PMA Monthly approvals from 9/1/2020 to 9/30/2020

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P200022	09/18/2020	PMAO - PMA Origi	SIMPLIFY® CERVICAL ARTIFICIAL DISC	SIMPLIFY MEDICAL, INC.	Approval for Simplify® Cervical Artificial Disc that is indicated for use in skeletally mature patients for reconstruction of the disc at one level from C3-C7 following single-level discectomy for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to a single-level abnormality localized to the level of the disc space and manifested by at least one of the following conditions confirmed by radiographic imaging (e.g., X-rays, computed tomography (CT), magnetic resonance imaging (MRI)): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels. Patients receiving Simplify® Cervical Artificial Disc should have failed at least six weeks of non-operative treatment or have the presence of progressive symptoms (e.g., numbness or tingling) prior to implantation. Simplify® Cervical Artificial Disc is implanted via an open anterior approach.

Total: 1

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S069	09/21/2020	Y - 135 Review Tra	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Approval for a second SURGICEL Powder manufacturing area referred to as Suite 2 in the existing Controlled Manufacturing Environment space at the Ethicon LLC, San Lorenzo, Puerto Rico facility.
N12159/S073	09/24/2020	R - Real-Time Proc	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Approval for a line extension for additional size variants within the previously approved size range.
P830055/S252	09/29/2020	R - Real-Time Proc	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for labeling modifications to include a surgical plan for a previously approved patient-specific alignment technique using standard instrumentation.
P860004/S360	09/22/2020	R - Real-Time Proc	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval for change to improve the final product yield in the final pack manufacturing step to confirm telemetry of the SynchroMed II Implantable Infusion Pump Model 8637 for the SynchroMed Infusion System.
P900060/S061	09/17/2020	Y - 135 Review Tra	CARBOMEDICS PROSTHETIC HEART VALVE (CPHV)	SORIN GROUP ITALIA S.R.L	Approval for the Optimization of Quality Control activities by removing duplicate QC inspections during manufacturing process.
P910023/S428	09/22/2020	R - Real-Time Proc	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ST. JUDE MEDICAL	Approval for a shelf-life extension from 6-months to 24-months for Avant, Gallant, Entrant, and Neutrino NxT" Family of ICDs and CRT-Ds.
P910023/S429	09/15/2020	R - Real-Time Proc	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ST. JUDE MEDICAL	Approval for use of a pre-molded header utilizing a one-piece contact assembly in lieu of a two-piece contact assembly.

Data as of 10/02/2020 03:59 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P920048/S016	09/03/2020	R - Real-Time Proc	FETAL FIBRONECTIN ENZYME IMMUNOASSAY KIT (EIK)	HOLOGIC, INC.	Approval for a change to the grade of cellulose acetate used in the manufacturing of nitrocellulose at a supplier. Nitrocellulose is used in the assembly of Rapid fFN Cassettes for the TLiIQ System.
P980016/S748	09/29/2020	R - Real-Time Proc	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for updates to the Model SW016, Model SW033, and Model SW022 programmer applications to update the H3 Battery Longevity Estimator functionality.
P000013/S017	09/30/2020	R - Real-Time Proc	TRIDENT SYSTEM	HOWMEDICA OSTEONICS CORP.	Approval for a change of the de-nesting lubricant sprayed on polyethylene terephthalate glycol sheets that are thermoformed into blister trays used in Trident Alumina Inserts packaging.
P000025/S114	09/25/2020	N - Normal 180 Day	COMBI 40+ COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Approval for the 1) Mi1260 SONATA 2 (with S-Vector Magnet); 2) optional tool S-Vector Magnet Replacement Kit; and 3) new S-Vector Magnet for use with the approved Mi1250 SYNCHRONY 2 (PIN).
P000025/S117	09/25/2020	R - Real-Time Proc	COMBI 40+ COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Approval for AudioStream, an alternative battery pack cover and AudioKey 2.0, a mobile application, used with compatible audio processors of the Med-El cochlear implant system.
P000025/S118	09/04/2020	O - Normal 180 Day	COMBI 40+ COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P010031/S708	09/29/2020	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for updates to the Model SW016, Model SW033, and Model SW022 programmer applications to update the H3 Battery Longevity Estimator functionality.
P030031/S100	09/30/2020	P - Panel Track	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Approval for the Biosense Webster THERMOCOOL SMARTTOUCH® SF Navigation Catheter and related accessory devices are indicated for catheter-based cardiac electrophysiological mapping (stimulating and recording) and, when used with a compatible RF generator, for the treatment of: 1) Type I atrial flutter in patients age 18 or older; 2) Drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used with compatible three-dimensional electroanatomic mapping systems; and 3) Drug refractory recurrent symptomatic persistent atrial fibrillation (defined as continuous atrial fibrillation that is sustained beyond 7 days but less than 1 year), refractory or intolerant to at least one Class I or III antiarrhythmic medicine, when used with compatible three-dimensional electroanatomic mapping systems. The THERMOCOOL SMARTTOUCH® SF Navigation Catheter provides a real-time measurement of contact force between the catheter tip and heart wall, as well as location information when used with CARTO® 3 Navigation System.
