PMA Monthly approvals from 7/1/2020 to 7/31/2020

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190031	07/28/2020	PMAO - PMA Origi	HER2 DUAL ISH DNA PROBE COCKTAIL	VENTANA MEDICAL SYSTEMS, INC.	Approval for the VENTANA HER2 Dual ISH DNA Probe Cocktail assay.

Total: 1

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830055/S249	07/14/2020	S - Special CBE	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval to amend the current Caliper tool measuring step in the machining section of the manufacturing step for Sigma RP and Sigma AOX RP bearings and replace it with the Shadow graph tool.
P840001/S427	07/01/2020	R - Real-Time Proc	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Approval for an update to the drawing for the Carrier-Electrode Plate, 5-6-5, Medtronic Part Number M926542A001, as a result of a molding manufacturing process change at the supplier, which included, but was not limited to, a change for manufacturing the carrier from a Silicone Molding process to a Liquid Injection Molding process.
P840024/S092	07/02/2020	N - Normal 180 Day	NUCLEUS MULTICHANNEL IMPLANTABLE HEARING PROSTHESI	COCHLEAR AMERICAS	Approval for Kanso 2 Sound Processor and associated accessories, Nucleus 7 for Nucleus 22, SmartNav System including SmartNav App and CP1150S Surgical Processor, and Custom Sound Pro.
P860003/S102	07/31/2020	N - Normal 180 Day	UVAR PHOTOPHERESIS SYSTEM	MALLINCKRODT PHARMACEUTICALS IRELAND LIMITED	Approval for software Version 5.4 and for hardware modifications to the CELLEX® Photopheresis System, including changes to the servo drive electrical isolation hardware and to the Ballast Monitor and Lamp Rear printed circuit board assemblies.
P890003/S430	07/24/2020	R - Real-Time Proc	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Approval for firmware updates to the MyCareLink Patient Monitor Model 24950.
P910073/S157	07/07/2020	O - Normal 180 Day	ENDOTAK LEAD SYSTEM	BOSTON SCIENTIFIC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P910077/S178	07/07/2020	R - Real-Time Proc	VENTAK(R) PRX (TM) MODEL 1700,1705 PULSE GENERATOR	BOSTON SCIENTIFIC	Approval for Model 3877 Programmer SW Application v1.01, updated telemetry firmware for Model 3300 LATITUDE Programmer to support communication with S-ICD devices, and other minor changes.

Data as of 08/04/2020 03:04 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P930036/S012	07/02/2020	Y - 135 Review Tra	ADVIA CENTAUR AFP REAGENTS AND CALIBRATORS	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Approval for the implementation of a new model luminometer utilized in the in-process testing of Lite Reagent components.
P950021/S019	07/02/2020	Y - 135 Review Tra	ADVIA CENTAUR & ADVIA CENTAUR CP PSA IMMUNOASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Approval for the implementation of a new model luminometer utilized in the in-process testing of Lite Reagent components.
P970004/S302	07/30/2020	N - Normal 180 Day	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODU LATION	Approval of the new InterStim Micro System with 1.5T and 3T full-body MR conditional labeling, an updated InterStim II System (including new SureScan MRI leads) with 1.5T and 3T full-body MR conditional labeling, an updated Verify Evaluation System that can accommodate newly developed leads, and related labeling updates.
P970051/S193	07/02/2020	N - Normal 180 Day	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for the Kanso 2 Sound Processor and associated accessories, Nucleus 7 for Nucleus 22, SmartNav System including SmartNav App and CP1150S Surgical Processor, and Custom Sound Pro.
P980016/S742	07/24/2020	R - Real-Time Proc	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for firmware updates to the MyCareLink Patient Monitor Model 24950
P980035/S628	07/24/2020	R - Real-Time Proc	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Approval for firmware updates to the MyCareLink Patient Monitor Model 24950
P990055/S019	07/02/2020	Y - 135 Review Tra	BAYER IMMUNO 1 COMPLEXED PSA ASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Approval for the implementation of a new model luminometer utilized in the in-process testing of Lite Reagent components.
P990071/S044	07/17/2020	N - Normal 180 Day	STOCKERT 70 RADIOFREQUENCY ABLATION GENERATOR	BIOSENSE WEBSTER, INC.	Approval for design, software and labeling changes to the nGEN pump.
P000006/S054	07/10/2020	R - Real-Time Proc	TITAN INFLATABLE PENILE PROSTHESIS	COLOPLAST CORP.	Approval for changing the silicone material used in the components of Titan Penile Prosthesis.
P000015/S041	07/02/2020	N - Normal 180 Day	NUCLEUS 24 AUDITORY BRAINSTEM IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for the Kanso 2 Sound Processor and associated accessories, Nucleus 7 for Nucleus 22, SmartNav System including SmartNav App and CP1150S Surgical Processor, and Custom Sound Pro.
P010012/S520	07/07/2020	O - Normal 180 Day	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P010015/S438	07/24/2020	R - Real-Time Proc	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Approval for firmware updates to the MyCareLink Patient Monitor Model 24950

