PMA Monthly approvals from 9/1/2021 to 9/30/2021

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180051	09/03/2021	PMAO - PMA Origi	ORGAN CARE SYSTEM (OCS) HEART SYSTEM	TRANSMEDICS, INC.	Approval for the Organ Care System (OCS) Heart System. This device is indicated for the preservation of donor-after-brain-death (DBD) hearts deemed unsuitable for procurement and transplantation at initial evaluation due to limitations of prolonged cold static cardioplegic preservation (e.g., > 4 hours of cross-clamp time).
P190023	09/17/2021	PMAO - PMA Origi	PORTICO TRANSCATHETER AORTIC VALVE IMPLANTATION SYSTEM	ABBOTT MEDICAL	Approval for the Portico Transcatheter Aortic Valve Implantation System. The device is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality >= 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P200004	09/26/2021	PMAO - PMA Origi	CONMED PADPRO MULTIFUNCTION ELECTRODES, CONMED PADPRO MULTIFUNCTION ELECTRODE ADAPTERS	CONMED CORPORATIO N	Approval for an Adult/Child 2001(radiotransparent), 2516(radiotranslucent):The ConMed PadPro radiotransparent and radiotranslucent external multifunction electrodes (MFEs). The device is indicated for use by trained medical professionals in medical facilities or medical transport environments to deliver energy for defibrillation, cardioversion, external pacing, and ECG monitoring applications. The MFE is a non-sterile, disposable device for single patient use only. The electrodes provide the conductive interface between the defibrillator and/or the external transcutaneous (noninvasive) cardiac pacemaker and the patients skin. This device is intended for use on defibrillators whose output is classified as low power (up to 360 Joule maximum). AED Use: When used in AED mode i.e. for victims of cardiac arrest where there is apparent lack of circulation as indicated by unconsciousness, absence of breathing, and absence of pulse, the electrode is intended for use on patients weighing 25 kg (55 lbs.) or more. PadPro MFEs are not intended to be used for public access pediatric AED defibrillation purposes. Manual Use:When used in manual mode, i.e. under direction of a qualified health care professional, the electrode is intended for use on adult / child patients weighing 10 kg (22 lbs.) or more. Adult/Child Model 2502 (Sterile):The ConMed PadPro radiotransparent external multifunction electrodes (MFEs) are indicated for use by trained medical professionals in medical facilities or medical transport environments to deliver energy for defibrillation, cardioversion, external pacing, and ECG monitoring applications. The MFE is a sterile, disposable device for single patient use only. The electrodes provide the conductive interface between the defibrillator and/or the external transcutaneous (noninvasive) cardiac pacemaker and the patients skin. The device is intended for use on defibrillators whose output is classified as low power (up to 360 Joule maximum). AED Use:See Adult/Child 2001, 2516 Manual Use:See Adult/Child 2001, 2516 Infant Model 2603 and Mini-Infant Model 2602:The ConMed PadPro radiotranslucent external multifunction electrodes (MFEs) are indicated for use by trained medical professionals in medical facilities to deliver energy for defibrillation, cardioversion, external pacing, and ECG monitoring applications. The MFE is a non-sterile, disposable device for single patient use only. The electrodes provide the conductive interface between the defibrillator and/or the external transcutaneous (noninvasive) cardiac pacemaker and the patient¿s skin. Not for use in AED mode. Manual Use:When used in the manual mode, i.e. under direction of a qualified health care professional, the electrode is intended for use on infant patients (3-10kg) and mini-infant patients (<3kg). Follow American Heart Association (AHA) guidelines for administration of energy levels, which recommends a first dose of 2J/kg, and subsequent doses of 4J/kg. During Refractory ventricular fibrillation, do not exceed a maximum energy level of 10J/kg. PadPro Adapters:The ConMed PadPro adapters are indicated for use by trained medical professionals in medical facilities or medical transport environments to adapt connection systems associated with a specific defibrillator/therapy cable to a different style connection system. The PadPro MFE adapters are intended for delivery of energy for defibrillation, cardioversion, external pacing, and ECG monitoring applications. The PadPro MFE adapter is a non-sterile, reusable device, providing conductive interface between the defibrillator and/or therapy cable and MFE electrode. This device is intended for use on defibrillators whose output is classified as low power (up to 360 Joule maximum).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P200031	09/28/2021	PMAO - PMA Origi	ORGAN CARE SYSTEM (OCS¿) LIVER	TRANSMEDICS, INC.	Approval for Organ Care System (OCS) Liver for the indication of: The TransMedics® Organ Care System (OCS) Liver is a portable extracorporeal liver perfusion and monitoring system indicated for preservation and monitoring of hemodynamics and metabolic function which allows for ex-vivo assessment of liver allografts from donors after brain death (DBD) or liver allografts from donors after circulatory death (DCD) <=55 years old and with <=30 mins of warm ischemic time, macrosteatosis <=15%, in a near-physiologic, normothermic and functioning state intended for a potential transplant recipient.

