PMA Monthly approvals from 8/1/2021 to 8/31/2021

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P200045	08/05/2021	PMAO - PMA Origi	RELAYPRO THORACIC STENT-GRAFT SYSTEM	BOLTON MEDICAL, INC.	Approval for The Relay®Pro Thoracic Stent-Graft System. The device is indicated for the endovascular repair of fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers in the descending thoracic aorta in patients having appropriate anatomy, including: -- Iliac or femoral access vessel morphology that is compatible with vascular access techniques, devices, and/or accessories; -- Non-aneurysmal aortic neck diameter in the range of 20 to 42 mm; and -- Non-aneurysmal proximal aortic neck lengths of: 15 mm for the 24 to 28 mm Bare Stent Configuration device diameters 20 mm for the 30 to 38 mm Bare Stent Configuration device diameters 25 mm for the 40 to 46 mm Bare Stent Configuration device diameters 25 mm for the 24 to 38 mm Non-Bare Stent Configuration device diameters 30 mm for the 40 to 46 mm Non-Bare Stent Configuration device diameters Non-aneurysmal distal aortic neck lengths of: 25 mm for the 24 to 38 mm device diameters 30 mm for the 40 to 46 mm device diameters.
P200049	08/14/2021	PMAO - PMA Origi	AMPLATZER¿ AMULET ¿ LEFT ATRIAL APPENDAGE OCCLUDER	ABBOTT MEDICAL	Approval for The Amplatzer Amulet Left Atrial Appendage Occluder. The device is a percutaneous transcatheter device intended to reduce the risk of thrombus embolization from the left atrial appendage (LAA) in patients who have nonvalvular atrial fibrillation and who are at increased risk for stroke and systemic embolism based on CHADS2 or CHA2DS2-VASc scores, are suitable for short term anticoagulation therapy, and have appropriate rationale to seek a non-pharmacologic alternative to oral anticoagulation, taking into consideration the safety and effectiveness of the device.
P210001	08/17/2021	PMAO - PMA Origi	VENTANA MMR RXDX PANEL	VENTANA MEDICAL SYSTEMS INC (ROCHE TISSUE DIAGNOSTICS)	Approval for the Ventana MMR RxDx Panel as a CDx for identifying patients with solid tumors with dMMR status who may benefit from treatment with JEMPERLI.
P210007	08/27/2021	PMAO - PMA Origi	VIVISTIM® SYSTEM	MICROTRANS PONDER, INC.	Approval the MicroTransponder® Vivistim® Paired VNS System (Vivistim ® System) is intended to be used to stimulate the vagus nerve during rehabilitation therapy in order to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment.