P030054/S380	09/22/2020	R - Real-Time Proc	ST JUDE MEDICAL EPIC HF SYSTEM	ST. JUDE MEDICAL	Approval for a shelf-life extension from 6-months to 24-months for Avant, Gallant, Entrant, and Neutrino NxT Family of ICDs and CRT-Ds.
P030054/S381	09/15/2020	R - Real-Time Proc	ST JUDE MEDICAL EPIC HF SYSTEM	ST. JUDE MEDICAL	Approval for use of a pre-molded header utilizing a one-piece contact assembly in lieu of a two-piece contact assembly.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P050018/S026	09/11/2020	N - Normal 180 Day	ANGIOSCULPT SCORING BALLOON CATHETER	SPECTRANETICS CORP.	Approval for various design changes, including additional coating to the transition tube and modifications to the balloon, distal tip, and scoring element.
P050023/S149	09/17/2020	O - Normal 180 Day	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval for a labeling update for the MultiPole Pacing feature of select ICDs and CRT-Ds.
P050038/S036	09/25/2020	S - Special CBE	ARISTA AH ABSORBABLE HEMOSTAT	DAVOL, INC.	Approval for the addition of a foreign matter inspection for Arista AH Absorbable Hemostatic Particles.
P100018/S028	09/21/2020	S - Special CBE	PIPELINE EMBOLIZATION DEVICE	MICRO THERAPEUTICS, INC. D/B/A EV3 NEUROVASCULAR	Approval for labeling changes to the instructions for use to strengthen information about possible device component separation, fracture, or breakage in the warnings, cautions and potential complications sections.
P100026/S084	09/28/2020	O - Normal 180 Day	NEUROPACE RNS SYSTEM	NEUROPACE INC	Approval to update the protocols and associated data collection and informed consent forms for PAS 2 and PAS 3 due to the current public health emergency.
P100047/S166	09/03/2020	R - Real-Time Proc	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for a change to the IFU regarding the replacement of the Monitor when the Monitor Battery no longer holds a sufficient charge.
P110010/S180	09/17/2020	R - Real-Time Proc	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a change to the Hypotube Corewire Assembly
P120005/S087	09/03/2020	O - Normal 180 Day	DEXCOM G4 PLATINUM CONTIUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Approval of the interim analysis for the post-approval study (PAS) protocol.
P140004/S024	09/15/2020	O - Normal 180 Day	SUPERION INTERSPINOUS SPACER	BOSTON SCIENTIFIC NEUROMODULATION	Approval for an alternate manufacturing site named Boston Scientific Limited located at Cashel Road, Clonmel, Ireland for sterile packaging and final packaging.
P140031/S112	09/09/2020	P - Panel Track	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for the Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve System. This device is indicated for patients with symptomatic heart disease due to failing (stenosed, insufficient, or combined) of a surgical or transcatheter bioprosthetic aortic valve or a surgical bioprosthetic mitral valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality greater than or equal to 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).
P140032/S057	09/22/2020	R - Real-Time Proc	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Approval for change to improve the final product yield in the final pack manufacturing step to confirm telemetry of the SynchroMed II Implantable Infusion Pump Model 8637 for the Implantable System for Remodulin.
P150002/S008	09/23/2020	O - Normal 180 Day	INCRAFT(R) AAA STENT GRAFT SYSTEM	CORDIS CORPORATION	Approval for updating the labeling to include 5-year INSPIRATION study data and minor editorial changes.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150003/S063	09/17/2020	R - Real-Time Proc	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for a change to the Hypotube Corewire Assembly.
P150033/S077	09/29/2020	R - Real-Time Proc	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval for updates to the Model SW016, Model SW033, and Model SW022 programmer applications to update the H3 Battery Longevity Estimator functionality.
P160016/S005	09/23/2020	N - Normal 180 Day	VERSANT HCV GENOTYPE 2.0 ASSAY (LIPA)	SIEMENS HEALTHCARE DIAGNOSTICS, INC.	Approval to replace the Triton X-705 detergent, a component of the 5X Rinse Solution and Conjugate Diluent used in the VERSANT HCV Genotyping 2.0 Assay, with the detergent Tergitol 15-S-40.
P160026/S020	09/16/2020	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 of the removal of a redundant capacitor C181 that causes physical interference between the C181 capacitor and front case assembly.
P160031/S003	09/30/2020	R - Real-Time Proc	ASPIRE CRISTALLE DIGITAL BREAST TOMOSYNTHESIS OPTION	FUJIFILM MEDICAL SYSTEMS U.S.A., INC.	Approval for 1) the integration of the DBT Option as a software module on the 510(k) cleared ASPIRE Bellus II (K171463) for the reconstruction of tomosynthesis acquisitions, and 2) an updated Indications for Use to include the optional integration of the DBT Option software module on the cleared ASPIRE Bellus II and its functionality.