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S703	07/24/2020	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for firmware updates to the MyCareLink Patient Monitor Model 24950
P010032/S162	07/01/2020	R - Real-Time Proc	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Approval for a minor design changes to the feed-thru component of the implanted pulse generators (IPGs).
P020024/S062	07/09/2020	O - Normal 180 Day	AMPLATZER DUCT OCCLUDER AND 180 DEGREE DELIVERY SYSTEM	ABBOTT MEDICAL	Approval for updates to the Amplatzer Piccolo occluder Instructions for Use (IFU).
P030039/S025	07/16/2020	R - Real-Time Proc	COSEAL SURGICAL SEALANT	BAXTER BIO SCIENCE	Approval for a shelf-life extension from 6 months to 12 months.
P030053/S050	07/17/2020	O - Normal 180 Day	MEMORYGEL SILICONE GEL -FILLED BREAST IMPLANTS	MENTOR CORP.	Approval for updates to the labeling.
P040002/S065	07/23/2020	S - Special CBE	ENDOLOGIX POWERLINK SYSTEM	ENDOLOGIX, INC.	Approval for an added destructive test to the process monitoring control for the AFX2 Bifurcated device.
P050006/S083	07/02/2020	S - Special CBE	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,I NC	Approval for a change to the device Instructions For Use to add a warning related to risks associated with physician modification of the device before use.
P050011/S007	07/01/2020	R - Real-Time Proc	ADEPT (4% ICODEXTRIN) ADHESION REDUCTION SOLUTION	BAXTER HEALTHCARE CORP.	Approval for a new welding profile for the polyvinylchloride storage bag for the ADEPT® Adhesion Reduction Solution.
P050016/S012	07/17/2020	O - Normal 180 Day	CORMET HIP RESURFACING SYSTEM	CORIN U.S.A.	Approval for an update to the device labeling (i.e., package insert) to include a summary of the results of the completed long-term post-approval study (PAS).
P050023/S147	07/16/2020	R - Real-Time Proc	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval for a minor design change to the battery cathode collector insulation used in select ICDs and CRT-Ds.
P050047/S077	07/17/2020	S - Special CBE	JUVEDERM 24HV, JUVEDERM 30 AND JUVEDERM 30HV GEL IMPLANTS	ALLERGAN	Approval for revisions to the clinician labeling of Juvéderm® Ultra, Juvéderm® Ultra XC, Juvéderm® Ultra Plus, Juvéderm® Ultra Plus XC, Juvéderm® Vollure XC, and Juvéderm® Volbella XC to include updated safety information based on post marketing surveillance data
P060028/S032	07/01/2020	O - Normal 180 Day	MENTOR MEMORYSHAPE BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P060028/S033	07/01/2020	O - Normal 180 Day	MENTOR MEMORYSHAPE BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P070026/S070	07/21/2020	O - Normal 180 Day	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDI CS, INC.	Approval for an update to the device labeling to include a summary of the results of the completed long-term post-approval study (PAS).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P080006/S147	07/15/2020	R - Real-Time Proc	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Approval for minor design specification changes for selected implantable leads.
P080013/S020	07/22/2020	S - Special CBE	DURASEAL EXACT SPINE SEALANT SYSTEM	INTEGRA LIFESCIENCES CORPORATION	Approval for labeling changes to add additional information on potential risks and adverse events identified in the Summary of Safety and Effectiveness Data for the DuraSeal Exact Spine Sealant System.
P080025/S197	07/30/2020	N - Normal 180 Day	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Approval of the new InterStim Micro System with 1.5T and 3T full-body MR conditional labeling, an updated InterStim II System (including new SureScan MRI leads) with 1.5T and 3T full-body MR conditional labeling, an updated Verify Evaluation System that can accommodate newly developed leads, and related labeling updates.
P100026/S081	07/14/2020	R - Real-Time Proc	NEUROPACE RNS SYSTEM	NEUROPACE INC	Approval for an update to the custom integrated circuit (IC) of the RNS® Neurostimulator, from Cinco 1E to Cinco 1F.
P100044/S046	07/01/2020	R - Real-Time Proc	PROPEL	INTERSECT ENT	Approval for a new packaging configuration and labeling changes for the Propel Mini Sinus Implant.
P100047/S132	07/09/2020	N - Normal 180 Day	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for modifications to the design of the outflow graft and strain relief, as well as modifications to the associated tools, packaging, and labeling. The modified design includes an Outflow Graft with an added Titanium Ring, a Strain Relief Clamp with a captured screw, and a Strain Relief Wrench to replace the Hex Driver
P110005/S004	07/10/2020	S - Special CBE	SINOVIAL (SODIUM HYALURONATE 0.8%)	IBSA INSTITUT BIOCHIMIQUE SA	Approval for inclusion of the routine use of bioindicators to monitor efficacy of the sterilization cycle for every batch of GELSYN-3.
P110033/S055	07/17/2020	S - Special CBE	JUVEDERM VOLUMA XC	ALLERGAN	Approval for revisions to the clinician labeling of Juvéderm® Ultra, Juvéderm® Ultra XC, Juvéderm® Ultra Plus, Juvéderm® Ultra Plus XC, Juvéderm® Vollure XC, and Juvéderm® Volbella XC to include updated safety information based on post marketing surveillance data.
P110042/S137	07/07/2020	R - Real-Time Proc	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for Model 3877 Programmer SW Application v1.01, updated telemetry firmware for Model 3300 LATITUDE Programmer to support communication with S-ICD devices, and other minor changes.
