PMA Monthly approvals from 1/1/2021 to 1/31/2021

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P200003	01/11/2021	PMAO - PMA Origi	IMAGIO BREAST IMAGING SYSTEM	SENO MEDICAL INSTRUMENTS, INC.	Approval for the Imagio® Breast Imaging System. This device is indicated for use by a trained and qualified healthcare provider for evaluation of palpable and non-palpable breast abnormalities in adult patients who are referred for a diagnostic imaging breast work-up, following clinical presentation or either screening or diagnostic mammography or other imaging examinations. The ultrasound mode should be initially used in a targeted fashion, to assess any focal area(s) of clinical or imaging concerns. In ultrasound mode, the device can be used to assign a BI-RADS category to either breast tissue or a mass that is causing clinical or imaging concerns. Masses that are classified as BI-RADS categories 3 through 5 can then be assessed using the Opto-Acoustic (OA) mode. In the OA mode, the Imagio® Breast Imaging System provides information about the central nidus, boundary and peripheral zones, based on vascularity and blood oxygen saturation of the imaged tissues, to assist in the diagnosis of the benign or malignant mass(es) of interest. For ultrasound BI-RADS 3-5 masses, using the OA features of the mass allows for improved classification of the mass of interest as compared to ultrasound alone. The OA mode is not indicated for ultrasound BI- RADS 1 and 2 findings. The Imagio® Breast Imaging System includes an artificial intelligence (AI) based software function to assist the users in assessing BI-RADS classifications. This device is not intended to be used as a replacement for mammographic screening or for definitive pathologic diagnosis.
P200028	01/28/2021	PMAO - PMA Origi	DIAMONDTEMP ABLATION SYSTEM	MEDTRONIC INC.	Approval for the DiamondTemp Catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and for treatment of drug refractory, recurrent, symptomatic paroxysmal atrial fibrillation when used in conjunction with the DiamondTemp RF Generator and accessories (DiamondTemp Catheter-to-RF Generator Cable, DiamondTemp GenConnect Cable, DiamondTemp EGM Cable, DiamondTemp Irrigation Pump, DiamondTemp Irrigation Tubing Set) and compatible mapping system.
Totals: 2					

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P790007/S063	01/05/2021	Y - 135 Review Tra	HANCOCK MODIFIED ORIFICE BIOPROSTHESIS	MEDTRONIC HEART VALVES	Approval for continued use of a tissue supplier after a change in the suppliers name and facility address.
P810025/S039	01/13/2021	Y - 135 Review Tra	AMVISC(R)	BAUSCH &	Approval to utilize a new facility to perform analytical quality control testing of the Amvisc/

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P820003/S138	01/21/2021	N - Normal 180 Day	VERSATRAX MODEL 7000 UNIVERSAL A-V PULSE GENERATOR	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for a labeling update for the affected reusable cable products.
P840001/S465	01/22/2021	O - Normal 180 Day	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Approval for an additional contract manufacturing site for kitting, sterilization, and final packaging of the Model 97725 Wireless External Neurostimulator (ENS) kit.
P840001/S475	01/29/2021	R - Real-Time Proc	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Approval for a design change to the battery cells, which is packaged with the external Model 97755 Intellis Recharger, with a reduced current output from 1760 mA to 1600 mA and different geometry requiring a thicker battery pack which requires to have a battery compartment cover to be included with the Model 97755 Recharger to fit over the new battery pack when inserted on the Model 97745 Controller.
P860004/S361	01/15/2021	N - Normal 180 Day	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval of: a material change from polyvinyl chloride (PVC) to Methyl Methacrylate Acrylonitrile Butadiene Styrene (MABS) on the extension set component of the Model 8551 Refill Kit and Model 8540 CAP Kit for the SynchroMed Infusion System.
P860047/S034	01/13/2021	Y - 135 Review Tra	HYDROXYPROPYLMETHYL CELLULOSE 20MG/ML	BAUSCH & LOMB, INC.	Approval to utilize a new facility to perform analytical quality control testing of the Amvisc/ Amvisc Plus and OcuCoat fill/finish products.
