MA Monthly approvals from 11/1/2018 to 11/30/2018

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150002	11/27/2018	PMAO - PMA Origi	INCRAFT AAA STENT GRAFT SYSTEM	CORDIS CORPORATIO N	Approval for the endovascular treatment of patients with infrarenal abdominal aortic aneurysms with the following characteristics: 1) Adequate, but complex iliac or femoral vessel morphology (e.g., high tortuosity index, heavily calcified, small diameter), that is compatible with vascular access techniques, devices or accessories; 2) Proximal neck length >= 10 mm; 3) Aortic neck diameters >=17 mm and <= 31 mm; 4) Aortic neck suitable for suprarenal fixation; 5) Infrarenal and suprarenal neck angulation <= 60°; 6) Iliac fixation length >= 15 mm; 7) Iliac diameters >= 7 mm and <= 22 mm; and 8) Minimum overall AAA treatment length (proximal landing location to distal landing location) >= 128 mm.
P180010	11/01/2018	PMAO - PMA Origi	GORE CAROTID STENT	W. L GORE & ASSOCIATES, INC	Approval for the GORE® Carotid Stent, used with the GORE® Embolic Filter. The device is indicated for the treatment of carotid artery stenosis in patients deemed at high surgical risk for carotid endarterectomy (CEA) and who meet the criteria below. 1) Patients with symptomatic carotid artery stenosis, >= 50%, as confirmed by ultrasound or angiography; 2) Patients with asymptomatic carotid artery stenosis, >=80%, as confirmed by ultrasound or angiography; and 3) Patients must have a Reference Vessel Diameter of 3.7 mm to 9.0 mm.

Total: 2

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S047	11/21/2018	N - Normal 180 Day	SURGICEL ENDOSCOPIC APPLICATOR	ETHICON, INC.	Approval for the addition of the Surgicel Endoscopic Applicator accessory to expand use of the Surgicel Powder Device to endoscopic or laparoscopic procedures.
N12159/S049	11/13/2018	R - Real-Time Proc	SURGICEL POWDER	ETHICON, INC.	Approval to modify the post-irradiation Yellowness Index (YI) release specification from <= 42 YI units to <= 49 YI units. The revised release specification of <= 49 YI units still ensures that product will meet the end of shelf life specification of ?68 YI at 18 months.
N12159/S050	11/08/2018	S - Special CBE	SURGICEL ABSORBABLE HEMOSTAT	ETHICON, INC.	Approval to strengthen warnings and precautions in the labeling.
N17679/S039	11/23/2018	Y - 135 Review Tra	TETRAFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION, INC.	Approval for the harmonization of calibration procedures.
P780007/S059	11/23/2018	Y - 135 Review Tra	POLYMACON SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION, INC.	Approval for the harmonization of calibration procedures.
P790005/S062	11/02/2018	Y - 135 Review Tra	EBI OSTEOGEN IMPLANTABLE BONE GROWTH STIMULATORS	EBI, LLC	Approval for implementation of an additional finished device cleaning process and associated new, semi-automated, PLC cleaning equipment to further ensure adequate removal of manufacturing materials and residue from finished devices has occurred through conformance to cleanliness requirements in accordance with Zimmer Biomet GES 09802 Implant Residual Materials and Endotoxin Limits.
P850035/S051	11/02/2018	Y - 135 Review Tra	SPF IMPLANTABLE SPINAL FUSION STIMULATORS	EBI, LLC	Approval for implementation of an additional finished device cleaning process and associated new, semi-automated, PLC cleaning equipment to further ensure adequate removal of manufacturing materials and residue from finished devices has occurred through conformance to cleanliness requirements in accordance with Zimmer Biomet GES 09802 Implant Residual Materials and Endotoxin Limits.
P850079/S077	11/23/2018	Y - 135 Review Tra	METHAFILCON A AND METHAFILCON B SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION, INC.	Approval for the harmonization of calibration procedures.
P890003/S396	11/21/2018	R - Real-Time Proc	MEDTRONIC CARELINK MODEL 9986 (2090 CARELINK PROGRAMMER), MODEL SW028 (29901 ENCORE PROGRAMMER)	MEDTRONIC, INC.	Approval for updates to the Medtronic CareLink Model 9986 Programmer Baseline Operating System Software.
P890023/S030	11/23/2018	Y - 135 Review Tra	OCUFILCON D SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	THE COOPER COMPANIES	Approval for the harmonization of calibration procedures.
P940015/S041	11/02/2018	Y - 135 Review Tra	SYNVISC AND SYNVISC-ONE	SANOFI GENZYME CORP.	Approval for an additional test point for sterility and endotoxin during manufacturing of the SynVisc and SynVisc One devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S686	11/06/2018	R - Real-Time Proc	EVERA MRI DF-1 ICD, EVERA MRI ICD, EVERA S DR/VR ICD, EVERA XT DR/ VR ICD, MIRRO MRI DR/VR ICD, PRIMO MRI DR/VR ICD, VISIA AF MRI DF1 ICD, VISIA AF MRI VR ICD, VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for a minor design change which implements design requirements for nitrogen content for select CRT-D and ICD devices.
P980040/S093	11/14/2018	O - Normal 180 Da	TECNIS SYMFONY TORIC IOL	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval of revisions to the post-approval study (PAS) protocol.
P000029/S083	11/08/2018	Y - 135 Review Tra	DEFLUX INJECTABLE GEL	PALETTE LIFE SCIENCES	Approval for change in the manufacturer of Teflon part of equipment used during manufacturing of the Deflux and Solesta Injectable Gel.
P010003/S031	11/01/2018	S - Special CBE	BIOGLUE SURGICAL ADHESIVE	CRYOLIFE, INC.	Approval for changes to the instructions for use.
P010014/S076	11/20/2018	Y - 135 Review Tra	OXFORD PARTIAL KNEE SYSTEM	BIOMET MANUFACTUR ING CORP.	Approval for the addition of more frequent cleaning intervals, introduction of new sterilants and test strips, and an new deep clean quarterly step.
P010014/S081	11/20/2018	Y - 135 Review Tra	OXFORD PARTIAL KNEE SYSTEM	BIOMET MANUFACTUR ING CORP.	Approval for replacing existing sealing equipment for the packaging of the Oxford Partial Knee System.
P010029/S027	11/19/2018	R - Real-Time Proc	EUFLEXXA	FERRING PHARMACEUT ICALS, INC.	Approval for a minor design and material change to the tip cap of the syringe utilized to inject EUFLEXXA.
P010031/S645	11/06/2018	R - Real-Time Proc	AMPLIA MRI CRT-D, AMPLIA MRI QUAD CRT-D, BRAVA CRT-D, BRAVA QUAD CRT-D, CLARIA MRI CRT-D, CLARIA MRI QUAD CRT-D, COMPIA MRI CRT-D, COMPIA MRI QUAD CRT-D, VIVA QUAD S/XT CRT-D, VIVA S/XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for a minor design change which implements design requirements for nitrogen content for select CRT-D and ICD devices.
P030006/S028	11/21/2018	O - Normal 180 Da	PROLIEVE THERMODILATION SYSTEM	MEDIFOCUS, INC	Approval for a labeling update with the results of the Post Approval Study (PAS)

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P030031/S093	11/15/2018	S - Special CBE	THERMOCOOL SMARTTOUCH SF UNI/BI-DIRECTIONAL NAVIGATION CATHETER	BIOSENSE WEBSTER, INC.	Approval for a minor change to clarify text in the instructions for use.
P040024/S101	11/02/2018	N - Normal 180 Day	RESTYLANE LYFT WITH LIDOCAINE CANNULA INJECTION	Q-MED AB	Approval for the use of a small bore, blunt tip cannula with Restylane Lyft with Lidocaine for cheek augmentation and the correction of age related midface contour deficiencies in patients over the age of 21.
P040044/S078	11/16/2018	N - Normal 180 Day	MYNXGRIP AND MYNX ACE VASCULAR CLOSURE DEVICE	ACCESS CLOSURE, INC.	Approval to add a new vendor for the hydrogel sealant components and to extend the shelf life of the hydrogel component to 25 months.
P050006/S069	11/06/2018	N - Normal 180 Day	CARDIOFORM SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Approval for the GORE CARDIOFORM Septal Occluder with Delivery System Improvements.
P060011/S014	11/14/2018	N - Normal 180 Day	RAYNER C-FLEX 570, C-FLEX ASPHERIC 970C, 600C ASPHERIC INTRAOCULAR LENSES	RAYNER INTRAOCULAR LENSES LTD.	Approval for manufacturing process improvements for all Rayner FDA-approved Intraocular Lenses (IOLs) and a new packaging configuration for your 6.0 mm Aspheric IOL, Model 600C, into a preloaded injector.
