PMA Monthly approvals from 6/1/2018 to 6/30/2018

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160048	06/21/2018	PMAO - PMA Origi	EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM	SENSEONICS, INCORPORATED	Approval for The Eversense CGM System. The device is indicated for continually measuring glucose levels in adults (18 years and older) with diabetes for up to 90 days. The system is intended to: 1) Provide real-time glucose readings; 2) Provide glucose trend information; and 3) Provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia). The system is a prescription device. Historical data from the system can be interpreted to aid in providing therapy adjustments. These adjustments should be based on patterns seen over time. The system is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home blood glucose monitoring devices.
P170043	06/21/2018	PMAO - PMA Origi	ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM (MODEL G2-M-IS)	GLAUKOS CORPORATION	Approval for the iStent inject® Trabecular Micro-Bypass System (Model G2-M-IS). This device is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma.
P180002	06/29/2018	PMAO - PMA Origi	ZEPHYR ENDOBRONCHIAL VALVE SYSTEM	PULMONX CORPORATION	Approval of the Pulmonx Zephyr® Endobronchial Valve System. The device is an implantable bronchial valve indicated for the bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180008	06/21/2018	PMAO - PMA Origi	T:SLIM X2 INSULIN PUMP WITH BASAL-IQ TECHNOLOGY	TANDEM DIABETES CARE, INC.	Approval for the use of the t:slim X2 Insulin Pump with Basal-IQ Technology. This device is indicated as follows: The t:slim X2 Insulin Pump with Basal-IQ Technology (the System) consists of the t:slim X2 Insulin Pump which contains the Basal-IQ technology, and a continuous glucose monitor (CGM). Compatible CGMs include the Dexcom G5 Mobile CGM and integrated continuous glucose monitors (iCGMs) that are listed in the labeling for this device. The t:slim X2 Insulin Pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The t:slim X2 Insulin Pump can be used solely for continuous insulin delivery and as part of the t:slim X2 Insulin Pump with Basal-IQ Technology System. When the System is used with the Dexcom G5 Mobile CGM or a compatible iCGM, the Basal-IQ Technology can be used to suspend insulin delivery based on CGM sensor readings. The Dexcom G5 Mobile CGM Continuous Glucose Monitoring System (Dexcom G5) is indicated for the management of diabetes in persons age 2 years and older. The Dexcom G5 is designed to replace fingerstick blood glucose testing for diabetes treatment decisions. Interpretation of the System results should be based on the trends and patterns seen with several sequential readings over time. The Dexcom G5 also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. The Dexcom G5 is intended for single patient use and requires a prescription. The System is indicated for use in individuals 6 years of age and greater. The System is intended for single patient use and requires a prescription. The System is indicated for use with NovoLog or Humalog U-100 insulin.