P160035/S013	09/23/2020	N - Normal 180 Day	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Approval for a design change to the polyurethane (PU) membrane and supplier/supplier production site change for the PU solutions.
P160042/S010	09/21/2020	P - Panel Track	REVANESSE ULTRA	PROLLENIUM MEDICAL TECHNOLOGIES INC.	Approval for the Revanesse® Lips+. The device is indicated for submucosal implantation for lip augmentation in patients 22 years of age or older.
P160043/S034	09/22/2020	P - Panel Track	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for expanding the labeling to include patients at high risk for bleeding. This device is indicated as follows: The Resolute Onyx Zotarolimus-Eluting Coronary Stent System is indicated for improving coronary luminal diameters in patients, including those with diabetes mellitus or high bleeding risk, with symptomatic ischemic heart disease due to de novo lesions of length <= 35 mm in native coronary arteries with reference vessel diameters of 2.0 mm to 5.0 mm. In addition, the Resolute Onyx Zotarolimus-Eluting Coronary Stent System is indicated for treating de novo chronic total occlusions.
P160045/S019	09/04/2020	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 RET fusions in non-small cell lung cancer patients who may benefit from treatment with GAVRETO (pralsetinib).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160047/S013	09/14/2020	R - Real-Time Proc	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	AEGEA MEDICAL , INC	Approval for changes to the packaging of the Mara Console and addition of additional zip-tie and screws to secure power cable and RS232 cable in place.
P170012/S023	09/11/2020	Y - 135 Review Tra	HEMOBLAST¿ BELLOWS	BIOM'UP FRANCE SAS	Approval for a change to the bioburden determination method.
P170024/S004	09/14/2020	R - Real-Time Proc	SURPASS STREAMLINE FLOW DIVERTER	STRYKER NEUROVASCULAR	Approval for a shelf-life extension of the Surpass Streamline Flow Diverter from one year to three years.
P170039/S003	09/04/2020	Y - 135 Review Tra	CUSTOMFLEX ARTIFICIAL IRIS	HUMANOPTICS AG	Approval for the addition of a second supplier of saline solution used for filling the artificial iris primary packaging.
P180013/S002	09/15/2020	O - Normal 180 Day	VICI VENOUS STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for a manufacturing site located at Confluent Medical, Free Zone and Business Park El Coyol, Building B14 Alajuela, Costa Rica for VICI stent component manufacturing.
P180013/S004	09/03/2020	N - Normal 180 Day	VICI VENOUS STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for the second stent delivery system ¿ the VICI RDS Venous Stent System.
P180036/S005	09/02/2020	N - Normal 180 Day	OPTIMIZER SMART SYSTEM	IMPULSE DYNAMICS (USA), INC.	Approval for the removal of the contraindication Patients with permanent or long-standing persistent atrial fibrillation or flutter.
P190008/S004	09/24/2020	R - Real-Time Proc	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Approval for a packaging change to the shelf carton.
P190008/S005	09/11/2020	O - Normal 180 Day	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Approval for updates to the analysis plan and case report forms for the New Enrollment IN.PACT AV Access PAS.

Total: 47

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S253	09/03/2020	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Add instructions, images, and an inspection for preforming battery cathode tabs.
N970012/S180	09/04/2020	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Add a new Kink Resistant Tubing (KRT) Fabrication Machine System to the KRT Production Line at the Boston Scientific St. Paul, Minnesota facility.
N970012/S181	09/09/2020	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Manufacturing site change to the St. Paul, Minnesota facility for the extrusion process for the cylinder components.
N970012/S182	09/16/2020	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Add Sanofi in Brindisi, Italy as a supplier of Rifampin.
P810006/S090	09/04/2020	X - 30-Day Notice	COLLASTAT	INTEGRA LIFESCIENCES CORPORATION	Replacement of two Yokogawa paperless cycle recorders used in Lyophilizers 1 and 2 in Integras manufacturing facility.
P830055/S255	09/08/2020	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Two changes to the current cleaning agents utilized in final and in-process cleaning: 1) The existing detergent (Galvex 17.30) is replaced by an alternate cleaning detergent (Liquinox); and 2) A new biocide (Acticide SPX) replaced the existing biocide (Dowicil 75) in Citrisurff formulation. These new cleaning agents are used in in-process cleaning and final cleaning steps during the manufacturing process.
P830055/S256	09/25/2020	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Proposal to introduce a new DMG Mori NTX 1000 Generation 2 Computer Numerical Control (CNC) to .independently complete all the machining steps and adding new Coordinate Measurement Machine (CMM) to inspect the Attune RP Revision Tibial Base components.
P840001/S466	09/06/2020	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Updates to the laboratory test methodology identified in the submission, documentation, and the LIMS system.
P840001/S467	09/09/2020	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Updates to selected electrolyte incoming inspection documentation.