P080011/S069	11/23/2018	Y - 135 Review Tra	COMFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION MANUFACTURING, LTD.	Approval for the harmonization of calibration procedures.
P100010/S084	11/09/2018	N - Normal 180 Day	ARCTIC FRONT ADVANCE AND ARCTIC FRONT ADVANCE PRO CARDIAC CRYOABLATION CATHETERS	MEDTRONIC CRYOCATH LP	Approval for design, manufacturing and product requirement changes to the Luer component of the Arctic Front Advance and Arctic Front Advance Pro Cardiac Cryoablation Catheters.
P100014/S020	11/08/2018	Y - 135 Review Tra	SOLESTA INJECTABLE GEL	PALETTE LIFE SCIENCES	Approval for change in the manufacturer of Teflon part of equipment used during manufacturing of the Deflux and Solesta Injectable Gel.
P100034/S018	11/30/2018	N - Normal 180 Day	OPTUNE	NOVOCURE, LTD.	Approval to update the Optune¿ device labeling with the clinical outcome data from the pivotal study conducted to treat newly diagnosed glioblastoma (Long-Term EF-14).
P100047/S120	11/15/2018	Y - 135 Review Tra	HEARTWARE LEFT VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for the implementation of a new profilometer with the capability to measure the leading-edge radius on the HVAD impeller.
P120016/S024	11/27/2018	P - Panel Track	VASCADE MVP VENOUS VASCULAR CLOSURE SYSTEM (VVCS)	CARDIVA MEDICAL, INC.	Approval for percutaneous closure of femoral venous access sites while reducing time to ambulation, total post-procedure time, time to hemostasis, and time to discharge eligibility in patients who have undergone catheter-based procedures utilizing 6-12F inner diameter procedural sheaths, with single or multiple access sites in one or both limbs.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130008/S034	11/01/2018	N - Normal 180 Day	INSPIRE MODEL 2740 PHYSICIAN PROGRAMMER	INSPIRE MEDICAL SYSTEMS	Approval for an update to the tablet hardware and software of the Model 2740 Physician Programmer.
P130028/S018	11/28/2018	N - Normal 180 Day	ALGOVITA SPINAL CORD STIMULATION SYSTEM	NUVECTRA CORPORATIO N	Approval for new MR Conditional labeling limited to transmit/receive head coils and head scans only for the implanted components of the Algovita SCS System.
P140004/S010	11/16/2018	O - Normal 180 Day	SUPERION® INDIRECT DECOMPRESSION SYSTEM	VERTIFLEX (R), INCORPORAT ED	Approval for revised labeling which incorporates data from the completed Post-Approval Study.
P140008/S014	11/28/2018	O - Normal 180 Day	ORBERA INTRAGASTRIC BALLOON	APOLLO ENDOSURGE RY INC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P140009/S041	11/14/2018	S - Special CBE	ST, JUDE MEDICAL INFINITY DEEP BRAIN STIMULATION (DBS) LEADS	ST. JUDE MEDICAL NEUROMODU LATION	Approval to add X-ray inspections during the manufacture of the electrode subassemblies to enhance the safety of the leads for the Infinity Deep Brain Stimulation System.
P140010/S043	11/16/2018	R - Real-Time Proc	IN.PACT ADMIRAL PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Approval for modifications to the shelf carton.
P140032/S022	11/29/2018	S - Special CBE	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Approval for changes to the Implantable System for Remodulin Technical Manual and Implantable System for Remodulin Refill Kit Package Label.
P150001/S050	11/20/2018	N - Normal 180 Day	MINIMED 630G INSULIN PUMP, GUARDIAN LINK (3) TRANSMITTER	MEDTRONIC MINIMED	Approval for updating the transmitter firmware to improve user experience and to correct various software anomalies.
P150001/S052	11/29/2018	R - Real-Time Proc	MINIMED 630G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED	Approval for a minor software design change to fix an anomaly in the main application software used in a specific hardware configuration.
P150005/S037	11/01/2018	O - Normal 180 Day	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval for the Post-Approval Study-INTERRUPT AF Study.
P150024/S008	11/09/2018	N - Normal 180 Day	ASPIREASSIST	ASPIRE BARIATRICS INC	Approval for modifications to the Companion, Tubing Set, Connector and Skin Port.
P150028/S002	11/14/2018	N - Normal 180 Day	NUDEL DELIVERY SYSTEM	NUMED, INC.	Approval for the NuDEL Delivery System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150048/S026	11/05/2018	O - Normal 180 Day	EDWARDS PERICARDIAL MITRAL BIOPROSTHESIS	EDWARDS LIFESCIENCES, LLC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P160003/S005	11/06/2018	O - Normal 180 Day	PRO-KINETIC ENERGY COBALT CHROMIUM (COCR) CORONARY STENT SYSTEM	BIOTRONIK, INC.	Approval for modifications to the labeling to include long-term follow-up data from the BIOHELIX-I study.
P160014/S003	11/14/2018	R - Real-Time Proc	COBRA PZF NANOCOATED CORONARY STENT SYSTEM	CELONOVA BIOSCIENCES, INC.	Approval for changes to the materials used in the inner member of the delivery system.
P160017/S048	11/20/2018	N - Normal 180 Day	MINIMED 670G INSULIN PUMP GUARDIAN LINK (3) TRANSMITTER	MEDTRONIC MINIMED, INC.	Approval for updating the transmitter firmware to improve user experience and to correct various software anomalies.
P160017/S051	11/29/2018	R - Real-Time Proc	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval for a minor software design change to fix an anomaly in the main application software used in a specific hardware configuration.
P160039/S002	11/02/2018	N - Normal 180 Day	REMEDE® SYSTEM	RESPICARDIA	Approval for an update to the tablet hardware and software of the Model 1002A Remede System Programmer.
P160040/S002	11/28/2018	N - Normal 180 Day	LEUKOSTRAT CDX FLT3 MUTATION ASSAY	INVIVOSCRIBE TECHNOLOGIES, INC	Approval for the LeukoStrat CDx FLT3 Mutation Assay. The device is a PCR-based in vitro diagnostic test designed to detect internal tandem duplications (ITD) and tyrosine kinase domain (TKD) mutations D835 and I836 in the FLT3 gene in genomic DNA extracted from mononuclear cells obtained from peripheral blood or bone marrow aspirates of patients diagnosed with acute myelogenous leukemia (AML). The LeukoStrat CDx FLT3 Mutation Assay is used as an aid in the selection of patients with AML for whom RYDAPT® (midostaurin) treatment is being considered. The LeukoStrat CDx FLT3 Mutation Assay is used as an aid in the selection of patients with AML for whom XOSPATA® (gilteritinib) treatment is being considered. The LeukoStrat CDx FLT3 Mutation Assay is to be performed only at Laboratory for Personalized Molecular Medicine (LabPMM) LLC, a single laboratory site, located at 10222 Barnes Canyon Rd., Bldg. 1, San Diego, CA 92121.
P160047/S003	11/29/2018	N - Normal 180 Day	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	AEGEA MEDICAL, INC	Approval for a change to the Pressure Sensor thermal offset determination process and a change to align the Device Lumen Patency Test sequence.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160048/S002	11/06/2018	N - Normal 180 Day	EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM (CGMS-ENTIRE SYSTEM), EVERSENSE SENSOR, EVERSENSE INSERTION TOOLS, EVERSENSE SMART TRANSMITTER AND EVERSENSE ADHESIVE PATCH, EVERSENSE MOBILE MEDICAL APPLICATION	SENSEONICS, INCORPORATED	Approval for modifying the instructions for use of the Eversense Continuous Glucose Monitoring System to specify that, in addition to physicians, nurse practitioners and physicians assistants who have completed the required training may insert and remove the Eversense sensor.
P160049/S003	11/16/2018	O - Normal 180 Day	STELLAREX 0.035 OTW DRUG-COATED ANGIOPLASTY BALLOON	THE SPECTRANETICS CORP.	Approval for a labeling update with 2 year data.
P170012/S009	11/16/2018	Y - 135 Review Tra	HEMOBLAST BELLOWS	BIOM'UP SA	Approval for modifications to the ice machine and cleaning process used in collagen extraction and purification.
P170024/S002	11/14/2018	S - Special CBE	SURPASS STREAMLINE FLOW DIVERTER	STRYKER NEUROVASCULAR	Approval for revisions to the Directions for Use (DFU) to include additional precautionary language regarding the use of magnetic resonance angiography (MRA) for patient follow-up to assess intracranial aneurysm occlusion.
P180008/S001	11/29/2018	R - Real-Time Proc	T:SLIM X2 INSULIN PUMP WITH BASAL-IQ TECHNOLOGY	TANDEM DIABETES CARE, INC.	Approval to update the occlusion detection software.
