PMA Monthly approvals from 6/1/2021 to 6/30/2021

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P200021	06/23/2021	PMAO - PMA Origi	NEURO COCHLEAR IMPLANT SYSTEM	OTICON MEDICAL	Approval for Neuro Cochlear Implant System (NCIS) The Neuro Cochlear Implant System (NCIS) is indicated for individuals eighteen (18) years of age or older, with bilateral severe-to-profound sensorineural hearing loss, who obtain limited benefit from appropriately fitted hearing aid(s). Severe-to-profound hearing loss is determined by a pure-tone average (PTA) superior or equal >= to 70 dB HL at 500, 1000 and 2000 Hz. Limited benefit from amplification is defined by scores of 50% or less on Hearing in Noise Test (HINT) sentences in quiet or noise, in the best-aided listening condition. Unless already appropriately fitted with hearing aids, it is recommended that candidates undergo a hearing aid trial period of three (3) months.

Total: 1

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830055/S269	06/30/2021	S - Special CBE	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for the introduction of two additional inspections at the machining process step for the screw thread feature of the Attune Revision Stems of the LCS Total Knee System.
P840001/S471	06/09/2021	N - Normal 180 Day	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Approval for 1) the Pain PC System for Spinal Cord Stimulation (SCS) which includes Implantable Neurostimulation Systems Vanta with AdaptiveStim and Sequentia LT; 2) modified labeling for the Model B31060 Connector Plug to reflect its intended use with the Pain PC system and 3) labeling updates for previously approved devices to be consistent with Pain PC system labeling.
P840001/S486	06/07/2021	R - Real-Time Proc	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Approval for a change to Model 977D160 Vectris® 1x8 SC (Subcompact) Trial Screening Lead and Model 977D260 Vectris® 1x8 Compact Trial Screening Lead, to add an alternate material, 304 stainless-steel wire, for the braided shield of the Vectris lead body.
P840024/S091	06/09/2021	N - Normal 180 Day	NUCLEUS MULTICHANNEL IMPLANTABLE HEARING PROSTHESI	COCHLEAR AMERICAS	Approval for labeling changes related to the MRI compatibility.
P880086/S319	06/28/2021	R - Real-Time Proc	ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS	ABBOTT MEDICAL	Approval for changes to the Merlin PCS 3650 Programmer Model 3330 Software to create v25.1.1.
P890027/S060	06/09/2021	N - Normal 180 Day	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT SYS / CHILDREN	COCHLEAR AMERICAS	Approval for labeling changes related to the MRI compatibility.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P890055/S074	06/22/2021	O - Normal 180 Day	MEDSTREAM PROGRAMMABLE INFUSION PUMP SYSTEM	INTERA ONCOLOGY	Approval for a manufacturing site located at Proven Process Medical Devices, 110 Forbes Road, Mansfield, Massachusetts 02048 which will perform manufacturing of the Intera 3000 Hepatic Artery Infusion Pump (Intera 3000, 30mL high flow rate).
P910023/S437	06/28/2021	R - Real-Time Proc	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ABBOTT MEDICAL	Approval for changes to the Merlin PCS 3650 Programmer Model 3330 Software to create v25.1.1.
P930014/S136	06/22/2021	R - Real-Time Proc	ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES	ALCON LABORATORIES, INC.	Approval to increase the spherical power range for the AcrySof IQ Vivity Extended Vision Intraocular Lenses (IOLs), AcrySof IQ Vivity Extended Vision Toric IOLs, AcrySof IQ Vivity Extended Vision UV Absorbing IOLs, and AcrySof IQ Vivity Extended Vision UV Absorbing Toric IOLs from 15 D to 25 D to 10 D to 30 D; and to add a higher cylindrical power toric model to the AcrySof IQ Vivity¿ Extended Vision Toric IOLs (Model DFT615) and AcrySof IQ Vivity Extended Vision UV Absorbing Toric IOLs (Model DAT615).
P950029/S130	06/25/2021	R - Real-Time Proc	CHORUS RM MODEL 7034 DDDR PACEMAKER INCL. OPUS RM MODEL 4534 SSIR PACEMAKER	MICROPORT CRM USA INC.	Approval for programmer and remote monitoring software updates to support Alizea and Celea pacemakers.
P960009/S385	06/09/2021	N - Normal 180 Day	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval for 1) the Pain PC System for Spinal Cord Stimulation (SCS) which includes Implantable Neurostimulation Systems Vanta with AdaptiveStim and Sequentia LT; and 2) modified labeling for the Model B31060 Connector Plug to reflect its intended use with the Pain PC system.3) labeling updates for previously approved devices to be consistent with Pain PC system labeling.
P960009/S400	06/30/2021	R - Real-Time Proc	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval for an update to the Medtronic Model A610 DBS Clinician Programmer Application (CPA).
P970013/S087	06/28/2021	R - Real-Time Proc	MICRONY PACEMAKERS	ABBOTT MEDICAL	Approval for changes to the Merlin PCS 3650 Programmer Model 3330 Software to create v25.1.1.
P970051/S190	06/09/2021	N - Normal 180 Day	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for labeling changes related to the MRI compatibility.
P980016/S780	06/29/2021	R - Real-Time Proc	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval to release new firmware RAMware to Cobalt and Crome ICD/CRT-D devices.
P980040/S136	06/16/2021	O - Normal 180 Day	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval to end subject enrollment for the post-approval study (PAS) protocol.
P980049/S142	06/25/2021	R - Real-Time Proc	DEFENDER II MODEL 9201 IMPLANTABLE CARDIOVERTER DEFIBRILLATOR	MICROPORT CRM USA INC.	Approval for programmer and remote monitoring software updates to support Alizea and Celea pacemakers.
P990004/S044	06/18/2021	R - Real-Time Proc	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Approval for the modification to the sterile Water for Injection (sWFI) needle-free prefilled syringe in the SURGIFLO Hemostatic Matrix Kit with Thrombin.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000015/S040	06/09/2021	N - Normal 180 Day	NUCLEUS 24 AUDITORY BRAINSTEM IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for labeling changes related to the MRI compatibility.
P000025/S120	06/25/2021	N - Normal 180 Day	COMBI 40+ COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Approval for Front-End Signal Processing Features: Ambient Noise Reduction, Transient Noise Reduction and Adaptive Intelligence.
P000040/S041	06/17/2021	O - Normal 180 Day	HYDRO THERMABLATOR ENDOMETRIAL ABLATION SYSTEM	MINERVA SURGICAL, INC.	Approval for a manufacturing site change to your new facility located at Apical Instruments, Inc, 2971 Spring Street, Redwood City, CA 94063. The facility operations at this site will involve the manufacturing of the Minerva Genesys HTA Controller.
P010013/S081	06/30/2021	N - Normal 180 Day	NOVASURE IMPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM	HOLOGIC, INC.	Approval for design modifications of the cervical collar tip and the liner, addition of marking to the external sheath, change in color of front grip handle, new logo and tag, and labeling modifications.
P010031/S742	06/29/2021	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval to release new firmware RAMware to Cobalt and Crome ICD/CRT-D devices.
P020012/S037	06/08/2021	R - Real-Time Proc	ARTEFILL, BELLAFILL PMMA COLLAGEN PERMANENT DERMAL FILLER	SUNEVA MEDICAL, INC.	Approval for change in secondary packaging tray lid material for the Bellafill Dermal Filler Treatment Kit and the Skin Test Kit, and change in co-packaged needle to TSK Steriject 27G Thin Wall needle for the Bellafill Dermal Filler Treatment Kit.
P030035/S186	06/28/2021	R - Real-Time Proc	ANTHEM AND FRONTIER II CRT-P'S	ABBOTT MEDICAL	Approval for changes to the Merlin PCS 3650 Programmer Model 3330 Software to create v25.1.1.
P030054/S392	06/28/2021	R - Real-Time Proc	ST JUDE MEDICAL EPIC HF SYSTEM	ABBOTT MEDICAL	Approval for changes to the Merlin PCS 3650 Programmer Model 3330 Software to create v25.1.1.