Total: 4

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S265	09/03/2021	R - Real-Time Proc	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Approval for the addition of Platinum/Iridium feedthru wires as an alternate to the Palladium/Iridium feedthru wires used in the Filtered Feedthru Assembly and minor design changes updating the extended life battery stack insulator.
N970003/S266	09/17/2021	R - Real-Time Proc	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Approval for the software modifications to the LATITUDE NXT Remote Patient Management System.
P810006/S095	09/07/2021	Y - 135 Review Tra	COLLASTAT	INTEGRA LIFESCIENCES CORPORATION	Approval for the removal of Heavy Metals testing from the routine monitoring of their Purified Water System used in the product manufacturing at their Puerto Rico facility
P830055/S263	09/21/2021	R - Real-Time Proc	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for an additional implant system surgical technique, i.e., VELYS¿ Robotic-Assisted Solution for Total Knee for the ATTUNE® Knee System
P830055/S274	09/10/2021	S - Special CBE	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for addition of inspection checks at the case creation stage and the segmentation stage, for the TRUMATCH Personalized Solutions patient-specific instruments for Total Knee Arthroplasty, within the LCS Total Knee System
P840062/S080	09/07/2021	Y - 135 Review Tra	COLLACOTE(TM)	INTEGRA LIFESCIENCES CORP.	Approval for the removal of Heavy Metals testing from the routine monitoring of their Purified Water System used in the product manufacturing at their Puerto Rico facility
P850010/S095	09/07/2021	Y - 135 Review Tra	HELISTAT(TM) ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	INTEGRA LIFESCIENCES CORPORATION	Approval for the removal of Heavy Metals testing from the routine monitoring of their Purified Water System used in the product manufacturing at their Puerto Rico facility
P880086/S317	09/15/2021	N - Normal 180 Day	ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS	ABBOTT MEDICAL	Approval for the Merlin 2 PCS Programmer Model MER3700 with Model MER3400 Software.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P880086/S321	09/15/2021	N - Normal 180 Day	ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS	ABBOTT MEDICAL	Approval for model line extensions in the Endurity, Endurity Core, Zenex, Zenus, Zenex MRI, and Zenus MRI families of pacemakers; the Quadra Assura MP, Quadra Assura, and Unify Assura families of CRT-Ds; and the Ellipse VR DR and Fortify Assura VR DR family of ICDs. This supplement also requested approval for the MR conditional labeling of a subset of these devices.
P900033/S094	09/07/2021	Y - 135 Review Tra	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Approval for the removal of Heavy Metals testing from the routine monitoring of their Purified Water System used in the product manufacturing at their Puerto Rico facility
P900060/S063	09/09/2021	S - Special CBE	CARBOMEDICS PROSTHETIC HEART VALVE (CPHV)	CORCYM S.R.L.	Approval for labeling changes which reduce risks and clearly explain how to use a newly designed accessory holder safely
P910001/S112	09/02/2021	N - Normal 180 Day	SPECTRANECTICS CVX-300 EXCIMER LASER SYSTEM	SPECTRANETICS CORP.	Approval for the next generation Philips Laser System (PLS), including compatibility with the ELCA coronary laser atherectomy catheter, Spectranetics Laser Sheath (SLS) and Glidelight Laser Sheath devices.
P910023/S435	09/15/2021	N - Normal 180 Day	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ABBOTT MEDICAL	Approval for the Merlin 2 PCS Programmer Model MER3700 with Model MER3400 Software.
P910023/S439	09/15/2021	N - Normal 180 Day	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ABBOTT MEDICAL	Approval for model line extensions in the Endurity, Endurity Core, Zenex, Zenus, Zenex MRI, and Zenus MRI families of pacemakers; the Quadra Assura MP, Quadra Assura, and Unify Assura families of CRT-Ds; and the Ellipse VR DR and Fortify Assura VR DR family of ICDs. This supplement also requested approval for the MR conditional labeling of a subset of these devices.
P910077/S185	09/17/2021	R - Real-Time Proc	VENTAK(R) PRX (TM) MODEL 1700,1705 PULSE GENERATOR	BOSTON SCIENTIFIC	Approval for the software modifications to the LATITUDE NXT Remote Patient Management System.
P920015/S256	09/15/2021	N - Normal 180 Day	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Approval for the removal of steroid coating from the lead helix electrode and to provide chemistry, manufacturing and controls information.
P950005/S080	09/22/2021	R - Real-Time Proc	WEBSTER DIAG./ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC	Approval for updated labeling, including modified warnings and directions for use.
P950005/S083	09/22/2021	O - Normal 180 Day	WEBSTER DIAG./ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC	Approval to add an alternate sterilization site.
P960040/S465	09/17/2021	R - Real-Time Proc	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Approval for the software modifications to the LATITUDE NXT Remote Patient Management System.
P960042/S070	09/02/2021	N - Normal 180 Day	SPECTRANETICS CVX-300 EXCIMER LASER SYSTEM & LASER SHEATH	SPECTRANETICS (PHILIPS)	Approval for the Philips Laser System and for inclusion of the Philips Laser System as a compatible device within the labeling for the ELCA and Spectranetics Laser Sheath (SLS) and Glidelight Laser Sheath devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960043/S112	09/24/2021	R - Real-Time Proc	PROSTAR 9 FR. PERCUTANEOUS VASCULAR SURGICAL (PVS) SYSTEM	ABBOTT VASCULAR INC.	Approval for a design change to the trimmer component of the Perclose suture trimmer accessory that is included as part of the Perclose ProGlide Suture-Mediated Closure System.
P970013/S085	09/15/2021	N - Normal 180 Day	MICRONY PACEMAKERS	ABBOTT MEDICAL	Approval for the Merlin 2 PCS Programmer Model MER3700 with Model MER3400 Software.
P980040/S133	09/10/2021	Y - 135 Review Tra	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for an alternative supplier for the manufacture of the lens module for SmartLOAD and Simplicity delivery systems.
P990025/S065	09/22/2021	R - Real-Time Proc	NAVI-STAR DIAGNOSTIC/ ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC.	Approval for updated labeling, including modified warnings and directions for use.
P990025/S068	09/22/2021	O - Normal 180 Day	NAVI-STAR DIAGNOSTIC/ ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC.	Approval to add an alternate sterilization site.
P990071/S046	09/23/2021	O - Normal 180 Day	STOCKERT 70 RADIOFREQUENCY ABLATION GENERATOR	BIOSENSE WEBSTER, INC.	Approval for a new manufacturing site located at STOCKERT GMBH, Boetzinger Strasse 31, Freiburg, Baden-Wurttemberg, Germany D-79111 for the manufacturing of the SMARTABLATE® System (which consists of the SMARTABLATE® Radiofrequency (RF) Generator, SMARTABLATE® Remote Control, SMARTABLATE® Irrigation Pump).
P990071/S052	09/22/2021	O - Normal 180 Day	STOCKERT 70 RADIOFREQUENCY ABLATION GENERATOR	BIOSENSE WEBSTER, INC.	Approval to add an alternate sterilization site.
P000025/S122	09/03/2021	O - Normal 180 Day	COMBI 40+ COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Approval for a new sterilization site located at Exlgasse 20, Innsbruck, 6020, Austria for sterilization of cochlear implants and surgical accessories
P010012/S539	09/17/2021	R - Real-Time Proc	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Approval for the software modifications to the LATITUDE NXT Remote Patient Management System.
P010030/S150	09/01/2021	R - Real-Time Proc	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Approval for the use of a new lithium-ion battery pack for the LifeVest 4000 device
P010030/S151	09/17/2021	R - Real-Time Proc	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Approval for a change in design of the front closure for the LifeVest 4000 Wearable Defibrillator.