P180008/S002	11/29/2018	R - Real-Time Proc	T:SLIM X2 INSULIN PUMP WITH BASAL-IQ TECHNOLOGY	TANDEM DIABETES CARE, INC.	Approval to modify the menu settings software and add a secondary display.
P180008/S003	11/29/2018	R - Real-Time Proc	T:SLIM X2 INSULIN PUMP WITH BASAL-IQ TECHNOLOGY	TANDEM DIABETES CARE, INC.	Approval for a new touch screen and memory chip.

Total: 58

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S232	11/16/2018	X - 30-Day Notice	ADVANTIO, INGENIO, VITALIO, FORMIO, ALTRUA, ALTRUA 2, ESSENTIO, PROPONENT, ACCOLADE	BOSTON SCIENTIFIC CORP.	Addition of alternative equipment to sterilize Accolade, NG3, NG4,and EMBLEM S-ICD product families using the new sterilization cycle DEV_PROD55_02 at the Clonmel, Ireland manufacturing facility.
N970012/S152	11/16/2018	X - 30-Day Notice	AMS 700 IMPLANTABLE PENILE PROSTHESIS WITH AND WITHOUT INHIBIZONE	BOSTON SCIENTIFIC CORP.	Changing the manufacturing site of a critical supplier that makes a critical component.
P830055/S214	11/14/2018	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Introduction of additional mechanisms for part identification, verification, and traceability throughout the manufacturing process.
P830055/S216	11/29/2018	X - 30-Day Notice	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Increase the number of devices which are packaged in the irradiation container .
P830055/S218	11/28/2018	X - 30-Day Notice	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Increase in Machined Parts Clean Room Max Occupancy from 10 to 15 trained personnel
P830061/S163	11/13/2018	X - 30-Day Notice	CAPSURE SENSE LEAD, CAPSURE SP LEAD, CAPSURE SP NOVUS LEAD AND VITATRON CRYSTALLINE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of updated version of Factory Works software (Release 9.5).
P830061/S164	11/19/2018	X - 30-Day Notice	CAPSURE SENSE LEAD, SP NOVUS LEAD; VITRON CRYSTALLINE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Site change and addition of a new mold press at external supplier FMI, Inc.
P840001/S410	11/08/2018	X - 30-Day Notice	RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS.	MEDTRONIC NEUROMODULATION	Implementation of the impacted Medtronic Neuromodulation Lithium-Ion batteries on the Universal Burn-In Test System (UBITS) Load Station 4 for production use at Medtronic¿s first tier supplier Medtronic Energy and Component Center (MECC).

P840001/S411	11/13/2018	X - 30-Day Notice	ITREL, SYNERGY AND INTELLIS, SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPNAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Update to the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.5.
P840001/S412	11/21/2018	X - 30-Day Notice	ITREL, SYNERGY AND INTELLIS SPNAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Change to consolidate the Laser Marking and Laser Ablation operations into a single operation at Ametek.
P840001/S413	11/08/2018	X - 30-Day Notice	ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Consolidate the laser weld pull strength monitoring tests for four model families into one group (affected models: 977A160, 977A175, 977A190, 977A260, 977A275, 977A290, 977D160, 977D260, 3776, 3777, 3778, 37081, 37082, 37083, 37085, 37086).
P840001/S414	11/30/2018	X - 30-Day Notice	ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Update to the external supplier site change and external supplier equipment change in the manufacturing of a critical component.
P840062/S070	11/07/2018	X - 30-Day Notice	COLLAPLUG ABSORBABLE COLLAGEN WOUND DRESSING FOR DENTAL SURGERY	INTEGRA LIFESCIENCES CORP.	Increasing the number of molds that may washed in the detergent wash and the number of times it may be reused (once) before draining and refilling.
P850064/S038	11/19/2018	X - 30-Day Notice	LIFEPULSE HIGH FREQUENCY VENTILATOR	BUNNELL, INC.	Adding an additional supplier of the Patient Box standoffs that are used in both models of the Patient Box (312 and 314). The change proposed does not affect the performance of the Patient Box and thus the LifePulse High Frequency Ventilator is not affected. There is no change to the design or any labeling. The following manufacturing facility is affected by the change(s): Bunnell Incorporated, 436 Lawndale Drive, Salt Lake City, Utah.
P850089/S137	11/13/2018	X - 30-Day Notice	CAPSURE SP NOVUS LEAD, CAPSURE SP Z LEAD AND VITATRON IMPULSE II LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of updated version of Factory Works software (Release 9.5).

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P850089/S138	11/19/2018	X - 30-Day Notice	CAPSURE SP, Z NOVUS LEAD; VITATRON IMPULSE II LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Site change and addition of a new mold press at external supplier FMI, Inc.
P860003/S099	11/01/2018	X - 30-Day Notice	THERAKOS CELLEX PROCEDURAL KIT	MALLINCKRODT PHARMACEUTICALS IRELAND LIMITED	Change in the device's manufacturing validation implementing the use of an automated inspection fixture that will inspect the integrity of 100% of all THERAKOS® CELLEX® Procedural Kit Centrifuge Outer Bowl welds.
P860004/S318	11/13/2018	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Update to the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.5.
P860004/S320	11/27/2018	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM, INTRATHECAL CATHETERS	MEDTRONIC INC.	Move the pyrogen and endotoxin limit specification to the sterile package level and to move the new lower endotoxin limit of the catheter introducer needle from the drawing note to the product specification and final packaging level.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860057/S183	11/20/2018	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT PERICARDIAL AORTIC BIOPROSTHESIS, THEON PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, RSR PERICARDIAL AORTIC BIOPROSTHESIS, THEON RSR PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, MAGNA PERICARDIAL AORTIC BIOPROSTHESIS, MAGNA PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, MAGNA EASE PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, PLUS PERICARDIAL MITRAL BIOPROSTHESIS, THEON PERICARDIAL MITRAL BIOPORSTHESIS WITH THERMAFIX TISSUE PROCESS AND MAGNA MITRAL EASE PERICARDIAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS	EDWARDS LIFESCIENCES, LLC.	Removal of the visual inspection for ¿Open Leaflet¿ in air for surgical pericardial heart valves.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860057/S184	11/19/2018	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT PERICARDIAL AORTIC BIOPROSTHESIS, THEON PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, RSR PERICARDIAL AORTIC BIOPROSTHESIS, THEON RSR PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, MAGNA PERICARDIAL AORTIC BIOPROSTHESIS, MAGNA PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, MAGNA EASE PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, PLUS PERICARDIAL MITRAL BIOPROSTHESIS, THEON PERICARDIAL MITRAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS AND CARPENTIER-EDWARDS PERIMOUNT MAGNA MITRAL EASE PERICARDIAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS	EDWARDS LIFESCIENCES, LLC.	Utilization of a portion of a new controlled environment as an additional storage area for processed pericardial tissue leaflets.
P890003/S399	11/13/2018	X - 30-Day Notice	CAPSURE VDD 2 LEAD AND VITATRON BRILLIANT S+ VDD LEAD	MEDTRONIC, INC.	Implementation of updated version of Factory Works software (Release 9.5).
P890003/S400	11/19/2018	X - 30-Day Notice	CAPSURE VDD 2 LEAD; VITATRON BRILLIANT S+ VDD LEAD	MEDTRONIC, INC.	Site change and addition of a new mold press at external supplier FMI, Inc.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P890055/S072	11/06/2018	X - 30-Day Notice	CODMAN 3000 SERIES CONSTANT-FLOW IMPLANTABLE INFUSION PUMP - TAPERED CATHETER (IP-37957)	CODMAN	Qualification of a new manufacturer/supplier for the tapered catheter used with the Codman 3000 infusion pumps system.
P900061/S150	11/13/2018	X - 30-Day Notice	ACE HEADER, END CAP, EPICARDIAL PATCH LEAD AND UPSIZING SLEEVE	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of updated version of Factory Works software (Release 9.5).
P900061/S151	11/19/2018	X - 30-Day Notice	EPICARDIAL PATCH LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Site change and addition of a new mold press at external supplier FMI, Inc.
P910001/S108	11/16/2018	X - 30-Day Notice	SPECTRANECTICS CVX-300 EXCIMER LASER SYSTEM	SPECTRANETICS CORP.	Updates to tooling equipment and part inspection test equipment and method.
P910023/S413	11/05/2018	X - 30-Day Notice	CURRENT+, FORTIFY, FORTIFY ASSURA, FORTIFY ASSURA (MR CONDITIONAL), ELLIPSE AND ELLIPSE (MR CONDITIONAL)	ST. JUDE MEDICAL	Add an alternate supplier for the current 1000V diode for high voltage implantable devices.