P040045/S116	06/25/2021	Y - 135 Review Tra	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Approval for the implementation of a new test method for measurement of a leachable component in VISTAKON® (senofilcon A) Brand Contact Lenses.
P050037/S111	06/08/2021	Y - 135 Review Tra	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Approval for the change in mixing the gel and media in a larger mixing bowl rather than multiple smaller mixing bowls during manufacturing of Radiesse Injectable Implant.
P050047/S081	06/23/2021	S - Special CBE	JUVEDERM 24HV, JUVEDERM 30 AND JUVEDERM 30HV GEL IMPLANTS	ALLERGAN	Approval for additional incoming testing for the phosphate buffer solution used in the manufacture of the Juvéderm injectable gel implants.
P050052/S130	06/08/2021	Y - 135 Review Tra	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval for the change in mixing the gel and media in a larger mixing bowl rather than multiple smaller mixing bowls during manufacturing of Radiesse Injectable Implant.
P050052/S131	06/25/2021	Y - 135 Review Tra	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval for the change in mixing the gel and media in a larger mixing bowl rather than multiple smaller mixing bowls during manufacturing of RADIESSE (+) Lidocaine Dermal Filler.
P080011/S120	06/03/2021	O - Normal 180 Day	BIOFINITY (COMFILCON A)	COOPERVISIO N, INC.	Approval for a new private label trade name.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100009/S042	06/03/2021	R - Real-Time Proc	MITRACLIP DELIVERY SYSTEM	ABBOTT VASCULAR INC.	Approval of nitinol gripper line change.
P100010/S110	06/18/2021	P - Panel Track	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Approval for expanding the indications to include the treatment of recurrent symptomatic paroxysmal atrial fibrillation as an alternative to antiarrhythmic drug therapy as an initial rhythm control strategy.
P100010/S114	06/10/2021	R - Real-Time Proc	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Approval for design and material modifications to the coaxial connector assembly located on the handle of the Arctic Front Advance and Arctic Front Advance Pro catheters.
P100047/S177	06/09/2021	Y - 135 Review Tra	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for a material change to the housing gasket in the Controller.
P100047/S178	06/28/2021	R - Real-Time Proc	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for the update of the documentation of the Outflow Graft Design Specification.
P100047/S180	06/09/2021	S - Special CBE	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for updates to the manufacturing procedures for the Battery pack.
P110019/S115	06/25/2021	P - Panel Track	XIENCE PRIME AND XIENCE PRIME LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Approval for the XIENCE Alpine Everolimus Eluting Coronary Stent Systems (XIENCE Alpine EECSS), XIENCE Sierra Everolimus Eluting Coronary Stent Systems (XIENCE Sierra EECSS), and the XIENCE Skypoint Everolimus Eluting Coronary Stent System (XIENCE Skypoint EECSS). The XIENCE [Alpine / Sierra / Skypoint] stent system is indicated for improving coronary artery luminal diameter in patients, including those at high risk for bleeding and those with diabetes mellitus, with symptomatic heart disease due to de novo native coronary artery lesions (length <= 32 mm) with reference vessel diameters of >= 2.25 mm to <= 4.25 mm. In addition, the XIENCE [Alpine / Sierra / Skypoint] stent system is indicated for treating de novo chronic total coronary occlusions.
P110033/S060	06/23/2021	S - Special CBE	JUVEDERM VOLUMA XC	ALLERGAN	Approval for additional incoming testing for the phosphate buffer solution used in the manufacture of the Juvéderm injectable gel implants.
P110042/S154	06/10/2021	N - Normal 180 Day	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for changes addressing lead fractures and the addition of a third sterilization chamber.
P120011/S021	06/29/2021	Y - 135 Review Tra	IDEAL IMPLANT SALINE-FILLED BREAST IMPLANT	IDEALIMPLANT	Approval for a change to the product release testing method for the posterior valve-patch joint.
P130016/S040	06/09/2021	N - Normal 180 Day	NUCLEUS HYBRID L24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for labeling changes related to the MRI compatibility.
P130022/S029	06/09/2021	Y - 135 Review Tra	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for addition of an alternate supplier of the Hysol epoxy materials used to make the header component of the implantable pulse generator (IPG) of the Senza neuromodulation system.
P130024/S040	06/03/2021	R - Real-Time Proc	LUTONIX DRUG COATED BALLOON PTA CATETER	LUTONIX	Approval for revised release specifications for related substances.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140003/S080	06/28/2021	N - Normal 180 Day	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for the use of a new epoxy adhesive to manufacture Impella catheters.
P140018/S024	06/15/2021	R - Real-Time Proc	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Approval for a T=12 and 30 month shelf-life specification for the Butylated hydroxyanisole (BHA) stabilizer of greater than or equal to 175 ug/g for the VenaSeal Adhesive.
P140029/S032	06/28/2021	P - Panel Track	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Restylane Contour is indicated for use in cheek augmentation and correction of midface contour deficiencies in patients over the age of 21.
P140029/S035	06/11/2021	Y - 135 Review Tra	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Approval for installation of new equipment and modification of a control panel in clean rooms at Uppsala, Sweden.
P140033/S067	06/28/2021	R - Real-Time Proc	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ABBOTT MEDICAL	Approval for changes to the Merlin PCS 3650 Programmer Model 3330 Software to create v25.1.1.
P150004/S044	06/22/2021	N - Normal 180 Day	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Approval for design changes to the delivery sheath and tunneling tool, including a new material and locking mechanism for the delivery sheath and a new handle and tip design for the tunneling tool, changes to the packaging configurations of the lead kit and accessories kit, and minor labeling changes to reflect the design and packaging changes. This supplement also requested approval for the addition of Microlumen, Inc. as the new supplier of the delivery sheath, Spectra Medical Inc. as the new supplier of the tunneling tool, and Xylem Company as an alternate supplier for the straight stylet.
P150009/S002	06/21/2021	N - Normal 180 Day	ANGELMED GUARDIAN SYSTEM	ANGEL MEDICAL SYSTEMS INC.	Approval for changes to the design of the Implantable Medical Device resulting in the AMSG3-E model with a 1-year shelf life and a 3-year implanted life.
P150014/S041	06/02/2021	S - Special CBE	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Approval for an update to the hazard information on the product labeling for kits on the cobas 6800/8800 Systems.
P150015/S043	06/02/2021	S - Special CBE	COBAS HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Approval for an update to the hazard information on the product labeling for kits on the cobas 6800/8800 Systems.
P150033/S102	06/21/2021	R - Real-Time Proc	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval for a change for new sub-tier suppliers for the tether component.
P150033/S104	06/17/2021	R - Real-Time Proc	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval for minor design changes to the endcap assembly used in the Micra and Micra AV Transcatheter Pacing Systems.
P160015/S005	06/28/2021	N - Normal 180 Day	AED PLUS AND FULLY AUTOMATIC AED PLUS	ZOLL MEDICAL CORPORATION	Approval for changes made to Zoll AED 3 and ZOLL AED 3 Automatic device including software update (Release 6), minor hardware changes, and introducing ZOLL AED 3 Aviation and ZOLL AED 3 Aviation Battery Pack.