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P010031/S750	09/29/2021	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval to release updates to the CareLink SmartSync Cobalt, Crome App.
P010032/S178	09/27/2021	R - Real-Time Proc	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Approval to 1) Adding an existing Abbott qualified supplier for diode components for 3 types of diodes. 2) Replacing tantalum decoupling capacitors with ceramic capacitors sourced from an existing Abbott qualified supplier; and 3) Reducing the number of tantalum output capacitors on the EPPIC charge pump.
P010068/S065	09/22/2021	R - Real-Time Proc	NAVISTAR/CELSIUS DS DIAGNOSTIC/ABLATION DEFLECTABLE 8MM TIP CATHETER	BIOSENSE WEBSTER, INC.	Approval for updated labeling, including modified warnings and directions for use.
P010068/S068	09/22/2021	O - Normal 180 Day	NAVISTAR/CELSIUS DS DIAGNOSTIC/ABLATION DEFLECTABLE 8MM TIP CATHETER	BIOSENSE WEBSTER, INC.	Approval to add an alternate sterilization site.
P020004/S182	09/24/2021	N - Normal 180 Day	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,I NC	Approval for an update to the labeling to allow use of the Gore Excluder Iliac Branch Endoprosthesis with the Gore Excluder Conformable Endoprosthesis
P020045/S097	09/10/2021	O - Normal 180 Day	7F FREEZOR CARDIAC CRYOABLATION CATHETER AND CCT.2 CRYOCONSOLE SYSTEM	MEDTRONIC CRYOCATH LP	Approval for an additional sterilization site (Sterigenics Queensbury) and a new sterilization cycle (Cycle 410).
P030004/S027	09/16/2021	N - Normal 180 Day	ONYX LIQUID EMBOLIC SYSTEM	EV3 NEUROVASC ULAR	Approval for the inclusion of radial access considerations in the Onyx Liquid Embolic System labeling.
P030005/S210	09/03/2021	R - Real-Time Proc	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Approval for the addition of Platinum/Iridium feedthru wires as an alternate to the Palladium/Iridium feedthru wires used in the Filtered Feedthru Assembly and minor design changes updating the extended life battery stack insulator.
P030005/S211	09/17/2021	R - Real-Time Proc	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Approval for the software modifications to the LATITUDE NXT Remote Patient Management System.
P030031/S120	09/22/2021	R - Real-Time Proc	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Approval for updated labeling, including modified warnings and directions for use.