P910056/S035	11/06/2018	X - 30-Day Notice	ENVISTA HYDROPHOBIC ACRYLIC INTRAOCULAR LENS	BAUSCH & LOMB, INC.	Change to the method of manufacturing the enVista® Hydrophobic Acrylic IOL, Model MX60E.
P910073/S151	11/13/2018	X - 30-Day Notice	ENDOTAK RELIANCE 4-SITE LEADS	BOSTON SCIENTIFIC	Implementation of the following two previously accepted changes for additional models: 1) change in a reactant used for preparation of the key intermediate in the synthesis of dexamethasone acetate; and 2) addition of a pull test process monitoring step.
P920015/S219	11/09/2018	X - 30-Day Notice	HV SPLITTER/ADAPTOR KIT, SPRINT QUATTRO LEAD.	MEDTRONIC INC.	Use of new equipment to perform the dimensional inspections, automation of select adhesive inspections and move both the dimensional and select adhesive inspections to occur in parallel with the electrical test.

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P920015/S220	11/13/2018	X - 30-Day Notice	"Y" ADAPTOR/EXTENDER KIT, DF-1 CONNECTOR PORT PIN PLUG, HV SPLITTER/ADAPTOR KIT, IS-1 CONNECTOR PORT PIN PLUG KIT, LEAD ADAPTOR, SPRINT QUATTRO LEAD, SUBCUTANEOUS LEAD, TRANSVENE CS-SVC LEAD AND TUNNELING TOOL	MEDTRONIC INC.	Implementation of updated version of Factory Works software (Release 9.5).
P920015/S221	11/19/2018	X - 30-Day Notice	"Y" ADAPTOR/EXTENDER KIT; HV SPLITTER/ ADAPTOR KIT; SPRINT QUATTRO LEAD.	MEDTRONIC INC.	Site change and addition of a new mold press at external supplier FMI, Inc.
P920015/S223	11/28/2018	X - 30-Day Notice	HV SPLITTER/ADAPTOR KIT AND SPRINT QUATTRO LEAD	MEDTRONIC INC.	Elimination of redundant testing and reduction of select inspection sample sizes in micro extrusion manufacturing.
P920047/S113	11/28/2018	X - 30-Day Notice	BLAZER II, BLAZER II HTD, BLAZER PRIME HTD	BOSTON SCIENTIFIC CORP.	Addition of new electrical test equipment for use with Blazer II, Blazer II XP, and Blazer Prime Ablation catheters.
P930014/S116	11/01/2018	X - 30-Day Notice	ACRYSOF INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Implement an alternate mold system for the AcrySof® and AcrySof® ReSTOR® Intraocular Lenses.
P930029/S063	11/26/2018	X - 30-Day Notice	RF MARINR CATHETERS	MEDTRONIC INC.	Implementation of process monitoring pull testing for bonding processes.
P930039/S192	11/13/2018	X - 30-Day Notice	CAPSUREFIX LEAD, CAPSUREFIX NOVUS LEAD AND VITATRON CRYSTALLINE ACTIVE FIXATION LEAD	MEDTRONIC, INC.	Implementation of updated version of Factory Works software (Release 9.5).
P930039/S193	11/19/2018	X - 30-Day Notice	CAPSUREFIX LEAD, NOVUS LEAD; VITATRON CRYSTALLINE ACTIVE FIXATION LEAD	MEDTRONIC, INC.	Site change and addition of a new mold press at external supplier FMI, Inc.
P950022/S122	11/07/2018	X - 30-Day Notice	DURATA, OPTISURE,	ST. JUDE MEDICAL, INC.	Reduce solvents analytical testing at release from a per batch basis to periodic testing.
P950024/S081	11/13/2018	X - 30-Day Notice	CAPSURE EPICARDIAL PACING LEAD	MEDTRONIC INC.	Implementation of updated version of Factory Works software (Release 9.5).

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P950024/S082	11/19/2018	X - 30-Day Notice	CAPSURE EPICARDIAL PACING LEAD	MEDTRONIC INC.	Site change and addition of a new mold press at external supplier FMI, Inc.
P960009/S327	11/08/2018	X - 30-Day Notice	ACTIVA DEEP BRIAN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Implementation of the impacted Medtronic Neuromodulation Lithium-Ion batteries on the Universal Burn-In Test System (UBITS) Load Station 4 for production use at Medtronic¿s first tier supplier Medtronic Energy and Component Center (MECC).
P960009/S328	11/13/2018	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Update to the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.5.
P960009/S329	11/08/2018	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Consolidate the laser weld pull strength monitoring tests for four model families into one group (affected models: 977A160, 977A175, 977A190, 977A260, 977A275, 977A290, 977D160, 977D260, 3776, 3777, 3778, 37081, 37082, 37083, 37085, 37086).
P960009/S330	11/30/2018	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Update to the external supplier site change and external supplier equipment change in the manufacturing of a critical component.
P960013/S102	11/07/2018	X - 30-Day Notice	TENDRILL SDX, OPTISENSE, TENDRILL STS, TENDRIL ST.	ST JUDE MEDICAL	Reduce solvents analytical testing at release from a per batch basis to periodic testing.
P960030/S061	11/07/2018	X - 30-Day Notice	ISOFLEX	ST. JUDE MEDICAL	Reduce solvents analytical testing at release from a per batch basis to periodic testing.
P960040/S430	11/16/2018	X - 30-Day Notice	PUNCTUA, ENERGEN, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN, MOMENTUM, VIGILANT, PERCIVA, RESONATE	BOSTON SCIENTIFIC	Addition of alternative equipment to sterilize Accolade, NG3, NG4, and EMBLEM S-ICD product families using the new sterilization cycle DEV_PROD55_02 at the Clonmel, Ireland manufacturing facility.
P960042/S065	11/16/2018	X - 30-Day Notice	SPECTRANETICS LASER SHEATHS SLS	SPECTRANETICS CORP.	Updates to tooling equipment and part inspection test equipment and method.
P970004/S279	11/13/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS URINARY)	MEDTRONIC NEUROMODULATION	Update to the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.5.
P970004/S280	11/30/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS URINARY)	MEDTRONIC NEUROMODULATION	Update to the external supplier site change and external supplier equipment change in the manufacturing of a critical component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S693	11/13/2018	X - 30-Day Notice	EVERA MRI DF-1 ICD, EVERA MRI ICD, EVERA S DR ICD, EVERA S VR ICD, EVERA XT DR ICD, MIRRO MRI DR ICD, MIRRO VR ICD, PRIMO MRI DR ICD, PRIMO MRI VR ICD, PROTECTA ICD, PROTECTA VR ICD, PROTECTEA XT ICD, SECURA DR ICD, SECURA ICD, VISIA AF MRI DF1 ICD, VISIA AF MRI VR ICD AND VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of updated version of Factory Works software (Release 9.5).
P980016/S694	11/15/2018	X - 30-Day Notice	EVERA MRI ICD,S DR ICD, S VR ICD, XT DR ICD, XT VR ICD; MIRRO MRI DR ICD, VR ICD; PRIMO MRI DR ICD,VR ICD: VISIA AF MRI VR ICD, AF VR ICD.	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to the Polymers Automated Welders software used on the connector components.
P980016/S695	11/19/2018	X - 30-Day Notice	EVERA MRI DF-1 ICD; EVERA MRI ICD; EVERA S DR, VR ICD; EVERA XT DR, VR ICD; MIRRO MRI DR , VR ICD; PRIMO MRI DR, VR ICD; PROTECTA VR, XT, ICD; SECURA DR ICD; VISIA AF MRI DFI ICD, VR ICD, AF VR ICD.	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Site change and addition of a new mold press at external supplier FMI, Inc.
P980016/S696	11/28/2018	X - 30-Day Notice	EVERA MRI DF-1 ICD, EVERA MRI ICD, EVERA S DR/VR ICD, EVERA XT DR/ VR ICD, MIRRO MRI DR/VR ICD, PRIMO MRI DR/VR ICD, PROTECTA ICD, PROTECTA VR/XT ICD, SECURA DR ICD, SECURA ICD, VISIA AF MRI DF1/VR ICD AND VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Change to the sub-tier raw material suppliers and process changes for tantalum and niobium pins.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980022/S206	11/02/2018	X - 30-Day Notice	PARADIGM REAL-TIME INSULIN PUMP	MEDTRONIC MINIMED	Implementation of a manufacturing aid in assembly of the Paradigm family of insulin pumps. The Paradigm pumps are components of the MiniMed 530G System, Paradigm REAL-Time System, and Paradigm REAL-Time Revel System.