P840064/S072	09/16/2020	X - 30-Day Notice	VISCOAT(TM)/DVOVISC/ DISCOVISC OPHTHALMIC VISCOSURGICAL DEVICES	ALCON LABORATORIES	Adding Lifecore as an additional release testing site for raw materials and primary packaging components used in the manufacturing process of VISCOAT, PROVISC and DUOVISC.
P850010/S090	09/04/2020	X - 30-Day Notice	HELISTAT(TM) ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	INTEGRA LIFESCIENCES CORPORATION	Replacement of two Yokogawa paperless cycle recorders used in Lyophilizers 1 and 2 in Integras manufacturing facility.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P850079/S089	09/01/2020	X - 30-Day Notice	HYDRASOFT (METHAFILCON B) CONTACT LENS	COOPERVISION, INC.	New water treatment system in the Scotsville facility as part of the facility renovation project.
P860004/S362	09/09/2020	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Updates to selected electrolyte incoming inspection documentation.
P890023/S043	09/01/2020	X - 30-Day Notice	H55 HYDROPHILIC CONTACT LENS	THE COOPER COMPANIES	New water treatment system in the Scotsville facility as part of the facility renovation project.
P890023/S044	09/16/2020	X - 30-Day Notice	H55 HYDROPHILIC CONTACT LENS	THE COOPER COMPANIES	Implementation of a new sterilizer installed at the CooperVision Manufacturing facility in Juana Diaz, Puerto Rico.
P890023/S045	09/22/2020	X - 30-Day Notice	H55 HYDROPHILIC CONTACT LENS	THE COOPER COMPANIES	Qualification of a wet line for the manufacture of Biomedics 55 Asphere (ocufilcon D) extended wear contact lenses with a base curve of 8.6 mm at the CooperVision facility located in Scottsville, New York.
P890047/S055	09/16/2020	X - 30-Day Notice	PROVISC(TM) VISCOELASTIC PREPARATION	ALCON RESEARCH, LTD.	Adding Lifecore as an additional release testing site for raw materials and primary packaging components used in the manufacturing process of VISCOAT, PROVISC and DUOVISC.
P900033/S089	09/04/2020	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Replacement of two Yokogawa paperless cycle recorders used in Lyophilizer's 1 and 2 in Integras manufacturing facility.
P900056/S187	09/10/2020	X - 30-Day Notice	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Modifications to the quality control inspection process for an Advancer component.
P900056/S188	09/29/2020	X - 30-Day Notice	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Automation of the manufacture of the Nose and Front Plug subassemblies.
P900056/S189	09/29/2020	X - 30-Day Notice	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Component supplier move.
P900056/S190	09/25/2020	X - 30-Day Notice	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Alternative oxidation removal agent.
P910023/S432	09/23/2020	X - 30-Day Notice	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ST. JUDE MEDICAL	Alternate use of the ILT Welder during the manufacturing welding process.
P910077/S181	09/17/2020	X - 30-Day Notice	VENTAK(R) PRX (TM) MODEL 1700,1705 PULSE GENERATOR	BOSTON SCIENTIFIC	Implement new flux and solder materials for use in the manufacture of the Model 3300 LATITUDE Programming System, Model 6395 Telemetry Wand, and Model 3200 EMBLEM S-ICD Programmer as part of the manufacturing process.
P930021/S026	09/02/2020	X - 30-Day Notice	BIORA EMDOGAIN(R)	THE STRAUMANN COMPANY	Update the water purification system with replacement of the Water for Injection (WFI) production and WFI distribution.
P930027/S024	09/08/2020	X - 30-Day Notice	IMMULITE SYSTEMS PSA & THIRD GENERATION PSA REAGENTS	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Remove select inspection criteria from the raw materials used to manufacture IMMULITE Substrate Reagent.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P930029/S067	09/25/2020	X - 30-Day Notice	ATAKR(TM) RFCA SYSTEM	MEDTRONIC INC.	Add the incoming inspection testing for Metallographic Interpretation and Metallographic Sample Preparation (Cross Section) at the MPROC Juncos facility.
P950005/S075	09/24/2020	X - 30-Day Notice	WEBSTER DIAG./ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC	Implementing an alternate laser wire stripping process.
P950020/S109	09/22/2020	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Modification of components method of manufacture.
P960004/S091	09/25/2020	X - 30-Day Notice	THINLINE ENDOCARDIAL PACING LEADS	BOSTON SCIENTIFIC	Updates to manufacturing work instructions and tool inspection for the cathode coil threading process for the FINELINE II Steroid-Eluting pacing leads.
P960009/S379	09/06/2020	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Updates to the laboratory test methodology identified in the submission, documentation, and the LIMS system.
P960009/S380	09/09/2020	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Updates to selected electrolyte incoming inspection documentation.
P960009/S381	09/11/2020	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Tightening of material controls of fluorinated carbon (CFx) material received from the external supplier.