P870078/S048	01/05/2021	Y - 135 Review Tra	HANCOCK PORCINE BIOPROSTHESIS	MEDTRONIC, INC.	Approval for continued use of a tissue supplier after a change in the suppliers name and facility address.
P890003/S437	01/21/2021	N - Normal 180 Day	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Approval for a labeling update for the affected reusable cable products.
P890055/S075	01/22/2021	Y - 135 Review Tra	MEDSTREAM PROGRAMMABLE INFUSION PUMP SYSTEM	INTERA ONCOLOGY	Approval for requested replacement of the sealing machine used at Intera Oncology, Inc. (Intera) subcontractor to seal the lid of the syringe barrel, which is a component included in the refill kits approved as accessories for the implanted infusion pumps.
P960009/S394	01/15/2021	S - Special CBE	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval for use of a screening tool to screen/filter out a list of invalid hybrid serial numbers from the next available 1,048,564 serial numbers. The resulting invalid hybrid serial numbers are to be programmed into the FACTORYworks table to prevent them from being used for future hybrid manufacturing builds.
P970029/S038	01/21/2021	O - Normal 180 Day	TMR HOLMIUM LASER SYSTEM	CRYOLIFE, INC.	Approval for a manufacturing site located at Parker Hannifin (CSS Merrillville), 1201 East 86th Place, Merrillville, Indiana 46410, for manufacturing of the SoloGrip III Handpiece which is part of the Cardiogenesis Laser System.
P970031/S068	01/05/2021	Y - 135 Review Tra	MEDTRONIC FREESTYLE AORTIC ROOT BIOPROSTHESIS	MEDTRONIC, INC.	Approval for continued use of a tissue supplier after a change in the suppliers name and facility address.
P980043/S074	01/05/2021	Y - 135 Review Tra	HANCOCK II PORCINE BIOPROSTHESIS	MEDTRONIC, INC.	Approval for continued use of a tissue supplier after a change in the suppliers name and facility address.
P990064/S083	01/05/2021	Y - 135 Review Tra	MEDTRONIC MOSAIC PORCINE BIOPROSTHETIC HEART VALVE	MEDTRONIC, INC.	Approval for continued use of a tissue supplier after a change in the suppliers name and facility address.
P010015/S456	01/28/2021	R - Real-Time Proc	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Approval for software updates necessary for release of software application releases SW030 (Orion) v8.2 and SW040 (CRT-P Quad) v8.4.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010030/S144	01/29/2021	R - Real-Time Proc	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Approval for updates to the snap fasteners used on the LifeVest garment.
P010032/S166	01/19/2021	N - Normal 180 Day	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Approval for addition of BurstDR programs with multiple stimsets for Proclaim SCS System, programming enhancements for SCS therapy, cybersecurity enhancements and other minor enhancements for improvement. Approval for cybersecurity enhancements and other minor enhancements for improvement.
P030031/S102	01/28/2021	O - Normal 180 Day	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Approval for labeling updates.
P040013/S025	01/15/2021	R - Real-Time Proc	GEM 21S (GROWTH-FACTOR ENHANCED MATRIX	LYNCH BIOLOGICS LLC	Approval for extending the expiration of the rhPDGF-BB syringe component of GEM21S Growth Factor Enhanced Matrix from 42 months to 48 months.
P040036/S070	01/28/2021	O - Normal 180 Day	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Approval for labeling updates.
P050053/S052	01/05/2021	Y - 135 Review Tra	INFUSE BONE GRAFT	MEDTRONIC INC.	Approval for a manufacturing process change in the preparation of stopper components used in the manufacture of the product.
P080011/S110	01/05/2021	O - Normal 180 Day	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Approval for a new private label trade name.
P080011/S112	01/07/2021	O - Normal 180 Day	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Approval for a new private label trade name, Natural Eyes HydraWear XW Multifocal, for the CooperVision comfilcon A soft (hydrophilic) contact lenses for extended wear.