Total: 4

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P780007/S060	06/01/2018	R - Real-Time Proc	BIOMEDICS38 (POLYMACON) SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION, INC.	Approval for 1) Removal of assay (% NaCl) test requirement from the in-process packaging solution specification; and 2) Addition of osmolality specification to the post-autoclave packaging solution specification.
P810006/S079	06/28/2018	Y - 135 Review Tra	COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC SPONGE AND COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC AGENT MICROFIBRILLAR FORM (INSTAT)	INTEGRA LIFESCIENCES CORPORATION	Approval for verification of a temporary ethylene oxide sterilization cycle for the collagen products manufactured and released from the Integra Neurosciences, Anasco, Puerto Rico facility.
P830055/S197	06/22/2018	R - Real-Time Proc	LCS TOTAL KNEE SYSTEM: TRUMATCH PERSONALIZED SOLUTIONS	DEPUY, INC.	Approval for the addition of TRUMATCH instrumentation which incorporates software changes within the TRUMATCH design process.
P830055/S198	06/27/2018	R - Real-Time Proc	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for adding the ATTUNE Cemented Tibial Bases, Rotating Platform (RP) as an extension to the ATTUNE Knee System, and to expand compatibility of the ATTUNE Cementless PS Femoral device to both the ATTUNE Cemented Tibial Base, RP and the ATTUNE Cementless RP Tibial Base.
P830055/S202	06/25/2018	S - Special CBE	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Approval of an additional manufacturing inspection step
P830061/S157	06/28/2018	N - Normal 180 Day	CAPSURE SENSE MRI SURESCAN LEAD AND CAPSURE SENSE MRI SURESCAN LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for an update to the indications for use to include pacing at the bundle of His. The device, as modified, will be marketed under the trade name SelectSecure MRI SureScan Lead Model 3830 and is indicated for: The Model 3830 lead is intended for pacing and sensing in the atrium or right ventricle. It is also intended for pacing and sensing at the bundle of His as an alternative to right ventricular pacing in a single or dual chamber pacing system.
P840001/S390	06/02/2018	Y - 135 Review Tra	MASTER RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEM AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Approval for adding an alternate supplier to manufacture the coil components used in the implanted leads of the Deep Brain Stimulator (DBS), Spinal Cord Stimulation (SCS), and Sacral Nerve Stimulation (SNS) devices.
P850010/S078	06/28/2018	Y - 135 Review Tra	HELISTAT ABSORBABLE COLLAGEN HEMOSTATIC AGENT AND HELITENE ABSORBABLE COLLAGEN HEMOSTATIC AGENT FIBRILLAR FORM	INTEGRA LIFESCIENCES CORPORATION	Approval for verification of a temporary ethylene oxide sterilization cycle for the collagen products manufactured and released from the Integra Neurosciences, Anasco, Puerto Rico facility.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860004/S300	06/13/2018	R - Real-Time Proc	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	Approval for software changes to Medtronics Model A810 SynchroMed II Clinician Programmer Application including the Advanced Prime and Single Bolus feature and resolving anomalies.
P860057/S172	06/13/2018	Y - 135 Review Tra	CARPENTIER-EDWARDS PERIMOUNT PERICARDIAL AORTIC BIOPROSTHESIS / WITH THERMALFIX TISSUE PROCESS/ RSR PERICARDIAL AORTIC BIOPROSTHESIS/ WITH TERMALFIX TISSUE PROCESS/ MEGNA PERICARDIAL AORTIC BIOPROSTHESIS / WITH THERMAFIX TISSUE PROCESS/ MEGNA EASE PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS. PERIMOUNT PLUS PERICARDIAL MITRAL BIOPROSTHESIS / WITH TERMAFIX TISSUE PROCESS/ MAGNA MITRAL EASE PERICARDIAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS	EDWARDS LIFESCIENCES, LLC.	Approval for a change from a manual to semi-automated process for ironing polyethylene terephthalate cloth used on pericardial valves.
P890023/S032	06/27/2018	O - Normal 180 Day	BIOMEDICS TORIC/ OCUFILCON D SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	THE COOPER COMPANIES	Approval for a manufacturing site located at CooperVision, Inc., 711 North Road, Scottsville, New York.
P910001/S097	06/29/2018	R - Real-Time Proc	CVX-300-P EXCIMER LASER SYSTEM	SPECTRANETICS CORP.	Approval for a design change to the Thyratron driver printed circuit assembly.
P910056/S027	06/08/2018	P - Panel Track	ENVISTA ONE-PIECE HYDROPHOBIC ACRYLIC TORIC INTRAOCULAR LENS (MODEL MX60T)	BAUSCH & LOMB, INC.	Approval for the enVista One-Piece Hydrophobic Acrylic Toric Intraocular Lens (Model MX60T). The device is indicated for primary implantation in the capsular bag of the eye in adult patients for visual correction of aphakia and corneal astigmatism following removal of a cataractous lens for improved uncorrected distance vision.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P920015/S213	06/28/2018	N - Normal 180 Day	IS-1 PLUG, SPRINT QUATTRO SECURE S MRI SURESCAN LEAD, SPRINT QUATTRO SECURE MRI SURESCAN AND SPRINT QUATTRO MRI SURESCAN	MEDTRONIC INC.	Approval for an update to the indications for use to include pacing at the bundle of His. The device, as modified, will be marketed under the trade name SelectSecure MRI SureScan Lead Model 3830 and is indicated for: The Model 3830 lead is intended for pacing and sensing in the atrium or right ventricle. It is also intended for pacing and sensing at the bundle of His as an alternative to right ventricular pacing in a single or dual chamber pacing system.
P930016/S053	06/15/2018	N - Normal 180 Day	IDESIGNREFRACTIVE STUDIO, STAR EXCIMER LASER SYSTEM	AMO MANUFACTURING USA, LLC	Approval to upgrade the software and hardware to its combined corneal topographer and wavefront aberrometry device, the iDesign Advanced WaveScan Studio System, and expansion of the indications for use of the iDesign system, in combination with the STAR S4 IR Excimer Laser Systems, to include the monovision treatment of myopic presbyopes. The device, as modified, will be marketed under the trade name iDesign Refractive Studio, STAR Excimer Laser System and is indicated for wavefront-guided laser assisted in situ keratomileusis (LASIK) to achieve monovision by the targeted retention of myopia (-1.25 to -2.00 D) in the non-dominant eye of presbyopic myopes: 1) 40 years or older who may benefit from increased spectacle independence across a range of distances with useful near vision,; 2) with myopic astigmatism up to -6.00 D spherical equivalent as measured by iDESIGN® Refractive Studio, with cylinder up to -3.00 D, and a minimum pre-operative myopia in their non-dominant eye at least as great as their targeted myopia; 3) with an agreement between manifest refraction (adjusted for optical infinity) and iDESIGN® Refractive Studio refraction as follows: a. Spherical Equivalent: Magnitude of the difference is less than 0.625 D. b. Cylinder: Magnitude of the difference is less than or equal to 0.5 D. c. Cylinder Axis: If either the manifest cylinder entered into the iDESIGN® Refractive Studio or the iDESIGN® Refractive Studio cylinder selected for treatment is less than 0.5 D, there is no requirement for axis tolerance. When both cylinders have a magnitude of at least 0.5 D, the axis tolerance is linearly reduced from 15>= (0.5 D) to 7.5 >= (7.0 D or greater) based on the average magnitude of both cylinders; 4) with documented evidence of a change in manifest refraction of no more than +0.5 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination; and 5) with a successful preoperative trial of monovision or history of monovision experience.
P930039/S186	06/28/2018	N - Normal 180 Day	CAPSUREFIX NOVUS MRI SURESCAN LEAD AND CAPSUREFIX NOVUS MRI SURESCAN LEAD	MEDTRONIC, INC.	Approval for an update to the indications for use to include pacing at the bundle of His. The device, as modified, will be marketed under the trade name SelectSecure MRI SureScan Lead Model 3830 and is indicated for: The Model 3830 lead is intended for pacing and sensing in the atrium or right ventricle. It is also intended for pacing and sensing at the bundle of His as an alternative to right ventricular pacing in a single or dual chamber pacing system.
P950008/S014	06/07/2018	S - Special CBE	SILIKON 1000 ENDOTAMPONADE	ALCON	Approval for proposed labeling modifications.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P950022/S119	06/27/2018	R - Real-Time Proc	DURATA AND OPTISURE LEADS	ST. JUDE MEDICAL, INC.	Approval for a shelf life extension for the Durata (Models 7120Q, 7121Q, 7122Q) and Optisure (Models LDA210Q, LDA220Q, LDA230Q) leads from 12 months to 36 months.
P950037/S187	06/19/2018	Y - 135 Review Tra	EVIA DR,DR-T,SR,SR-T; ENTOVIS DR,DR-T,SR-T; ESTELLA DR,DR-T,SR,SR-T; EFFECTA D,S; EDORA 8 DR, 8 SR; ETRINSA 8 DR-T,SR-T, 6 DR, 6 SR, 6 SR-T; EPYRA 8 DR-T, 8 SR-T, 6 DR-T, 6 SR-T; ELUNA 8 DR-T, 8 DR, 8 SR, 8 SR-T, EDORA 8 DR-T, 8 SR-T, ENITRA 8 DR-T, 6 DR-T, 8 SR-T, 6 SR: ENTICOS 4 DR, 8 SR-T, 4 S; EVITY 6 DR-T, 6 SR-T, ENITRA 6 DR, 6 SR-T, ENTICOS 8 DR-T, 4 D, 4 SR, EVITY 8 DR-T, 8 SR-T	BIOTRONIK, INC.	Approval for changes to the visual inspection of embedded particulate matter within the header matrix of ICDs and pacemakers.
P960009/S309	06/02/2018	Y - 135 Review Tra	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Approval for adding an alternate supplier to manufacture the coil components used in the implanted leads of the Deep Brain Stimulator (DBS), Spinal Cord Stimulation (SCS), and Sacral Nerve Stimulation (SNS) devices.
P960042/S062	06/28/2018	S - Special CBE	SLS II/GLIDELIGHT CATHETERS	SPECTRANETICS CORP.	Approval for an additional visual inspection on the marker band on the distal tip of the SLS GlideLight laser lead extraction catheters.
P970004/S265	06/02/2018	Y - 135 Review Tra	INTERSTIM, THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS URINARY LEAD)	MEDTRONIC NEUROMODULATION	Approval for adding an alternate supplier to manufacture the coil components used in the implanted leads of the Deep Brain Stimulator (DBS), Spinal Cord Stimulation (SCS), and Sacral Nerve Stimulation (SNS) devices.
P970018/S036	06/21/2018	O - Normal 180 Day	BD PREPSTAIN SYSTEM	BD DIAGNOSTIC SYSTEMS	Approval of manufacturing site change.
P970051/S173	06/13/2018	N - Normal 180 Day	NUCLEUS COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for the modifications to the firmware and software of the Nucleus 7 system as well as a modification to the Custom Sound EP used with the Nucleus 6 system.
P980016/S663	06/05/2018	R - Real-Time Proc	EVERA MRI DF-1, EVERA MRI ICD'S; MIRRO MIR DR, MIRRO MIR VR ICD'S; PRIMO MRI DR, PRIMO MRI VR ICD'S; VISIA AF MRI DF1, VISIA AF MRI VR, AND VISIA AF VR ICD'S	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for incorporating two new alternate integrated circuits into the circuitry of select Medtronic ICD and CRT-D devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S668	06/28/2018	N - Normal 180 Day	EVERA MRIS XT DR/XT VR/ S DR/S VR SURESCAN, VISIA AF MRI XT AND S VR SURESCAN, PRIMO MRI SURESCAN AND MIRRO MRI SURESCAN	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for an update to the indications for use to include pacing at the bundle of His. The device, as modified, will be marketed under the trade name SelectSecure MRI SureScan Lead Model 3830 and is indicated for: The Model 3830 lead is intended for pacing and sensing in the atrium or right ventricle. It is also intended for pacing and sensing at the bundle of His as an alternative to right ventricular pacing in a single or dual chamber pacing system.
P980035/S549	06/28/2018	N - Normal 180 Day	ADVISA MRI DR SURESCAN, ADVISA MRI SR SURESCAN, IMPLANTABLE PULSE GENERATORS (IPGS), ATTESTA DR MRI SURESCAN (ATDR01), ATTESTA L DR MRI SURESCAN (ATDRL1), ATTESTA S DR MRI SURESCAN (ATDRS1), ATTESTA SR MRI SURESCAN (ATSR01), SPHERA DR MRI SURESCAN (SPDR01), SPHERA L DR MRI SURESCAN (SPDRL1), SHPERA SR SURESCAN (SPSR01) IMPLANTABLE PULSE GENERATOR, ASTRA XT DR MRI IPG (X1DRO1), ASTRA S DR MRI IPG (X3DR01), ASTRA S SR MRI IPG (X3SR01), ASTRA XT SR MRI IPG (X1SR01), AZURE S DR MRI IPG (W3DR01), AZURE S SR MRI IPG (W3SR01), AZURE XT DR MRI IPG (W1DR01), AND AZURE XT SR MRI IPG (W1SR01)	MEDTRONIC INC.	Approval for an update to the indications for use to include pacing at the bundle of His. The device, as modified, will be marketed under the trade name SelectSecure MRI SureScan Lead Model 3830 and is indicated for: The Model 3830 lead is intended for pacing and sensing in the atrium or right ventricle. It is also intended for pacing and sensing at the bundle of His as an alternative to right ventricular pacing in a single or dual chamber pacing system.