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P160022/S019	06/28/2021	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 changes made to ZOLL AED 3 BLS device for Software update (Release 6), minor hardware changes and Battery Pack.
P160028/S004	06/15/2021	S - Special CBE	PHILIPS HEARTSTART FR3 DEFIBRILLATOR	PHILIPS MEDICAL SYSTEMS, INC.	Approval for updating the safety alert from a Caution to a Warning in the instructions for use for the FRx and FR3 Infant/Child Keys.
P160032/S005	06/10/2021	N - Normal 180 Day	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 AED defibrillation pad and battery pack model numbers DP-100, DDP-200P, DBP-1400, DBP-2800, DDP-2001, DDP-2002, DBP-2003, and DBP-2013.
P160041/S033	06/02/2021	S - Special CBE	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Approval for an update to the hazard information on the product labeling for kits on the cobas 6800/8800 Systems.
P160047/S021	06/09/2021	N - Normal 180 Day	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	AEGEA MEDICAL , INC	Approval for changes to device software, design modifications, and updated labeling to reflect the software changes.
P170003/S021	06/03/2021	R - Real-Time Proc	LUTONIX® 035 DRUG COATED BALLOON PTA CATHETER, MODEL 9010	LUTONIX	Approval for revised release specifications for related substances.
P170011/S026	06/28/2021	N - Normal 180 Day	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval for the implementation of an updated design and supplier for the outflow area component of the Impella RP catheter.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170011/S029	06/15/2021	O - Normal 180 Day	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval for various labeling updates to add the results of the pediatric post-approval study.
P170011/S030	06/28/2021	N - Normal 180 Day	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval for a design modification to the Impella RP System involving the addition of a fiber-optic pressure sensor.
P170011/S032	06/28/2021	N - Normal 180 Day	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval for the use of a new epoxy adhesive to manufacture Impella catheters.
P170019/S023	06/30/2021	N - Normal 180 Day	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval for Expanding the indications for use to include a CDx indication for detecting ALK rearrangements in non-small cell lung cancer patients who may be candidates for brigatinib treatment.
P170027/S005	06/01/2021	O - Normal 180 Day	THEROX DOWNSTREAM SYSTEM	THEROX, INC.	Approval for a manufacturing site located at ZOLL Circulation Facility (2000 Ringwood Ave, San Jose, CA, 95131) for the final assembly, testing, final acceptance, and pack-out activities of the TherOx® DownStream® System Console only.
P170030/S007	06/24/2021	N - Normal 180 Day	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Approval for a modified stent delivery system containing multiple material and design changes including an updated hub/luer connector, packaging changes to accommodate the modified stent delivery system, and a change to the stent crimping manufacturing process.
P170034/S005	06/04/2021	O - Normal 180 Day	HYDRUS MICROSTENT	IVANTIS, INC.	Approval for modified labeling that reflects the findings of the Post-Approval Study (PAS) designated as Continuation of Premarket Cohort PAS.
P180013/S007	06/29/2021	O - Normal 180 Day	VICI VENOUS STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for labeling update which incorporates the final 3-year results from the VIRTUS Continued Follow-Up Study of patients enrolled in the premarket study.
P180028/S008	06/15/2021	S - Special CBE	HEARTSTART FRX DEFIBRILLATOR	PHILIPS MEDICAL SYSTEMS	Approval for updating the IFU for the FRx and FR3 Infant/Child keys safety alert from Caution to Warning.
P180046/S025	06/11/2021	N - Normal 180 Day	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for the addition of "3T RF whole-body coil conditional MRI scans at MC 2 mode" labeling on the Axonics Sacral Neuromodulation System.
P190006/S025	06/11/2021	N - Normal 180 Day	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for the addition of "3T RF whole-body coil conditional MRI scans at MC 2 mode" labeling on the Axonics Sacral Neuromodulation System.
P190014/S005	06/24/2021	S - Special CBE	MYCHOICE HRD CDX	MYRIAD GENETIC LABORATORIES, INC	Approval for an update to the contamination detection algorithm which is a quality control change to the myChoice CDx device software.
P190025/S006	06/01/2021	R - Real-Time Proc	ALINITY M HCV	ABBOTT MOLECULAR, INC.	Approval for tp release the software version 1.6.2 in the United States, incorporating into the Alinity m System Software version 1.6.0, version 1.6.1 and 1.6.2, which are currently released outside, the US.
P190028/S005	06/02/2021	S - Special CBE	COBAS HPV FOR USE ON THE COBAS 6800/8800 SYSTEMS	ROCHE MOLECULAR SYSTEMS, INC.	Approval for an update to the hazard information on the product labeling for kits on the cobas 6800/8800 Systems.