Total: 4

Supplements

Data as of 09/02/2021 03:13 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P810002/S113	08/19/2021	S - Special CBE	BILEAFLET-CENTER OPENING CARDIAC VALVE	ST. JUDE MEDICAL, INC.	Approval for labeling changes specific for each valve configuration in a precaution statement in the Instructions for Use.
P830055/S270	08/02/2021	O - Normal 180 Day	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for a manufacturing site located at Smithstown Light Engineering Ltd. Smithstown Ind Estate, Shannon, Co. Clare, Ireland V14 NW92 for manufacturing the ATTUNE Cementless RP Tibial Base component of the LCS® Total Knee System.
P840001/S484	08/30/2021	Y - 135 Review Tra	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Approval for a cleaning process change at DSM Biomedical in Berkeley California, a supplier to Medtronic Neuromodulation, that involves the addition of an option to replace solvent cleaning the equipment between material lots with a process that uses the next lot of material to purge the system (the first 30 seconds of material coming out of this portion of the manufacturing line is discarded). The change involves the continuous reactor system to be purged between production batches of same hardness grade and purged and cleaned between production batches of different hardness.
P840001/S488	08/12/2021	R - Real-Time Proc	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Approval for a design change to the Recharger Therapy Manager (RTM) model 97755, to modify the interface between the antenna and the cable, to include an additional strain relief. This strain relief at the antenna-cable interface will include an elongated antenna section that is overmolded with a strain relief at the antenna-cable interface. Additionally, RTM cable length specification changes from 37 ± 1 inches to 35.4 ± 2 inches and the Crimp Ferrule minimum pull force strength will be increased from 3 lbs. minimum to 4.2 lbs.
P840001/S489	08/25/2021	R - Real-Time Proc	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Approval for 1) design changes to add an alternative glassed feedthrough assembly component which has the same fit, form and function, to the current brazed feedthrough assembly component in the Model 97715 and Model 97716 Intellis Implantable Neurostimulators, and 2) manufacturing changes to include a new chemical treatment step (i.e., Nitric/HF acid) to clean the titanium array plate (A distilled water rinse step will be added after the new chemical treatment step to remove any residual chemicals from the feedthrough).
P860004/S368	08/30/2021	Y - 135 Review Tra	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval for a cleaning process change at DSM Biomedical in Berkeley California, a supplier to Medtronic Neuromodulation, that involves the addition of an option to replace solvent cleaning the equipment between material lots with a process that uses the next lot of material to purge the system (the first 30 seconds of material coming out of this portion of the manufacturing line is discarded). The change involves the continuous reactor system to be purged between production batches of same hardness grade and purged and cleaned between production batches of different hardness.
P890003/S445	08/16/2021	N - Normal 180 Day	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Approval for the CareLink SmartSync MRI Access Application.
P900009/S047	08/31/2021	N - Normal 180 Day	SONIC ACCELERATED FRACTURE HEALING SYSTEM MODEL 2A	BIOVENTUS LLC	Approval for design improvements to the Printed Circuit Board Assembly (PCBA) and the transducer cable assembly.
P910018/S029	08/06/2021	Y - 135 Review Tra	LIPOSORBER(R) LA-15 SYSTEM ADSORPTION COLUMN, SULFUX(R) FS-05 PLASMA SEPARATOR, AND TUB. SYST. FOR PLASMAPHER. (LT-MA2).	KANEKA PHARMA AMERICA CORP.	Approval for the addition of the gel bioburden reduction tank, used for washing the cellulose gel material, to the manufacturing procedure for the LIPOSORBER LA-15 LDL Adsorption Column (LA-15 Column).
P920047/S124	08/05/2021	N - Normal 180 Day	EPT-1000 CARDIAC ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for an adhesive change, minor manufacturing changes, and modification of a product specification.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P950029/S129	08/13/2021	N - Normal 180 Day	CHORUS RM MODEL 7034 DDDR PACEMAKER INCL. OPUS RM MODEL 4534 SSIR PACEMAKER	MICROPORT CRM USA INC.	Approval for the creation of new models of home monitors (Smart Monitor, Smart Spot) which will upgrade the modems and replace obsolete components.
P960009/S396	08/30/2021	Y - 135 Review Tra	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval for a cleaning process change at DSM Biomedical in Berkeley California, a supplier to Medtronic Neuromodulation, that involves the addition of an option to replace solvent cleaning the equipment between material lots with a process that uses the next lot of material to purge the system (the first 30 seconds of material coming out of this portion of the manufacturing line is discarded). The change involves the continuous reactor system to be purged between production batches of same hardness grade and purged and cleaned between production batches of different hardness.
P970004/S329	08/30/2021	Y - 135 Review Tra	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Approval for a cleaning process change at DSM Biomedical in Berkeley California, a supplier to Medtronic Neuromodulation, that involves the addition of an option to replace solvent cleaning the equipment between material lots with a process that uses the next lot of material to purge the system (the first 30 seconds of material coming out of this portion of the manufacturing line is discarded). The change involves the continuous reactor system to be purged between production batches of same hardness grade and purged and cleaned between production batches of different hardness.
P980006/S032	08/27/2021	R - Real-Time Proc	PURE VISION VISIBILITY TINTED CONTACT LENS FOR EXTENDED WEAR	BAUSCH & LOMB, INC.	Approval to remove the Sagittal Depth measurement acceptance criteria from the finished product specifications for PureVision (balafilcon A) Contact Lens.
P980035/S684	08/16/2021	N - Normal 180 Day	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Approval for the CareLink SmartSync MRI Access Application.
P980037/S086	08/12/2021	O - Normal 180 Day	ANGIOJET RHEOLYTIC THROMBECTOMY LF140 CATHETER	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Boston Scientific Corporation, 4100 Hamline Avenue North, St. Paul, MN 32577 in order to perform release/acceptance, labeling, packaging, repair/servicing, and distribution activities.
P980049/S141	08/13/2021	N - Normal 180 Day	DEFENDER II MODEL 9201 IMPLANTABLE CARDIOVERTER DEFIBRILLATOR	MICROPORT CRM USA INC.	Approval for the creation of new models of home monitors (Smart Monitor, Smart Spot) which will upgrade the modems and replace obsolete components.
P990004/S045	08/13/2021	Y - 135 Review Tra	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Approval for a change in the reference to the drug master file (DMF) for the syringe pre-filled sterile water for injection (sWFI) used in the SURGIFOAM Absorbable Gelatin Sponge (U.S.P.).
P990004/S049	08/25/2021	S - Special CBE	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Approval for implementation of a new additional strategy for monitoring of the endotoxin levels in raw materials, components, intermediates and finished products at Ferrosan Medical Devices A/S
P010015/S475	08/16/2021	N - Normal 180 Day	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Approval for the CareLink SmartSync MRI Access Application.
P010019/S078	08/27/2021	O - Normal 180 Day	FOCUS NIGHT AND DAY (LOTRAFILCON A) SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Approval for a manufacturing site located at CIBA VISION Asia Manufacturing and Logistics Pte Ltd., 133 Tuas South Avenue 3, Singapore 637550 Manufacturing Operation: Repackaging.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S747	08/16/2021	N - Normal 180 Day	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the CareLink SmartSync MRI Access Application.
P010047/S063	08/17/2021	N - Normal 180 Day	PROGEL PLEURAL AIR LEAK SEALANT	NEOMEND, INC.	Approval for replacing the 5mL sterile water vial with a 10mL vial
P020004/S179	08/02/2021	O - Normal 180 Day	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Approval of a new ethylene oxide sterilization cycle to be performed at a new sterilization site (Sterigenics US, LLC located at 2400 Airport Road, Santa Teresa, NM)
P020025/S129	08/05/2021	N - Normal 180 Day	EP TECHNOLOGIES EPT-1000 XP RF ABLATION SYSTEM	BOSTON SCIENTIFIC	Approval of an adhesive change, minor manufacturing changes, and modification of a product specification.
P020025/S132	08/17/2021	R - Real-Time Proc	EP TECHNOLOGIES EPT-1000 XP RF ABLATION SYSTEM	BOSTON SCIENTIFIC	Approval for updated labeling, including modified warnings and directions for use.
P020045/S099	08/22/2021	R - Real-Time Proc	7F FREEZOR CARDIAC CRYOABLATION CATHETER AND CCT.2 CRYOCONSOLE SYSTEM	MEDTRONIC CRYOCATH LP	Approval for a software change to the CryoConsole system, primarily to enable the CryoMapping Mode for the Freezor Xtra Cardiac Cryoablation Catheter.
P040027/S086	08/02/2021	O - Normal 180 Day	GORE VIATORR TIPS	W. L. GORE & ASSOCIATES, INC.	Approval of a new ethylene oxide sterilization cycle to be performed at a new sterilization site (Sterigenics US, LLC located at 2400 Airport Road, Santa Teresa, NM)
P040037/S143	08/02/2021	O - Normal 180 Day	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Approval of a new ethylene oxide sterilization cycle to be performed at a new sterilization site (Sterigenics US, LLC located at 2400 Airport Road, Santa Teresa, NM)
P040043/S123	08/02/2021	O - Normal 180 Day	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Approval of a new ethylene oxide sterilization cycle to be performed at a new sterilization site (Sterigenics US, LLC located at 2400 Airport Road, Santa Teresa, NM)
P050006/S091	08/02/2021	O - Normal 180 Day	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Approval of a new ethylene oxide sterilization cycle to be performed at a new sterilization site (Sterigenics US, LLC located at 2400 Airport Road, Santa Teresa, NM)
P050037/S110	08/27/2021	N - Normal 180 Day	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Approval for modification of the Calcium Hydroxylapatite (CaHA) particle manufacturing process to allow for an Alternate Processing Pathway (APP) to process CaHA particle byproducts.
P050038/S039	08/20/2021	R - Real-Time Proc	ARISTA AH ABSORBABLE HEMOSTAT	DAVOL, INC.	Approval for replacement of an in vitro hemostasis specification and test method used for lot release testing.
P050050/S019	08/23/2021	O - Normal 180 Day	SCANDINAVIAN TOTAL ANKLE REPLACEMENT SYSTEM (S.T.A.R.ANKLE)	DJO GLOBAL	Approval for revisions to device labeling that was updated to include information on the Post-Approval Study(PAS)of the Scandinavian Total Ankle Replacement (S.T.A.R. Ankle). .
P050052/S128	08/27/2021	N - Normal 180 Day	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval for modification of the Calcium Hydroxylapatite (CaHA) particle manufacturing process to allow for an Alternate Processing Pathway (APP) to process CaHA particle byproducts.