P980035/S567	11/13/2018	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ADVISA DR IPG, ADVISA DR MRI IPG, ADVISA DR MRI IPG, ASTRA S DR MRI IPG, ASTRA S SR MRI IPG, ASTRA XT DR MRI IPG, ASTRA XT SR MRI IPG, ATTESTA DR MRI IPG, ATTESTA SR MRI IPG, AZURE S DR MRI IPG, AZURE S SR MRI IPG, AZURE XT DR MRI IPG, AZURE XT SR MRI IPG, RELIA IPG, SPHERA DR MRI IPG AND SPHERA SR MRI IPG	MEDTRONIC INC.	Implementation of updated version of Factory Works software (Release 9.5).
P980035/S568	11/19/2018	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG; ADVISA DR, MRI IPG,SR MRI IPG, S DR, SR, XT DR, XT SR MRI IPG; ATTESTA DR, SR MRI IPG; AZURE S DR, S SR, XT DR, XT SR MRI IPG; RELIA IPG; SPHERA DR, SR MRI IPG.	MEDTRONIC INC.	Site change and addition of a new mold press at external supplier FMI, Inc.
P980035/S569	11/12/2018	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG; ATTESTA SR MRI IPG; RELIA IPG; SPHERA SR MRI IPG	MEDTRONIC INC.	Add router equipment.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980035/S570	11/28/2018	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ADVISA DR IPG, ADVISA DR MRI IPG, ADVISA SR MRI IPG, ASTRA S DR MRI IPG, ASTRA S SR MRI IPG, ASTRA XT DR MRI IPG, ASTRA XT SR MRI IPG, ATTESTA DR MRI IPG, ATTESTA SR MRI IPG, AZURE S DR MRI IPG, AZURE S SR MRI IPG, AZURE XT DR MRI IPG, AZURE XT SR MRI IPG, RELIA IPG, SHPERA DR MRI IPG AND SPHERA SR MRI IPG	MEDTRONIC INC.	Change to the sub-tier raw material suppliers and process changes for tantalum and niobium pins.
P980037/S071	11/06/2018	X - 30-Day Notice	ANGIOJET RHEOLYTIC THROMBECTOMY SYSTEM	BOSTON SCIENTIFIC CORP.	Removal of an in-process inspection of a non-critical component.
P980044/S049	11/13/2018	X - 30-Day Notice	SUPARTZ FX/VISCO-3	SEIKAGAKU CORP.	Sharing the facility and equipment used to manufacture SUPARTZ FX and VISCO-3 for the purpose of manufacturing another product.
P980050/S120	11/13/2018	X - 30-Day Notice	TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Implementation of updated version of Factory Works software (Release 9.5).
P000008/S044	11/30/2018	X - 30-Day Notice	LAP-BAND ADJUSTABLE GASTRIC BANDING SYSTEM	APOLLO ENDOSURGERY INC	Change of a testing equipment at a contract manufacturing site.
P000054/S051	11/09/2018	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Modify the General Inspection Level and Acceptable Quality Level (AQL) of the absorbable collagen sponge (ACS) component of Infuse Bone Graft to align with ISO 14971:2012.
P000058/S070	11/09/2018	X - 30-Day Notice	INFUSE BONE GRAFT/ MEDTRONIC INTERBODY FUSION DEVISE	MEDTRONIC SOFAMOR DANEK USA, INC.	Modify the General Inspection Level and Acceptable Quality Level (AQL) of the absorbable collagen sponge (ACS) component of Infuse Bone Graft to align with ISO 14971:2012.
P010012/S491	11/16/2018	X - 30-Day Notice	ORIGEN, INOGEN, DYNAGEN, AUTOGEN, MOMENTUM, VIGILANT, RESONATE	BOSTON SCIENTIFIC CORP.	Addition of alternative equipment to sterilize Accolade, NG3, NG4, and EMBLEM S-ICD product families using the new sterilization cycle DEV_PROD55_02 at the Clonmel, Ireland manufacturing facility.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S383	11/13/2018	X - 30-Day Notice	ATTAIN BIPOLAR OTW LEAD, ATTAIN OTW LV LEAD, CONSULTA CRT-P, PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-D, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P, SOLARA BIPOLAR CRT-P, SOLAR QUADRIPOLAR CRT-P, SYNCRA CRT-P AND VIVA CRT-P	MEDTRONIC INC.	Implementation of updated version of Factory Works software (Release 9.5).
P010015/S384	11/19/2018	X - 30-Day Notice	ATTAIN BIPOLAR OTW LV LEAD; CONSULTA CRT-P; PERCEPTA BIPOLAR CRT-P, QUADRIPOLAR CRT-P; SERENA BIPOLAR CRT-P, QUARDRIPOLAR CRT-P; SOLARA BIPOLAR, QUADRIPOLAR CRT-P; VIVA CRT-P	MEDTRONIC INC.	Site change and addition of a new mold press at external supplier FMI, Inc.
P010015/S386	11/28/2018	X - 30-Day Notice	CONSULTA CRT-P, PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P, SOLARA BIPOLAR CRT-P, SOLARA QUADRIPOLAR CRT-P, SYNCRA CRT-P AND VIVA CRT-P	MEDTRONIC INC.	Change to the sub-tier raw material suppliers and process changes for tantalum and niobium pins.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S651	11/13/2018	X - 30-Day Notice	AMPLIA MRI CRT-D, AMPLIA MRI QUAD CRT-D, BRAVA CRT-D, BRAVA QUAD CRT-D, CLARIA MRI CRT-D, CLARIA MRI CRT-D, CLARIA MRI QUAD CRT-D, COMPIA MRI CRT-D, COMPIA MRI QUAD CRT-D, CONSULTA CRT-D, PROTECTA CRT-D, PROTECTA XT CRT-D, VIVA QUAD S CRT-D, VIVA QUAD XT CRT-D, VIVA S CRT-D AND VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of updated version of Factory Works software (Release 9.5).
P010031/S652	11/15/2018	X - 30-Day Notice	AMPLIA MRI CRT-D, QUAD CRT-D; BRAVA CRT-D, QUAD CRT-D; CLARIA MRI CRT-D, QUAD CRT-D; COMPIA MRI CRT-D, QUAD CRT-D; VIVA QUAD S CRT-D, XT CRT-D, S CRT-D, XT CRT-D.	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to the Polymers Automated Welders software used on the connector components.
P010031/S653	11/19/2018	X - 30-Day Notice	AMPLIA MRI CRT-D, QUARD CRT-D; BRAVA CRT-D, QUARD CRT-D; CLARIA MRI CRT-D, QUARD CRT-DCOMPIA MRI CRT-D, QUARD CRT-D; CONSULTA CRT-D; PROTECTA CRT-D, XT CRT-D; VIVA QUARD S CRT-D, QUARD XT CRT-D, S CRT-D, XT CRT-D;	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Site change and addition of a new mold press at external supplier FMI, Inc.

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P010031/S655	11/28/2018	X - 30-Day Notice	AMPLIA MRI CRT-D AMPLIA MRI QUAD CRT-D, BRAVA CRT-D, BRAVA QUAD CRT-D, CLARIA MRI CRT-D, CLARIA MRI QUAD CRT-D, COMPIA MRI CRT-D, COMPIA MRI QUAD CRT-D, CONSULTA CRT-D, PROTECTA CRT-D, PROTECTA XT CRT-D, VIVA QUAD S/XT CRT-D AND VIVA S/XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Change to the sub-tier raw material suppliers and process changes for tantalum and niobium pins.
P010032/S144	11/14/2018	X - 30-Day Notice	PROCLAIM IPG	ST. JUDE MEDICAL	Extending the primer solution mix time for header attach for Proclaim and Infinity IPGs.
P010054/S039	11/06/2018	X - 30-Day Notice	ELECSYS ANTI-HBS	ROCHE DIAGNOSTICS CORP.	Addition of a secondary manufacturer/supplier of a component raw material.
P020025/S116	11/28/2018	X - 30-Day Notice	BLAZER II XP AND BLAZER PRIME XP	BOSTON SCIENTIFIC	Addition of new electrical test equipment for use with Blazer II, Blazer II XP, and Blazer Prime Ablation catheters.
P030005/S178	11/16/2018	X - 30-Day Notice	INVIVE, INTUA, VALITUDE, VALITUDE X4, VISIONIST, VISIONIST X4	GUIDANT CORP.	Addition of alternative equipment to sterilize Accolade, NG3, NG4,and EMBLEM S-ICD product families using the new sterilization cycle DEV_PROD55_02 at the Clonmel, Ireland manufacturing facility.
P030017/S320	11/23/2018	X - 30-Day Notice	PRECISION SPECTRA, PRECISION NOVI, PRECISION MONTAGE, PRECISION MONTAGE MRI AND PRECISION SPECTRA WAVEWRITER SPINAL CORD STIMULATOR (SCS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Add an alternate qualified supplier for the Printed Circuit Board Assembly (PCBA) used in the Programming Wand.