P100030/S013	01/26/2021	Y - 135 Review Tra	ARTERX SURGICAL SEALANT	BAXTER HEALTHCARE CORPORATION	Approval for an alternate supplier of chitosan chloride and a modification to the preparation steps of the proteinaceous solution component of Preveleak Surgical Sealant.
P110016/S072	01/06/2021	R - Real-Time Proc	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Approval for modifications to the Instructions for Use (IFU) manuals to indicate the compatibility with the EnSite X EP System.
P130021/S082	01/15/2021	O - Normal 180 Day	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Approval for modifications to the Instructions for Use to reflect the findings of the final Post-Approval Study (PAS) Report submitted for the CoreValve High Risk Pivotal and CoreValve High Risk Continued Access Post Approval Studies
P130026/S063	01/10/2021	Y - 135 Review Tra	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Approval for manufacturing changes to the optical fiber connector, including fixture, inspection, and print note changes.
P130026/S066	01/10/2021	R - Real-Time Proc	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Approval for modifications to the Instructions for Use (IFU) manuals to indicate the compatibility with the EnSite X EP System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140009/S062	01/19/2021	N - Normal 180 Day	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Approval for addition of BurstDR programs with multiple stimsets for Proclaim SCS System, programming enhancements for SCS therapy, cybersecurity enhancements and other minor enhancements for improvement. Approval for cybersecurity enhancements and other minor enhancements for improvement.
P140018/S021	01/21/2021	R - Real-Time Proc	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Approval for the supplied HDPE resin and supplier location used for the over molding on the hub of the introducer, dilator and catheter of the VenaSeal delivery system.
P140029/S027	01/29/2021	P - Panel Track	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Approval for Restylane Defyne. The device is indicated for injection into the mid-to deep dermis (subcutaneous and/ or supraperiosteal) for augmentation of the chin region to improve the chin profile in patients with mild to moderate chin retrusion over the age of 21.
P140031/S099	01/27/2021	O - Normal 180 Day	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for the Edwards Costa Rica manufacturing site to manufacture the SAPIEN 3 Ultra transcatheter heart valve (Model 9750TFX, sizes 20mm, 23mm, and 26mm), located at: Zona Franca La Lima, De la entrada de Pequeno Mundo 100 mts oeste y 200 mts sur Finca 31 y 32 Guadalupe, Cartago Costa Rica 30106
P140032/S058	01/15/2021	N - Normal 180 Day	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Approval of a material change from polyvinyl chloride (PVC) to Methyl Methacrylate Acrylonitrile Butadiene Styrene (MABS) on the extension set component of the Model 201106 Refill Kit for the Implantable System for Remodulin (ISR).
P150001/S084	01/14/2021	Y - 135 Review Tra	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	Approval for manufacturing changes related to sterilization process for Guardian Sensor (3). The Guardian Sensor (3) is component of the MiniMed 670G System, the Guardian Connect System, and the MiniMed 630G System with SmartGuard.
P150003/S054	01/22/2021	N - Normal 180 Day	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for a new stent design for the 3.50 to 5.00 mm sizes along with modifications to the expansion balloon and manifold.
P150004/S040	01/21/2021	O - Normal 180 Day	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Approval of the revised protocol for the post-approval study (PAS0 protocol.
P150004/S041	01/19/2021	N - Normal 180 Day	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Approval for addition of BurstDR programs with multiple stimsets for Proclaim SCS System, programming enhancements for SCS therapy, cybersecurity enhancements and other minor enhancements for improvement. Approval for cybersecurity enhancements and other minor enhancements for improvement.
P150031/S034	01/21/2021	N - Normal 180 Day	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the Vercise Genus Deep Brain Stimulation (DBS) System.
P150033/S090	01/21/2021	R - Real-Time Proc	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval for an update to a marker band raw material used for the Micra Transcatheter Pacing System.
P160007/S035	01/14/2021	Y - 135 Review Tra	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Approval for manufacturing changes related to sterilization process for Guardian Sensor (3). The Guardian Sensor (3) is component of the MiniMed 670G System, the Guardian Connect System, and the MiniMed 630G System with SmartGuard.