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P060027/S105	08/13/2021	N - Normal 180 Day	OVATIO CRT SYSTEM	MICROPORT CRM USA INC.	Approval for the creation of new models of home monitors (Smart Monitor, Smart Spot) which will upgrade the modems and replace obsolete components.
P080025/S224	08/30/2021	Y - 135 Review Tra	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Approval for a cleaning process change at DSM Biomedical in Berkeley California, a supplier to Medtronic Neuromodulation, that involves the addition of an option to replace solvent cleaning the equipment between material lots with a process that uses the next lot of material to purge the system (the first 30 seconds of material coming out of this portion of the manufacturing line is discarded). The change involves the continuous reactor system to be purged between production batches of same hardness grade and purged and cleaned between production batches of different hardness.
P100010/S116	08/06/2021	O - Normal 180 Day	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Approval for a manufacturing site located at Medtronic Puerto Rico Operations Co., Villalba for full assembly, sterilization, packaging, and distribution.
P100045/S053	08/10/2021	N - Normal 180 Day	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ST. JUDE MEDICAL	Approval for device use and implantation through an internal jugular vein access site.
P100045/S054	08/10/2021	R - Real-Time Proc	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ST. JUDE MEDICAL	Approval for a replacement cellular modem in the patient electronics system.
P100047/S174	08/12/2021	Y - 135 Review Tra	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for changes to the acceptance activities for the O-rings in the HVAD Driveline Splice Kit.
P110015/S008	08/10/2021	R - Real-Time Proc	GASTRIC EMPTYING BREATH TEST (GEBT)	ADVANCED BREATH DIAGNOSTICS	Approval for a change to labeling that will facilitate telehealth administration of the device.
P120016/S028	08/06/2021	N - Normal 180 Day	VASCADE VASCULAR CLOSURE SYSTEM	CARDIVA MEDICAL, INC.	Approval for the expansion of the indication for the VASCADE MVP Venous Vascular Closure System to include same day discharge in addition to existing claims.
P130006/S082	08/02/2021	O - Normal 180 Day	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Approval of a new ethylene oxide sterilization cycle to be performed at a new sterilization site (Sterigenics US, LLC located at 2400 Airport Road, Santa Teresa, NM)
P130008/S068	08/31/2021	R - Real-Time Proc	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval for the revision of Model 2740 Programmer cable firmware to v1.7.
P130021/S094	08/12/2021	N - Normal 180 Day	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Approval for various modifications to the CoreValve Evolut PRO+ System. The device, as modified, will be marketed under the trade name Medtronic Evolut FX Sys.
P130021/S097	08/10/2021	O - Normal 180 Day	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Approval for modifications to the Instructions for Use to reflect the 1-year findings of the Medtronic CoreValve Low Risk Bicuspid Post Approval Study.
P130024/S038	08/06/2021	Y - 135 Review Tra	LUTONIX DRUG COATED BALLOON PTA CATETER	LUTONIX	Approval to modify an in-process drug content inspection.
P130026/S069	08/03/2021	O - Normal 180 Day	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Approval for a labeling update for the TactiCath Quartz Contact Force Ablation Catheter Instructions for Use to included a summary of the long-term effectiveness data from the TactiCath Quartz Post-Approval Study.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140008/S022	08/12/2021	R - Real-Time Proc	ORBERA INTRAGASTRIC BALLOON	APOLLO ENDOSURGERY INC	Approval for a change in the material used to manufacture the fill tube component.
P140031/S131	08/12/2021	R - Real-Time Proc	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for a labeling update to add a precaution regarding limitations of deriving gradient estimates from Doppler echocardiography.
P140032/S074	08/31/2021	O - Normal 180 Day	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Approval of Request for Post-Approval Study Termination.
P140033/S068	08/13/2021	R - Real-Time Proc	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ABBOTT MEDICAL	Approval for use of two new MRI inductor component models in Assurity and Endurity MRI pacemaker devices and to add an alternate supplier of these components.
P150004/S051	08/05/2021	O - Normal 180 Day	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Approval of the revised protocol for the post-approval study (PAS) requesting removal of 18- and 24-month follow-up visits.
P150005/S061	08/05/2021	N - Normal 180 Day	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval for an adhesive change, minor manufacturing changes, and modification of a product specification.
P150016/S019	08/17/2021	N - Normal 180 Day	TRIDYNE VASCULAR SEALANT	NEOMEND, INC.	Approval for replacing the 5mL sterile water vial with a 10mL vial.
P160013/S008	08/02/2021	R - Real-Time Proc	ORGAN CARE SYSTEM (OCS¿) LUNG SYSTEM	TRANSMEDICS, INC	Approval for an alternate check valve for the OCS Lung System.
P160021/S029	08/02/2021	O - Normal 180 Day	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Approval of a new ethylene oxide sterilization cycle to be performed at a new sterilization site (Sterigenics US, LLC located at 2400 Airport Road, Santa Teresa, NM)
P160037/S005	08/24/2021	N - Normal 180 Day	BD ONCLARITY HPV ASSAY	BECTON, DICKINSON AND COMPANY	Approval for use of the BD Onclarity HPV Assay on the BD COR (PX/GX) instrument system.
P160040/S007	08/26/2021	N - Normal 180 Day	LEUKOSTRAT CDX FLT3 MUTATION ASSAY	INVIVOSCRIBE TECHNOLOGIES, INC	Approval for the improvement of the manufacturing method for the FLT3 TKD Positive Control included with the LeukoStrat CDx FLT3 Mutation Assay.
P160040/S008	08/05/2021	S - Special CBE	LEUKOSTRAT CDX FLT3 MUTATION ASSAY	INVIVOSCRIBE TECHNOLOGIES, INC	Approval of changes made to the Instructions for Use of the LeukoStrat CDx FLT3 Mutation Assay.
P160045/S028	08/25/2021	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 single nucleotide variants in IDH1 in cholangiocarcinoma patients who may benefit from treatment with TIBSOVO (ivosidenib).