P990012/S032	06/13/2018	R - Real-Time Proc	ELECSYS HBSAG IMMUNOASSAY	ROCHE DIAGNOSTICS CORP.	Approval for a software update (version 06-05) for the cobas 8000 Modular Analyzer Series.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P990056/S033	06/13/2018	R - Real-Time Proc	ELECSYS TOTAL PSA	ROCHE DIAGNOSTICS CORP.	Approval for a software update (version 06-05) for the cobas 8000 Modular Analyzer Series.
P990071/S039	06/15/2018	S - Special CBE	SMARTABLATE SYSTEM	BIOSENSE WEBSTER, INC.	Approval for a labeling change to clarify the maximum impedance cut off recommendation.
P000015/S027	06/13/2018	N - Normal 180 Day	NUCLEUS AUDITORY BRAINSTEM IMPLANT	COCHLEAR AMERICAS	Approval for the modifications to the firmware and software of the Nucleus 7 system as well as a modification to the Custom Sound EP used with the Nucleus 6 system.
P000027/S031	06/13/2018	R - Real-Time Proc	ELECSYS FREE PSA	ROCHE DIAGNOSTICS CORP.	Approval for a software update (version 06-05) for the cobas 8000 Modular Analyzer Series.
P000057/S010	06/29/2018	O - Normal 180 Day	ASCENSION MCP	INTEGRA LIFESCIENCES CORPORATION	Approval for a manufacturing site located at Integra Life Sciences Corporation (Integra), 11101 Metric Boulevard, Austin, Texas.
P010015/S368	06/28/2018	N - Normal 180 Day	PERCEPTA QUAD CRT-P MRI SURESCAN, PERCEPTA CRT-P MRI SURESCAN, SERENA QUAD CRT-P MRI SURESCAN, SERENA CRT-P MRI SURESCAN, SOLARA QUAD CRT-P MRI SURESCAN, SOLARA CRT-P MRI SURESCAN AND IMPLANTABLE PULSE GENERATORS WITH CARDIAC RESYNCHRONIZATION THERAPY	MEDTRONIC INC.	Approval for an update to the indications for use to include pacing at the bundle of His. The device, as modified, will be marketed under the trade name SelectSecure MRI SureScan Lead Model 3830 and is indicated for: The Model 3830 lead is intended for pacing and sensing in the atrium or right ventricle. It is also intended for pacing and sensing at the bundle of His as an alternative to right ventricular pacing in a single or dual chamber pacing system.
P010031/S626	06/28/2018	N - Normal 180 Day	AMPLIA MRI AND AMPLIA MRI QUAD CRT-D SURESCAN, COMPIA MRI AND COMPIA MRI QUAD CRT-D SURESCAN AND CLARIA MRI AND CLARIA MRI QUAD CRT-D SURESCAN	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for an update to the indications for use to include pacing at the bundle of His. The device, as modified, will be marketed under the trade name SelectSecure MRI SureScan Lead Model 3830 and is indicated for: The Model 3830 lead is intended for pacing and sensing in the atrium or right ventricle. It is also intended for pacing and sensing at the bundle of His as an alternative to right ventricular pacing in a single or dual chamber pacing system.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010054/S036	06/13/2018	R - Real-Time Proc	ELECSYS ANTI-HBS	ROCHE DIAGNOSTICS CORP.	Approval for a software update (version 06-05) for the cobas 8000 Modular Analyzer Series.
P020056/S046	06/27/2018	Y - 135 Review Tra	NATRELLE SILICON-FILLED BREAST IMPLANTS	ALLERGAN	Approval to implement an additional incoming specification, i.e., verify the color of the gel material by using the Ultra Scan VIS Sensor System to confirm that the gel color does not change between shipment and receipt. There are no changes to existing incoming specification, manufacturing process, and final device specifications. The addition of this assessment is specific to the 900 Parkway Global Park, La Aurora, Heredia, Costa Rica manufacturing site.
P030017/S314	06/25/2018	R - Real-Time Proc	PRECISION SPINAL CORD STIMULATOR SYSTEM, PRECISION SPECTRA SPINAL CORD STIMULATOR SYSTEM, SPECTRA WAVEWRITER SPINAL CORD STIMULATOR SYSTEM, PRECISION NOVI SPINAL CORD STIMULATOR SYSTEM, PRECISION MONTAGE AND PRECISION MONTAGE MRI SPINAL CORD STIMULATOR SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for increasing the inner diameter for the receptacle components of the adapter, and including an alternate qualified supplier for the coil connector with the increased inner diameter.
P030031/S086	06/01/2018	N - Normal 180 Day	VISITAG SURPOINT EXTERNAL PROCESSING UNIT (EPU)	BIOSENSE WEBSTER, INC.	Approval for the VISITAG SURPOINT External Processing Unit.
P030036/S100	06/28/2018	N - Normal 180 Day	SELECTSECURE MRI SURESCAN LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for an update to the indications for use to include pacing at the bundle of His.
P040046/S027	06/27/2018	Y - 135 Review Tra	NATRELLE 410 HIGHLY COHESIVE ANATOMICALLY SHAPED SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Approval to implement an additional incoming specification, i.e., verify the color of the gel material by using the Ultra Scan VIS Sensor System to confirm that the gel color does not change between shipment and receipt. There are no changes to existing incoming specification, manufacturing process, and final device specifications. The addition of this assessment is specific to the 900 Parkway Global Park, La Aurora, Heredia, Costa Rica manufacturing site.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P050023/S117	06/19/2018	Y - 135 Review Tra	LESTO 7 DR-T, LPERIA 7 DR-T, LFORIA 7 DR-T, LNVENTRA 7 DR-T, LLESTO 5 DR-T, LTREVIA 5 DR-T, LFORIA 5 DR-T, LPERIA 5 DR-T, LTREVIA 7 DR-T, LNVENTRA 5 DR-T, LLIVIA 7 DR-T (GB/LI), LNLEXA 7 DR-T (GB/LI), LLIVIA 7 DR-T DF4 (GB/LI) LNLEXA 7 DR-T DF4 (GB/LI), LNTICA 7 DR-T (GB/LI), LNLEXA 3 DR-T (GB/LI), LNTICA 7 DR-T DF4 (GB/LI), LNLEXA 3 DR-T DF4 (GB/LI), LNTICA 5 DR-T (GB/LI), LNTICA 5 DR-T DF4 (GB/LI)	BIOTRONIK, INC.	Approval for changes to the visual inspection of embedded particulate matter within the header matrix of ICDs and pacemakers.
P070008/S091	06/19/2018	Y - 135 Review Tra	EVIA HF, HF-T, ENTOVIS HF, HF-T, EDORA 8 HF-T, ENITRA HF-T, ETRINSA 8 HF-T, EPYRA 8 HF-T, ELUNA 8 HF-T, EDORA 8 HF-T QP, ENITRA 8 HF-T QP, ENTICOS 8 HF-T QP, ENTICOS 8 HF-T, EVITY 8 HF-T, EVITY 8 HF-T QP	BIOTRONIK, INC.	Approval for changes to the visual inspection of embedded particulate matter within the header matrix of ICDs and pacemakers.
P080003/S007	06/22/2018	R - Real-Time Proc	SELENIA DIMENSIONS / 3DIMENSIONS	HOLOGIC, INC.	Approval for a change to the Selenia Dimensions/3Dimensions detector subsystem for approval of a new Application Specific Integrated Circuit (ASIC), and also the necessary changes to some of the detector PCB hardware, detector embedded software and detector firmware in order to support dual sourcing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P080006/S121	06/28/2018	N - Normal 180 Day	ATTAIN ABILITY MRI SURESCAN LEAD/ABILITY PLUS MRI SURESCAN LEAD AND ATTAIN ABILITY STRAIGHT MRI SURESCAN LEAD AND ATTAIN PERFORMA MRI SURESCAN LEAD/ PERFORMA STRAIGHT MRI SURESCAN LEAD, ATTAIN PERFORMA S MRI SURESCAN LEAD AND ATTAIN STABILITY QUAD MRI SURESCAN 4798 LEAD	MEDTRONIC INC.	Approval for an update to the indications for use to include pacing at the bundle of His. The device, as modified, will be marketed under the trade name SelectSecure MRI SureScan Lead Model 3830 and is indicated for: The Model 3830 lead is intended for pacing and sensing in the atrium or right ventricle. It is also intended for pacing and sensing at the bundle of His as an alternative to right ventricular pacing in a single or dual chamber pacing system.
P080025/S160	06/02/2018	Y - 135 Review Tra	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS BOWEL LEADS)	MEDTRONIC NEUROMODU LATION	Approval for adding an alternate supplier to manufacture the coil components used in the implanted leads of the Deep Brain Stimulator (DBS), Spinal Cord Stimulation (SCS), and Sacral Nerve Stimulation (SNS) devices.
P090008/S020	06/13/2018	R - Real-Time Proc	ELECSYS ANTI-HCV IMMUNOASSAY	ROCHE DIAGNOSTICS CORP.	Approval for a software update (version 06-05) for the cobas 8000 Modular Analyzer Series.
P090013/S281	06/28/2018	N - Normal 180 Day	REVO MRI SURESCAN AND CAPSUREFIX MRI SURESCAN LEAD	MEDTRONIC, INC	Approval for an update to the indications for use to include pacing at the bundle of His. The device, as modified, will be marketed under the trade name SelectSecure MRI SureScan Lead Model 3830 and is indicated for: The Model 3830 lead is intended for pacing and sensing in the atrium or right ventricle. It is also intended for pacing and sensing at the bundle of His as an alternative to right ventricular pacing in a single or dual chamber pacing system.
P100006/S005	06/12/2018	P - Panel Track	AUGMENT INJECTABLE	BIOMIMETIC THERAPEUTI CS,LLC	Approval for AUGMENT Injectable. This combination product is indicated for use as an alternative to autograft in arthrodesis (i.e., surgical fusion procedures) of the ankle (tibiotalar joint) and/or hindfoot (including subtalar, talonavicular, and calcaneocuboid joints, alone or in combination), due to osteoarthritis, post- traumatic arthritis, rheumatoid arthritis, psoriatic arthritis, avascular necrosis, joint instability, joint deformity, congenital defect, or joint arthropathy in patients with preoperative or intraoperative evidence indicating the need for supplemental graft material.
P100009/S027	06/29/2018	Y - 135 Review Tra	MITRACLIP CLIP DELIVERY SYSTEM (NTR AND XTR)	ABBOTT VASCULAR INC.	Approval for a supplier change for the Lock Line component of the MitraClip NTR/XTR Clip Delivery System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100018/S017	06/15/2018	O - Normal 180 Day	PIPELINE FLEX EMBOLIZATION DEVICE (PFED)	MICRO THERAPEUTICS DBA EV3 NEUROVASCULAR	Approval for modifications to the device labeling to include a summary of the long-term follow-up results of the Pipeline for Uncoilable or Failed Aneurysms - Post Approval Study (PUFS-PAS).
P100031/S024	06/13/2018	R - Real-Time Proc	ELECSYS ANTI-HBC II	ROCHE DIAGNOSTICS CORP.	Approval for a software update (version 06-05) for the cobas 8000 Modular Analyzer Series
P100047/S110	06/22/2018	N - Normal 180 Day	HEARTWARE HVAD SYSTEM	MEDTRONIC	Approval for a modification to the HeartWare HVAD System¿s driveline outer sheath material.
P110004/S027	06/07/2018	Y - 135 Review Tra	NIRXCELL COCR CORONARY STENT ON RX SYSTEM	MEDINOL LTD.	Approval for an adjustment of pre-crimping and crimping forces for a single device size.
P110008/S009	06/21/2018	O - Normal 180 Day	PARADIGM SPINE COFLEX INTERLAMINAR STABILIZATION DEVICE	PARADIGM SPINE, LLC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P110016/S057	06/13/2018	S - Special CBE	FLEXABILITY ABLATION CATHETER, SENSOR ENABLED (FLEXABILITY SE)	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Approval for updating Connector assembly and associated manufacturing for including a temporary grommet to improve reliability of the FlexAbility catheter.
P110022/S025	06/13/2018	R - Real-Time Proc	ELECSYS ANTI-HBC IGM	ROCHE DIAGNOSTICS CORP.	Approval for a software update (version 06-05) for the cobas 8000 Modular Analyzer Series.
P110038/S018	06/15/2018	S - Special CBE	RELAY THORACIC STENT-GRAFT WITH PLUS DELIVERY SYSTEM	BOLTON MEDICAL, INC.	Approval for minor updates to the drawing and associated manufacturing and quality procedures for the delivery system constraining sleeve.
P120010/S117	06/28/2018	S - Special CBE	MINIMED 530G SYSTEM	MEDTRONIC INC.	Approval for the addition of two 100% visual inspections to the needle hub assembly used in the Guardian Sensor (3) and Enlite Glucose Sensor. The Guardian Sensor (3) is a component of the MiniMed 630G System with SmartGuard, Guardian Connect System, and MiniMed 670G System. The Enlite Sensor is a component of the MiniMed 530G System, Paradigm Real-Time Revel System, MiniMed 630G System With SmartGuard, and MiniMed iPro2 CGM System with Enlite Sensor.
P120014/S008	06/27/2018	N - Normal 180 Day	THXID BRAF ASSAY KIT	BIOMERIEUX, INC.	Approval for the THxID®-BRAF kit. It is an In Vitro Diagnostic device intended for the qualitative detection of the BRAF V600E and V600K mutations in DNA samples extracted from formalin-fixed paraffin-embedded (FFPE) human melanoma tissue. The THxID®-BRAF kit is a real-time PCR test on the ABI 7500 Fast Dx system and is intended to be used as an aid in selecting melanoma patients whose tumors carry: the BRAF V600E or V600K mutation for treatment with encorafenib [Braftovi] in combination with binimetinib [Mektovi], the BRAF V600E mutation for treatment with dabrafenib [Tafinlar®], the BRAF V600E or V600K mutation for treatment with trametinib [Mekinist®].