P160017/S083	01/14/2021	Y - 135 Review Tra	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval for manufacturing changes related to sterilization process for Guardian Sensor (3). The Guardian Sensor (3) is component of the MiniMed 670G System, the Guardian Connect System, and the MiniMed 630G System with SmartGuard.

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P160028/S002	01/11/2021	R - Real-Time Proc	PHILIPS HEARTSTART FR3 DEFIBRILLATOR	PHILIPS MEDICAL SYSTEMS, INC.	Approval of battery cell modifications to the FR3 Rechargeable Battery (model number 989803150241) due to discontinuation of previous battery cells.
P170032/S004	01/11/2021	N - Normal 180 Day	WOVEN ENDOBRIDGE (WEB) ANEURYSM EMBOLIZATION SYSTEM	MICROVENTION, INC.	Approval for new device models of the WEB Aneurysm Embolization System (WEB 017).
P190014/S004	01/27/2021	N - Normal 180 Day	MYCHOICE HRD CDX	MYRIAD GENETIC LABORATORIES, INC	Approval for Myriad myChoice® CDx to expand labeling based on SOLO1 study for the treatment of the patients with BRCA mutated advanced ovarian cancer with LYNPARZA (olaparib).
Total: 45					

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P810006/S092	01/19/2021	X - 30-Day Notice	COLLASTAT	INTEGRA LIFESCIENCES CORPORATION	Split of an existing Compressed Air Point of Use to support additional packaging capacities at the Integra LifeSciences Corporation, Collagen Manufacturing Center in Plainsboro, New Jersey.
P840001/S481	01/08/2021	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Incorporate the Post Wafer Probe Check system to monitor the steps for all wafer lots that have completed wafer probe testing.
P840062/S078	01/19/2021	X - 30-Day Notice	COLLACOTE(TM)	INTEGRA LIFESCIENCES CORP.	Split of an existing Compressed Air Point of Use to support additional packaging capacities at the Integra LifeSciences Corporation, Collagen Manufacturing Center in Plainsboro, New Jersey.
P850010/S092	01/19/2021	X - 30-Day Notice	HELISTAT(TM) ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	INTEGRA LIFESCIENCES CORPORATION	Split of an existing Compressed Air Point of Use to support additional packaging capacities at the Integra LifeSciences Corporation, Collagen Manufacturing Center in Plainsboro, New Jersey.
P860004/S367	01/08/2021	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Incorporate the Post Wafer Probe Check system to monitor the steps for all wafer lots that have completed wafer probe testing.
P880081/S046	01/08/2021	X - 30-Day Notice	UV ABSORBING SILICONE POSTERIOR CHAMBER INTRAOCULAR LENSES	JOHNSON & JOHNSON SURGICAL VISION, INC.	Alternate ethylene oxide sterilization cycle parameters.
P900033/S092	01/19/2021	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Split of an existing Compressed Air Point of Use to support additional packaging capacities at the Integra LifeSciences Corporation, Collagen Manufacturing Center in Plainsboro, New Jersey.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P910061/S026	01/04/2021	X - 30-Day Notice	MODEL LI30U SOFLEX(TM) UV-ABSORB. INTRAOCULAR LENS	BAUSCH & LOMB	New process for electroplating molds for intraocular lens models LI61SE and LI61AO.
P910073/S159	01/13/2021	X - 30-Day Notice	ENDOTAK LEAD SYSTEM	BOSTON SCIENTIFIC	Add a new supplier of nitrile gloves, Ansell.
P960004/S092	01/13/2021	X - 30-Day Notice	THINLINE ENDOCARDIAL PACING LEADS	BOSTON SCIENTIFIC	Add a new supplier of nitrile gloves, Ansell.
P960006/S050	01/13/2021	X - 30-Day Notice	SWEET TIP(R) RX STEROID ELUTING LEAD	BOSTON SCIENTIFIC	Add a new supplier of nitrile gloves, Ansell.