P970004/S313	09/06/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Updates to the laboratory test methodology identified in the submission, documentation, and the LIMS system.
P970004/S314	09/09/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Updates to selected electrolyte incoming inspection documentation.
P980006/S030	09/28/2020	X - 30-Day Notice	PURE VISION VISIBILITY TINTED CONTACT LENS FOR EXTENDED WEAR	BAUSCH & LOMB, INC.	Qualification of an additional manufacturer of a raw material for Bausch + Lomb Ultra (samfilcon A) Visibility Tinted Soft (hydrophilic) Contact Lenses and Bausch + Lomb PureVision (balafilcon A) Visibility Tinted Soft (hydrophilic) Contact Lenses.
P980016/S753	09/15/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add a second supplier of raw shields, shield monitors and shield assemblies for Percepta, Serena and Solara devices and to add a second supplier of shield assemblies for Cobalt and Crome devices.
P980016/S754	09/18/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of modifications to select manufacturing processes of the backfill hole weld.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S755	09/30/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Implementation of modifications of selected manufacturing processes related to the packaging processes associated with the Backfill Hole Weld Process.
P980035/S639	09/18/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implementation of modifications to select manufacturing processes of the backfill hole weld.
P980035/S640	09/23/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implementation of modifications of selected manufacturing processes related to updating UBD Control for the Backfill Hole Weld Process.
P980035/S641	09/25/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implementation of modifications to the medical adhesive process for selected pulse generators as part of the backfill hole weld rework process.
P980035/S642	09/30/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implementation of modifications of selected manufacturing processes related to the packaging processes associated with the Backfill Hole Weld Process.
P980040/S121	09/23/2020	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Conducting the flat time test prior to sterilization as opposed to post sterilization as an in-process control for IOLs, within 24 hours of samples being delivered to the flat test area at AMO Puerto Rico site.
P980040/S122	09/23/2020	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Addition of a raw material supplier for the polymer resin used to mold the pushrod component in the TECNIS iTEC Preloaded Delivery System and in the TECNIS Simplicity Delivery System.
P990004/S043	09/25/2020	X - 30-Day Notice	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Change of the washing program in two washing machines used for cleaning ancillary equipment used in the manufacturing of SURGIFLO Hemostatic Matrix and SURGIFLO Hemostatic Matrix with Thrombin products.
P990009/S062	09/09/2020	X - 30-Day Notice	FLOSEAL MATRIX/ FLOSEAL MATRIX HEMOSTATIC SEALANT/ PROCEED HEMOSTATIC SEALANT	BAXTER HEALTHCARE CORP.	Change to the sodium chloride diluent syringe filling equipment for Floseal Hemostatic Matrix.
P990025/S060	09/24/2020	X - 30-Day Notice	NAVI-STAR DIAGNOSTIC/ ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC.	Implementing an alternate laser wire stripping process.
P000053/S116	09/17/2020	X - 30-Day Notice	AMS SPHINCTER 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Add Sanofi in Brindisi, Italy as a supplier of rifampin.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010007/S013	09/08/2020	X - 30-Day Notice	IMMULITE/IMMULITE 1000 AFP AND IMMULITE 2000/ IMMULITE 2500 AFP	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Remove select inspection criteria from the raw materials used to manufacture IMMULITE Substrate Reagent.
P010015/S448	09/15/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Add a second supplier of raw shields, shield monitors and shield assemblies for Percepta, Serena and Solara devices and to add a second supplier of shield assemblies for Cobalt and Crome devices.
P010015/S449	09/23/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implementation of modifications of selected manufacturing processes related to updating UBD Control for the Backfill Hole Weld Process.
P010015/S450	09/30/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implementation of modifications of selected manufacturing processes related to the packaging processes associated with the Backfill Hole Weld Process.
P010030/S142	09/17/2020	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Update to the Automated Test System for the LifeVest 4000 electrode belts.
P010031/S714	09/15/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add a second supplier of raw shields, shield monitors and shield assemblies for Percepta, Serena and Solara devices and to add a second supplier of shield assemblies for Cobalt and Crome devices.
P010031/S715	09/18/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of modifications to select manufacturing processes of the backfill hole weld.
P010031/S716	09/30/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of modifications of selected manufacturing processes related to the packaging processes associated with the Backfill Hole Weld Process.
P010050/S018	09/08/2020	X - 30-Day Notice	IMMULITE 2000 XPI HBSAG	SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS, LTD	Remove select inspection criteria from the raw materials used to manufacture IMMULITE Substrate Reagent.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010051/S013	09/08/2020	X - 30-Day Notice	IMMULITE 2000 XPI ANTI-HBC	SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS, LTD	Remove select inspection criteria from the raw materials used to manufacture IMMULITE Substrate Reagent.
P010052/S014	09/08/2020	X - 30-Day Notice	IMMULITE 2000 XPI ANTI-HBS	SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS, LTD	Remove select inspection criteria from the raw materials used to manufacture IMMULITE Substrate Reagent.