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P200013/S005	06/01/2021	R - Real-Time Proc	ALINITY M HBV	ABBOTT MOLECULAR, INC.	Approval to release the software version 1.6.2 in the United States, incorporating into the Alinity m System Software version 1.6.0, version 1.6.1 and 1.6.2, which are currently released outside the US.
P200015/S010	06/29/2021	O - Normal 180 Day	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Approval for a manufacturing site located at Edwards Lifesciences Technology SARL, Hwy #402 N Km 1.4, Añasco, Puerto Rico for ethylene oxide (EO) sterilization of the Commander Delivery System and Crimper accessory for the SAPIEN 3 Transcatheter Heart Valve System.
P200028/S005	06/02/2021	R - Real-Time Proc	DIAMONDTEMP ABLATION SYSTEM	MEDTRONIC INC.	Approval for design and manufacturing process changes for the Bidirectional DiamondTemp Ablation Catheters.
P200039/S002	06/04/2021	O - Normal 180 Day	SHOCKWAVE INTRAVASCULAR LITHOTRIPSY (IVL) SYSTEM WITH SHOCKWAVE C2 CORONARY INTRAVASCULAR LITHOTRIPSY (IVL) CATHETER	SHOCKWAVE MEDICAL, INC.	Approval for the revised protocol for the post-approval study (PAS) protocol.

Total: 82

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830055/S267	06/14/2021	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Removing the use of bovine derivative polish and grease consumable from the manufacturing process (Matchless HF1 and Matchless 16) and replace with non-bovine polish and grease consumable (Abracut C and BG-58) in the manufacture of all LCS Complete MB Patella in DePuy Synthes, Ireland.
P830061/S195	06/23/2021	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to the cleaning process of stylet components manufactured at the supplier.
P830063/S019	06/24/2021	X - 30-Day Notice	GAMBRO FIBER PLASMAFILTER	BAXTER INTERNATIONAL, INC.	Transfer the production of some components of the Prismaflex TPE2000 set to alternate Baxter locations.
P840001/S490	06/25/2021	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Newly defined and characterized solder paste inspection (SPI) process at Medtronic Tempe Campus (MTC), Medtronics internal supplier of hybrids used in the manufacturing of Medtronic Neuromodulation (Neuro) products.
P840001/S493	06/30/2021	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Newly defined and characterized solder paste inspection (SPI) process at Medtronic Tempe Campus (MTC), Medtronics internal supplier of hybrids used in the manufacturing of Medtronic Neuromodulation (Neuro) products.