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P030031/S124	09/22/2021	O - Normal 180 Day	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Approval to add an alternate sterilization site.
P030035/S184	09/15/2021	N - Normal 180 Day	ANTHEM AND FRONTIER II CRT-P'S	ABBOTT MEDICAL	Approval for the Merlin 2 PCS Programmer Model MER3700 with Model MER3400 Software.
P030053/S059	09/24/2021	Y - 135 Review Tra	MEMORYGEL SILICONE GEL -FILLED BREAST IMPLANTS	MENTOR CORP.	Approval for implementation of a new texturing press in the manufacturing process for MemoryGel® Silicone Gel-Filled Breast Implants and MemoryShape Gel-Filled Breast Implants.
P030054/S389	09/15/2021	N - Normal 180 Day	ST JUDE MEDICAL EPIC HF SYSTEM	ABBOTT MEDICAL	Approval for the Merlin 2 PCS Programmer Model MER3700 with Model MER3400 Software.
P030054/S394	09/15/2021	N - Normal 180 Day	ST JUDE MEDICAL EPIC HF SYSTEM	ABBOTT MEDICAL	Approval for model line extensions in the Endurity, Endurity Core, Zenex, Zenus, Zenex MRI, and Zenus MRI families of pacemakers; the Quadra Assura MP, Quadra Assura, and Unify Assura families of CRT-Ds; and the Ellipse VR DR and Fortify Assura VR DR family of ICDs. This supplement also requested approval for the MR conditional labeling of a subset of these devices.
P040021/S047	09/17/2021	R - Real-Time Proc	SJM BIOCOR VALVE / SJM BIOCOR SUPRA VALVE	ABBOTT MEDICAL	Approval for a modification to the sewing cuff components intended to increase valve radiopacity.
P040036/S082	09/22/2021	R - Real-Time Proc	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Approval for updated labeling, including modified warnings and directions for use.
P040036/S086	09/22/2021	O - Normal 180 Day	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Approval to add an alternate sterilization site.
P050052/S129	09/01/2021	P - Panel Track	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval for Radiesse (+) injectable implant for expanding the indications to include deep injection (subdermal and/or supraperiosteal) for soft tissue augmentation to improve moderate to severe loss of jawline contour in adults over the age of 21
P060028/S038	09/24/2021	Y - 135 Review Tra	MENTOR MEMORYSHAPE BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Approval for implementation of a new texturing press in the manufacturing process for MemoryGel® Silicone Gel-Filled Breast Implants and MemoryShape Gel-Filled Breast Implants.
P070004/S029	09/23/2021	Y - 135 Review Tra	SIENTRA SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Approval for the addition of a shell curing oven used in the manufacturing process of Sientra OPUS Silicone Gel Breast Implants
P100010/S117	09/10/2021	O - Normal 180 Day	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Approval for an additional sterilization site.
P100045/S049	09/21/2021	N - Normal 180 Day	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ST. JUDE MEDICAL	Approval for the next generation CardioMEMS Hospital System (CM3100).
P100047/S173	09/14/2021	Y - 135 Review Tra	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for automated software to automatically inspect battery charger Light Emitting Diodes (LEDs) by using photosensors.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110005/S009	09/02/2021	Y - 135 Review Tra	SINOVIAL (SODIUM HYALURONATE 0.8%)	IBSA INSTITUT BIOCHIMIQUE SA	Approval for addition of an alternative supplier of a raw hyaluronic acid salt material component.
P110033/S062	09/10/2021	O - Normal 180 Day	JUVEDERM VOLUMA XC	ALLERGAN	Approval for labeling update in response to the Approval Condition #7 in FDA¿s approval order for P110033/S053, Juvéderm® Volbella¿ XC, dated May 28, 2021.
P110042/S157	09/17/2021	R - Real-Time Proc	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for the software modifications to the LATITUDE NXT Remote Patient Management System.
P120021/S020	09/27/2021	N - Normal 180 Day	AMPLATZER PFO OCCLUDER	ABBOTT MEDICAL	Approval for the Amplatzer Talisman PFO Occluder (Talisman PFO); a line extension of the current Amplatzer PFO Occluder (PFO) product family.
P130001/S007	09/20/2021	R - Real-Time Proc	EPI PROCOLON	EPIGENOMICS AG	Approval for the Epi proColon test is a qualitative in vitro diagnostic test for the detection of methylated Septin 9 DNA in EDTA plasma derived from patient whole blood specimens. Methylation of the target DNA sequence in the promoter region of the SEPT9_v2 transcript has been associated with the occurrence of colorectal cancer (CRC). The test uses a real-time polymerase chain reaction (PCR) with a fluorescent hydrolysis probe for the methylation specific detection of the Septin 9 DNA target. The Epi proColon test is indicated to screen adults of either sex, 50 years or older, defined as average risk for CRC, who have been offered and have a history of not completing CRC screening. Tests that are available and recommended in the USPSTF 2008 CRC screening guidelines should be offered and declined prior to offering the Epi proColon test. Patients with a positive Epi proColon test result should be referred for diagnostic colonoscopy. The Epi proColon test results should be used in combination with physician's assessment and individual risk factors in guiding patient management.
P130008/S065	09/21/2021	Y - 135 Review Tra	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval for two additional sterilization chambers for the sterilization of Model 3028 Implantable Pulse Generator (IPG) at the Inspire Medical Systems Incs contract manufacturer/sterilizer, Steris Isomedix.
P130008/S073	09/10/2021	O - Normal 180 Day	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval for the revised protocol for the post-approval study (PAS) protocol.
P130021/S102	09/24/2021	O - Normal 180 Day	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Approval for modifications to the Instructions for Use to reflect the 5-year findings of the continued follow-up of premarket cohort post-approval studies.
P140009/S071	09/27/2021	R - Real-Time Proc	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Approval for 1) Adding an existing Abbott qualified supplier for diode components for 3 types of diodes. 2) Replacing tantalum decoupling capacitors with ceramic capacitors sourced from an existing Abbott qualified supplier; and 3) Reducing the number of tantalum output capacitors on the EPPIC charge pump.
P140031/S130	09/17/2021	O - Normal 180 Day	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for modifications to the Instructions for Use to reflect the findings of the final Post-Approval Study (PAS) Report submitted for the SAPIEN 3 High or Greater Surgical Risk study