P120006/S036	07/09/2020	S - Special CBE	OVATION ABDOMINAL STENT GRAFT SYSTEM	ENDOLOGIX, INC.	Approval for updating the IFU with the following language: Polymer leaks are a unique potential risk of the Ovation device platform that have been reported post-market. The complications of polymer leakage in to the vasculature have ranged from transient hypotension to severe life-threatening anaphylactoid reactions, tissue necrosis and death. When polymer leaks occur, underfilling of the Ovation iX sealing rings have led to intraoperative Type Ia endoleaks that have required additional therapy. The risk of polymer leak should be carefully considered along with the risks associated with alternative treatment options when making personalized treatment decisions for those individuals who fall within the indicated patient population as defined by the Instructions for Use. This updated language was agreed upon as part of the mitigation strategy of the Class I Recall of the Ovation iX.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130013/S035	07/21/2020	P - Panel Track	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Approval for the WATCHMAN FLX Left Atrial Appendage Closure Device with Delivery System and WATCHMAN Left Atrial Appendage Closure Device with Delivery System. The supplement requested approval for a modified version of the WATCHMAN Left Atrial Appendage Closure Device with Delivery System referred to as the WATCHMAN FLX Left Atrial Appendage Closure Device with Delivery System and to expand the indications to include anticoagulation therapy. These devices are indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who: 1) Are at increased risk for stroke and systemic embolism based on CHADS2 or CHA2DS2-VASc scores and are recommended for anticoagulation therapy; 2) Are deemed by their physicians to be suitable for anticoagulation therapy:; and 3) Have an appropriate rationale to seek a non-pharmacologic alternative to anticoagulation therapy, taking into account the safety and effectiveness of the device compared to anticoagulation therapy.
P130014/S007	07/10/2020	R - Real-Time Proc	ADHERUS AUTOSPRAY DURAL SEALANT	HYPERBRANCH MEDICAL TECHNOLOGY, INC.	Approval for alternate transport packaging to allow the single unit sale of the Adherus AutoSpray ET Dural Sealant.
P130016/S041	07/02/2020	N - Normal 180 Day	NUCLEUS HYBRID L24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for the Kanso 2 Sound Processor and associated accessories, Nucleus 7 for Nucleus 22, SmartNav System including SmartNav App and CP1150S Surgical Processor, and Custom Sound Pro.
P130016/S042	07/28/2020	O - Normal 180 Day	NUCLEUS HYBRID L24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for PAS Final labeling Extended Follow-up Study.
P130017/S037	07/14/2020	O - Normal 180 Day	COLOGUARD	EXACT SCIENCES CORPORATION	Approval for a manufacturing site located at Exact Sciences Corporation, 650 Forward Drive, Madison, Wisconsin.
P140003/S073	07/10/2020	R - Real-Time Proc	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for one-way data-streaming from the Automated Impella Controller through Impella Connect for external viewing via the internet
P140004/S017	07/22/2020	O - Normal 180 Day	SUPERION INTERSPINOUS SPACER	BOSTON SCIENTIFIC NEUROMODULATION	Approval for a manufacturing site, named Synergy Health Westport, a STERIS Company, located at Lodge Road, Westport, Co. Mayo, Ireland for sterilization.
P140009/S058	07/01/2020	R - Real-Time Proc	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Approval for minor design changes to the feed-thru component of the implanted pulse generators (IPGs).
P140019/S004	07/22/2020	O - Normal 180 Day	I-FACTOR PEPTIDE ENHANCED BONE GRAFT	CERAPEDICS, LLC	Approval for updated labeling to include the results from the completed 72-month follow-up post-approval study.
P140031/S107	07/22/2020	N - Normal 180 Day	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for modifying the labeling to remove the precaution regarding patients with a congenital bicuspid aortic valve.
P150004/S037	07/01/2020	R - Real-Time Proc	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Approval for minor design changes to the feed-thru component of the implanted pulse generators (IPGs).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150026/S011	07/01/2020	O - Normal 180 Day	HEARTLIGHT ENDOSCOPIC ABLATION SYSTEM	CARDIOFOCUS, INC.	Approval of the protocol for the post-approval study (PAS) protocol.
P150033/S075	07/24/2020	R - Real-Time Proc	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval for firmware updates to the MyCareLink Patient Monitor Model 24950
P150033/S078	07/30/2020	O - Normal 180 Day	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval to add Quality of Life surveys at select study sites for the post-approval study (PAS) protocol.
P150048/S029	07/10/2020	N - Normal 180 Day	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Approval for the KONECT RESILIA Aortic Valved Conduit (AVC), Model 11060A.
P160022/S017	07/07/2020	R - Real-Time Proc	X SERIES®, R SERIES®, AED PRO®, AED 3¿ BLS PROFESSIONAL DEFIBRILLATORS, PRO-PADZ RADIOTRANSPARENT ELECTRODE, SUREPOWER ¿ BATTERY PACK, SUREPOWER II¿ BATTERY PACK, AED PRO® NON-RECHARGEABLE LITHIUM BATTERY PACK, AED 3 ¿ BATTERY PACK, SUREPOWER¿ CHARGER, AND SUREPOWER ¿ SINGLE BAY CHARGER	ZOLL MEDICAL CORPORATION	Approval for a new software release, MCU 19, for the R Series device.