P010053/S012	09/08/2020	X - 30-Day Notice	IMMULITE 2000 XPI ANTI-HBC IMG	SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS, LTD	Remove select inspection criteria from the raw materials used to manufacture IMMULITE Substrate Reagent.
P010068/S060	09/24/2020	X - 30-Day Notice	NAVISTAR/CELSIUS DS DIAGNOSTIC/ABLATION DEFLECTABLE 8MM TIP CATHETER	BIOSENSE WEBSTER, INC.	Implementing an alternate laser wire stripping process.
P020004/S176	09/16/2020	X - 30-Day Notice	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Implementation of a manufacturing aid fixture, constraining sleeve manufacturing process reorder, additional instructions and an additional inspection in the manufacturing of the GORE EXCLUDER AAA Endoprosthesis and the GORE EXCLUDER Iliac Branch Endoprosthesis.
P020047/S073	09/11/2020	X - 30-Day Notice	MULTI-LINK VISION/MINI/8 CORONARY STENT SYSTEMS	ABBOTT VASCULAR	Change the resin of a molded component on the delivery system.
P030005/S199	09/03/2020	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Add instructions, images, and an inspection for preforming battery cathode tabs.
P030017/S341	09/22/2020	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Implementation of an alternate cleaning agent.
P030017/S342	09/30/2020	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Change in the electrical resistance testing specification and an update to the supporting test equipment software.
P030031/S108	09/24/2020	X - 30-Day Notice	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Implementing an alternate laser wire stripping process.
P030054/S385	09/23/2020	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ST. JUDE MEDICAL	Alternate use of the ILT Welder during the manufacturing welding process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040034/S032	09/16/2020	X - 30-Day Notice	DURASEAL DURAL SEALANT SYSTEM	INTEGRA LIFESCIENCES CORPORATION	Move the production of the packaging from Building #1 to Building #2.
P040038/S036	09/03/2020	X - 30-Day Notice	XACT CAROTID STENT SYSTEM	ABBOTT VASCULAR INC.	Changes to the suppliers of plastic injection molded components.
P040043/S119	09/02/2020	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implementation of water leakage evaluation, as a secondary test, in Quality Control testing of Gore TAG Conformable Thoracic Stent Graft with Active Control System.
P050018/S028	09/21/2020	X - 30-Day Notice	ANGIOSCULPT SCORING BALLOON CATHETER	SPECTRANETICS CORP.	Material change at a supplier.
P060005/S012	09/08/2020	X - 30-Day Notice	IMMULITE / IMMULITE 1000 AND IMMULITE 2000 FREE PSA ASSAYS	SIEMENS MEDICAL SOLUTIONS DIAGNOSTICS LIMITED	Remove select inspection criteria from the raw materials used to manufacture IMMULITE Substrate Reagent.
P060037/S067	09/24/2020	X - 30-Day Notice	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Replacement of the Prolong UHMWPE crosslinked material specification document, change in references of inspection methodology procedure from the firms internal document to ASTM standards, removal of Free Radical Level by Electron Spin Resonance requirement, and elimination of critical process parameters from the specification document as the ownership of the process is being transferred to a supplier and the supplier will be responsible to maintain these critical process parameters and process monitoring.
P060037/S068	09/25/2020	X - 30-Day Notice	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Addition of a new furnace equipment for the Hot Isostatic Pressing (HIP) process in the casting process for the NexGen Femoral components.
P070014/S061	09/25/2020	X - 30-Day Notice	LIFESTENT FLEXSTAR & FLEXSTAR XL VASCULAR STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	Alternate supplier of delivery system handle lock marking and thermoplastic staking processes.
P080006/S151	09/22/2020	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Add additional inspection during the finished device manufacturing process for select leads.
P080011/S114	09/04/2020	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Manufacture of Biofinity Energys (Asphere) lenses on Biofinity Line 9 at the CooperVision Manufacturing, Ltd. facility in Hamble, United Kingdom.
P080011/S115	09/16/2020	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Implementation of a new sterilizer installed at the CooperVision Manufacturing facility in Juana Diaz, Puerto Rico.
P080011/S116	09/21/2020	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Introduction of an additional MTO (Made To Order) collation and packaging machine for the Biofinity XR Toric and Biofinity Toric Multifocal (comfilcon A) soft (hydrophilic) contact lenses for extended wear at the CooperVision Manufacturing, Ltd. facility in Hamble, United Kingdom

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P080013/S021	09/16/2020	X - 30-Day Notice	DURASEAL EXACT SPINE SEALANT SYSTEM	INTEGRA LIFESCIENCES CORPORATION	Move the production of the packaging from Building #1 to Building #2.
P080025/S208	09/06/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Updates to the laboratory test methodology identified in the submission, documentation, and the LIMS system.
P080025/S209	09/09/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Updates to selected electrolyte incoming inspection documentation.