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P850064/S046	06/25/2021	X - 30-Day Notice	MODEL 203 LIFE PULSE HIGH FREQUENCY VENTILATOR	BUNNELL, INC.	New process using the 844USB EPRO programmer.
P850089/S155	06/23/2021	X - 30-Day Notice	CAPSURE SP, CAPSURE, CAPSURE 2 LEADS, EXCELLENCE S, IMPULSE, IMPLUSE II EXCELLENCE SS, LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to the cleaning process of stylet components manufactured at the supplier.
P860004/S374	06/02/2021	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Implementation of new visual inspections and additional controls to the SynchroMed II pump head and pump tube assembly steps .
P860004/S375	06/25/2021	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Newly defined and characterized solder paste inspection (SPI) process at Medtronic Tempe Campus (MTC), Medtronics internal supplier of hybrids used in the manufacturing of Medtronic Neuromodulation (Neuro) products.
P890003/S446	06/23/2021	X - 30-Day Notice	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Changes to the cleaning process of stylet components manufactured at the supplier.
P900056/S192	06/24/2021	X - 30-Day Notice	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Modifications to quality control inspection equipment for a supplied component.
P910073/S162	06/08/2021	X - 30-Day Notice	ENDOTAK LEAD SYSTEM	BOSTON SCIENTIFIC	Add a visual inspection to the defibrillation lead connector terminal subassembly.
P920015/S255	06/23/2021	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Changes to the cleaning process of stylet components manufactured at the supplier.
P930039/S227	06/02/2021	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Acceptance to implement process improvements in the plasma tubing cut-to-length manufacturing process step.
P930039/S228	06/23/2021	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Changes to the cleaning process of stylet components manufactured at the supplier.
P940015/S048	06/29/2021	X - 30-Day Notice	SYNVISC ONE	SANOFI GENZYME CORP.	Incorporation of a magnetic filter into the manufacturing process for Synvisc and Synvisc-One.
P940035/S016	06/15/2021	X - 30-Day Notice	MATRITECH NMP22(TM) TEST KIT	ALERE SCARBOROUGH, INC	New vendor for the resin contained in the nitrocellulose membrane.
P950034/S053	06/09/2021	X - 30-Day Notice	SEPRAFILM(TM) (HAL-F (TM)) BIORESORBABLE MEMBRANE	BAXTER HEALTHCARE CORPORATION	Establishment of clean hold times for new equipment used in the manufacturing process of Seprafilm Adhesion Barrier.
P950037/S222	06/02/2021	X - 30-Day Notice	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Introduce changes to the battery feedthroughs.

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P950037/S223	06/02/2021	X - 30-Day Notice	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Addition of an alternative supplier for a battery subcomponent and the automation of a process used in the manufacture of medium and high-rate batteries.
P950037/S224	06/22/2021	X - 30-Day Notice	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Remove redundant visual optical check and optimize sampling for the tensile test.
P960009/S401	06/25/2021	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Newly defined and characterized solder paste inspection (SPI) process at Medtronic Tempe Campus (MTC), Medtronics internal supplier of hybrids used in the manufacturing of Medtronic Neuromodulation (Neuro) products.
P970004/S333	06/22/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Update the connector assembly resistance spot welding process window for the InterStim Micro INS (model 97810) at the Medtronic¿s manufacturing facility located in Juncos, Puerto Rico.
P970004/S334	06/25/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Newly defined and characterized solder paste inspection (SPI) process at Medtronic Tempe Campus (MTC), Medtronics internal supplier of hybrids used in the manufacturing of Medtronic Neuromodulation (Neuro) products.
P970020/S085	06/21/2021	X - 30-Day Notice	MULTI-LINK ULTRA/ ZETA CORONARY STENT SYSTEMS	ABBOTT VASCULAR INC.	New resin colorant supplier for delivery system components.
P980016/S784	06/16/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates to the accelerometer test systems.
P980016/S785	06/04/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to the Solder Paste Inspection at Medtronic Tempe Campus (MTC).
P980035/S683	06/16/2021	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Updates to the accelerometer test systems.
P980035/S685	06/04/2021	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Changes to the Solder Paste Inspection at Medtronic Tempe Campus (MTC).
P980040/S135	06/07/2021	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Complete the manufacturing for the TECNIS Synergy IOL with TECNIS Simplicity® Delivery System, Model DFR00V and TECNIS Synergy Toric II IOL with TECNIS Simplicity® Delivery System, Models DFW150, DFW225, DFW300, DFW375 at the AMO Puerto Rico Manufacturing Inc. facility.