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P130005/S024	06/12/2018	R - Real-Time Proc	DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM	CARDIOVASCULAR SYSTEMS, INC.	Approval for a weld design change.
P130015/S015	06/13/2018	R - Real-Time Proc	ELECSYS HBCAG	ROCHE DIAGNOSTICS OPERATIONS INC	Approval for a software update (version 06-05) for the cobas 8000 Modular Analyzer Series
P130016/S032	06/13/2018	N - Normal 180 Day	NUCLEUS HYBRID L24 IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for the modifications to the firmware and software of the Nucleus 7 system as well as a modification to the Custom Sound EP used with the Nucleus 6 system.
P140013/S010	06/21/2018	R - Real-Time Proc	MINERVA ENDOMETRIAL ABLATION SYSTEM	MINERVA SURGICAL	approval for software modifications to the RF controller and the implementation of additional software checks
P140021/S014	06/13/2018	R - Real-Time Proc	ELECSYS ANTI-HCV II	ROCHE DIAGNOSTICS OPERATIONS INC	Approval for a software update (version 06-05) for the cobas 8000 Modular Analyzer Series
P150001/S046	06/28/2018	S - Special CBE	MINIMED 630G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED	Approval for the addition of two 100% visual inspections to the needle hub assembly used in the Guardian Sensor (3) and Enlite Glucose Sensor. The Guardian Sensor (3) is a component of the MiniMed 630G System with SmartGuard, Guardian Connect System, and MiniMed 670G System. The Enlite Sensor is a component of the MiniMed 530G System, Paradigm Real-Time Revel System, MiniMed 630G System With SmartGuard, and MiniMed iPro2 CGM System with Enlite Sensor.