P960009/S392	01/08/2021	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Incorporate the Post Wafer Probe Check system to monitor the steps for all wafer lots that have completed wafer probe testing.
P960009/S393	01/15/2021	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Addition of a product test for a distribution center testing tool.
P970004/S327	01/08/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODU LATION	Incorporate the Post Wafer Probe Check system to monitor the steps for all wafer lots that have completed wafer probe testing.
P980040/S127	01/08/2021	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Alternate ethylene oxide sterilization cycle parameters.
P980040/S128	01/08/2021	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Modification of the sampling plan and monomer residual testing for soft acrylic OptiBlue material.
P980040/S129	01/26/2021	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Addition of a raw material supplier for the nut component used in the TECNIS Simplicity Delivery System.
P990080/S055	01/08/2021	X - 30-Day Notice	CEEON EDGE FOLDABLE ULTRAVIOLET LIGHT-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS, MODEL 911A	JOHNSON & JOHNSON SURGICAL VISION, INC.	Alternate ethylene oxide sterilization cycle parameters.
P000006/S059	01/08/2021	X - 30-Day Notice	TITAN INFLATABLE PENILE PROSTHESIS	COLOPLAST CORP.	Change in the spring supplier and manufacturing process.
P010012/S531	01/13/2021	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Add a new supplier of nitrile gloves, Ansell.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P020004/S177	01/22/2021	X - 30-Day Notice	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Computer hardware and software upgrades for bacterial endotoxin testing equipment.
P030031/S111	01/22/2021	X - 30-Day Notice	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Transfer the extrusion process for the Quad Lumen Core subcomponent from the Biosense Webster Inc. Irwindale, CA facility to the Biosense Webster, Inc. Juarez, MX facility.
P040027/S082	01/22/2021	X - 30-Day Notice	GORE VIATORR TIPS	W. L. GORE & ASSOCIATES, INC.	Computer hardware and software upgrades for bacterial endotoxin testing equipment.
P040036/S076	01/22/2021	X - 30-Day Notice	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Transfer the extrusion process for the Quad Lumen Core subcomponent from the Biosense Webster Inc. Irwindale, CA facility to the Biosense Webster, Inc. Juarez, MX facility.
P040037/S141	01/22/2021	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Computer hardware and software upgrades for bacterial endotoxin testing equipment.
P040043/S121	01/22/2021	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Computer hardware and software upgrades for bacterial endotoxin testing equipment.
P050006/S088	01/22/2021	X - 30-Day Notice	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Computer hardware and software upgrades for bacterial endotoxin testing equipment.
P050006/S089	01/26/2021	X - 30-Day Notice	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Site changes to the LAL testing requirement and removal of cytotoxicity and infrared spectroscopy inspections for incoming components.
P050027/S026	01/06/2021	X - 30-Day Notice	KARL STORZ PHOTODYNAMIC DIAGNOSTIC D-LIGHT C (PDD) SYSTEM	KARL STORZ ENDOSCOPY-AMERICA, INC.	Manufacturing change to add the Rofin Performance Unlimited Laser Welder.
P050027/S027	01/08/2021	X - 30-Day Notice	KARL STORZ PHOTODYNAMIC DIAGNOSTIC D-LIGHT C (PDD) SYSTEM	KARL STORZ ENDOSCOPY-AMERICA, INC.	Process change to modify the software of the automatic Quality Control equipment.
P050046/S030	01/13/2021	X - 30-Day Notice	ACUITY STEERABLE LEAD SYSTEM	GUIDANT CORP.	Add a new supplier of nitrile gloves, Ansell.
P050050/S016	01/13/2021	X - 30-Day Notice	SCANDINAVIAN TOTAL ANKLE REPLACEMENT SYSTEM (S.T.A.R.ANKLE)	STRYKER CORPORATION	Replace a broken coordinate measuring machine (CMM) used in the production of the STAR Tibial, Talar, and UHMWPE Mobile Bearing (also referred to as the Sliding Cores) components with another CMM (Zeiss Contura CMM) at the Waldemar Link contract manufacturing facility in Germany.