P030017/S321	11/27/2018	X - 30-Day Notice	PRECISION NOVI, MONTAGE, SPECTRA, SPECTRA WAVEWRITER SPINAL CORD STIMULATOR SYSTEM (SCS)	BOSTON SCIENTIFIC CORP.	Relocation of a current component supplier to a new manufacturing site.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030036/S104	11/13/2018	X - 30-Day Notice	ANCHORING SLEEV KIT AND SELECTSECURE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of updated version of Factory Works software (Release 9.5).
P030036/S105	11/19/2018	X - 30-Day Notice	ANCHORING SLEEVE KIT	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Site change and addition of a new mold press at external supplier FMI, Inc.
P030036/S107	11/28/2018	X - 30-Day Notice	SELECTSECURE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Elimination of redundant testing and reduction of select inspection sample sizes in micro extrusion manufacturing.
P030054/S361	11/07/2018	X - 30-Day Notice	QUICKFLEX U, QUARTET	ST. JUDE MEDICAL	Reduce solvents analytical testing at release from a per batch basis to periodic testing.
P030054/S363	11/05/2018	X - 30-Day Notice	PROMOTE+, UNIFY, UNIFY QUADRA, UNIFY ASSURA, QUADRA ASSURA, QUADRA ASSURA (MR CONDITIONAL), QUADRA ASSURA MP (MR CONDITIONAL) AND QUADRA ASSURA MP	ST. JUDE MEDICAL	Add an alternate supplier for the current 1000V diode for high voltage implantable devices.
P040020/S084	11/01/2018	X - 30-Day Notice	ACRYSOF RESTOR INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Implement an alternate mold system for the AcrySof® and AcrySof® ReSTOR® Intraocular Lenses.
P040027/S068	11/20/2018	X - 30-Day Notice	GORE VIATORR TIPS ENDOPROSTHESIS AND GORE VIATORR TIPS ENDOPROSTHESIS WITH CONTROLLED EXPANSION	W. L. GORE & ASSOCIATES, INC.	Implementation of a second sterilization chamber at the contract sterilizer.
P040034/S028	11/28/2018	X - 30-Day Notice	DURASEAL DURAL SEALANT SYSTEM	INTEGRA LIFESCIENCES CORPORATION	Use of an additional freezer for the production of DuraSeal Dural Sealant System.

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P040045/S102	11/29/2018	X - 30-Day Notice	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Modification of a raw material specification for VISTAKON® (senofilcon A) Brand Contact Lenses.
P050042/S036	11/07/2018	X - 30-Day Notice	ARCHITECT ANTI-HCV REGENT KIT (100, 500 TEST)	ABBOTT LABORATORIES INC	Implement mixing and scale-up processes for bulk materials.
P050042/S037	11/09/2018	X - 30-Day Notice	ARCHITECT ANTI-HCV (LN 1L79)	ABBOTT LABORATORIES INC	Modification of environmental monitoring and bioburden testing at a manufacturing facility.
P050051/S034	11/14/2018	X - 30-Day Notice	ARCHITECT AUSAB (LN 1L82)	ABBOTT LABORATORIES INC	Modification of environmental monitoring and bioburden testing at a manufacturing facility.
P050053/S042	11/09/2018	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC INC.	Change the AQL levels.
P060035/S027	11/20/2018	X - 30-Day Notice	ARCHITECT CORE-M (LN 6L23), CALIBRATORS, CONTROLS AND REAGENT KIT	ABBOTT LABORATORIES	Change in-process and incoming raw material QC testing specifications at a manufacturing facility.
P060039/S091	11/13/2018	X - 30-Day Notice	ATTAIN STARFIX LEAD	MEDTRONIC INC.	Implementation of updated version of Factory Works software (Release 9.5).
P060039/S092	11/19/2018	X - 30-Day Notice	ATTAIN STARFIX LEAD	MEDTRONIC INC.	Site change and addition of a new mold press at external supplier FMI, Inc.
P080006/S127	11/13/2018	X - 30-Day Notice	ATTAIN ABILITY LEAD AND ATTAIN PERFORMA LEAD	MEDTRONIC INC.	Implementation of updated version of Factory Works software (Release 9.5).
P080006/S128	11/19/2018	X - 30-Day Notice	ATTAIN ABILITY LEAD, PERFORMA LEAD	MEDTRONIC INC.	Site change and addition of a new mold press at external supplier FMI, Inc.
P080011/S083	11/16/2018	X - 30-Day Notice	BIOFINITY SPHERE	COOPERVISION MANUFACTURING, LTD.	Addition of the Biofinity Line 20 Back End Platform for use in the manufacture of Biofinity sphere (comfilcon A) soft contact lenses.
P080011/S084	11/30/2018	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION MANUFACTURING, LTD.	Introduction and validation of a new labeling line.

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P080013/S016	11/28/2018	X - 30-Day Notice	DURASEAL EXACT SPINE SEALANT SYSTEM	INTEGRA LIFESCIENCES CORPORATION	Use of an additional freezer for the production of DuraSeal Dural Sealant System.
P080014/S024	11/15/2018	X - 30-Day Notice	CERVISTA HPV HR ASSAY	HOLOGIC, INC.	Changes to manufacturing sites or vendors of critical raw materials.
P080015/S016	11/15/2018	X - 30-Day Notice	CERVISTA HPV 16/18 ASSAY	HOLOGIC, INC.	Changes to manufacturing sites or vendors of critical raw materials.
P080023/S030	11/09/2018	X - 30-Day Notice	ARCHITECT CORE (LN 6L22)	ABBOTT LABORATORIES	Modification of environmental monitoring and bioburden testing at a manufacturing facility.
P080025/S174	11/13/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS BOWEL)	MEDTRONIC NEUROMODULATION	Update to the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.5.
P080025/S175	11/30/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS BOWEL)	MEDTRONIC NEUROMODULATION	Update to the external supplier site change and external supplier equipment change in the manufacturing of a critical component.
P090013/S291	11/13/2018	X - 30-Day Notice	CAPSUREFIX MRI LEAD	MEDTRONIC, INC	Implementation of updated version of Factory Works software (Release 9.5).
P090013/S292	11/19/2018	X - 30-Day Notice	CAPSUREFIX MRI LEAD	MEDTRONIC, INC	Site change and addition of a new mold press at external supplier FMI, Inc.
P100020/S039	11/23/2018	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Change in formulation of a QC testing reagent of the critical kit subcomponent.
P100022/S031	11/08/2018	X - 30-Day Notice	ZILVER PTX DRUG-ELUTING PERIPHERAL STENT	COOK MEDICAL INCORPORATED	Extension to the raw material retest period
P100026/S061	11/29/2018	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Modify the Automatic Test Equipment (ATE) database and software to improve yield of components of the RNS® Neurostimulator (model RNS-320).
P100029/S037	11/14/2018	X - 30-Day Notice	TRIFECTA VALVE WITH GLIDE TECHNOLOGY (TRIFECTA GT) TRIFECTA VALVE.	ST. JUDE MEDICAL, INC.	Change to the harvest procedure for bovine and porcine pericardial tissue.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100031/S025	11/06/2018	X - 30-Day Notice	ELECSYS ANTI-HBC II	ROCHE DIAGNOSTICS CORP.	Addition of a secondary manufacturer/supplier of a component raw material.
P100032/S019	11/06/2018	X - 30-Day Notice	ELECSYS ANTI-HBC II	ROCHE DIAGNOSTICS CORP.	Addition of a secondary manufacturer/supplier of a component raw material.
P100045/S033	11/06/2018	X - 30-Day Notice	CARDIOMEMS HF SYSTEM	ST. JUDE MEDICAL	Retrospective approval to add an alternate supplier for a capacitor which is a component installed within the HF Electronics systems.
P100049/S025	11/09/2018	X - 30-Day Notice	LINX REFLUX MANAGEMENT SYSTEM	TORAX MEDICAL	Adding a step to the incoming inspection process for the washers and male bead cases of the LINX Reflux Management System.
P110004/S031	11/16/2018	X - 30-Day Notice	NIRXCELL COCR CORONARY STENT ON RX SYSTEM	MEDINOL LTD.	Addition of a semi-automatic flare machine for manufacturing the delivery system.
P110019/S103	11/20/2018	X - 30-Day Notice	XIENCE SIERRA RX EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Change to the split mode fixture.
P110022/S026	11/06/2018	X - 30-Day Notice	ELECSYS ANTI-HBC IGM	ROCHE DIAGNOSTICS CORP.	Addition of a secondary manufacturer/supplier of a component raw material.
P110025/S022	11/06/2018	X - 30-Day Notice	ELECSYS ANTI-HBC IGM	ROCHE DIAGNOSTICS CORP.	Addition of a secondary manufacturer/supplier of a component raw material.