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P150013/S009	06/12/2018	P - Panel Track	PD-L1 IHC 22C3 PHARMDX	DAKO NORTH AMERICA, INC.	Approval for the PD-L1 IHC 22C3 pharmDx. PD-L1 IHC 22C3 pharmDx is a qualitative immunohistochemical assay using Monoclonal Mouse Anti-PD-L1, Clone 22C3 intended for use in the detection of PD-L1 protein in formalin fixed, paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC), gastric or gastroesophageal junction (GEJ) adenocarcinoma and cervical cancer tissues using EnVision FLEX visualization system on Autostainer Link 48. Non-Small Cell Lung Cancer (NSCLC) PD-L1 protein expression in NSCLC is determined by using Tumor Proportion Score (TPS), which is the percentage of viable tumor cells showing partial or complete membrane staining at any intensity. The specimen should be considered to have PD-L1 expression if TPS >= 1% and high PD-L1 expression if TPS >= 50%. PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying NSCLC patients for treatment with KEYTRUDA® (pembrolizumab). See the KEYTRUDA® product label for expression cutoff values guiding therapy in specific clinical circumstances. Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma PD-L1 protein expression in gastric or GEJ adenocarcinoma is determined by using Combined Positive Score (CPS), which is the number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100. The specimen should be considered to have PD-L1 expression if CPS >=1. PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying gastric or GEJ adenocarcinoma patients for treatment with KEYTRUDA® (pembrolizumab). Cervical Cancer PD-L1 protein expression in cervical cancer is determined by using Combined Positive Score (CPS), which is the number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100. The specimen should be considered to have PD-L1 expression if CPS >= 1. PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying cervical cancer patients for treatment with KEYTRUDA® (pembrolizumab).
P150019/S043	06/28/2018	S - Special CBE	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Approval for the addition of two 100% visual inspections to the needle hub assembly used in the Guardian Sensor (3) and Enlite Glucose Sensor. The Guardian Sensor (3) is a component of the MiniMed 630G System with SmartGuard, Guardian Connect System, and MiniMed 670G System. The Enlite Sensor is a component of the MiniMed 530G System, Paradigm Real-Time Revel System, MiniMed 630G System With SmartGuard, and MiniMed iPro2 CGM System with Enlite Sensor.