P060001/S031	01/04/2021	X - 30-Day Notice	PROTEGE GPS AND PROTEGE RX CAROTID STENT SYSTEMS	MEDTRONIC VASCULAR INC	Additional ultra-fine rolling mill machines at the Supplier Fort Wayne Metals (FWM).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P080004/S038	01/08/2021	X - 30-Day Notice	HOYA ISPHERIC MODEL YA-60BB INTRAOCULAR LENS	HOYA SURGICAL OPTICS, INC.	ISert intraocular lens models 230 and 231 to be manufactured on production line 5.
P080004/S039	01/13/2021	X - 30-Day Notice	HOYA ISPHERIC MODEL YA-60BB INTRAOCULAR LENS	HOYA SURGICAL OPTICS, INC.	Changes to the mold tool used to produce the PSC-60 injection cartridge tip for the 3-piece IOL models.
P080010/S020	01/08/2021	X - 30-Day Notice	TECNIS MULTIFOCAL FOLDABLE POSTERIOR CHAMBER INTRAOCULAR LENS (IOL)	JOHNSON & JOHNSON SURGICAL VISION, INC.	Alternate ethylene oxide sterilization cycle parameters.
P080011/S121	01/12/2021	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISIO N, INC.	Manufacture of Biotinity XR Toric lenses on an additional manufacturing line.
P080011/S122	01/15/2021	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISIO N, INC.	Increase in the maximum UV cure time on the Biofinity MTO (Made to Order) lines.
P080025/S222	01/08/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODU LATION	Incorporate the Post Wafer Probe Check system to monitor the steps for all wafer lots that have completed wafer probe testing.
P090022/S038	01/07/2021	X - 30-Day Notice	LENSTEC SOFTEC HD POSTERIOR CHAMBER INTRAOCULAR LENS	LENSTEC, INC.	Introduction of two additional steam sterilizers into the existing sterilization process of Lenstec's HEMA intraocular lenses.
P110023/S031	01/04/2021	X - 30-Day Notice	EVERFLEX SELF-EXPANDING PERIPHERAL STENT SYSTEM (EVERFLEX)	MEDTRONIC VASCULAR INC	Additional ultra-fine rolling mill machines at the Supplier Fort Wayne Metals (FWM).
P110042/S152	01/13/2021	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATIO N	Add a new supplier of nitrile gloves, Ansell.
P130005/S032	01/14/2021	X - 30-Day Notice	DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM	CARDIOVASC ULAR SYSTEMS, INC.	New sterilization cycle with a mixed sterilization load using Chamber 12 at the Minneapolis, MN sterilization facility and Chambers 1 & 4 at the El Paso, TX sterilization facility.
P130006/S080	01/22/2021	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,I NC	Computer hardware and software upgrades for bacterial endotoxin testing equipment.
P130021/S084	01/06/2021	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Addition of a new cleanroom.
P140032/S065	01/08/2021	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Incorporate the Post Wafer Probe Check system to monitor the steps for all wafer lots that have completed wafer probe testing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150012/S106	01/13/2021	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Add a new supplier of nitrile gloves, Ansell.
P150021/S052	01/05/2021	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Introducing an alternate higher cavitation mold tooling and injection molding machine at Abbott Diabetes Care supplier for the sensor component manufacturing process. The Sensor is a component of the FreeStyle Libre Pro Flash Glucose Monitoring System and Freestyle Libre Flash Glucose Monitoring System.
P160021/S027	01/22/2021	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Computer hardware and software upgrades for bacterial endotoxin testing equipment.
P160022/S024	01/05/2021	X - 30-Day Notice	X SERIES®, R SERIES®, AED PRO®, AED 3¿ BLS PROFESSIONAL DEFIBRILLATORS, PRO-PADZ RADIOTRANSPARENT ELECTRODE, SUREPOWER ¿ BATTERY PACK, SUREPOWER II¿ BATTERY PACK, AED PRO® NON-RECHARGEABLE LITHIUM BATTERY PACK, AED 3 ¿ BATTERY PACK, SUREPOWER¿ CHARGER, AND SUREPOWER ¿ SINGLE BAY CHARGER	ZOLL MEDICAL CORPORATION	Addition of a selective soldering machine used during printed circuit board assembly (PCBA) manufacturing.