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P170003/S019	08/06/2021	Y - 135 Review Tra	LUTONIX® 035 DRUG COATED BALLOON PTA CATHETER, MODEL 9010	LUTONIX	Approval to modify an in-process drug content inspection.
P170008/S032	08/20/2021	O - Normal 180 Day	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Approval for updates to the device labeling reflecting the 5-year continued follow-up of the BIONICS Clinical Study.
P170035/S013	08/27/2021	R - Real-Time Proc	BAUSCH + LOMB ULTRA (SAMFILCON A) CONTACT LENSES	BAUSCH AND LOMB, INC.	Approval to remove the Sagittal Depth measurement acceptance criteria from the finished product specifications for Ultra (samfilcon A) Contact Lens.
P170036/S008	08/06/2021	O - Normal 180 Day	M6-C ARTIFICIAL CERVICAL DISC	SPINAL KINETICS LLC	Approval for Infinity Labs SD located at 1836 Stone Avenue, San Jose, California, 95125, for ethylene oxide sterilization of the M6-C Artificial Cervical Disc system.
P170038/S007	08/19/2021	O - Normal 180 Day	CENTRIMAG CIRCULATORY SUPPORT SYSTEM	ABBOTT	Approval of the revised protocol for the post-approval study (PAS) protocol.
P170043/S009	08/31/2021	Y - 135 Review Tra	ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM (MODEL G2-M-IS)	GLAUKOS CORPORATION	Approval for an alternate manufacturing process and supplier for the singulator holder assembly.
P180002/S019	08/13/2021	O - Normal 180 Day	ZEPHYR ENDOBRONCHIAL VALVE SYSTEM	PULMONX CORPORATION	Approval for modifications to the protocol to include collection of perfusion data at baseline, extension of high-resolution computed tomography (HRCT) baseline data collection window from 3 months to 6 months prior to Informed Consent date, and collection of HRCT data at 12 months.
P180032/S006	08/27/2021	R - Real-Time Proc	CERENE® CRYOTHERAPY DEVICE	CHANNEL MEDSYSTEMS, INC.	Approval for a design change to the Inflow Solenoid, miniature solenoid valve, and miniature solenoid valve gasket.
P180038/S005	08/10/2021	R - Real-Time Proc	LIAISON XL MUREX ANTI-HBC, LIAISON MUREX CONTROL ANTI-HBC	DIASORIN INC.	Approval for a software version change for the LIAISON XL Analyzer from the approved LIAISON XL version 4.2.2.3 SP1 to software version 4.2.2.4.
P180039/S004	08/10/2021	R - Real-Time Proc	LIAISON® XL MUREX ANTI-HBS, LIAISON® XL MUREX CONTROL ANTI-HBS AND LIAISON® XL MUREX ANTI-HBS VERIFIERS	DIASORIN INC.	Approval for a software version change for the LIAISON XL Analyzer from the approved LIAISON XL version 4.2.2.3 SP1 to software version 4.2.2.4.
P180045/S002	08/10/2021	R - Real-Time Proc	LIAISON® XL MUREX HBC IGM, LIAISON® XL MUREX CONTROL HBC IGM	DIASORIN INC.	Approval for a software version change for the LIAISON XL Analyzer from the approved LIAISON XL version 4.2.2.3 SP1 to software version 4.2.2.4.
P180047/S010	08/10/2021	R - Real-Time Proc	LIAISON QUANTIFERON - TB GOLD PLUS, LIAISON CONTROL QUANTIFERON - TB GOLD PLUS AND LIAISON QUANTIFERON SOFTWARE	DIASORIN, INC.	Approval for a software version change for the LIAISON XL Analyzer from the approved LIAISON XL version 4.2.2.3 SP1 to software version 4.2.2.4.
P180048/S002	08/10/2021	R - Real-Time Proc	LIAISON® XL MUREX HBEAG, LIAISON® XL MUREX CONTROL HBEAG	DIASORIN INC.	Approval for a software version change for the LIAISON XL Analyzer from the approved LIAISON XL version 4.2.2.3 SP1 to software version 4.2.2.4.