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P980040/S137	06/29/2021	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Addition of an alternate sterilization chamber for sterilization of the subject intraocular lenses preloaded in the TECNIS Simplicity Delivery System.
P980040/S138	06/29/2021	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Modification to the endotoxin extraction method currently conducted at AMO Groningen B.V. manufacturing facility for the subject devices.
P980050/S133	06/23/2021	X - 30-Day Notice	MEDTRONIC(R) JEWEL(R) AF 7250 DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATOR, MODEL 9961 PROGRAMMER APPLICATION SOF	MEDTRONIC INC.	Changes to the cleaning process of stylet components manufactured at the supplier.
P990004/S048	06/02/2021	X - 30-Day Notice	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Change to the supplier location of gamma irradiation services for dose audit samples.
P990074/S046	06/25/2021	X - 30-Day Notice	NATRELLE SALINE BREAST IMPLANTS	ALLERGAN	Change to implement an Electronic Data Acquisition (EDA) System to record and store the cycle parameters of the dry heat sterilization process used in the manufacture of Allergan Natrelle® Saline-Filled Breast Implants and Allergan Natrelle® Silicone-Filled Breast Implants
P990075/S050	06/04/2021	X - 30-Day Notice	MENTOR CORPORATION SALINE-FILLED AND SPECTRUM (R) MAMMARY PROSTHESES	MENTOR WORLDWIDE LLC	Changes in the primary packaging equipment used in the manufacturing process for MemoryShape, MemoryGel, and Saline-Filled and Spectrum Breast Implants.
P000009/S091	06/02/2021	X - 30-Day Notice	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Addition of an alternative supplier for a battery subcomponent and the automation of a process used in the manufacture of medium and high-rate batteries.
P000046/S028	06/02/2021	X - 30-Day Notice	STAARVISC II	ANIKA THERAPEUTICS, INC.	Use of an alternate stopper from the current supplier for the syringe that holds your approved ophthalmic viscosurgical device.
P010001/S023	06/30/2021	X - 30-Day Notice	CERAMIC TRANSCEND HIP ARTICULATION SYSTEM	CERAMTEC GMBH	The firm identified a process optimization with its new HIP equipment (APG 3076-03). The intent of the process optimization (i.e., slight increase of the SR-T limits) in the HIP-sintering step is to ensure a better process capability as well as improved ceramic material and product properties.
P010015/S474	06/16/2021	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Updates to the accelerometer test systems.
P010015/S476	06/04/2021	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Changes to the Solder Paste Inspection at Medtronic Tempe Campus (MTC).
P010015/S477	06/23/2021	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Changes to the cleaning process of stylet components manufactured at the supplier.

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P010031/S746	06/16/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Updates to the accelerometer test systems.
P010031/S748	06/04/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Changes to the Solder Paste Inspection at Medtronic Tempe Campus (MTC).
P010032/S175	06/08/2021	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Replacement of the current MSP430 microcontroller chip on the implantable pulse generator's printed circuit board with an MSP430 chip with updated packaging.
P010050/S019	06/09/2021	X - 30-Day Notice	IMMULITE 2000 XPI HBSAG	SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS, LTD	Update the expiry of a raw material.
P010055/S011	06/30/2021	X - 30-Day Notice	PROSTALUND CORETHERM SYSTEM MICROWAVE THERMOTHERAPY FOR BPH	PROSTALUND AB	Manufacturing change to move facilities including relocating critical analytical equipment.
P020045/S096	06/01/2021	X - 30-Day Notice	7F FREEZOR CARDIAC CRYOABLATION CATHETER AND CCT.2 CRYOCONSOLE SYSTEM	MEDTRONIC CRYOCATH LP	Replacement of a reflow oven used at a supplier.
P020056/S055	06/25/2021	X - 30-Day Notice	NATRELLE SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Change to implement an Electronic Data Acquisition (EDA) System to record and store the cycle parameters of the dry heat sterilization process used in the manufacture of Allergan Natrelle® Saline-Filled Breast Implants and Allergan Natrelle® Silicone-Filled Breast Implants
P030017/S346	06/02/2021	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Update the Implantable Pulse Generator (IPG) Automatic Test Equipment (ATE) software to clear the manufacturing data logs created during the Printed Circuit Board assembly (PCBA) manufacturing process at the Boston Scientific Clonmel manufacturing site
P030053/S060	06/04/2021	X - 30-Day Notice	MEMORYGEL SILICONE GEL -FILLED BREAST IMPLANTS	MENTOR CORP.	Changes in the primary packaging equipment used in the manufacturing process for MemoryShape, MemoryGel, and Saline-Filled and Spectrum Breast Implants.
P030053/S061	06/04/2021	X - 30-Day Notice	MEMORYGEL SILICONE GEL -FILLED BREAST IMPLANTS	MENTOR CORP.	Change in the gel filling equipment used in the manufacturing process.
P040002/S068	06/17/2021	X - 30-Day Notice	ENDOLOGIX POWERLINK SYSTEM	ENDOLOGIX, LLC	Supplier and manufacturing changes for the suture material used in the delivery system and in process manufacturing for the AFX Endovascular AAA System.