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P140033/S065	09/15/2021	N - Normal 180 Day	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ABBOTT MEDICAL	Approval for the Merlin 2 PCS Programmer Model MER3700 with Model MER3400 Software.
P140033/S070	09/15/2021	N - Normal 180 Day	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ABBOTT MEDICAL	Approval for model line extensions in the Endurity, Endurity Core, Zenex, Zenus, Zenex MRI, and Zenus MRI families of pacemakers; the Quadra Assura MP, Quadra Assura, and Unify Assura families of CRT-Ds; and the Ellipse VR DR and Fortify Assura VR DR family of ICDs. This supplement also requested approval for the MR conditional labeling of a subset of these devices.
P150004/S049	09/27/2021	R - Real-Time Proc	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Approval for 1) Adding an existing Abbott qualified supplier for diode components for 3 types of diodes. 2) Replacing tantalum decoupling capacitors with ceramic capacitors sourced from an existing Abbott qualified supplier; and 3) Reducing the number of tantalum output capacitors on the EPPIC charge pump.
P150012/S112	09/03/2021	R - Real-Time Proc	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Approval for the addition of Platinum/Iridium feedthru wires as an alternate to the Palladium/Iridium feedthru wires used in the Filtered Feedthru Assembly and minor design changes updating the extended life battery stack insulator.
P150012/S114	09/17/2021	R - Real-Time Proc	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Approval for the software modifications to the LATITUDE NXT Remote Patient Management System.
P150021/S053	09/01/2021	R - Real-Time Proc	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval of a change in the membrane layer polymer of the Libre Sensor. The Libre Sensor is a component of the FreeStyle Libre Pro Flash Glucose Monitoring System and Freestyle Libre Flash Glucose Monitoring System.
P160002/S015	09/28/2021	S - Special CBE	VENTANA PD-L1(SP142) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approved for removal of the triple negative breast cancer (TNBC) indication from the device intended use statement and labeling.
P160030/S047	09/01/2021	R - Real-Time Proc	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval of a change in the membrane layer polymer of the Libre Sensor. The Libre Sensor is a component of the FreeStyle Libre Pro Flash Glucose Monitoring System and Freestyle Libre Flash Glucose Monitoring System.
P160032/S010	09/10/2021	R - Real-Time Proc	LIFELINE/REVIVER DDU-100, LIFELINE/ REVIVER AUTO DDU-120, LIFELINE/REVIVER VIEW DDU-2300, LIFELINE/ REVIVER VIEW AUTO DDU-2200, LIFELINE/ REVIVER ECG DDU-2450, AND LIFELINE/REVIVER ECG+ DDU-2475 AUTOMATED EXTERNAL DEFIBRILLATORS	DEFIBTECH, LLC	Approval for hardware design changes to the DDU-100 Series LV board component & HV board component DDU-2000 Series Main board component as a result of field actions.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160045/S029	09/15/2021	P - Panel Track	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Approval to expand the intended use of the Oncomine Dx Target Test to include a companion diagnostic indication for the detection of EGFR exon 20 insertion mutations in non-small cell lung cancer patients who may benefit from the treatment with EXKIVITY (mobocertinib).
P160053/S004	09/20/2021	O - Normal 180 Day	MAGTRACETM AND SENTIMAG(R) MAGNETIC LOCATIZATION SYSTEM	ENDOMAGNETICS LTD.	Approval for site located at 305 Ashcake Road, Suite L, Ashland, Virginia 23005 USA
P170003/S022	09/07/2021	R - Real-Time Proc	LUTONIX® 035 DRUG COATED BALLOON PTA CATHETER, MODEL 9010	LUTONIX	Approval for a shelf-life extension from 12 to 24 months for the 8-9 mm diameter devices and a shelf-life extension from 12 to 36 months for the 7x80 mm and 7x100 mm device sizes.
P170013/S005	09/16/2021	N - Normal 180 Day	LOW-PROFILE VISUALIZED INTRALUMINAL SUPPORT (LVIS) AND LVIS JR.	MICROVENTION, INC.	Approval for the LVIS X and LVIS Jr. X that contains a novel polymer surface treatment to the neurovascular coil-assist stent.
P170043/S010	09/10/2021	N - Normal 180 Day	ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM (MODEL G2-M-IS)	GLAUKOS CORPORATION	Approval for design changes to the Model G2-W injector.
P180007/S008	09/01/2021	O - Normal 180 Day	SPIRATION® VALVE SYSTEM	GYRUS ACMI, INC.	Approval for the Gyrus ACMI (Spiration) PAS Revisions to EMPROVE Study Protocol.
P180027/S002	09/16/2021	N - Normal 180 Day	FLOW RE-DIRECTION ENDOLUMINAL DEVICE (FRED®) SYSTEM	MICROVENTION, INC.	Approval for the FRED X System that contains a novel polymer surface treatment on the neurovascular flow-diverting stent.
P180034/S005	09/07/2021	O - Normal 180 Day	TACK ENDOVASCULAR SYSTEM (6F)	PHILIPS IMAGE GUIDED THERAPY CORPORATION	Approval for the labeling updates which incorporate the final 36-month results from the TOBA II Post Approval Study.
P180046/S027	09/16/2021	Y - 135 Review Tra	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval to increase the maximum sterilization load.
P180047/S008	09/17/2021	O - Normal 180 Day	LIAISON QUANTIFERON - TB GOLD PLUS, LIAISON CONTROL QUANTIFERON - TB GOLD PLUS AND LIAISON QUANTIFERON SOFTWARE	DIASORIN, INC.	Approval for site change, to include manufacturing facility of DiaSorin Inc. located in Stillwater, Minnesota.
P190006/S027	09/16/2021	Y - 135 Review Tra	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval to increase the maximum sterilization load.

Total: 85

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N12159/S083	09/10/2021	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Addition of new and duplicate equipment to support automation of the operations and increase manufacturing capacity at the Ethicon, LLC, San Lorenzo, Puerto Rico facility.
N12159/S084	09/30/2021	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Use of a new Beamer 007-BM-206B Traverser attachment during the manufacture of Oxidized Regenerated Cellulose (ORC) for SURGICEL® SNoW Absorbable Hemostat at the Janssen Pharmaceuticals Inc. facility in Athens, Georgia, USA.
N970003/S268	09/24/2021	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Change the adhesive and liner used on the tray label stock for pulse generators and Leads.
N970012/S189	09/08/2021	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Changes to the valve block molding equipment and process for cavities 9 and 10.
P840001/S498	09/01/2021	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Approval for 1) equipment updates in the CEA 2-3 Silicone Molding area (e.g., six additional ovens), updated option for use of temperature recorder (Vaisala Monitoring System Model VL-1700-54T), updated oven mode for the new ovens to use Manual Mode, removal of monitor lot for all ovens, removal of setup lot of new ovens, addition of a new and smaller basket for oven use, and addition of a new toolmaker scope (Nikon MM-40), 2) an update to the applicable work instructions (WI); and 3) the oven operation of allowing the new ovens to be opened during the middle of a run to add or remove lots from the oven and FACTORYworks (FW) updates to support the changes.
P860057/S203	09/08/2021	X - 30-Day Notice	EDWARDS LIFESCIENCES PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Reduction of the number of in-process glutaraldehyde solution change-outs for surgical pericardial heart valves.
P880047/S042	09/10/2021	X - 30-Day Notice	INTERCEED TC7 ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Addition of new and duplicate equipment to support automation of the operations and increase manufacturing capacity at the Ethicon, LLC, San Lorenzo, Puerto Rico facility.
P900066/S013	09/28/2021	X - 30-Day Notice	PERFLUOROPROPANE	AIRGAS USA, LLC	Use an additional supplier for toxicity testing as a product release test for perfluoropropane.
P910023/S440	09/01/2021	X - 30-Day Notice	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ABBOTT MEDICAL	Acceptance to add an alternate supplier of connector assemblies that will be mounted on the hybrids for ICD and CRT-D devices.
P910073/S163	09/24/2021	X - 30-Day Notice	ENDOTAK LEAD SYSTEM	BOSTON SCIENTIFIC	Use a new controlled environment area at the Boston Scientific Dorado, Puerto Rico facility.
P910073/S164	09/24/2021	X - 30-Day Notice	ENDOTAK LEAD SYSTEM	BOSTON SCIENTIFIC	Change the adhesive and liner used on the tray label stock for pulse generators and Leads.
P920047/S125	09/07/2021	X - 30-Day Notice	EPT-1000 CARDIAC ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of an inspection for an electrical component located inside the handle of IntellaNav catheters.
P930039/S230	09/17/2021	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Automate a cleaning process for plasma-treated tubing used in implantable cardiac pacing leads.