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P150021/S009	06/12/2018	Y - 135 Review Tra	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval for adding an alternate supplier of the redox polymer for FreeStyle Libre Pro sensors. The FreeStyle Libre Pro sensors are part of the FreeStyle Libre Pro Flash Glucose Monitoring System.
P150024/S011	06/19/2018	S - Special CBE	ASPIREASSIST	ASPIRE BARIATRICS INC	Approval for changes to the A-tube IFU, Physician Guide and Patient Guide.
P150029/S019	06/28/2018	S - Special CBE	MINIMED IPRO2 CGM SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Approval for the addition of two 100% visual inspections to the needle hub assembly used in the Guardian Sensor (3) and Enlite Glucose Sensor. The Guardian Sensor (3) is a component of the MiniMed 630G System with SmartGuard, Guardian Connect System, and MiniMed 670G System. The Enlite Sensor is a component of the MiniMed 530G System, Paradigm Real-Time Revel System, MiniMed 630G System With SmartGuard, and MiniMed iPro2 CGM System with Enlite Sensor.
P150036/S022	06/13/2018	Y - 135 Review Tra	EDWARDS INTUITY VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Approval for a change from a manual to semi-automated process for ironing polyethylene terephthalate cloth used on pericardial valves.
P150048/S005	06/27/2018	Y - 135 Review Tra	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS	EDWARDS LIFESCIENCES, LLC.	Approval to remove an in-process tissue inspection for valve leaflets.
P150048/S011	06/13/2018	Y - 135 Review Tra	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS/ EDWARDS INSPIRIS RESILIA AORTIC VALVE	EDWARDS LIFESCIENCES, LLC.	Approval for a change from a manual to semi-automated process for ironing polyethylene terephthalate cloth used on pericardial valves.
P160001/S015	06/22/2018	R - Real-Time Proc	OBALON BALLOON KIT	OBALON THERAPEUTICS, INC.	Approval for a design change in the Proximal Luer Hub and subsequent supplier change.
P160007/S006	06/28/2018	S - Special CBE	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Approval for the addition of two 100% visual inspections to the needle hub assembly used in the Guardian Sensor (3) and Enlite Glucose Sensor. The Guardian Sensor (3) is a component of the MiniMed 630G System with SmartGuard, Guardian Connect System, and MiniMed 670G System. The Enlite Sensor is a component of the MiniMed 530G System, Paradigm Real-Time Revel System, MiniMed 630G System With SmartGuard, and MiniMed iPro2 CGM System with Enlite Sensor.
P160013/S001	06/14/2018	O - Normal 180 Day	ORGAN CARE SYSTEM (OCS) LUNG SYSTEM	TRANSMEDICS, INC	Approval for protocol for post-approval study (PAS) protocol.
P160017/S031	06/21/2018	P - Panel Track	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval for the MiniMed 670G System. The Medtronic MiniMed 670G system is intended for continuous delivery of basal insulin (at user selectable rates) and administration of insulin boluses (in user selectable amounts) for the management of Type 1 diabetes mellitus in persons, seven years of age and older, requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed 670G System includes SmartGuard technology, which can be programmed to automatically adjust delivery of basal insulin based on Continuous Glucose Monitor sensor

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					glucose values, and can suspend delivery of insulin when the sensor glucose value falls below or is predicted to fall below predefined threshold values. The Medtronic MiniMed 670G System consists of the following devices: MiniMed 670G Pump, the Guardian Link (3) Transmitter, the Guardian Sensor (3), One-Press Serter, and the Contour NEXT Link 2.4 Glucose Meter. The system requires a prescription. The Guardian Sensor (3) glucose values are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on values provided by the Guardian Sensor (3). Guardian Sensor (3) The Guardian Sensor (3) is intended for use with the MiniMed 670G system to continuously monitor glucose levels in persons with diabetes. It is intended to be used for detecting trends and tracking patterns, and to be used by the MiniMed 670G system to automatically adjust basal insulin levels. It is indicated for use as an adjunctive device to complement, not replace, information obtained from standard blood glucose monitoring devices. The sensor is intended for single use and requires a prescription. The Guardian Sensor (3) is indicated for 7 days of continuous use. One-press Serter The One-press serter is used as an aid for inserting the sensor. It is indicated for single-patient use and it is not intended for multiple-patient use. Guardian Link (3) Transmitter The Guardian Link (3) Transmitter is intended for use with the MiniMed 670G System. The Guardian Link (3) Transmitter powers the glucose sensor, collects and calculates sensor data, and wirelessly sends the data to the MiniMed 670G insulin pump. The Transmitter is intended for single-patient multi-use. Contour NEXT Link 2.4 Glucose Meter The Contour Next Link 2.4 Wireless Blood Glucose Monitoring System is an over the counter (OTC) device utilized by persons with diabetes in home settings for the measurement of glucose in whole blood, and is for single patient use only and should not be shared. The Contour Next Link 2.4 wireless blood glucose monitoring system is indicated for use with fresh capillary whole blood samples drawn from the fingertip and palm only. The Contour NEXT Test Strips are intended for self-testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples from 20 to 600 mg/dL. The Contour Next Link 2.4 wireless blood glucose monitoring system is intended to be used to transmit glucose values to the MiniMed 670G pump and facilitate transfer of information to Medtronic CareLink Software through the use of radio frequency communication. The Contour Next Link 2.4 Wireless Blood Glucose Monitoring System is

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					not intended for the diagnosis of, or screening for, diabetes mellitus. It is not intended for use on neonates.
P160017/S044	06/28/2018	S - Special CBE	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval for the addition of two 100% visual inspections to the needle hub assembly used in the Guardian Sensor (3) and Enlite Glucose Sensor. The Guardian Sensor (3) is a component of the MiniMed 630G System with SmartGuard, Guardian Connect System, and MiniMed 670G System. The Enlite Sensor is a component of the MiniMed 530G System, Paradigm Real-Time Revel System, MiniMed 630G System With SmartGuard, and MiniMed iPro2 CGM System with Enlite Sensor.
P160019/S007	06/13/2018	R - Real-Time Proc	ELECSYS HBSAG II	ROCHE DIAGNOSTICS , INC.	Approval for a software update (version 06-05) for the cobas 8000 Modular Analyzer Series.
P160046/S004	06/01/2018	O - Normal 180 Day	VENTANA PD-L1 (SP263)	VENTANA MEDICAL SYSTEMS, INC.	Approval for additional analytical validation data and associated updated product labeling.
P170003/S002	06/15/2018	S - Special CBE	LUTONIX® 035 DRUG COATED BALLOON PTA CATHETER	LUTONIX	Approval for minor updates to the Instructions for Use.
P170008/S004	06/07/2018	O - Normal 180 Day	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Approval for adding a manufacturing site for a component, the D-catheter delivery system, for the EluNIR Ridaforolimus Eluting Coronary Stent System.

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N16895/S101	06/11/2018	X - 30-Day Notice	SOFLENS 38 (POLYMACON) VISIBILITY TINTED CONTACT LENS	BAUSCH & LOMB, INC.	Use ultra-violet bulbs manufactured at a new facility in the Soflens 38 (polymacon) contact lens manufacturing process.

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N17679/S040	06/29/2018	X - 30-Day Notice	TETRAFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION, INC.	Replacement of the paper system used for managing the preparation and documentation of the solution records at the CooperVision, Inc. Scottsville, NY manufacturing facility with a computer based system.
P790007/S057	06/29/2018	X - 30-Day Notice	HANCOCK MODIFIED ORIFICE VALVED CONDUIT	MEDTRONIC HEART VALVES	Modification to the glutaraldehyde processing solutions used for valve manufacturing.
P830055/S204	06/25/2018	X - 30-Day Notice	ATTUNE REVISION RP TIBIAL BASE	DEPUY, INC.	Modification to the Blast Plug used in the manufacturing process for the ATTUNE Revision RP Tibial Base.
P830061/S159	06/11/2018	X - 30-Day Notice	ADHESIVE, CAPSURE SENSE LEAD, CAPSURE SP LEAD, CAPSURE SP NOVUS LEAD, VITATRON CRYSTALLINE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add a blood or tissue contacting component endotoxin assessment/monitoring program.
P830061/S160	06/28/2018	X - 30-Day Notice	VITATRON CRYSTALLINE LEAD AND VITATRON EXCELLENCE + LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Reduction in frequency of environmental monitoring testing in manufacturing areas.
P840001/S398	06/01/2018	X - 30-Day Notice	RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS; PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Update of the software used to apply, collect, and record data from the Helium Leak Test on batteries and capacitors, and a change in the platform used to execute FACTORYworks transactions for the leak test systems.
P840001/S399	06/15/2018	X - 30-Day Notice	MASTR RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Changes in component material, associated equipment, process sequence, and supplier of Ethylene tetrafluoroethylene used for insulating battery headers of the impacted devices.