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P040012/S061	06/16/2021	X - 30-Day Notice	ACCULINK CAROTID STENT SYSTEM AND RX ACCULINK CAROTID STENT SYSTEM	ABBOTT VASCULAR	Alternate supplier of delivery system injection molded components.
P040043/S129	06/16/2021	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Additional stent graft manufacturing equipment to expand production capacity.
P040045/S121	06/04/2021	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 existing production line to produce VISTAKON (senofilcon A) ACUVUE OASYS Brand Contact Lenses with HYDRACLEAR Plus.
P050007/S041	06/15/2021	X - 30-Day Notice	STARCLOSE VASCULAR CLOSURE SYSTEM	ABBOTT VASCULAR DEVICES	Increase the maximum pressure for the Clip Applier wire control machine that is used during the wire controller assembly process for StarClose SE® Vascular Closure System
P050023/S155	06/02/2021	X - 30-Day Notice	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Introduce changes to the battery feedthroughs.
P050023/S156	06/02/2021	X - 30-Day Notice	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Addition of an alternative supplier for a battery subcomponent and the automation of a process used in the manufacture of medium and high-rate batteries.
P060011/S027	06/15/2021	X - 30-Day Notice	C-FLEX MODEL 570C INTRAOCULAR LENS (IOL)	RAYNER INTRAOCULAR LENSES LTD.	Option to use an alternative lathe plus polishing process for the manufacture of RayOne EMV intraocular lenses.
P060028/S039	06/04/2021	X - 30-Day Notice	MENTOR MEMORYSHAPE BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Changes in the primary packaging equipment used in the manufacturing process for MemoryShape, MemoryGel, and Saline-Filled and Spectrum Breast Implants
P060028/S040	06/04/2021	X - 30-Day Notice	MENTOR MEMORYSHAPE BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Change in the gel filling equipment used in the manufacturing process.
P060037/S071	06/14/2021	X - 30-Day Notice	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Change to an external process challenge device (PCD) vial diameter for hydrogen peroxide gas plasma sterilization in order to adjust the resistance level of the PCD to an appropriate level.
P060039/S107	06/23/2021	X - 30-Day Notice	ATTAIN STARFIX MODEL 4195 LEAD	MEDTRONIC INC.	Changes to the cleaning process of stylet components manufactured at the supplier.
P070008/S124	06/02/2021	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.	Introduce changes to the battery feedthroughs.
P070008/S125	06/02/2021	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.	Addition of an alternative supplier for a battery subcomponent and the automation of a process used in the manufacture of medium and high-rate batteries.

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P070014/S062	06/03/2021	X - 30-Day Notice	LIFESTENT FLEXSTAR & FLEXSTAR XL VASCULAR STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	New supplier and manufacturing processes for delivery system handle components.
P080004/S041	06/10/2021	X - 30-Day Notice	HOYA ISPHERIC MODEL YA-60BB INTRAOCULAR LENS	HOYA SURGICAL OPTICS, INC.	Qualify a new polymer resin used in the HOYA OEM sterile pouches.
P080006/S161	06/23/2021	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Changes to the cleaning process of stylet components manufactured at the supplier.
P080011/S129	06/04/2021	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISIO N, INC.	Upgrade of sensor and evaluation units used in the extraction and hydration module for the manufacture of the Biofinity (comfilcon A) family of lenses.
P080025/S228	06/22/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODU LATION	Update the connector assembly resistance spot welding process window for the InterStim Micro INS (model 97810) at the Medtronics manufacturing facility located in Juncos, Puerto Rico.
P080025/S229	06/25/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODU LATION	Newly defined and characterized solder paste inspection (SPI) process at Medtronic Tempe Campus (MTC), Medtronics internal supplier of hybrids used in the manufacturing of Medtronic Neuromodulation (Neuro) products.
P090013/S315	06/23/2021	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Changes to the cleaning process of stylet components manufactured at the supplier.
P100047/S181	06/21/2021	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Change in the EO aeration cycle time of the felt used in the sewing ring.
P100047/S182	06/23/2021	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Change to add rework operation and instructions to the battery charger manufacturing assembly procedures.
P110001/S014	06/21/2021	X - 30-Day Notice	RX HERCULINK ELITE RENAL STENT SYSTEM	ABBOTT VASCULAR	New resin colorant supplier for delivery system components.
P110001/S015	06/22/2021	X - 30-Day Notice	RX HERCULINK ELITE RENAL STENT SYSTEM	ABBOTT VASCULAR	Change to the sub-assembly stent inspection process to increase manufacturing efficiency.
P110016/S077	06/25/2021	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)	Alternate supplier for a spooled wire and electrode subassembly.
P130008/S066	06/11/2021	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Replacement component in the pressure sensor capsule from a new supplier.
P130008/S067	06/24/2021	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Modifications to the strain relief molding tool used to manufacture power and antenna cable assemblies for the Model 2740 Programmer Cable.