P160026/S016	07/28/2020	R - Real-Time Proc	LIFEPAK 1000 DEFIBRILLATOR, LIFEPAK 20 DEFIBRILLATOR/ MONITOR, LIFEPAK 20E DEFIBRILLATOR/ MONITOR, LIFEPAK 15 MONITOR/DEFIBRILLATOR, LIFEPAK 12 DEFIBRILLATOR/ MONITOR	PHYSIO-CONTROL. INC.	Approval for design changes related to the System Printed Circuit Board Assembly (PCBA) component of the LIFEPAK 15 monitor/defibrillator and additional design improvements.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160026/S017	07/29/2020	R - Real-Time Proc	LIFEPAK 1000 DEFIBRILLATOR, LIFEPAK 20 DEFIBRILLATOR/ MONITOR, LIFEPAK 20E DEFIBRILLATOR/ MONITOR, LIFEPAK 15 MONITOR/DEFIBRILLATOR, LIFEPAK 12 DEFIBRILLATOR/ MONITOR	PHYSIO-CONTROL. INC.	approval for design changes associated with the Auxiliary Power Harness component of the LIFEPAK 15 monitor/defibrillator due to obsolescence of the potting material.
P160026/S018	07/09/2020	R - Real-Time Proc	LIFEPAK 1000 DEFIBRILLATOR, LIFEPAK 20 DEFIBRILLATOR/ MONITOR, LIFEPAK 20E DEFIBRILLATOR/ MONITOR, LIFEPAK 15 MONITOR/DEFIBRILLATOR, LIFEPAK 12 DEFIBRILLATOR/ MONITOR	PHYSIO-CONTROL. INC.	Approval for replacement of an obsolete component from the Patient Parameter Printed Circuit Board Assembly (PP PCBA) in the LIFEPAK 20e defibrillator/monitor device.
P160054/S029	07/10/2020	N - Normal 180 Day	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATION	Approval for a packaging design change and a supplier process change to the HeartMate 3 Coring Tool.
P170011/S024	07/10/2020	R - Real-Time Proc	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval for one-way data-streaming from the Automated Impella Controller through Impella Connect for external viewing via the internet.
P170018/S005	07/13/2020	R - Real-Time Proc	LIFEPAK® CR2 DEFIBRILLATOR	PHYSIO-CONTROL, INC	Approval for a new supplier for an equivalent chemical used in the electrode hydrogel material.
P170019/S019	07/24/2020	R - Real-Time Proc	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval of software infrastructure modifications for FoundationOne CDx (F1CDx), including modifications involving migrating the analysis pipeline and associated software to the Amazon Web Services (AWS) cloud.
P170043/S005	07/02/2020	N - Normal 180 Day	ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM (MODEL G2-M-IS)	GLAUKOS CORPORATION	Approval for design changes to the stent implant and injector.
P180031/S001	07/30/2020	P - Panel Track	NEUROFORM ATLAS® STENT SYSTEM	STRYKER NEUROVASCULAR	Approval for the Neuroform Atlas Stent System indicated for use with neurovascular embolization coils in the anterior and posterior circulation of the neurovasculature for the endovascular treatment of patients >= 18 years of age with saccular wide-necked (neck width >= 4 mm or a dome-to-neck ratio of < 2) intracranial aneurysms arising from a parent vessel with a diameter of >= 2.0 mm and <= 4.5 mm.
P180032/S001	07/08/2020	N - Normal 180 Day	CERENE® CRYOTHERAPY DEVICE	CHANNEL MEDSYSTEMS, INC.	Approval for changes to the specifications of the device including the upper limit of the amount of N2O delivered, the operating temperature range, and the parameter range of initiating a fault, as well as changes to LCD prompts, the venting mechanism, hardware, tray packaging, software, and contractors for sterilizing, packaging, and labeling.
P180046/S011	07/01/2020	N - Normal 180 Day	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for the addition of 3T MRI RF Body Coil Conditional to the labeling.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180046/S013	07/21/2020	R - Real-Time Proc	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for an update to the software for the implantable pulse generator Model 1101.
P180047/S003	07/23/2020	R - Real-Time Proc	LIAISON QUANTIFERON - TB GOLD PLUS, LIAISON CONTROL QUANTIFERON - TB GOLD PLUS AND LIAISON QUANTIFERON SOFTWARE	DIASORIN, INC.	Approval of change in the LIAISON QuantiFERON-TB Gold Plus assay protocol reagent dispensation sequence.
P190006/S011	07/01/2020	N - Normal 180 Day	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for the addition of 3T MRI RF Body Coil Conditional to the labeling.
P190006/S014	07/21/2020	R - Real-Time Proc	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for an update to the software for the implantable pulse generator Model 1101.
P190015/S001	07/31/2020	O - Normal 180 Day	TREO® ABDOMINAL STENT-GRAFT SYSTEM	BOLTON MEDICAL INC.	approval of the protocol for the post-approval study (PAS) protocol.
P190018/S001	07/15/2020	N - Normal 180 Day	CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM, CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM	ALCON RESEARCH, LTD.	Approval for 3 changes related to the shelf life of the Clareon IOLs: 1) 3 year shelf life labeling for the Clareon and Clareon Toric IOLs presented in the AutonoMe Pre-Loaded Delivery System (Models CNAOTO and CNAOT3-CNAOT9); 2) a revision of the labeled storage condition to 15-30 °C for the Clareon and Clareon Toric IOLs presented in the AutonoMe Pre-Loaded Delivery System (Models CNAOTO and CNAOT3-CNAOT9); and 3) a revision to the ongoing real-time shelf life study protocols to streamline planned testing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190018/S002	07/20/2020	R - Real-Time Proc	CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM, CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM	ALCON RESEARCH, LTD.	Approval for the Clareon PanOptix Trifocal Hydrophobic IOL Model CNWTT0 and the Clareon PanOptix Trifocal Hydrophobic IOL with the AutonoMe Automated Preloaded Delivery System Model CNATT0.
P190018/S003	07/20/2020	R - Real-Time Proc	CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM, CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM	ALCON RESEARCH, LTD.	Approval for Clareon Aspheric UV Absorbing intraocular lens (IOL) Model CC60WF and Clareon Aspheric UV Absorbing IOL with the AutonoMe Automated Preloaded Delivery Device Model CCA0T0.