P100047/S170	09/04/2020	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Change the foreign material (FM) acceptance criteria of the PEEK End Link component at the supplier Donatelle Plastics.
P100047/S171	09/30/2020	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Implement updated test software for the HeartWare Ventricular Assist Device (HVAD), Battery Pack, Printed Circuit Board Assembly (PCBA) test to automatically verify the firmware and configuration file.
P110013/S104	09/25/2020	X - 30-Day Notice	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Changes to the acceptance criteria for the temperature probes during product parameter profile studies conducted during requalification of the sterilization cycle.
P110042/S144	09/17/2020	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Implement new flux and solder materials for use in the manufacture of the Model 3300 LATITUDE Programming System, Model 6395 Telemetry Wand, and Model 3200 EMBLEM S-ICD Programmer as part of the manufacturing process.
P110042/S145	09/10/2020	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Add a 30-minute dwell time step after all sterilization loads for S-ICD pulse generators.
P110043/S012	09/11/2020	X - 30-Day Notice	OMNILINK ELITE PERIPHERAL BALLOON-EXPANDABLE STENT SYSTEM	ABBOTT VASCULAR-CARDIAC THERAPIES	Change the resin of a molded component on the delivery system.
P120020/S024	09/30/2020	X - 30-Day Notice	SUPERA PERIPHERAL STENT SYSTEM	ABBOTT VASCULAR (IDEF TECHNOLOGIES INC)	Addition of new stent passivation equipment.
P130008/S058	09/16/2020	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Change to the cleaning process of Model 3028 IPG involving the replacement of trichloroethylene with an alcohol-based solvent.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130008/S059	09/24/2020	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Implementation of a new capillary tool for wire bonding process for the membrane subassembly used in Model 4340 sensing lead.
P130008/S060	09/29/2020	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Changes to the Hybrid Test System software from Version 2.0 to Version 2.0.1 to address false test failures due to improper startup of hybrids under test.
P130009/S111	09/07/2020	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Modifications in cleanroom entry pathways and shifting manufacturing lines between cleanrooms for improved operational efficiency.
P140003/S075	09/09/2020	X - 30-Day Notice	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Implementation of a semi-automated test fixture for the final qualification testing process for the Impella 2.5, Impella CP, Impella CP with SmartAssist, and Impella 5.5 with SmartAssist.
P140004/S020	09/16/2020	X - 30-Day Notice	SUPERION INTERSPINOUS SPACER	BOSTON SCIENTIFIC NEUROMODULATION	Alternate machining equipment.
P140004/S021	09/09/2020	X - 30-Day Notice	SUPERION INTERSPINOUS SPACER	BOSTON SCIENTIFIC NEUROMODULATION	Alternate pouch heat sealer.
P140004/S022	09/17/2020	X - 30-Day Notice	SUPERION INTERSPINOUS SPACER	BOSTON SCIENTIFIC NEUROMODULATION	Addition of an injection molding process for instrument manufacture.
P140004/S023	09/09/2020	X - 30-Day Notice	SUPERION INTERSPINOUS SPACER	BOSTON SCIENTIFIC NEUROMODULATION	Addition of automated equipment for deburring.
P140018/S020	09/21/2020	X - 30-Day Notice	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Process changes to a raw material.
P140028/S063	09/02/2020	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	New equipment for the silicone coating process.
P140031/S118	09/07/2020	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Modifications in cleanroom entry pathways and shifting manufacturing lines between cleanrooms for improved operational efficiency.
P140031/S119	09/25/2020	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Modification of acceptance criteria for in-process inspection of the valve crimp section of the Commander delivery system.
P140032/S059	09/06/2020	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Updates to the laboratory test methodology identified in the submission, documentation, and the LIMS system.
P140032/S060	09/09/2020	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Updates to selected electrolyte incoming inspection documentation.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150001/S087	09/02/2020	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	IntriCon Corporation (IntriCon Red Fox), 1260 Red Fox Road, Saint Paul, MN as an alternative finished product manufacturing facility and IntriCon Corporation Grey Fox (IntriCon Grey Fox), 1275 Grey Fox Road Arden Hills, MN as an alternate final packaging process facility for the Guardian Link (3) and Guardian Connect Transmitter. The transmitters are components of the MiniMed 630G System with SmartGuard, Guardian Connect System, and MiniMed 670G System. The submission also requested approval of process changes related to the new manufacturing facilities including a new inspection process and equipment.
P150012/S098	09/03/2020	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Add instructions, images, and an inspection for preforming battery cathode tabs.
P150036/S052	09/07/2020	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Modifications in cleanroom entry pathways and shifting manufacturing lines between cleanrooms for improved operational efficiency.
P150048/S048	09/07/2020	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	IImplementation of a new washer/dryer to automate the process for cleaning and sanitizing fixtures and accessories used in Edwards Integrity Preservation Technology processing at the Irvine Facility.
