES LLC	Implement an additional supplier for the implant catheter shaft component of the PASCAL Precision Transcatheter Valve Repair System.
P220003/S004	12/07/2022	X - 30-Day Notice	PASCAL PRECISION TRANSCATHETER VALVE REPAIR SYSTEM	EDWARDS LIFESCIENCES LLC	Implement a new supplier for the nitinol clasp and extension plate components of the PASCAL Ace implant.

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P220003/S005	12/20/2022	X - 30-Day Notice	PASCAL PRECISION TRANSCATHETER VALVE REPAIR SYSTEM	EDWARDS LIFESCIENCES LLC	Update to the in-process visual inspection criteria for flash in the suture lumens and center lumen of the shaft component during the manufacturing of the Implant Catheter.

Total: 121