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P180049/S002	08/10/2021	R - Real-Time Proc	LIAISON® XL MUREX ANTI-HBE, LIAISON® XL MUREX CONTROL ANTI-HBE	DIASORIN INC.	Approval for a software version change for the LIAISON XL Analyzer from the approved LIAISON XL version 4.2.2.3 SP1 to software version 4.2.2.4.
P190011/S004	08/10/2021	R - Real-Time Proc	LIAISON XL MUREX HCV AB; LIAISON XL MUREX CONTROL HCV AB	DIASORIN INC.	Approval for a software version change for the LIAISON XL Analyzer from the approved LIAISON XL version 4.2.2.3 SP1 to software version 4.2.2.4.
P190017/S002	08/10/2021	R - Real-Time Proc	LIAISON® XL MUREX HBSAG QUAL, LIAISON® MUREX CONTROL HBSAG, AND LIAISON® XL MUREX HBSAG CONFIRMATORY TEST	DIASORIN INC	Approval for a software version change for the LIAISON XL Analyzer from the approved LIAISON XL version 4.2.2.3 SP1 to software version 4.2.2.4.
P200014/S003	08/10/2021	O - Normal 180 Day	COBAS® EZH2 MUTATION TEST	ROCHE MOLECULAR SYSTEM, INC.	Approval for the revised Instructions for Use for the cobas® EZH2 Mutation Test.
P200021/S001	08/20/2021	O - Normal 180 Day	NEURO COCHLEAR IMPLANT SYSTEM	OTICON MEDICAL	Approval of the protocol for the post-approval study (PAS) protocol.
P200022/S001	08/03/2021	O - Normal 180 Day	SIMPLIFY® CERVICAL ARTIFICIAL DISC	NUVASIVE, INC.	Approval for a new manufacturing facility for the Simplify® Cervical Artificial Disc.
P200029/S002	08/19/2021	R - Real-Time Proc	THERASPHERE	BOSTON SCIENTIFIC CORPORATION	Approval for removing the needleless luer component from the TheraSphere Administration Sets.

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30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S081	08/16/2021	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Change to the sampling plan used in the Finished Goods testing and incoming inspection of components of SURGICEL Absorbable Hemostats at Ethicons Puerto Rico site.
N12159/S082	08/31/2021	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Expansion of the controlled manufacturing environment (CME) in the Ethicon, LLC, San Lorenzo, Puerto Rico facility.
P810006/S097	08/12/2021	X - 30-Day Notice	COLLASTAT	INTEGRA LIFESCIENCES CORPORATION	Qualification of upgrades to the lyophilizer system software and hardware.
P810025/S043	08/27/2021	X - 30-Day Notice	AMVISC(R)	BAUSCH & LOMB, INC.	Changes of the Sodium Hyaluronate release specifications to align with the European Pharmacopoeia.
P830055/S271	08/19/2021	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Manufacturing material change for the polishing process for the LCS Total Knee System.

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P830061/S197	08/17/2021	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Minor modifications, including new ovens and a new toolmaker's scope at Medtronic Rice Creek.
P830061/S198	08/20/2021	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Improvements to the 3830 outer coil cell operating system (COS) conversion and legacy COS.
P840001/S496	08/13/2021	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Change to the welding process and equipment at external supplier, Bal Seal Engineering (BSE), who supplies Radial Spring Contacts to Medtronic Energy and Component Center (MECC).
P840062/S083	08/12/2021	X - 30-Day Notice	COLLACOTE(TM)	INTEGRA LIFESCIENCES CORP.	Qualification of upgrades to the lyophilizer system software and hardware.
P850010/S099	08/12/2021	X - 30-Day Notice	HELISTAT(TM) ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	INTEGRA LIFESCIENCES CORPORATION	Qualification of upgrades to the lyophilizer system software and hardware.
P850089/S156	08/17/2021	X - 30-Day Notice	CAPSURE SP, CAPSURE, CAPSURE 2 LEADS, EXCELLENCE S, IMPULSE, IMPLUSE II EXCELLENCE SS, LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Minor modifications, including new ovens and a new toolmaker's scope at Medtronic Rice Creek.
P850089/S157	08/20/2021	X - 30-Day Notice	CAPSURE SP, CAPSURE, CAPSURE 2 LEADS, EXCELLENCE S, IMPULSE, IMPLUSE II EXCELLENCE SS, LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Improvements to the 3830 outer coil cell operating system (COS) conversion and legacy COS.
P880047/S041	08/31/2021	X - 30-Day Notice	INTERCEED TC7 ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Expansion of the controlled manufacturing environment (CME) in the Ethicon, LLC, San Lorenzo, Puerto Rico facility.
P890003/S447	08/17/2021	X - 30-Day Notice	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Minor modifications, including new ovens and a new toolmaker's scope at Medtronic Rice Creek.
P900033/S097	08/12/2021	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Qualification of upgrades to the lyophilizer system software and hardware.