P110029/S028	11/14/2018	X - 30-Day Notice	ARCHITECT HBSAG QUALITATIVE (LN 4P53) AND HBSAG QUALITATIVE CONFIRMATORY (LN 4P54)	ABBOTT LABORATORIES	Modification of environmental monitoring and bioburden testing at a manufacturing facility.
P110031/S023	11/06/2018	X - 30-Day Notice	ELECSYS ANTI-HBC IGM	ROCHE DIAGNOSTICS CORP.	Addition of a secondary manufacturer/supplier of a component raw material.
P110035/S048	11/01/2018	X - 30-Day Notice	EPIC VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of an alternate Visicon system for stent inspection.
P110038/S020	11/08/2018	X - 30-Day Notice	RELAY THORACIC STENT-GRAFT WITH PLUS DELIVERY SYSTEM	BOLTON MEDICAL, INC.	Changes to the manual sewing process for the delivery system inner sheath.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110042/S116	11/16/2018	X - 30-Day Notice	EMBLEM, EMBLEM MRI	BOSTON SCIENTIFIC CORPORATION	Addition of alternative equipment to sterilize Accolade, NG3, NG4,and EMBLEM S-ICD product families using the new sterilization cycle DEV_PROD55_02 at the Clonmel, Ireland manufacturing facility.
P110042/S118	11/29/2018	X - 30-Day Notice	EMBLEM S-ICD PG MODELS A209 AND A219	BOSTON SCIENTIFIC CORPORATION	Add AT&S Korea as a second supplier of the dump resistor component.
P120010/S121	11/02/2018	X - 30-Day Notice	MINIMED 530G INSULIN PUMP	MEDTRONIC INC.	Implementation of a manufacturing aid in assembly of the Paradigm family of insulin pumps. The Paradigm pumps are components of the MiniMed 530G System, Paradigm REAL-Time System, and Paradigm REAL-Time Revel System.
P120010/S122	11/14/2018	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Manufacturing facility move at one of Medtronics tier one supplier for the manual needle-hub assembly and one-press serter base component. The one-press serter is a component of the Enlite Sensor and Guardian Sensor (3). The needle-hub assembly component is used in the Medtronic Enlite Sensor and the Guardian Sensor (3). The Enlite Sensor is a component of the Medtronic MiniMed 530G, 630G with SmartGuard, Paradigm Real-Time Revel System and iPro2 Continuous Glucose Monitoring Systems and Guardian Sensor (3) are components of the Medtronic MiniMed 670G and MiniMed 630G Continuous Glucose Monitoring Systems
P120010/S123	11/30/2018	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	New glucose analyzers to be used for in-process testing and lot release activities for the Enlite and Guardian Sensor 3 continuous glucose monitoring sensors. These sensors are components of the MiniMed Paradigm Real-Time Revel, iPro2, 530G, 630G, 670G, and Guardian Connect systems.
P120010/S125	11/30/2018	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Approval for the use of the barcode labels for the material identification process for the Enlite Sensor components/assembly at Medtronic Puerto Rico Operations Company (MPROC) for the following systems: MiniMed 530G System, MiniMed 630G System with SmartGuard, iPro2 CGM System with Enlite Sensor, and Paradigm Real-Time Revel System.
P120017/S015	11/13/2018	X - 30-Day Notice	MYOCARDIAL PACING LEAD	MEDTRONIC INC.	Implementation of updated version of Factory Works software (Release 9.5).
P120017/S016	11/19/2018	X - 30-Day Notice	MYOCARDIAL PACING LEAD	MEDTRONIC INC.	Site change and addition of a new mold press at external supplier FMI, Inc.
P130008/S036	11/19/2018	X - 30-Day Notice	INSPIRE MODEL 4323 SENSING LEAD	INSPIRE MEDICAL SYSTEMS	Additional laser welder for use in the production of the pressure sensor used in the Model 4323 lead.
P130009/S094	11/19/2018	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Utilization of a portion of a new controlled environment as an additional storage area for processed pericardial tissue leaflets.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130015/S016	11/06/2018	X - 30-Day Notice	ELECSYS HBEAG	ROCHE DIAGNOSTICS OPERATIONS INC	Addition of a secondary manufacturer/supplier of a component raw material.
P130021/S055	11/09/2018	X - 30-Day Notice	COREVALVE EVOLUT R, PRO BIOPROSTHESIS	MEDTRONIC COREVALVE LLC	Modification to the leaflet thickness mapping process and the leaflet and skirts mapping templates for the Evolut R and Evolut PRO Transcatheter Aortic Valves.
P140002/S018	11/09/2018	X - 30-Day Notice	MISAGO RX SELF-EXPANDING PERIPHERAL STENT	TERUMO MEDICAL CORPORATION	Minor changes to the packaging process for the sterile barrier system of the MISAGO RX Self-expanding Peripheral Stent ("MISAGO") System.
P140003/S042	11/30/2018	X - 30-Day Notice	IMPELLA CP WITH SMARTASSIST	ABIOMED, INC.	Addition of a second supplier for the patient cable of the Impella CP with SmartAssist System.
P140003/S043	11/30/2018	X - 30-Day Notice	IMPELLA CP WITH SMARTASSIST	ABIOMED, INC.	Upgrade to the laser welding workstation and associated Computer Numeric Control (CNC) program for the manufacture of the Pump Housing Assembly of the Impella CP with SmartAssist System.
P140009/S042	11/09/2018	X - 30-Day Notice	INFINITY IPG	ST. JUDE MEDICAL NEUROMODULATION	Extending the primer solution mix time for header attach for Proclaim and Infinity IPGs.
P140021/S015	11/06/2018	X - 30-Day Notice	ELECSYS ANTI-HCV II (100/200 TESTS)	ROCHE DIAGNOSTICS OPERATIONS INC	Addition of a secondary manufacturer/supplier of a component raw material.
P140029/S015	11/19/2018	X - 30-Day Notice	RESTYLANE REFYNE AND RESTYLANE DEFYNE	Q-MED AB	Change in the manufacturing procedure/introduction of an In-Process Control (IPC) used in the bulk process for Restylane Refyne and Restylane Defyne.
P140031/S077	11/19/2018	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Utilization of a portion of a new controlled environment as an additional storage area for processed pericardial tissue leaflets.
P140031/S078	11/13/2018	X - 30-Day Notice	EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC.	Change to the incoming inspection method and sampling plan for the Edwards Commander Balloon Shaft.
P140032/S021	11/13/2018	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Update to the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.5.
P140033/S039	11/07/2018	X - 30-Day Notice	TENDRIL MRI	ST. JUDE MEDICAL, INC.	Reduce solvents analytical testing at release from a per batch basis to periodic testing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150001/S053	11/14/2018	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED	Manufacturing facility move at one of Medtronics tier one supplier for the manual needle-hub assembly and one-press serter base component. The one-press serter is a component of the Enlite Sensor and Guardian Sensor (3). The needle-hub assembly component is used in the Medtronic Enlite Sensor and the Guardian Sensor (3). The Enlite Sensor is a component of the Medtronic MiniMed 530G, 630G with SmartGuard, Paradigm Real-Time Revel System and iPro2 Continuous Glucose Monitoring Systems and Guardian Sensor (3) are components of the Medtronic MiniMed 670G and MiniMed 630G Continuous Glucose Monitoring Systems.
P150001/S054	11/30/2018	X - 30-Day Notice	MINIMED 630G SYSTEM	MEDTRONIC MINIMED	New glucose analyzers to be used for in-process testing and lot release activities for the Enlite and Guardian Sensor 3 continuous glucose monitoring sensors. These sensors are components of the MiniMed Paradigm Real-Time Revel, iPro2, 530G, 630G, 670G, and Guardian Connect systems.
P150001/S055	11/30/2018	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED	Use of the barcode labels for the material identification process for the Enlite Sensor components/assembly at Medtronic Puerto Rico Operations Company (MPROC) for the following systems: MiniMed 530G System, MiniMed 630G System with SmartGuard, iPro2 CGM System with Enlite Sensor, and Paradigm Real-Time Revel System
P150012/S065	11/09/2018	X - 30-Day Notice	INGEVITY LEADS	BOSTONSCIENTIFIC	Add a redundant downstream human visual inspection as well as clarifications to the welding work instruction.
P150012/S066	11/16/2018	X - 30-Day Notice	INGENIO MRI, VITALIO MRI, FORMIO MRI, ESSENTIO MRI, PROPONENT MRI, ACCOLADE MRI	BOSTONSCIENTIFIC	Addition of alternative equipment to sterilize Accolade, NG3, NG4,and EMBLEM S-ICD product families using the new sterilization cycle DEV_PROD55_02 at the Clonmel, Ireland manufacturing facility.