Total: 78

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S072	07/15/2020	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Change of the endotoxin testing services provider.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970012/S179	07/30/2020	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Updates to the software and utilities for sterilization preconditioning and aeration at the BSC Coventry, Rhode Island facility.
P830055/S250	07/07/2020	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Laser marking equipment added to the manufacturing process.
P830055/S251	07/13/2020	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Supplier relocation of its manufacturing facility
P830055/S253	07/17/2020	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Equipment used to inspect Attune PS Cemented Femoral Components at the inspection process step following the Plastic Drag process step from the current calibrated gages to the automated Redlux Coordinate measurement machine (CMMQ0088) at the DePuy Cork Manufacturing Facility.
P830061/S182	07/22/2020	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Test method updates including technical content changes based on test method validation reports.
P830061/S183	07/10/2020	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement a Leads Blister Components Loading and Inspection System to to automate several process steps of the Leads Blister Pack Cell.
P850079/S088	07/28/2020	X - 30-Day Notice	HYDRASOFT (METHAFILCON B) CONTACT LENS	COOPERVISION, INC.	Hardware and software updates to an existing autoclave at the CooperVision Manufacturing facility.
P850089/S148	07/22/2020	X - 30-Day Notice	CAPSURE SP, CAPSURE, CAPSURE 2 LEADS, EXCELLENCE S, IMPULSE, IMPLUSE II EXCELLENCE SS, LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Test method updates including technical content changes based on test method validation reports.
P870076/S025	07/02/2020	X - 30-Day Notice	FALOPE RING BAND AND APPLICATOR SYSTEMS	GYRUS ACMI, INC.	Falope-Ring Band (FRB-30) sterilization site change from Viant to Steris, Inc. in Minneapolis, Minneapolis.
P880047/S037	07/15/2020	X - 30-Day Notice	INTERCEED TC7 ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Change of the endotoxin testing services provider.
P890003/S432	07/22/2020	X - 30-Day Notice	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Test method updates including technical content changes based on test method validation reports.
P900056/S186	07/16/2020	X - 30-Day Notice	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Modifications to quality control inspection process.

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P900061/S159	07/22/2020	X - 30-Day Notice	MEDTRONIC PCD TACHYARRHYTHMIA CONTROL SYSTEM	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Test method updates including technical content changes based on test method validation reports.
P920015/S244	07/22/2020	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Test method updates including technical content changes based on test method validation reports.
P930029/S066	07/23/2020	X - 30-Day Notice	ATAKR(TM) RFCA SYSTEM	MEDTRONIC INC.	Transfer the incoming inspection process SEM/EDS and FTIR testing activities to the MPROC Juncos facility laboratories.
P930031/S068	07/22/2020	X - 30-Day Notice	WALLSTENT(R) TIPS ENDOPROSTHESIS WITH UNISTEP PLUS DELIVERY SYSTEM	BOSTON SCIENTIFIC CORP.	Change in the sampling plan for an extrusion process.
P930039/S212	07/22/2020	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Test method updates including technical content changes based on test method validation reports.
P930039/S213	07/10/2020	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Implement a Leads Blister Components Loading and Inspection System to to automate several process steps of the Leads Blister Pack Cell.
P940015/S046	07/17/2020	X - 30-Day Notice	SYNVISC ONE	SANOFI GENZYME CORP.	Change of storage time and storage conditions for dry fibers used in manufacture of Synvisc and Synvisc-One.
P940019/S059	07/22/2020	X - 30-Day Notice	WALLSTENT(R) ILIAC ENDOPROSTHESIS	BOSTON SCIENTIFIC SCIMED, INC.	Change in the sampling plan for an extrusion process.
P950018/S019	07/24/2020	X - 30-Day Notice	PERFLUORON (PURIFIED PERFLUORO-N-OCTANE LIQUID)	ALCON LABORATORIES	Replacement of clean steam generator.
P950024/S093	07/22/2020	X - 30-Day Notice	MEDTRONIC(R) CAPSURE (R) EPI PACING LEAD MODEL 4695	MEDTRONIC INC.	Test method updates including technical content changes based on test method validation reports.
P960058/S150	07/22/2020	X - 30-Day Notice	CLARION MULTI-STRATEGY COCHLEAR IMPLANT	ADVANCED BIONICS	Expansion to an existing implant capacitor supplier to provide additional capacitors for Ultra Family of cochlear implants to enhance the supply chain.
P980016/S743	07/08/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add additional tests to the final functional test program at a BTLE module supplier.

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P980016/S745	07/16/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Implement a new marking equipment in the manufacturing process.
P980016/S746	07/21/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update specifications and methodologies of the Titan final functional tests for select ICD and CRT-D devices.
P980016/S747	07/22/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Test method updates including technical content changes based on test method validation reports.
P980033/S058	07/22/2020	X - 30-Day Notice	WALLSTENT ENDOPROSTHESIS	BOSTON SCIENTIFIC CORPORATIO N	Change in the sampling plan for an extrusion process.
P980035/S629	07/08/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Add additional tests to the final functional test program at a BTLE module supplier.
P980035/S631	07/22/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Test method updates including technical content changes based on test method validation reports.
P980035/S632	07/29/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Update the soak ovens used for the soak process for medium rate batteries used in various CRT-P and IPGs.
P980044/S053	07/17/2020	X - 30-Day Notice	SUPARTZ FX	SEIKAGAKU CORP.	Automation of the existing bacterial endotoxin test process.
P980050/S127	07/22/2020	X - 30-Day Notice	MEDTRONIC(R) JEWEL(R) AF 7250 DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATOR, MODEL 9961 PROGRAMMER APPLICATION SOF	MEDTRONIC INC.	Test method updates including technical content changes based on test method validation reports.
P990004/S040	07/08/2020	X - 30-Day Notice	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Change of donor catalyst used in the manufacturing of polypropylene resins.