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P900061/S165	08/17/2021	X - 30-Day Notice	MEDTRONIC PCD TACHYARRHYTHMIA CONTROL SYSTEM	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Minor modifications, including new ovens and a new toolmaker's scope at Medtronic Rice Creek.
P910054/S008	08/31/2021	X - 30-Day Notice	INOUE BALLOON CATHETER	TORAY INDUSTRIES (AMERICA), INC.	Change to the location of the supplier of latex tube components.
P920015/S257	08/19/2021	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Updates to the automated tip grinding process for helix coils.
P920015/S258	08/19/2021	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Implementation of incoming inspections of silicone rubber tubing received at Medtronic Rice Creek facility to replace inspections no longer occurring at MECC.
P920015/S259	08/17/2021	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Minor modifications, including new ovens and a new toolmaker's scope at Medtronic Rice Creek.
P930014/S139	08/23/2021	X - 30-Day Notice	ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES	ALCON LABORATORIES, INC.	Implement the use of a new Blister Sealer System for the packaging of the AcrySert® and UltraSert® Lens Delivery Systems.
P930036/S017	08/25/2021	X - 30-Day Notice	ADVIA CENTAUR AFP REAGENTS AND CALIBRATORS	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Changing primary reagent label to one common label for Atellica IM and ADVIA Centaur ReadyPacks.
P930039/S229	08/17/2021	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Minor modifications, including new ovens and a new toolmaker's scope at Medtronic Rice Creek.
P950022/S141	08/09/2021	X - 30-Day Notice	TVL(TM) LEAD SYSTEM	ABBOTT MEDICAL	Increase hold times for MCRD components.
P950024/S099	08/17/2021	X - 30-Day Notice	MEDTRONIC(R) CAPSURE (R) EPI PACING LEAD MODEL 4695	MEDTRONIC INC.	Minor modifications, including new ovens and a new toolmaker's scope at Medtronic Rice Creek.
P950037/S227	08/19/2021	X - 30-Day Notice	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Implement new automated equipment for their pickling process associated with various components used in manufacture of IPGs, ICDs, and leads.
P960009/S404	08/13/2021	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Change to the welding process and equipment at external supplier, Bal Seal Engineering (BSE), who supplies Radial Spring Contacts to Medtronic Energy and Component Center (MECC).
P960009/S405	08/20/2021	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Update the monitoring process for the SenSight Directional Leads and SenSight Extensions.

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P960013/S120	08/09/2021	X - 30-Day Notice	TENDRIL DX MODEL 1388T & 1388K ENDOCARDIAL PACING LEADS	ABBOTT MEDICAL	Increase hold times for MCRD components.
P970004/S337	08/13/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Change to the welding process and equipment at external supplier, Bal Seal Engineering (BSE), who supplies Radial Spring Contacts to Medtronic Energy and Component Center (MECC).
P970004/S339	08/18/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Changes to in-process inspection acceptance activities for bubble and cosmetic foreign material detection.
P970004/S341	08/24/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Change to sterilization process, addition of the Cardiac Rhythm Management (CRM) sterilization area at the Villalba site for the sterilization of the leads (models 978A1 and 978B1) and extensions (models 3560022 and 3560030).
P970037/S012	08/11/2021	X - 30-Day Notice	AUTODELFIA HAFP TEST KIT	PERKINELMER, INC.	Adding the WAVE25 system and the Cogent M1 TFF system to the in vitro manufacturing of antibodies.
P980016/S788	08/12/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Acceptance to add a downstream software verification to ensure battery Use-By-Date has not been reached at electrical interconnection.
P980016/S789	08/17/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Minor modifications, including new ovens and a new toolmaker's scope at Medtronic Rice Creek.
P980023/S107	08/19/2021	X - 30-Day Notice	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Implement new automated equipment for their pickling process associated with various components used in manufacture of IPGs, ICDs, and leads.
P980035/S688	08/12/2021	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Add a rework process for laser soldering pins to the hybrid board.
P980035/S689	08/17/2021	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Minor modifications, including new ovens and a new toolmaker's scope at Medtronic Rice Creek.
P980037/S085	08/11/2021	X - 30-Day Notice	ANGIOJET RHEOLYTIC THROMBECTOMY LF140 CATHETER	BOSTON SCIENTIFIC CORP.	Change to incorporate a hydration step in the production of device pump components.
P980044/S057	08/06/2021	X - 30-Day Notice	SUPARTZ FX	SEIKAGAKU CORP.	Replacement of water ultrafiltration modules.