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P130018/S002	06/10/2021	X - 30-Day Notice	PROACT ADJUSTABLE CONTINENCE THERAPY FOR MEN	UROMEDICA INC	Update the sterilization dose auditing frequency from every three to 12 months.
P130021/S096	06/17/2021	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Relocation of tissue processing worksteps to new controlled environments including introduction of new equipment, systems, and layout changes.
P130021/S098	06/30/2021	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Implementation of new equipment and modification to the manufacturing process flow sequence for a delivery catheter system component.
P130026/S074	06/25/2021	X - 30-Day Notice	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Alternate supplier for a spooled wire and electrode subassembly.
P140002/S021	06/09/2021	X - 30-Day Notice	MISAGO PERIPHERAL SELF-EXPANDING STENT SYSTEM	TERUMO MEDICAL CORPORATIO N	Replace UV irradiation equipment.
P140009/S069	06/08/2021	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Replacement of the current MSP430 microcontroller chip on the implantable pulse generators printed circuit board with an MSP430 chip with updated packaging.
P140032/S071	06/02/2021	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Implementation of new visual inspections and additional controls to the SynchroMed II pump head and pump tube assembly steps .
P140032/S072	06/25/2021	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Newly defined and characterized solder paste inspection (SPI) process at Medtronic Tempe Campus (MTC), Medtronic¿s internal supplier of hybrids used in the manufacturing of Medtronic Neuromodulation (Neuro) products
P150004/S047	06/08/2021	X - 30-Day Notice	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Replacement of the current MSP430 microcontroller chip on the implantable pulse generator's printed circuit board with an MSP430 chip with updated packaging.
P150030/S009	06/30/2021	X - 30-Day Notice	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Firms supplier (Marle SA) has integrated a glass coating as lubrication for the forging of the POLARSTEM stem forged blanks.
P150030/S010	06/30/2021	X - 30-Day Notice	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Tecomet, one of the current forging blanks suppliers, has added a new extrusion press for the forging process of POLARSTEM Stems during early production.
P150030/S011	06/29/2021	X - 30-Day Notice	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Addition of manufacturing equipment used in the raw material forging of the POLARSTEM Standard and Lateral Femoral Stems with Ti/HA, which are approved for use in combination with the R3 Delta Ceramic Acetabular System.
P150031/S043	06/02/2021	X - 30-Day Notice	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Update the Implantable Pulse Generator (IPG) Automatic Test Equipment (ATE) software to clear the manufacturing data logs created during the Printed Circuit Board assembly (PCBA) manufacturing process at the Boston Scientific Clonmel manufacturing site
P150033/S108	06/16/2021	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Updates to the accelerometer test systems.
P150033/S109	06/04/2021	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Changes to the Solder Paste Inspection at Medtronic Tempe Campus (MTC).
P150033/S110	06/21/2021	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Implementation of updates to Micra AV mixed signal IC test requirement specification at MTC.

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P150033/S111	06/25/2021	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Updates to the wafer test configuration used during manufacturing.
P150048/S054	06/02/2021	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Manufacturing process transfer of the Graft to Sewing Ring Sub-Assembly to a different cleanroom within the Irvine, CA facility.
P160008/S016	06/08/2021	X - 30-Day Notice	HEARTSINE TECHNOLOGIES LLC'S SAMARITAN PUBLIC ACCESS AUTOMATED EXTERNAL DEFIBRILLATORS (SAM 350P, SAM 360P AND SAM 450P) AND ACCESSORIES	HEARTSINE TECHNOLOGIES, LTD.	Implement changes to the manufacturing equipment used to seal pouches and stud the electrodes.
P160026/S026	06/22/2021	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.	Implement improvements to the final testing process at the keypad component supplier.
P160026/S027	06/23/2021	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.	Implement the use of a new tool to verify the connection of electronic assemblies.
P160029/S012	06/15/2021	X - 30-Day Notice	HEARTSTART ONSITE DEFIBRILLATOR (MODEL M5066A) AND HEARTSTART HOME DEFIBRILLATOR (MODEL M5068A)	PHILIPS MEDICAL SYSTEMS, INC.	New battery end of line test equipment for the HS1 and FRx Primary Battery, and the FRx Aviation Battery at the contract manufacturer.
P160033/S008	06/14/2021	X - 30-Day Notice	POWERHEART® G5 AED, POWERHEART® AED G3 PLUS, AND POWERHEART® AED G3	ZOLL MEDICAL CORPORATION	Add a supplier for the AED main PCBA.

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P160045/S030	06/11/2021	X - 30-Day Notice	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Move the work-in-process and raw materials used in the manufacturing to a new storage location.
P160054/S037	06/10/2021	X - 30-Day Notice	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATION	Add an additional supplier for laser welding the connectors on the HeartMate 3 Modular Cable.
P170008/S036	06/16/2021	X - 30-Day Notice	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Manufacturing site transfer for a coating material supplier.
P170018/S013	06/08/2021	X - 30-Day Notice	LIFEPAK® CR2 DEFIBRILLATOR	PHYSIO-CONTROL, INC	New assembly tool to optimize the manufacturing of electrodes used with the LIFEPAK CR2 Defibrillators.
P170024/S008	06/09/2021	X - 30-Day Notice	SURPASS STREAMLINE FLOW DIVERTER	STRYKER NEUROVASCULAR	Supplier to update to a newer model of a heat treatment furnace for the manufacturing of the Surpass Streamline Flow Diverter System and the Surpass Evolve Flow Diverter System.
P170032/S008	06/01/2021	X - 30-Day Notice	WOVEN ENDOBRIDGE (WEB) ANEURYSM EMBOLIZATION SYSTEM	MICROVENTION, INC.	Updated sampling plan for the quality control inspection step in the WEB over coil subassembly process.
P170042/S009	06/03/2021	X - 30-Day Notice	COVERA¿ VASCULAR COVERED STENT	C.R. BARD, INC	New supplier and manufacturing processes for delivery system handle components.
P180028/S009	06/15/2021	X - 30-Day Notice	HEARTSTART FRX DEFIBRILLATOR	PHILIPS MEDICAL SYSTEMS	New battery end of line test equipment for the HS1 and FRx Primary Battery, and the FRx Aviation Battery at the contract manufacturer.
P180037/S005	06/03/2021	X - 30-Day Notice	VENOVO VENOUS STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	New supplier and manufacturing processes for delivery system handle components.
P200030/S003	06/09/2021	X - 30-Day Notice	GORE EXCLUDER CONFORMABLE AAA ENDOPROSTHESIS (CEXC)	W. L. GORE AND ASSOCIATES, INC.	Implementation of an alternate manufacturing location for sealing cuff component of the Gore EXCLUDER Conformable AAA Endoprosthesis.
Total: 113					