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P990004/S041	07/24/2020	X - 30-Day Notice	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Change of drying time for gelatin foam plates.
P990074/S044	07/30/2020	X - 30-Day Notice	NATRELLE SALINE BREAST IMPLANTS	ALLERGAN	Addition of an alternative detection method for the Quality Control bacterial endotoxin testing of the finished devices.
P000029/S089	07/09/2020	X - 30-Day Notice	DEFLUX INJECTABLE GEL	PALETTE LIFE SCIENCES	Extension of shelf life for a critical raw material due to a change in secondary packaging and the addition of a quality control specification limit for the raw material.
P000040/S039	07/30/2020	X - 30-Day Notice	HYDRO THERMABLATOR ENDOMETRIAL ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Updates to the software and utilities for sterilization preconditioning and aeration at the BSC Coventry, Rhode Island facility.
P000053/S114	07/30/2020	X - 30-Day Notice	AMS SPHINCTER 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Updates to the software and utilities for sterilization preconditioning and aeration at the BSC Coventry, Rhode Island facility.
P000054/S059	07/10/2020	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Optimization of the pre-sterilization phase set points of in-process autoclave cycles and addition of a second Tyvek wrapping for equipment, parts, and components sterilized in the in-process autoclaves.
P000058/S078	07/10/2020	X - 30-Day Notice	INFUSE BONE GRAFT/LT-CAGE LUMBAR TAPERED FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Optimization of the pre-sterilization phase set points of in-process autoclave cycles and addition of a second Tyvek wrapping for equipment, parts, and components sterilized in the in-process autoclaves.
P010015/S440	07/08/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Add additional tests to the final functional test program at a BTLE module supplier.
P010015/S441	07/22/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Test method updates including technical content changes based on test method validation reports.
P010015/S442	07/29/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Update the soak ovens used for the soak process for medium rate batteries used in various CRT-P and IPGs.
P010030/S140	07/02/2020	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Manufacturing fixture to discharge batteries to the optimal storage voltage.
P010031/S704	07/08/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add additional tests to the final functional test program at a BTLE module supplier.

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P010031/S705	07/16/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement a new marking equipment in the manufacturing process.
P010031/S706	07/21/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update specifications and methodologies of the Titan final functional tests for select ICD and CRT-D devices.
P010031/S707	07/22/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Test method updates including technical content changes based on test method validation reports.
P020004/S175	07/31/2020	X - 30-Day Notice	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Implementation of an alternate manufacturing process for the tubular sleeve component of the GORE EXCLUDER AAA Endoprosthesis and GORE EXCLUDER Iliac Branch Endoprosthesis.
P020011/S016	07/21/2020	X - 30-Day Notice	VERSANT HCV RNA QUALITATIVE ASSAY	GEN-PROBE	Change the shipping container used to ship refrigerated product.
P020056/S051	07/30/2020	X - 30-Day Notice	NATRELLE SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Addition of an alternative detection method for the Quality Control bacterial endotoxin testing of the finished devices.
P030031/S107	07/10/2020	X - 30-Day Notice	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Implementation of an automated manufacturing process for a PEEK shaft component.
P030036/S121	07/22/2020	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Test method updates including technical content changes based on test method validation reports.
P040027/S079	07/15/2020	X - 30-Day Notice	GORE VIATORR TIPS	W. L. GORE & ASSOCIATES, INC.	Change to knitting process equipment for a delivery system component.
P040036/S075	07/10/2020	X - 30-Day Notice	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Implementation of an automated manufacturing process for a PEEK shaft component.