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P840001/S400	06/23/2018	X - 30-Day Notice	RESTORE, ITREL, SYNERGY, AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS (INTELLIS)	MEDTRONIC NEUROMODULATION	Update of the Neuromodulation Distribution Center Sorter Tool (DCST) System, which is an existing automated tool used at a distribution center to sort devices returned from the field, adding an application software for Intellis Product Family as a stand-alone software application.
P840001/S401	06/21/2018	X - 30-Day Notice	RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS (INTELLIS NEUROMODULATION SYSTEM)	MEDTRONIC NEUROMODULATION	Implementation of a Vision System and Nip Roller Modification.
P840064/S069	06/28/2018	X - 30-Day Notice	VISCOAT/DUOVISC OPHTHALMIC VISCOELASTIC SYSTEM	ALCON LABORATORIES	Use of an alternate additional large scale manufacturing process to manufacture VISCOAT® and VISCOAT® as part of DUOVISC® at the Alcon-Couvreur Manufacturing Site.
P850079/S079	06/29/2018	X - 30-Day Notice	METHAFILCON B SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION, INC.	Replacement of the paper system used for managing the preparation and documentation of the solution records at the CooperVision, Inc. Scottsville, NY manufacturing facility with a computer based system.
P850089/S133	06/11/2018	X - 30-Day Notice	CAPSURE SP NOVUS LEAD, CAPSURE SP Z LEAD, CAPSURE Z NOVUS LEAD, VITATRON IMPULSE II LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add a blood or tissue contacting component endotoxin assessment/monitoring program.
P850089/S134	06/28/2018	X - 30-Day Notice	VITATRON EXCELLENCE SS+ LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Reduction in frequency of environmental monitoring testing in manufacturing areas.
P860004/S307	06/06/2018	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	Manufacturing facility change for a current sub-tier device component supplier.
P860004/S308	06/01/2018	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Update of the software used to apply, collect, and record data from the Helium Leak Test on batteries and capacitors, and a change in the platform used to execute FACTORYworks transactions for the leak test systems.

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P860004/S309	06/15/2018	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM, AND ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Changes in component material, associated equipment, process sequence, and supplier of Ethylene tetrafluoroethylene used for insulating battery headers of the impacted devices.
P860004/S310	06/19/2018	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	Reorganization of the resistance spot welding process (RSW) steps and a modification to the current RWS inspection process in the manufacturing line of the Synchromed II pump.
P870078/S042	06/29/2018	X - 30-Day Notice	HANCOCK VALVED CONDUIT	MEDTRONIC, INC.	Modification to the glutaraldehyde processing solutions used for valve manufacturing.
P880086/S300	06/15/2018	X - 30-Day Notice	ASSURITY, ASSURITY +, ENDURITY, ACCENT AND VICTORY XL	ST. JUDE MEDICAL, INC.	Implementation of an automated environment monitoring system.
P890003/S391	06/11/2018	X - 30-Day Notice	CAPSURE VDD 2 LEAD, VITATRON BRILLIANT S+ VDD LEAD	MEDTRONIC, INC.	Add a blood or tissue contacting component endotoxin assessment/monitoring program.
P890003/S392	06/28/2018	X - 30-Day Notice	VITATRON BRILLIANT S+ VDD LEAD	MEDTRONIC, INC.	Reduction in frequency of environmental monitoring testing in manufacturing areas.
P900061/S149	06/11/2018	X - 30-Day Notice	ACE HEADER, DEFIBRILLATION SUPPORT DEVICE (DISD), END CAP, EPICARDIAL PATCH LEAD, UPSIZING SLEEVE	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add a blood or tissue contacting component endotoxin assessment/monitoring program.
P910023/S409	06/15/2018	X - 30-Day Notice	ELLIPSE, FORTIFY, FORTIFY ASSURA AND QUADRA ASSURA MP	ST. JUDE MEDICAL	Implementation of an automated environment monitoring system.
P910066/S029	06/19/2018	X - 30-Day Notice	OL1000/OL1000 SC AND SPINALOGIC BONE GROWTH STIMULATORS	DJO, LLC	Change in supplier of the sensor board.
P920015/S214	06/11/2018	X - 30-Day Notice	"Y" ADAPTOR/EXTENDER KIT, DF-1/IS-1 CONNECTOR PORT PIN PLUG, HV SPLITTER/ADAPTOR KIT, LEAD ADAPTOR, SPRINT QUATRO LEAD, SUBCUTANEOUS LEAD, TRANSVENE CS/SVC LEAD, TUNNELING TOOL	MEDTRONIC INC.	Add a blood or tissue contacting component endotoxin assessment/monitoring program.
P920015/S215	06/28/2018	X - 30-Day Notice	SPRINT QUATTRO LEAD, SUBCUTANEOUS LEAD AND TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Reduction in frequency of environmental monitoring testing in manufacturing areas.

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P930029/S060	06/28/2018	X - 30-Day Notice	RF CONTACTR, RF CONDUCTR AND RF MARINR	MEDTRONIC INC.	Reduction in frequency of environmental monitoring testing in manufacturing areas.
P930039/S188	06/11/2018	X - 30-Day Notice	CAPSUREFIX LEAD, CAPSUREFIX NOVUS LEAD, VITATRON CRYSTALLINE ACTIVE FIXATION LEAD	MEDTRONIC, INC.	Add a blood or tissue contacting component endotoxin assessment/monitoring program.
P930039/S189	06/28/2018	X - 30-Day Notice	VITATRON CRYSTALLINE ACTIVE FIXATION LEAD AND VITATRON PIROUET LEAD	MEDTRONIC, INC.	Reduction in frequency of environmental monitoring testing in manufacturing areas.
P940016/S025	06/28/2018	X - 30-Day Notice	H.E.L.P. FUTURA APHERESIS SYSTEM	B. BRAUN AVITUM AG	Change to the fiber bundle of the H.E.L.P. Ultrafilter HI PS 20 included in the H.E.L.P. Futura Set.
P950024/S079	06/11/2018	X - 30-Day Notice	CAPSURE EPICARDIAL PACING LEAD	MEDTRONIC INC.	Add a blood or tissue contacting component endotoxin assessment/monitoring program.
P950037/S189	06/12/2018	X - 30-Day Notice	SIELLO S 45, SIELLO S 53, SIELLO S 60, SOLIA S 45, SOLIA S 53, SOLIA S 60	BIOTRONIK, INC.	Alternate supplier for certain subassemblies of the Siello/Solia S leads.
P950037/S191	06/13/2018	X - 30-Day Notice	EVIA DR /DR-T /SR/SR-T ;/ ENTOVIS DR /DR-T /SR /SR-T; ESTELLA DR / DR-T/ SR / SR-T; EFFECTA D /S ;/ ENDORA 8 DR/ 8 SR; / ENITRA 6 SR; /ENTICOS 8 SR-T; ENTICOS 4 S; EVITY 6 DR-T, EVITY 6 SR-T ; ETRINA 8 DR-T /8 SR-T / 6 DR /6 SR / 6 SR-T; EPYRA 8 DR-T /SR-T / 6 DR-T /6 SR-T; ELUNA 8 DR-T /8 SR /8 SR-T; EDORA 8 DR-T /8 SR-T; ENTIRA 8 DR-T /6 DR /6 SR-T; ENTICID 8 DR-T /4 D / 4 SR; EVITY 8 DR-T/8 ST-T	BIOTRONIK, INC.	Changes to the visual inspection of polishing residuals on the header surface.
P960009/S315	06/01/2018	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Update of the software used to apply, collect, and record data from the Helium Leak Test on batteries and capacitors, and a change in the platform used to execute FACTORYworks transactions for the leak test systems.