P150019/S047	11/02/2018	X - 30-Day Notice	PARADIGM REAL-TIME REVEL INSULIN PUMP	MEDTRONIC MINIMED	Implementation of a manufacturing aid in assembly of the Paradigm family of insulin pumps. The Paradigm pumps are components of the MiniMed 530G System, Paradigm REAL-Time System, and Paradigm REAL-Time Revel System.
P150019/S048	11/14/2018	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Manufacturing facility move at one of Medtronics tier one supplier for the manual needle-hub assembly and one-press serter base component. The one-press serter is a component of the Enlite Sensor and Guardian Sensor (3). The needle-hub assembly component is used in the Medtronic Enlite Sensor and the Guardian Sensor (3). The Enlite Sensor is a component of the Medtronic MiniMed 530G, 630G with SmartGuard, Paradigm Real-Time Revel System and iPro2 Continuous Glucose Monitoring Systems and Guardian Sensor (3) are components of the Medtronic MiniMed 670G and MiniMed 630G Continuous Glucose Monitoring Systems
P150019/S049	11/30/2018	X - 30-Day Notice	MINIMED PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	New glucose analyzers to be used for in-process testing and lot release activities for the Enlite and Guardian Sensor 3 continuous glucose monitoring sensors. These sensors are components of the MiniMed Paradigm Real-Time Revel, iPro2, 530G, 630G, 670G, and Guardian Connect systems.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150019/S051	11/30/2018	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Use of the barcode labels for the material identification process for the Enlite Sensor components/assembly at Medtronic Puerto Rico Operations Company (MPROC) for the following systems: MiniMed 530G System, MiniMed 630G System with SmartGuard, iPro2 CGM System with Enlite Sensor, and Paradigm Real-Time Revel System.
P150029/S022	11/14/2018	X - 30-Day Notice	IPRO2 CGM SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Manufacturing facility move at one of Medtronics tier one supplier for the manual needle-hub assembly and one-press serter base component. The one-press serter is a component of the Enlite Sensor and Guardian Sensor (3). The needle-hub assembly component is used in the Medtronic Enlite Sensor and the Guardian Sensor (3). The Enlite Sensor is a component of the Medtronic MiniMed 530G, 630G with SmartGuard, Paradigm Real-Time Revel System and iPro2 Continuous Glucose Monitoring Systems and Guardian Sensor (3) are components of the Medtronic MiniMed 670G and MiniMed 630G Continuous Glucose Monitoring Systems.
P150029/S023	11/30/2018	X - 30-Day Notice	MINIMED IPRO2 CGM SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	New glucose analyzers to be used for in-process testing and lot release activities for the Enlite and Guardian Sensor 3 continuous glucose monitoring sensors. These sensors are components of the MiniMed Paradigm Real-Time Revel, iPro2, 530G, 630G, 670G, and Guardian Connect systems.
P150029/S024	11/30/2018	X - 30-Day Notice	IPRO2 CGM SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Use of the barcode labels for the material identification process for the Enlite Sensor components/assembly at Medtronic Puerto Rico Operations Company (MPROC) for the following systems: MiniMed 530G System, MiniMed 630G System with SmartGuard, iPro2 CGM System with Enlite Sensor, and Paradigm Real-Time Revel System.
P150031/S010	11/26/2018	X - 30-Day Notice	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Add an additional manufacturing site for current supplier FMI, Inc., (FMI).
P150033/S045	11/13/2018	X - 30-Day Notice	MICRA TPS	MEDTRONIC INC.	Implementation of updated version of Factory Works software (Release 9.5).
P150033/S046	11/19/2018	X - 30-Day Notice	MICRA TPS	MEDTRONIC INC.	Site change and addition of a new mold press at external supplier FMI, Inc.
P150033/S047	11/29/2018	X - 30-Day Notice	MICRA TRANSCATHETER PACING SYSTEM	MEDTRONIC INC.	Changes to sampling requirements for Bacterial Endotoxin Testing (BET).
P150036/S033	11/20/2018	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Removal of the visual inspection for ¿Open Leaflet¿ in air for surgical pericardial heart valves.
P150036/S034	11/19/2018	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Utilization of a portion of a new controlled environment as an additional storage area for processed pericardial tissue leaflets.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150048/S027	11/20/2018	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS AND EDWARDS INSPIRIS RESILIA AORTIC VALVE	EDWARDS LIFESCIENCES, LLC.	Removal of the visual inspection for ¿Open Leaflet¿ in air for surgical pericardial heart valves.
P150048/S028	11/19/2018	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS AND EDWARDS INSPIRIS RESILIA AORTIC VALVE	EDWARDS LIFESCIENCES, LLC.	Utilization of a portion of a new controlled environment as an additional storage area for processed pericardial tissue leaflets.
P160001/S024	11/07/2018	X - 30-Day Notice	OBALON TOUCH DISPENSER	OBALON THERAPEUTICS, INC.	Modifications to the manufacturing test procedure for release of the Touch Dispenser.
P160001/S025	11/07/2018	X - 30-Day Notice	OBALON TOUCH DISPENSER	OBALON THERAPEUTICS, INC.	Modifications to the Touch Dispenser pressure regulator conditioning process during manufacturing.
P160001/S026	11/07/2018	X - 30-Day Notice	OBALON TOUCH DISPENSER	OBALON THERAPEUTICS, INC.	Modification of inspection steps and manufacturing process for a device preparatory equipment.
P160001/S028	11/20/2018	X - 30-Day Notice	OBALON TOUCH DISPENSER	OBALON THERAPEUTICS, INC.	Addition of a memory check to the programming manufacturing process for the Touch Dispenser.
P160004/S022	11/26/2018	X - 30-Day Notice	GORE TIGRIS VASCULAR STENT	W. L. GORE & ASSOCIATES, INC.	Changes to the sampling plan and process monitor for several acceptance test attributes.
P160007/S010	11/14/2018	X - 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Manufacturing facility move at one of Medtronics tier one supplier for the manual needle-hub assembly and one-press serter base component. The one-press serter is a component of the Enlite Sensor and Guardian Sensor (3). The needle-hub assembly component is used in the Medtronic Enlite Sensor and the Guardian Sensor (3). The Enlite Sensor is a component of the Medtronic MiniMed 530G, 630G with SmartGuard, Paradigm Real-Time Revel System and iPro2 Continuous Glucose Monitoring Systems and Guardian Sensor (3) are components of the Medtronic MiniMed 670G and MiniMed 630G Continuous Glucose Monitoring Systems.
P160007/S011	11/30/2018	X - 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	New glucose analyzers to be used for in-process testing and lot release activities for the Enlite and Guardian Sensor 3 continuous glucose monitoring sensors. These sensors are components of the MiniMed Paradigm Real-Time Revel, iPro2, 530G, 630G, 670G, and Guardian Connect systems.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160017/S052	11/14/2018	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Manufacturing facility move at one of Medtronics tier one supplier for the manual needle-hub assembly and one-press serter base component. The one-press serter is a component of the Enlite Sensor and Guardian Sensor (3). The needle-hub assembly component is used in the Medtronic Enlite Sensor and the Guardian Sensor (3). The Enlite Sensor is a component of the Medtronic MiniMed 530G, 630G with SmartGuard, Paradigm Real-Time Revel System and iPro2 Continuous Glucose Monitoring Systems and Guardian Sensor (3) are components of the Medtronic MiniMed 670G and MiniMed 630G Continuous Glucose Monitoring Systems
P160017/S053	11/30/2018	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	New glucose analyzers to be used for in-process testing and lot release activities for the Enlite and Guardian Sensor 3 continuous glucose monitoring sensors. These sensors are components of the MiniMed Paradigm Real-Time Revel, iPro2, 530G, 630G, 670G, and Guardian Connect systems.
P160019/S008	11/06/2018	X - 30-Day Notice	ELECSYS HBSAG II (100/200 TESTS)	ROCHE DIAGNOSTICS , INC.	Addition of a secondary manufacturer/supplier of a component raw material.
P160045/S011	11/16/2018	X - 30-Day Notice	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Change of location for the manufacturing of a subcomponent.
P160045/S012	11/29/2018	X - 30-Day Notice	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Move the storage location of finished component materials.
P160054/S014	11/09/2018	X - 30-Day Notice	THORATEC HEARTMATE 3 LEFT VENTRICULAR ASSIST SYSTEM (LVAS)	THORATEC CORPORATION	Addition of a new laser welding system.
P170008/S010	11/16/2018	X - 30-Day Notice	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Addition of a semi-automatic flare machine for manufacturing the delivery system.
P170012/S012	11/29/2018	X - 30-Day Notice	HEMOBLAST BELLOWS	BIOM'UP SA	1. Change of agitation schedule for first delipidation/dehydration acetone soak in the production of The Basic Fibrous Collagen; and 2. Addition of a stirrer to be employed in the Pre-Grinding Baths in the production of The Basic Fibrous Collagen.

Total: 182