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P040037/S139	07/15/2020	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Change to knitting process equipment for a delivery system component.
P040043/S115	07/09/2020	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implementation of updates to the sleeve trimming procedure and addition of inspection for damage to the deployment line of the GORE TAG Thoracic Stent Graft with ACTIVE CONTROL System.
P040043/S116	07/31/2020	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Relocate manufacturing equipment to a new, equivalent cleanroom within the same manufacturing facility.
P040046/S032	07/30/2020	X - 30-Day Notice	NATRELLE HIGHLY COHESIVE SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Addition of an alternative detection method for the Quality Control bacterial endotoxin testing of the finished devices.
P050027/S025	07/29/2020	X - 30-Day Notice	KARL STORZ PHOTODYNAMIC DIAGNOSTIC D-LIGHT C (PDD) SYSTEM	KARL STORZ ENDOSCOPY-AMERICA, INC.	Change in supplier of three subassembly components used in the Karl Storz PDD System.
P050037/S106	07/30/2020	X - 30-Day Notice	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Remove the Tumble Wash process step from the CaHA particle manufacturing process.
P050052/S124	07/30/2020	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Remove the Tumble Wash process step from the CaHA particle manufacturing process.
P050053/S050	07/10/2020	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC INC.	Optimization of the pre-sterilization phase set points of in-process autoclave cycles and addition of a second Tyvek wrapping for equipment, parts, and components sterilized in the in-process autoclaves.
P060037/S065	07/13/2020	X - 30-Day Notice	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Change in the gamma sterilization process monitoring for conventional ultra-high weight polyethylene (UHMWPE) articular surface components in NexGen LPS-Flex/LPS Mobile Bearing Knee System.
P060039/S100	07/22/2020	X - 30-Day Notice	ATTAIN STARFIX MODEL 4195 LEAD	MEDTRONIC INC.	Test method updates including technical content changes based on test method validation reports.
P070026/S073	07/08/2020	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Addition of an alternate supplier.
P070026/S075	07/15/2020	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Supplier relocation of manufacturing facility.
P080006/S149	07/22/2020	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Test method updates including technical content changes based on test method validation reports.
P080011/S107	07/28/2020	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Hardware and software updates to an existing autoclave at the CooperVision Manufacturing facility.
P080011/S108	07/28/2020	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	implementation of a new secondary packaging line for the Biofinity (comfilcon A) soft (hydrophilic) contact lenses for extended wear at the CooperVision, Inc. facility in West Henrietta, New York
P080020/S038	07/17/2020	X - 30-Day Notice	GEL-ONE	SEIKAGAKU CORP.	Automation of the existing bacterial endotoxin test process.
P090013/S306	07/22/2020	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Test method updates including technical content changes based on test method validation reports.

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P090013/S307	07/10/2020	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Implement a Leads Blister Components Loading and Inspection System to to automate several process steps of the Leads Blister Pack Cell.
P100014/S027	07/09/2020	X - 30-Day Notice	SOLESTA INJECTABLE GEL	PALETTE LIFE SCIENCES	Extension of shelf life for a critical raw material due to a change in secondary packaging and the addition of a quality control specification limit for the raw material .
P100021/S081	07/23/2020	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	New primary supplier and raw material suppliers for the Endurant and Valiant Captivia packaging trays; and dimensional changes to the tabs on the Endurant and Valiant Captivia packaging trays.
P100022/S036	07/31/2020	X - 30-Day Notice	ZILVER PTX DRUG-ELUTING PERIPHERAL STENT	COOK IRELAND, LTD.	Change to raw drug substance expiry and retest period.
P100026/S083	07/14/2020	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Use of an alternate sub-tier supplier to cut the polyester mesh, which is subsequently fully encapsulated within the NeuroPace Cortical Strip Leads during manufacturing.
P100033/S012	07/21/2020	X - 30-Day Notice	PROGENSA PCA3 ASSAY	GEN-PROBE INCORPORATED	Use of a new reusable shipping container for shipping refrigerated products.
P100040/S040	07/23/2020	X - 30-Day Notice	VALIANT THORACIC STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	New primary supplier and raw material suppliers for the Endurant and Valiant Captivia packaging trays; and dimensional changes to the tabs on the Endurant and Valiant Captivia packaging trays.
P100042/S031	07/21/2020	X - 30-Day Notice	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Change the shipping container used to ship refrigerated product
P100045/S044	07/28/2020	X - 30-Day Notice	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ST. JUDE MEDICAL	Addition of alternate manufacturing equipment and an alternate supplier for the metal deposition phase of the Pressure Sensor assembly.
P100047/S167	07/15/2020	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Replace the existing recording system for monitoring parameters in the manufacturing areas and water system with an automated environmental monitoring application at the Miami Lakes facility.
P100047/S168	07/20/2020	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Add controls to existing work instructions to enhance the batteries manufacturing process at Inventus Power.
P110029/S033	07/30/2020	X - 30-Day Notice	ARCHITECT HBSAG QUALITATIVE, QUALITATIVE CONFIRMATORY, CONFIRMATORY MANUAL DILUENT, CALIBRATORS, AND CONTROLS	ABBOTT LABORATORIES	Addition of quality control testing for manual diluent and incoming bovine serum.
P110035/S060	07/30/2020	X - 30-Day Notice	EPIC SELF-EXPANDING NITINOL STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Updates to the software and utilities for sterilization preconditioning and aeration at the BSC Coventry, Rhode Island facility.
P110035/S061	07/22/2020	X - 30-Day Notice	EPIC SELF-EXPANDING NITINOL STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Change in the sampling plan for an extrusion process.

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P110042/S139	07/22/2020	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Two manufacturing changes to the feedthru underfill dispense process.
P120007/S028	07/21/2020	X - 30-Day Notice	APTIMA HPV 16 18/45 GENOTYPE ASSAY	GEN-PROBE INCORPORATED	Change the shipping container used to ship refrigerated product
P120011/S020	07/31/2020	X - 30-Day Notice	IDEAL IMPLANT SALINE-FILLED BREAST IMPLANT	IDEALIMPLANT	Change in manufacturing process at their approved TSS site.
P120017/S022	07/22/2020	X - 30-Day Notice	MODEL 5071 LEAD	MEDTRONIC INC.	Test method updates including technical content changes based on test method validation reports.
P130004/S009	07/16/2020	X - 30-Day Notice	RESURE SEALANT	OCULAR THERAPEUTIX, INC.	Change to the reference dose and the delivered dose range for the routine gamma radiation process.
P130005/S030	07/15/2020	X - 30-Day Notice	DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM	CARDIOVASCULAR SYSTEMS, INC.	Material and supplier changes to an internal device component.
P130006/S078	07/15/2020	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Change to knitting process equipment for a delivery system component.
P130008/S054	07/20/2020	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Changes to the manufacturing of Model 4340 respiratory sensing lead involving the addition of a new MRSI Die Bonder for Hermetic Pressure Sensor Assembly Membrane and Network die bonding process.
P130009/S110	07/22/2020	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Add two chambers to the previously approved ethylene oxide sterilization cycle.
P130021/S079	07/13/2020	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Change in tissue cutting parameters for the transcatheter aortic valves (TAVs) of the Evolut PRO, PRO+, and R systems.
P130030/S069	07/01/2020	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE	BOSTON SCIENTIFIC CORP.	Increase to the barrel extrusion temperature used during the manufacturing of the balloon tube.
P140028/S061	07/30/2020	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Updates to the software and utilities for sterilization preconditioning and aeration at the BSC Coventry, Rhode Island facility.
P140028/S062	07/20/2020	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Modifying the process and aids used for stent expansion.