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P940015/S049	09/03/2021	X - 30-Day Notice	SYNVISC ONE	SANOFI GENZYME CORP.	Use of sterile connectors for manufacture of Synvisc and Synvisc-One as an alternative to aseptic connections.
P950020/S113	09/22/2021	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Change to a design verification production process control.
P960004/S095	09/24/2021	X - 30-Day Notice	THINLINE ENDOCARDIAL PACING LEADS	BOSTON SCIENTIFIC	Use a new controlled environment area at the Boston Scientific Dorado, Puerto Rico facility.
P960004/S096	09/24/2021	X - 30-Day Notice	THINLINE ENDOCARDIAL PACING LEADS	BOSTON SCIENTIFIC	Change the adhesive and liner used on the tray label stock for pulse generators and Leads.
P960006/S053	09/24/2021	X - 30-Day Notice	SWEET TIP(R) RX STEROID ELUTING LEAD	BOSTON SCIENTIFIC	Use a new controlled environment area at the Boston Scientific Dorado, Puerto Rico facility.
P960009/S406	09/01/2021	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Equipment updates in the CEA 2-3 Silicone Molding area (e.g., six additional ovens), updated option for use of temperature recorder (Vaisala Monitoring System Model VL-1700-54T), updated oven mode for the new ovens to use Manual Mode, removal of monitor lot for all ovens, removal of setup lot of new ovens, addition of a new and smaller basket for oven use, and addition of a new toolmaker scope (Nikon MM-40); 2) an update to the applicable work instructions (WI); and 3) the oven operation of allowing the new ovens to be opened during the middle of a run to add or remove lots from the oven and FACTORYworks (FW) updates to support the changes.
P960009/S407	09/09/2021	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Add a duplicate inspection to the SenSight Lead Stringing Work Instructions for SenSight Lead Coil subassemblies used in models B33005 and B33015. The updated manufacturing process impacts subcomponents for the SenSight Directional Lead occurring at the Medtronic Danvers facility located in Danvers, MA.
P960040/S469	09/20/2021	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Update the general visual inspection criteria for cathode damage observed during high voltage capacitor manufacturing used in NG3 ICDs and CRT-Ds.
P960040/S470	09/24/2021	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Change the adhesive and liner used on the tray label stock for pulse generators and Leads.
P960043/S113	09/07/2021	X - 30-Day Notice	PROSTAR 9 FR. PERCUTANEOUS VASCULAR SURGICAL (PVS) SYSTEM	ABBOTT VASCULAR INC.	Addition of a manufacturing site, Clonmel Ireland, to mix the PVP K-90 solution that is applied to the Perclose Prostyle Suture Trimmer.
P960043/S114	09/22/2021	X - 30-Day Notice	PROSTAR 9 FR. PERCUTANEOUS VASCULAR SURGICAL (PVS) SYSTEM	ABBOTT VASCULAR INC.	Removal of a redundant adhesive application step during subassembly manufacturing of the ProGlide Suture-Mediated Closure System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970004/S338	09/01/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Equipment updates in the CEA 2-3 Silicone Molding area (e.g., six additional ovens), updated option for use of temperature recorder (Vaisala Monitoring System Model VL-1700-54T), updated oven mode for the new ovens to use Manual Mode, removal of monitor lot for all ovens, removal of setup lot of new ovens, addition of a new and smaller basket for oven use, and addition of a new toolmaker scope (Nikon MM-40); 2) an update to the applicable work instructions (WI); and 3) the oven operation of allowing the new ovens to be opened during the middle of a run to add or remove lots from the oven and FACTORYworks (FW) updates to support the changes.
P980016/S790	09/01/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Addition of new backfill welding equipment.
P980016/S791	09/10/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Change to the lid lock socket assembly tooling used in the Burn-in manufacturing process.
P980016/S792	09/23/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement modifications to the medical adhesive rework process at Swiss Manufacturing Operations.
P980016/S793	09/24/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the tackweld remediation process at Swiss Manufacturing Operations.
P980035/S690	09/08/2021	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implement alternate final functional hybrid testing.
P980035/S691	09/23/2021	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implement modifications to the medical adhesive rework process at Swiss Manufacturing Operations.
P980035/S692	09/24/2021	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Update the tackweld remediation process at Swiss Manufacturing Operations.