P160007/S037	09/02/2020	X - 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	IntriCon Corporation (IntriCon Red Fox), 1260 Red Fox Road, Saint Paul, MN as an alternative finished product manufacturing facility and IntriCon Corporation Grey Fox (IntriCon Grey Fox), 1275 Grey Fox Road Arden Hills, MN as an alternate final packaging process facility for the Guardian Link (3) and Guardian Connect Transmitter. The transmitters are components of the MiniMed 630G System with SmartGuard, Guardian Connect System, and MiniMed 670G System. The submission also requested approval of process changes related to the new manufacturing facilities including a new inspection process and equipment.
P160017/S086	09/02/2020	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	IntriCon Corporation (IntriCon Red Fox), 1260 Red Fox Road, Saint Paul, MN as an alternative finished product manufacturing facility and IntriCon Corporation Grey Fox (IntriCon Grey Fox), 1275 Grey Fox Road Arden Hills, MN as an alternate final packaging process facility for the Guardian Link (3) and Guardian Connect Transmitter. The transmitters are components of the MiniMed 630G System with SmartGuard, Guardian Connect System, and MiniMed 670G System. The submission also requested approval of process changes related to the new manufacturing facilities including a new inspection process and equipment.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160022/S020	09/29/2020	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	Change in the HiPot and Electrical Test Equipment used during the manufacture of the OneStep Cable Assembly for the X Series and Propaq MD defibrillators.
P160022/S021	09/17/2020	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	Use of new Defibrillator Analyzers to measure the defibrillator energy output for the ZOLL AED 3 units.
P160022/S022	09/29/2020	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	Replacement of two Automated Optical Inspection (AOI) machines located at supplier facilities.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160024/S009	09/24/2020	X - 30-Day Notice	LIFESTREAM BALLOON EXPANDABLE VASCULAR COVERED STENT	BARD PERIPHERAL VASCULAR, INC.	Implement an optimized laser process for a bond on the balloon catheter.
P160035/S015	09/03/2020	X - 30-Day Notice	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Implement a new version of Mobile Test Unit (MTU) for testing the Ikus driving unit used with the Berlin Heart EXCOR Pediatric Ventricular Assist Device (VAD)
P160038/S017	09/02/2020	X - 30-Day Notice	PRAXIS EXTENDED RAS PANEL	ILLUMINA, INC.	Implementation of two new quantitative quality control (QC) testing assays.
P160043/S038	09/25/2020	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Changes to the acceptance criteria for the temperature probes during product parameter profile studies conducted during requalification of the sterilization cycle.
P170018/S008	09/17/2020	X - 30-Day Notice	LIFEPAK® CR2 DEFIBRILLATOR	PHYSIO-CONTROL, INC	Allow the Energy Storage Capacitor supplier's manufacturing process to confirm the shorting bar component meets its dimensional requirements.
P170035/S009	09/28/2020	X - 30-Day Notice	BAUSCH + LOMB ULTRA (SAMFILCON A) CONTACT LENSES	BAUSCH AND LOMB, INC.	Qualification of an additional manufacturer of a raw material for Bausch + Lomb Ultra (samfilcon A) Visibility Tinted Soft (hydrophilic) Contact Lenses and Bausch + Lomb PureVision (balafilcon A) Visibility Tinted Soft (hydrophilic) Contact Lenses.
P170042/S007	09/25/2020	X - 30-Day Notice	COVERA VASCULAR COVERED STENT	C.R. BARD, INC	Alternate supplier of delivery system handle lock marking and thermoplastic staking processes.
P180011/S036	09/02/2020	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	New equipment for the silicone coating process.
P180025/S008	09/18/2020	X - 30-Day Notice	MANTA VASCULAR CLOSURE DEVICE	ESSENTIAL MEDICAL, INC.	Implementation of Keyence Systems to aid the toggle tuck inspection, to automate the suture spooling inspection, and to automate the toggle angle inspection.
P180029/S026	09/17/2020	X - 30-Day Notice	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	Supplier change for the dowel pins in the LOTUS Edge delivery system.
P180034/S003	09/28/2020	X - 30-Day Notice	TACK ENDOVASCULAR SYSTEM (6F)	INTACT VASCULAR, INC.	Pad printed component supplier change.
P180037/S002	09/09/2020	X - 30-Day Notice	VENOVO VENOUS STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	New equipment in the delivery system tip-forming process.
P180037/S003	09/25/2020	X - 30-Day Notice	VENOVO VENOUS STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	Alternate supplier of delivery system handle lock marking and thermoplastic staking processes.
P180046/S021	09/21/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Addition of a new laser welder.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190006/S021	09/21/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Addition of a new laser welder.
P190018/S006	09/29/2020	X - 30-Day Notice	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.	Addition of an alternate supplier for the AutonoMe Delivery System nozzle component (V. 3.6).
P190027/S001	09/28/2020	X - 30-Day Notice	TACK ENDOVASCULAR SYSTEM (4F, 1.5-4.5MM)	INTACT VASCULAR, INC.	Pad printed component supplier change.

Total: 132