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P140029/S026	07/01/2020	X - 30-Day Notice	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Change from manual handling of syringes during visual inspection to semiautomatic handling of syringes for Restylane Refyne, Restylane Defyne, and Restylane Kysse Injectable Gels.
P140031/S117	07/22/2020	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Add two chambers to the previously approved ethylene oxide sterilization cycle.
P150021/S049	07/30/2020	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Introduction of an alternate supplier for the Sensor Applicator and addition of an inspection step 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.
P150033/S076	07/22/2020	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Test method updates including technical content changes based on test method validation reports.
P150048/S046	07/22/2020	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Add two chambers to the previously approved ethylene oxide sterilization cycle.
P160008/S012	07/17/2020	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.	Addition of a modified tooling for the assembly of the pogo pin components used in the manufacture of SAM350P, SAM360P, and SAM450P AEDs and accessories.
P160023/S019	07/21/2020	X - 30-Day Notice	APTIMA HCV QUANT DX ASSAY	HOLOGIC, INC.	Change the shipping container used to ship refrigerated product.
P160029/S004	07/16/2020	X - 30-Day Notice	HEARTSTART ONSITE DEFIBRILLATOR (MODEL M5066A) AND HEARTSTART HOME DEFIBRILLATOR (MODEL M5068A)	PHILIPS MEDICAL SYSTEMS, INC.	Implementation of a semi-automated tool used during speaker assembly.
P160030/S043	07/30/2020	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Introduction of an alternate supplier for the Sensor Applicator and addition of an inspection step 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.
P160047/S011	07/01/2020	X - 30-Day Notice	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	AEGEA MEDICAL , INC	Addition of the NRTL label (Nationally Recognized Test Lab label) to the back of the Mara Console.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160047/S012	07/21/2020	X - 30-Day Notice	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	AEGEA MEDICAL , INC	Change in the adhesive used in the Pressure Sensor Assembly of the MARA Water Vapor Ablation System.
P170025/S016	07/21/2020	X - 30-Day Notice	APTIMA HBV QUANT ASSAY	HOLOGIC, INC	Change the shipping container used to ship refrigerated product.
P170035/S008	07/14/2020	X - 30-Day Notice	BAUSCH + LOMB ULTRA (SAMFILCON A) CONTACT LENSES	BAUSCH AND LOMB, INC.	Implementation of a new power measurement method on the Spin-Blot System for the Bausch + Lomb Ultra® (samfilcon A) Visibility Tinted soft (hydrophilic) contact lenses.
P180011/S033	07/10/2020	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Change to the residual solvents test frequency.
P180011/S034	07/30/2020	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	updates to the software and utilities for sterilization preconditioning and aeration at the BSC Coventry, Rhode Island facility
P180011/S035	07/20/2020	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Modifying the process and aids used for stent expansion.
P180027/S001	07/17/2020	X - 30-Day Notice	FLOW RE-DIRECTION ENDOLUMINAL DEVICE (FRED®) SYSTEM	MICROVENTION TERUMO	Addition of braiding and furnace equipment for the FRED implant at the MicroVention Costa Rica facility.
P180028/S001	07/16/2020	X - 30-Day Notice	HEARTSTART FRX DEFIBRILLATOR	PHILIPS MEDICAL SYSTEMS	Implementation of a semi-automated tool used during speaker assembly.
P180046/S016	07/02/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Qualification of additional sterilization chambers.
P180046/S017	07/10/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Axonics Charging Device uses a printed circuit board assembly (PCBA) that is currently tested manually using test procedure, 120-0113 (VOL# 27, file #009 of original submission). To support an increase in production, Axonics developed a test fixture (# 200-0198-001, built with software 150-0113-001) that automates the tests that are in the original manual test procedure. A complete traceability of test steps in the original manual test procedure to the proposed automated test fixture requirements is provided
P180046/S018	07/08/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Addition of a new supplier facility.
P180046/S019	07/28/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Contract manufacturer¿s addition of manufacturing equipment

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P190006/S016	07/02/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Qualification of additional sterilization chambers.
P190006/S017	07/10/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Axonics Charging Device uses a printed circuit board assembly (PCBA) that is currently tested manually using test procedure, 120-0113 (VOL# 27, file #009 of original submission). To support an increase in production, Axonics developed a test fixture (# 200-0198-001, built with software 150-0113-001) that automates the tests that are in the original manual test procedure. A complete traceability of test steps in the original manual test procedure to the proposed automated test fixture requirements is provided.
P190006/S018	07/08/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Addition of a new supplier facility.
P190006/S019	07/28/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Contract manufacturers addition of manufacturing equipment.

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