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P000039/S075	09/22/2021	X - 30-Day Notice	THE AMPLATZER(R) SEPTAL OCCLUDER (ASO) AND THE AMPLATZER EXCHANGE SYSTEM	ABBOTT MEDICAL	Addition of a sterilization chamber (Chamber 5) at the Steris sterilization facility in Costa Rica.
P010012/S542	09/24/2021	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Use a new controlled environment area at the Boston Scientific Dorado, Puerto Rico facility.
P010012/S544	09/20/2021	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Update the general visual inspection criteria for cathode damage observed during high voltage capacitor manufacturing used in NG3 ICDs and CRT-Ds.
P010012/S545	09/24/2021	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Change the adhesive and liner used on the tray label stock for pulse generators and Leads.
P010015/S482	09/08/2021	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implement a new burn-in oven system to replace the existing burn-in oven system.
P010015/S483	09/23/2021	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implement modifications to the medical adhesive rework process at Swiss Manufacturing Operations.
P010015/S484	09/24/2021	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Update the tackweld remediation process at Swiss Manufacturing Operations.
P010019/S079	09/10/2021	X - 30-Day Notice	FOCUS NIGHT AND DAY (LOTRAFILCON A) SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Decommissioning of the strip blister inspection system (SBI) at the packaging lines in the production of Alcon lotrafilcon A and lotrafilcon B soft contact lenses for daily and extended wear.
P010019/S080	09/28/2021	X - 30-Day Notice	FOCUS NIGHT AND DAY (LOTRAFILCON A) SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Implementation of an automated lens loading system at the primary packaging lines for Lotralcon B soft contact lenses for extended wear
P010031/S755	09/01/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Addition of new backfill welding equipment.

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P010031/S756	09/10/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Change to the lid lock socket assembly tooling used in the Burn-in manufacturing process.
P010031/S757	09/23/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Implement modifications to the medical adhesive rework process at Swiss Manufacturing Operations.
P010031/S758	09/24/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update the tackweld remediation process at Swiss Manufacturing Operations.
P010047/S066	09/15/2021	X - 30-Day Notice	PROGEL PLEURAL AIR LEAK SEALANT	NEOMEND, INC.	Adding verification dose audit function to STERIS-RCT in Libertyville, IL.
P020025/S133	09/07/2021	X - 30-Day Notice	EP TECHNOLOGIES EPT-1000 XP RF ABLATION SYSTEM	BOSTON SCIENTIFIC	Addition of an inspection for an electrical component located inside the handle of IntellaNav catheters.
P030004/S028	09/14/2021	X - 30-Day Notice	ONYX LIQUID EMBOLIC SYSTEM	EV3 NEUROVASC ULAR	Change to add an alternate test equipment for pouch seal tensile testing.
P030005/S213	09/24/2021	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Change the adhesive and liner used on the tray label stock for pulse generators and Leads.
P030031/S123	09/07/2021	X - 30-Day Notice	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Additional supplier to produce a thermocouple wire component.
P030054/S395	09/01/2021	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ABBOTT MEDICAL	Acceptance to add an alternate supplier of connector assemblies that will be mounted on the hybrids for ICD and CRT-D devices.
P040027/S088	09/24/2021	X - 30-Day Notice	GORE VIATORR TIPS	W. L. GORE & ASSOCIATES, INC.	Replacement zipper braider machine.

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P040036/S085	09/07/2021	X - 30-Day Notice	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Additional supplier to produce a thermocouple wire component.
P040037/S146	09/24/2021	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Replacement zipper braider machine.
P040044/S086	09/29/2021	X - 30-Day Notice	MATRIX VASCULAR CLOSURE SYSTEM (VSG)	CORDIS US CORPORATION	Use of an alternate syringe supplier for the syringe packaged with the Mynx Control VCD.
P050046/S032	09/24/2021	X - 30-Day Notice	ACUITY STEERABLE LEAD SYSTEM	GUIDANT CORP.	Use a new controlled environment area at the Boston Scientific Dorado, Puerto Rico facility.
P050051/S042	09/09/2021	X - 30-Day Notice	ABBOTT ARCHITECT AUSAB	ABBOTT LABORATORIES INC	Extension of shelf life for two in-process materials.
P070008/S129	09/03/2021	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.	Add an alternate supplier for certain sub-assemblies of the Sentus QP leads.
P070026/S085	09/10/2021	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Use of a new chemical formulation for final cleaning and passivation and a change of temperature during one step of the final clean line.
P080025/S233	09/01/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Equipment updates in the CEA 2-3 Silicone Molding area (e.g., six additional ovens), updated option for use of temperature recorder (Vaisala Monitoring System Model VL-1700-54T), updated oven mode for the new ovens to use Manual Mode, removal of monitor lot for all ovens, removal of setup lot of new ovens, addition of a new and smaller basket for oven use, and addition of a new toolmaker scope (Nikon MM-40); 2) an update to the applicable work instructions (WI); and 3) the oven operation of allowing the new ovens to be opened during the middle of a run to add or remove lots from the oven and FACTORYworks (FW) updates to support the changes.
P090022/S039	09/28/2021	X - 30-Day Notice	LENSTEC SOFTEC HD POSTERIOR CHAMBER INTRAOCULAR LENS	LENSTEC, INC.	Use of an alternate lens cleaner in the final cleaning process.
P090031/S010	09/03/2021	X - 30-Day Notice	MONOVISC	ANIKA THERAPEUTICS, INC.	Alternate supplier of the glass syringes used in manufacture of the 5mL sizes of Monovisc.
P100013/S021	09/28/2021	X - 30-Day Notice	CORDIS EXOSEAL VASCULAR CLOSURE DEVICE	CORDIS US CORPORATION	Change to the degreasing solution and system used in the manufacturing of the indicator wire component of the EXOSEAL Vascular Closure Device.
P100021/S095	09/10/2021	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Implementing the addition of a verification fixture to ensure use of the correct stent stop assembly size in the manufacturing of the Endurant II and Endurant IIs Stent Graft System.
P100045/S058	09/16/2021	X - 30-Day Notice	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ST. JUDE MEDICAL	Updates to the temperature sensitivity manufacturing process.