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P980050/S134	08/17/2021	X - 30-Day Notice	MEDTRONIC(R) JEWEL(R) AF 7250 DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATOR, MODEL 9961 PROGRAMMER APPLICATION SOF	MEDTRONIC INC.	Minor modifications, including new ovens and a new toolmaker's scope at Medtronic Rice Creek.
P000009/S094	08/19/2021	X - 30-Day Notice	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Implement new automated equipment for their pickling process associated with various components used in manufacture of IPGs, ICDs, and leads.
P010013/S084	08/30/2021	X - 30-Day Notice	NOVASURE IMPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM	HOLOGIC, INC.	Change in supplier of NovaSure mechanism components, ASY-02797 (NovaSure Gen 3) and ASY-09341 (NovaSure Gen 4.1 & V5).
P010015/S479	08/12/2021	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Acceptance to add a downstream software verification to ensure battery Use-By-Date has not been reached at electrical interconnection.
P010015/S480	08/12/2021	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Add a rework process for laser soldering pins to the hybrid board.
P010015/S481	08/17/2021	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Minor modifications, including new ovens and a new toolmaker's scope at Medtronic Rice Creek.
P010031/S753	08/12/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Acceptance to add a downstream software verification to ensure battery Use-By-Date has not been reached at electrical interconnection.
P010031/S754	08/17/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Minor modifications, including new ovens and a new toolmaker's scope at Medtronic Rice Creek.
P020004/S183	08/13/2021	X - 30-Day Notice	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Modify the vertical and post-bake ovens used to manufacture delivery sheaths.
P030036/S131	08/17/2021	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Minor modifications, including new ovens and a new toolmaker's scope at Medtronic Rice Creek.

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P030036/S132	08/20/2021	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Improvements to the 3830 outer coil cell operating system (COS) conversion and legacy COS.
P040024/S126	08/25/2021	X - 30-Day Notice	RESTYLANE INJECTABLE GEL	Q-MED AB	Change in the implementation of interface between ERP system and gLIMS system.
P040037/S145	08/13/2021	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Modify the vertical and post-bake ovens used to manufacture delivery sheaths.
P040045/S122	08/23/2021	X - 30-Day Notice	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Additional flexible reprocessing cartoner used to repackage VISTAKON® (senofilcon A) Brand Contact Lenses.
P050006/S094	08/13/2021	X - 30-Day Notice	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Modify the vertical and post-bake ovens used to manufacture delivery sheaths.
P050023/S159	08/13/2021	X - 30-Day Notice	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Acceptance to implement optimization of production processes for capacity expansion and to introduce a robotic arm for automated device transfer.
P050023/S160	08/19/2021	X - 30-Day Notice	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Implement new automated equipment for their pickling process associated with various components used in manufacture of IPGs, ICDs, and leads.
P050028/S085	08/11/2021	X - 30-Day Notice	COBAS TAQMAN HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Change the manufacturer/supplier of a critical sub-assembly component.
P060011/S028	08/03/2021	X - 30-Day Notice	C-FLEX MODEL 570C INTRAOCULAR LENS (IOL)	RAYNER INTRAOCULAR LENSES LTD.	Software updates to existing optical measuring equipment.
P060030/S086	08/11/2021	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Change the manufacturer/supplier of a critical sub-assembly component.
P060037/S074	08/17/2021	X - 30-Day Notice	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Remove moisture testing and specification requirement from the PMMA beads material specification.
P060039/S108	08/17/2021	X - 30-Day Notice	ATTAIN STARFIX MODEL 4195 LEAD	MEDTRONIC INC.	Minor modifications, including new ovens and a new toolmaker's scope at Medtronic Rice Creek.
P070008/S128	08/19/2021	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.	Implement new automated equipment for their pickling process associated with various components used in manufacture of IPGs, ICDs, and leads.

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P070014/S063	08/05/2021	X - 30-Day Notice	LIFESTENT FLEXSTAR & FLEXSTAR XL VASCULAR STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	Implement an alternative external process challenge device (ePCD) used in the sterilization process.
P070026/S084	08/19/2021	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Manufacturing material change for the polishing process for the Ceramax Total Hip System.
P080006/S162	08/17/2021	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Minor modifications, including new ovens and a new toolmaker's scope at Medtronic Rice Creek.
P080007/S025	08/05/2021	X - 30-Day Notice	BARD E-LUMINEXX VASCULAR STENT	BARD PERIPHERAL VASCULAR, INC.	Implement an alternative external process challenge device (ePCD) used in the sterilization process.
P080020/S044	08/06/2021	X - 30-Day Notice	GEL-ONE	SEIKAGAKU CORP.	Replacement of water ultrafiltration modules.
P080025/S232	08/13/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Change to the welding process and equipment at external supplier, Bal Seal Engineering (BSE), who supplies Radial Spring Contacts to Medtronic Energy and Component Center (MECC).
P080025/S234	08/18/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Changes to in-process inspection acceptance activities for bubble and cosmetic foreign material detection.
P080025/S236	08/24/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Change to sterilization process, addition of the Cardiac Rhythm Management (CRM) sterilization area at the Villalba site for the sterilization of the leads (models 978A1 and 978B1) and extensions (models 3560022 and 3560030).
P100009/S043	08/01/2021	X - 30-Day Notice	MITRACLIP DELIVERY SYSTEM	ABBOTT VASCULAR INC.	Use of two new heated dryers to manufacture the MitraClip NTR/XTR and G4 Systems.
P100021/S094	08/05/2021	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Manufacturing changes to be implemented by the first-tier supplier (Phillips) of components for the delivery systems of Valiant Captivia and Endurant series devices.
P100040/S048	08/05/2021	X - 30-Day Notice	VALIANT THORACIC STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Manufacturing changes to be implemented by the first-tier supplier (Phillips) of components for the delivery systems of Valiant Captivia and Endurant series devices.
P100047/S186	08/03/2021	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Changes to the inspection process and manufacturing procedures related to spatter on the HVAD pump inflow tube.
P100047/S188	08/10/2021	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Modifications to the inspection procedures at a sub-tier supplier and at the contract manufacturer of the HVAD Battery Chargers.
P110010/S197	08/16/2021	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Change to the analytical chemistry method for evaluating drug content.