P160022/S025	01/05/2021	X - 30-Day Notice	X SERIES®, R SERIES®, AED PRO®, AED 3¿ BLS PROFESSIONAL DEFIBRILLATORS, PRO-PADZ RADIOTRANSPARENT ELECTRODE, SUREPOWER ¿ BATTERY PACK, SUREPOWER II¿ BATTERY PACK, AED PRO® NON-RECHARGEABLE LITHIUM BATTERY PACK, AED 3 ¿ BATTERY PACK, SUREPOWER¿ CHARGER, AND SUREPOWER ¿ SINGLE BAY CHARGER	ZOLL MEDICAL CORPORATION	Additional test fixture and selective solder machine used during printed circuit board assembly (PCBA) manufacturing.
P160030/S046	01/05/2021	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Introducing an alternate higher cavitation mold tooling and injection molding machine at Abbott Diabetes Care supplier for the sensor component manufacturing process. The Sensor is a component of the FreeStyle Libre Pro Flash Glucose Monitoring System and Freestyle Libre Flash Glucose Monitoring System.

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P160035/S019	01/13/2021	X - 30-Day Notice	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Replacing External Process Device used during EO sterilization.
P160047/S017	01/05/2021	X - 30-Day Notice	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	AEGEA MEDICAL , INC	Changes to the multi-lumen extrusion tail trimming fixture and the air connector bonding alignment tool.
P160047/S019	01/14/2021	X - 30-Day Notice	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	AEGEA MEDICAL , INC	Changes to the pressure sensor assembly's fiber optic cable etching process and fiber optic cable length specification.
P160047/S020	01/27/2021	X - 30-Day Notice	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	AEGEA MEDICAL , INC	Changes to the sheath material source and the sheath bonding process.
P160054/S033	01/07/2021	X - 30-Day Notice	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATION	Addition of an alternate sub-tier supplier for the Integrated Motor Control (IMC) printed circuit board assembly.
P170005/S002	01/19/2021	X - 30-Day Notice	ABBOTT REALTIME IDH2	ABBOTT MOLECULAR INC.	Changes to a vendor's manufacturing procedure.
P170012/S024	01/13/2021	X - 30-Day Notice	HEMOBLAST¿ BELLOWS	BIOM'UP FRANCE SAS	Modification to the facility floorplan at the HEMOBLAST Bellows manufacturing facility.
P170023/S008	01/14/2021	X - 30-Day Notice	BULKAMID URETHRAL BULKING SYSTEM	CONTURA INTERNATIONAL A/S	Change in the sterilization site of the Bulkamid Rotatable Sheath, a component of the Bulkamid Urethral Bulking System.
P170034/S006	01/07/2021	X - 30-Day Notice	HYDRUS MICROSTENT	IVANTIS, INC.	Reduction in sampling from 100% to AQL sampling plans specified by the sponsor.
P170041/S003	01/19/2021	X - 30-Day Notice	ABBOTT REALTIME IDH1	ABBOTT MOLECULAR, INC.	Changes to a vendor's manufacturing procedure.
P190019/S005	01/07/2021	X - 30-Day Notice	RANGER¿ PACLITAXEL-COATED PTA BALLOON CATHETER	BOSTON SCIENTIFIC CORPORATION	Addition of equipment to the manufacturing line.
P190025/S003	01/19/2021	X - 30-Day Notice	ALINITY M HCV	ABBOTT MOLECULAR, INC.	Changes to a vendor's manufacturing procedure.

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P200013/S001	01/19/2021	X - 30-Day Notice	ALINITY M HBV	ABBOTT MOLECULAR, INC.	Changes to a vendor's manufacturing procedure.
Total: 65					