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P110010/S198	09/22/2021	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Change to a design verification production process control.
P110016/S078	09/22/2021	X - 30-Day Notice	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Addition of a sterilization chamber (Chamber 5) at the Steris sterilization facility in Costa Rica.
P110042/S158	09/24/2021	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Use a new controlled environment area at the Boston Scientific Dorado, Puerto Rico facility.
P110042/S162	09/24/2021	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Change the adhesive and liner used on the tray label stock for pulse generators and Leads.
P120020/S027	09/30/2021	X - 30-Day Notice	SUPERA PERIPHERAL STENT SYSTEM	ABBOTT VASCULAR (IDEF TECHNOLOGIES INC)	Change in the stent braiding process.
P130006/S085	09/24/2021	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Replacement zipper braider machine.
P130013/S046	09/09/2021	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Modification to the implant frame measurement system software used for dimensional inspection.
P130014/S012	09/15/2021	X - 30-Day Notice	ADHERUS AUTOSPRAY DURAL SEALANT	HYPERBRANCH MEDICAL TECHNOLOGY, INC.	Alternate supplier to supply ET parts for the delivery system of Adherus AutoSpray ET Dural Sealant.
P130021/S103	09/22/2021	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	The following changes implemented to Evolut FX: 1) relocation of tissue processing worksteps to new controlled environments including introduction of new equipment, systems, and layout changes; 2) implementation of new equipment and process re-sequencing for a delivery catheter system component; 3) dimensional modifications to a measurement tool used for in-process inspection of the delivery catheter; and 4) addition of a new tissue supplier.
P130026/S075	09/22/2021	X - 30-Day Notice	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Addition of a sterilization chamber (Chamber 5) at the Steris sterilization facility in Costa Rica.

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P140028/S068	09/13/2021	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Implementation of a new mold for an injection molded delivery system component.
P140028/S069	09/10/2021	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Change to visual inspection acceptance criteria of a delivery system component.
P140031/S132	09/03/2021	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	New clean room and preliminary packaging room at the Cartago, Costa Rica facility.
P140031/S134	09/22/2021	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Reduction in sampling plan for in-process inspection of the cloth skirt.
P150003/S078	09/22/2021	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Change to a design verification production process control.
P150005/S067	09/07/2021	X - 30-Day Notice	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Addition of an inspection for an electrical component located inside the handle of IntellaNav catheters.
P150009/S006	09/17/2021	X - 30-Day Notice	ANGELMED GUARDIAN SYSTEM	ANGEL MEDICAL SYSTEMS INC.	Additional supplier of capacitors used in the EXD system.
P150012/S115	09/24/2021	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Use a new controlled environment area at the Boston Scientific Dorado, Puerto Rico facility.
P150012/S117	09/24/2021	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Change the adhesive and liner used on the tray label stock for pulse generators and Leads.
P150016/S021	09/15/2021	X - 30-Day Notice	TRIDYNE VASCULAR SEALANT	NEOMEND, INC.	Adding verification dose audit function to STERIS-RCT in Libertyville, IL.
P150021/S054	09/30/2021	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Add an alternate manufacturing site for sensor container assembly and finished sensor kit packing. The sensor container and sensor kit are components of the FreeStyle Libre Pro Flash continuous glucose monitoring (CGM) device
P150033/S118	09/15/2021	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Implement a rework coating process and associated updates for manufacturing documentation.
P150033/S119	09/28/2021	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Modification to the medical adhesive dispense process during electrode module assembly

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P150036/S056	09/08/2021	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Reduction of the number of in-process glutaraldehyde solution change-outs for surgical pericardial heart valves.
P150048/S057	09/08/2021	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Reduction of the number of in-process glutaraldehyde solution change-outs for surgical pericardial heart valves.
P160021/S032	09/01/2021	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Changing the electropolishing process and implementing a new EO sterilization chamber control system.
P160026/S029	09/15/2021	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.	Update to the final electrical inspection test step and implementation of a new electrical test fixture.
P180011/S044	09/13/2021	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Implementation of a new mold for an injection molded delivery system component.
P180011/S045	09/10/2021	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Change to visual inspection acceptance criteria of a delivery system component.
P180028/S010	09/24/2021	X - 30-Day Notice	HEARTSTART FRX DEFIBRILLATOR	PHILIPS MEDICAL SYSTEMS	Change to the hardliner sealing process for the SMART Padz II.
P180032/S009	09/01/2021	X - 30-Day Notice	CERENE® CRYOTHERAPY DEVICE	CHANNEL MEDSYSTEMS, INC.	Modification to the manufacturing procedure for the Cerene Cryotherapy Device ¿ namely, an update to the manufacturing test software and manufacturing instructions.
P190016/S003	09/08/2021	X - 30-Day Notice	TULA® SYSTEM	TUSKER MEDICAL, INC.	Addition of two new cleanrooms (Controlled Environment Rooms) to the existing manufacturing facility for the Tula System.
P200015/S013	09/22/2021	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Reduction in sampling plan for in-process inspection of the cloth skirt.
P200021/S003	09/08/2021	X - 30-Day Notice	NEURO COCHLEAR IMPLANT SYSTEM	OTICON MEDICAL	Modification to the acceptance criteria for the incoming screening test of each CI-Link unit when they are received by Oticon Medical from the supplier.
P200021/S004	09/10/2021	X - 30-Day Notice	NEURO COCHLEAR IMPLANT SYSTEM	OTICON MEDICAL	Modifications to the acceptance criteria for the chemical composition of the feedthrough sandblasting material and to the leak test method for the magnet casing.
P200021/S005	09/22/2021	X - 30-Day Notice	NEURO COCHLEAR IMPLANT SYSTEM	OTICON MEDICAL	Installation of a laminar flow workbench to improve environmental controls and increase production capacity.

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P200049/S001	09/22/2021	X - 30-Day Notice	AMPLATZER¿ AMULET ¿ LEFT ATRIAL APPENDAGE OCCLUDER	ABBOTT MEDICAL	Addition of a sterilization chamber (Chamber 5) at the Steris sterilization facility in Costa Rica.
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