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P110013/S114	08/31/2021	X - 30-Day Notice	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Change to the analytical chemistry method for lot release.
P110037/S056	08/11/2021	X - 30-Day Notice	COBAS® AMPLIPREP/ COBAS® TAQMAN® CMV TEST (CAP/CTM CMV TEST)	ROCHE MOLECULAR SYSTEMS, INC.	Change the manufacturer/supplier of a critical sub-assembly component.
P120017/S028	08/17/2021	X - 30-Day Notice	MODEL 5071 LEAD	MEDTRONIC INC.	Minor modifications, including new ovens and a new toolmaker's scope at Medtronic Rice Creek.
P130006/S084	08/13/2021	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,I NC	Modify the vertical and post-bake ovens used to manufacture delivery sheaths.
P130008/S071	08/12/2021	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Process change to increase the allowed upper limit of the range for titanium/niobium sputter thickness.
P130013/S045	08/25/2021	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Add an alternate sterilization site with additional PCDs to sterilize the WATCHMAN FLX LAAC device.
P130024/S041	08/05/2021	X - 30-Day Notice	LUTONIX DRUG COATED BALLOON PTA CATETER	LUTONIX	Replacement of a manual feed system with an automated feed system.
P130029/S010	08/05/2021	X - 30-Day Notice	FLUENCY PLUS ENDOVASCULAR STENT GRAFT	BARD PERIPHERAL VASCULAR, INC.	Implement an alternative external process challenge device (ePCD) used in the sterilization process.
P140003/S087	08/23/2021	X - 30-Day Notice	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Modification of the Impella 5.5 with SmartAssist packaging.
P140004/S025	08/26/2021	X - 30-Day Notice	SUPERION INTERSPINOUS SPACER	BOSTON SCIENTIFIC NEUROMODU LATION	Distribute the device incorporating the change as requested in this supplement. This change applies to the final assembly of the Superion Indirect Decompression System (IDS) device. The following manufacturing facility is affected by the change: Boston Scientific Limited, Cashel Rd, ClonmelCo, Tipperary, Ireland.
P140017/S019	08/03/2021	X - 30-Day Notice	MELODY TRANSCATHETER PULMONARY VALVE (TPV), ENSEMBLE TRANSCATHETER VALVE DELIVERY SYSTEM (DS)	MEDTRONIC INC.	Update to the Bioburden Correction Factor.
P140031/S133	08/31/2021	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCE S, LLC.	Change to the receiving inspection for the Final Stopper component of the Crimp Stopper.
P150005/S066	08/06/2021	X - 30-Day Notice	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Alternate supplier for the catheter connector.

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P150036/S055	08/31/2021	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Ttransfer of downstream manufacturing processes for the EDWARDS INTUITY Elite Valve (Model 8300AB) to another established facility.
P160015/S012	08/13/2021	X - 30-Day Notice	AED PLUS AND FULLY AUTOMATIC AED PLUS	ZOLL MEDICAL CORPORATION	Addition of an alternate soldering machine, replacement of an existing wash machine, replacement of an existing ionograph machine, and replacement of existing IC manual programming.
P160022/S030	08/13/2021	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 an alternate soldering machine, replacement of an existing wash machine, replacement of an existing ionograph machine, and replacement of existing IC manual programming.
P160029/S013	08/10/2021	X - 30-Day Notice	HEARTSTART ONSITE DEFIBRILLATOR (MODEL M5066A) AND HEARTSTART HOME DEFIBRILLATOR (MODEL M5068A)	PHILIPS MEDICAL SYSTEMS, INC.	Change to the mixing process for hydrogel pads.
P160040/S009	08/11/2021	X - 30-Day Notice	LEUKOSTRAT CDX FLT3 MUTATION ASSAY	INVIVOSCRIBE TECHNOLOGIES, INC	Qualification of an automated process for fill, finish, and label the kit components.
P160043/S051	08/13/2021	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Allow for shelf life expiration date (SLED) and pouch and labeling rework at Medtronic Memphis Distribution Center.
P160043/S052	08/09/2021	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Introduction of new stent crimp equipment on the Resolute Onyx manufacturing line to perform the final crimp of the stent onto the balloon of the delivery system.
P160043/S054	08/31/2021	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Change to the analytical chemistry method for lot release.
P170002/S018	08/13/2021	X - 30-Day Notice	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Addition of a new cleanroom and extension of maximum holding times at two points during the manufacturing of RHA 2, RHA 3, and RHA 4 gels.

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P170003/S023	08/05/2021	X - 30-Day Notice	LUTONIX® 035 DRUG COATED BALLOON PTA CATHETER, MODEL 9010	LUTONIX	Replacement of a manual feed system with an automated feed system.
P170038/S006	08/05/2021	X - 30-Day Notice	CENTRIMAG CIRCULATORY SUPPORT SYSTEM	ABBOTT	Implementation of a new set of mandrels for the CentriMag cannulae body manufacturing process.
P170042/S010	08/05/2021	X - 30-Day Notice	COVERA¿ VASCULAR COVERED STENT	C.R. BARD, INC	Implement an alternative external process challenge device (ePCD) used in the sterilization process.
P180011/S043	08/04/2021	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Modifications to the endotoxin sampling plan.
P180037/S006	08/05/2021	X - 30-Day Notice	VENOVO VENOUS STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	Implement an alternative external process challenge device (ePCD) used in the sterilization process.
P200015/S012	08/31/2021	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Change to the receiving inspection for the Final Stopper component of the Crimp Stopper.
Total: 105					