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P960009/S316	06/15/2018	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Changes in component material, associated equipment, process sequence, and supplier of Ethylene tetrafluoroethylene used for insulating battery headers of the impacted devices.
P960009/S317	06/15/2018	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Removal of endotoxin testing requirement for external cables, external pin connectors, and external stimulators or programmers.
P960040/S425	06/01/2018	X - 30-Day Notice	IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD), DYNAGEN EL/MINI ICD, INOGEN EL/MINI ICD, ORIGEN EL ICD/MINI ICD, AUTOGEN EL ICD, VIGILANT EL ICD, PERCIVA ICD, RESONATE EL ICD, PERCIVA HF ICD, RESONATE HF ICD, MOMENTUM EL ICD, PUNCTUA ICD, ENERGEN ICD, INCEPTA ICD	BOSTON SCIENTIFIC	Add an additional supplier for the raw stainless steel material for battery interconnect tabs used in Tachy and Subcutaneous Implantable Cardioverter Defibrillator pulse generator devices.
P970004/S272	06/01/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS URINARY)	MEDTRONIC NEUROMODULATION	Update of the software used to apply, collect, and record data from the Helium Leak Test on batteries and capacitors, and a change in the platform used to execute FACTORYworks transactions for the leak test systems.
P970004/S273	06/15/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, AND VERIFY EVALUATION SYSTEM (SNS URINARY NEUROSTIMULATOR IMPLANTABLE INTERSTIM)	MEDTRONIC NEUROMODULATION	Changes in component material, associated equipment, process sequence, and supplier of Ethylene tetrafluoroethylene used for insulating battery headers of the impacted devices.
P970004/S274	06/15/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, AND VERIFY EVALUATION SYSTEM (SNS URINARY SCREENING)	MEDTRONIC NEUROMODULATION	Removal of endotoxin testing requirement for external cables, external pin connectors, and external stimulators or programmers.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S673	06/11/2018	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 ICD, VISIA AF MRI VR ICD, VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Add a blood or tissue contacting component endotoxin assessment/monitoring program.
P980016/S674	06/13/2018	X - 30-Day Notice	EVERA MRI DF-1 ICD, EVERA MRI ICD, EVERA S DR ICD, EVERA S VR ICD, EVERA XT DR ICD, EVERA XT VR ICD, MIRRO MRI DR/ VR ICD. PRIMO MRI DR/VR ICD. VISIA AF MRI DFI/VR ICD, VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Changes to the capacitor electrical testing.
P980016/S675	06/15/2018	X - 30-Day Notice	EVERA MRI DF-1 ICD, EVERA MRI ICD, EVERA S DR ICD, EVERA S VR ICD, EVERA XT DR ICD, EVERA XT VR ICD, MIRRO MRI DR ICD, MIRRO MRI VR ICD, PRIMO MRI DR ICD, PRIMO MRI VR ICD, VISIA AF MRI DF2 ICD, VISIA AF MRI VR ICD, AND VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Implementation of a vision inspection system and nip roller station for components used in battery manufacturing.
P980016/S676	06/01/2018	X - 30-Day Notice	EVERA MRI DF-1 ICD, EVERA MRI ICD, EVERA S DR ICD, EVERA S VR ICD, EVERA XT DR ICD, EVERA XT VR ICD, VISIA AF MRI DF2 ICD, VISIA AF MRI VR ICD, AND VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Implementation of Nitrogen content process monitoring.
P980035/S553	06/05/2018	X - 30-Day Notice	ASTRA XT/S DR MRI IPG, ASTRA S/XT SR MRI IPG, AZURE S/XT DR MRI IPG, AZURE S/XT SR MRI IPG	MEDTRONIC INC.	Add an alternate manufacturing site for the Surface Mount Technology Antenna.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980035/S555	06/08/2018	X - 30-Day Notice	ADVISA DR IPG, ADVISA DR/SR MRI IPG	MEDTRONIC INC.	Manufacturing updates to the battery header subassemblies for medium rate batteries.
P980035/S556	06/11/2018	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ADVISA DR IPG, ADVISA DR/SR MRI IPG, ASTRA XT/ S DR MRI IPG, ASTRA S/XT SR MRI IPG, ATTESTA DR/SR MRI IPG, AZURE S DR/XT DR MRI IPG, AZURE XT DR/XT SR MRI IPG, RELIA IPG, SPHERA DR/SR MRI IPG	MEDTRONIC INC.	Add a blood or tissue contacting component endotoxin assessment/monitoring program.
P980035/S557	06/14/2018	X - 30-Day Notice	ASTRA XT DR MRI IPG, ASTRA S DR MRI IPG, ASTRA S SR MRI IPG, ASTRA XT SR MRI IPG, AZURE S DR MRI IPG, AZURE S SR MIR IPG, AZURE XT DR MRI IPG AND AZURE XT SR MRI IPG	MEDTRONIC INC.	Addition of a test measurement offset for the Surface Mount Technology antenna resistance hybrid test.
P980040/S090	06/12/2018	X - 30-Day Notice	TECNIS 1-PIECE IOL, TECNIS OPTIBLUE 1-PIECE IOL, TECNIS MULTIFOCAL 1-PIECE IOLS, TECNIS TORIC 1-PIECE IOLS, TECNIS TORIC 1-PIECE IOL WITH THE TECNIS ITEC PRELOADED DELIVERY SYSTEM, TECNIS SYMFONY EXTENDED RANGE OF VISION IOL AND TECNIS SYMFONY TORIC EXTENDED RANGE OF VISION IOLS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Second purified water generation system at Johnson & Johnson Surgical Inc.'s AMO Groningen manufacturing facility.
P980040/S091	06/11/2018	X - 30-Day Notice	TECNIS SYMFONY TORIC EXTENDED RANGE OF VISION IOL AND TECNIS TORIC 1-PIECE IOL	JOHNSON & JOHNSON SURGICAL VISION, INC.	Manufacture the TECNIS® Toric 1-Piece IOL, Models ZCT150, ZCT225, ZCT300, ZCT375, ZCT400, ZCT450, ZCT525 and ZCT600, and the TECNIS® Symfony Toric Extended Range of Vision IOLs, Models ZXT150, ZXT225, ZXT300 and ZXT375, at Johnson & Johnson Surgical Vision, Inc.¿s (J&J Vision) AMO Puerto Rico Manufacturing, Inc. facility in Añasco, Puerto Rico.
P980043/S067	06/29/2018	X - 30-Day Notice	HANCOCK II BIOPROSTHESIS	MEDTRONIC, INC.	Modification to the glutaraldehyde processing solutions used for valve manufacturing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980044/S046	06/08/2018	X - 30-Day Notice	SUPARTZ FX, VISCO-3	SEIKAGAKU CORP.	Replacement of a mechanical seal in a dissolution tank used in the manufacture of SUPARTZ FX and VISCO-3.
P980050/S117	06/11/2018	X - 30-Day Notice	TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Add a blood or tissue contacting component endotoxin assessment/monitoring program.
P980050/S118	06/28/2018	X - 30-Day Notice	TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Reduction in frequency of environmental monitoring testing in manufacturing areas.
P990038/S028	06/28/2018	X - 30-Day Notice	ETI-MAK-2 PLUS, HBSAG CONFIRMATORY TEST ASSAYS	DIASORIN, INC.	Change to testing of a reagent and contracting shipping logistics responsibilities of the finished kits to a qualified company.
P990040/S026	06/26/2018	X - 30-Day Notice	TRUFILL N-BUTYL CYANOACRYLATE (N-BCA) LIQUID EMBOLIC SYSTEM	CODMAN & SHURTLEFF, INC.	Replace the test method and test facility for the n-butyl cyanoacrylate (n-BCA) purity calculation.
P990041/S027	06/28/2018	X - 30-Day Notice	ETI-AB-EBK PLUS ASSAY	DIASORIN, INC.	Change to testing of a reagent and contracting shipping logistics responsibilities of the finished kits to a qualified company.
P990042/S024	06/28/2018	X - 30-Day Notice	ETI-AB-AUK PLUS ASSAY	DIASORIN, INC.	Change to testing of a reagent and contracting shipping logistics responsibilities of the finished kits to a qualified company.
P990043/S028	06/28/2018	X - 30-Day Notice	ETI-EBK PLUS ASSAY	DIASORIN, INC.	Change to testing of a reagent and contracting shipping logistics responsibilities of the finished kits to a qualified company.
P990044/S025	06/28/2018	X - 30-Day Notice	ETI-CORE-IGMK PLUS ASSAY	DIASORIN, INC.	Change to testing of a reagent and contracting shipping logistics responsibilities of the finished kits to a qualified company.
P990045/S025	06/28/2018	X - 30-Day Notice	ETI-AB-COREK PLUS ASSAY	DIASORIN, INC.	Change to testing of a reagent and contracting shipping logistics responsibilities of the finished kits to a qualified company.
P990075/S044	06/26/2018	X - 30-Day Notice	MENTOR SALINE-FILLED AND SPECTRUM BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Addition of an automated lot verification process prior to primary packaging and expansion of the primary packaging room configuration.
P010003/S030	06/25/2018	X - 30-Day Notice	BIOGLUE SURGICAL ADHESIVE	CRYOLIFE, INC.	Change in the sterilization dosimetry system for BioGlue Surgical Adhesive.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010012/S485	06/01/2018	X - 30-Day Notice	CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR (CRT-D), DYNAGEN CRT-D/ X4 CRT-D, INOGEN CRT-D/ X4 CRT-D, ORIGEN CRT-D/ X4 CRT-D, AUTOGEN CRT-D/X4 CRT-D, MOMENTUM CRT-D/X4 CRT, VIGILANT CRT-D/X4 CRT-D, RESONATE CRT-D/X4/HF CRT-D, PUNCTUA CRT-D, ENERGEN CRT-D, INCEPTA CRT-D	BOSTON SCIENTIFIC CORP.	Add an additional supplier for the raw stainless steel material for battery interconnect tabs used in Tachy and Subcutaneous Implantable Cardioverter Defibrillator pulse generator devices.
P010014/S077	06/01/2018	X - 30-Day Notice	OXFORD PARTIAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Modifications to the package integrity testing methods to better align with the ASTM standards.
P010015/S371	06/05/2018	X - 30-Day Notice	PERCEPTA BIPOLAR/ QUADRIPOLAR CRT-P, SERENA BIPOLAR/ QUADRIPOLAR CRT-P, SOLARA BIPOLAR/ QUADRIPOLAR CRT-P	MEDTRONIC INC.	Add an alternate manufacturing site for the Surface Mount Technology Antenna.
P010015/S372	06/08/2018	X - 30-Day Notice	CONSULTA CRT-P, PERCEPTA BIPOLAR/ QUADRIPOLAR CRT-P, SERENA BIPOLAR/ QUADRIPOLAR CRT-P, SOLARA BIPOLAR/ QUADRIPOLAR CRT-P, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	Manufacturing updates to the battery header subassemblies for medium rate batteries.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S373	06/11/2018	X - 30-Day Notice	ATTAIN BIPOLAR OTW LEAD, ATTAIN OTW LV LEAD, CONSULTA CRT-P, PERCEPTA BIPOLAR/ QUADRIPOLAR CRT-P, SERENA BIPOLAR/ QUADRIPOLAR CRT-P, SOLARA BIPOLAR/ QUADRIPOLAR CRT-P, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	Add a blood or tissue contacting component endotoxin assessment/monitoring program.
P010015/S374	06/28/2018	X - 30-Day Notice	ATTAIN BIPOLAR OTW LEAD AND ATTAIN OTW LV LEAD	MEDTRONIC INC.	Reduction in frequency of environmental monitoring testing in manufacturing areas.
P010031/S631	06/11/2018	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 CRT-D, VIVA QUAD XT CRT-D, VIVA S/XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add a blood or tissue contacting component endotoxin assessment/monitoring program.
P010031/S632	06/13/2018	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 MI QUAD CRT-D, COMPIA MRI CRT-D, COMPIA MRI QUAD CRT-D.VIVA QUAD S CRT-D, VIVA QUAD XT CRT-D. VIVA S CRT-D, VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to the capacitor electrical testing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S633	06/15/2018	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, 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 a vision inspection system and nip roller station for components used in battery manufacturing.
P010031/S634	06/01/2018	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, 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 Nitrogen content process monitoring.
P010031/S635	06/22/2018	X - 30-Day Notice	BRAVA QUAD CRT-D, VIVA QUAD S/XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add manufacturing equipment to increase manufacturing capacity at the second shot assembly process.
P010047/S057	06/12/2018	X - 30-Day Notice	PLEURAL AIR LEAK SEALANT	NEOMEND, INC.	Change to the number of unsterilized kits for bioburden testing, change to location of testing EO sterilized product and modification of a gowning certification program.
P010047/S058	06/13/2018	X - 30-Day Notice	PROGEL PLEURAL AIR LEAK SEALANT	NEOMEND, INC.	New supplier of the Self Contained Biological Indicator (SCBI) used to monitor sterilization of the Progel Pleural Air Leak Sealant.
P030004/S015	06/06/2018	X - 30-Day Notice	ONYX LIQUID EMBOLIC SYSTEM	EV3 NEUROVASCULAR	Site change of the hydrophilic coating components supplier to expand its capacity and process efficiency.
P030035/S170	06/15/2018	X - 30-Day Notice	ALLURE, ALLURE QUADRA, QUADRA ALLURE MP, AND ANTHEM	ST. JUDE MEDICAL, INC.	Implementation of an automated environment monitoring system.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030036/S101	06/11/2018	X - 30-Day Notice	ANCHORING SLEEVE KIT, SELECTSECURE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add a blood or tissue contacting component endotoxin assessment/monitoring program.
P030036/S102	06/28/2018	X - 30-Day Notice	SELECTSECURE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Reduction in frequency of environmental monitoring testing in manufacturing areas.
P030053/S047	06/26/2018	X - 30-Day Notice	MENTOR MEMORYGEL SILICONE GEL-FILLED BREAST IMPLANTS	MENTOR CORP.	Addition of an automated lot verification process prior to primary packaging and expansion of the primary packaging room configuration.
P030054/S354	06/15/2018	X - 30-Day Notice	QUADRA ASSURA, UNIFY, UNIFY ASSURA AND UNIFY QUADRA	ST. JUDE MEDICAL	Implementation of an automated environment monitoring system.
P040021/S036	06/12/2018	X - 30-Day Notice	ST.JUDE MEDICAL BIOCOR, EPIC AND EPIC SUPRA VALVES	ST. JUDE MEDICAL, INC.	Addition of an alternate porcine tissue supplier.
P040037/S114	06/01/2018	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS, GORE VIABAHN ENDOPROSTHESIS WITH HEAPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Supplier and processing change to coating raw material.
P040037/S115	06/14/2018	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Implementation of new equipment at the existing pouch supplier.
P040045/S098	06/19/2018	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Alternate supplier for a raw material used in VISTAKON® (senofilcon A) Brand Contact Lenses.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040045/S099	06/28/2018	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Modification of a process parameter for VISTAKON® senofilcon A Brand Contact Lenses with toric designs.
P050017/S016	06/26/2018	X - 30-Day Notice	ZILVER VASCULAR STENT	COOK INCORPORATED	Alternate manufacturing aid used for stent crimping.
P050023/S120	06/13/2018	X - 30-Day Notice	LLESTO 7 VT-T / 5 VR-T , 7 VR-T DX; IFORA 7 VR-T /5 VR-T /7 VR-T DX , 5 VR-T DX ; ITREVIA 7 VT-T/ DX (GBLI), INTICA 5 VR-T DX (GBLI); LIIVIA 7/ 5 HF-T DF4 VR-T ; INTICA 7 VT-T/7 ; INLEXA 3 VR-T, 7 & 3 VR-T DF 4 ; INLEXA 7 DR-T AND DR4 (GB/LI), IPERIA 7/5 DR-T INVENTRA 7 /5 DR-T / 5HF-T; 7/5 HF-T QP ; ITREVIA 7/5 HF-T QP; IPERIA 7/5 HT=T QP; INTICIA 5 HF-T DF-1 & DF4 IS-1; LLIVIA 7 HF-T QP DF-1 IS4; ENITRA 6 DR-T / 8 SR-T/ 6DR; ENTICOS 4 DR/ 8 SR-T, 4 S; LLIVIA 7 HF -T DF4 IS-1 (LI),& 7 HF -T QP DF4 IS4(GB); INTICA 7 HF-T DF-1 /DF4 IS-1; INTICA 7 HF-T DF4 /DF-A IS-1; INLEXA 7 HF-T DF-1/ DF-4 IS-1;INLEXA 7HF-T DF-1 IS-1; INLEXA 3 HF-T DF4 IS-1 ; INLEXA 3HF-T QP DF4 IS 4 (GB/LI)	BIOTRONIK, INC.	Changes to the visual inspection of polishing residuals on the header surface.
P050028/S065	06/14/2018	X - 30-Day Notice	ROCHE CBAS TAQMAN HBV TEST, V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Elimination of in-process functional testing for a kit component.

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P060028/S029	06/26/2018	X - 30-Day Notice	MENTOR MEMORYSHAPE BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Addition of an automated lot verification process prior to primary packaging and expansion of the primary packaging room configuration.
P060039/S087	06/11/2018	X - 30-Day Notice	ATTAIN STARFIX LEAD	MEDTRONIC INC.	Add a blood or tissue contacting component endotoxin assessment/monitoring program.
P060039/S088	06/28/2018	X - 30-Day Notice	ATTAIN STARFIX LEAD	MEDTRONIC INC.	Reduction in frequency of environmental monitoring testing in manufacturing areas.
P060040/S070	06/01/2018	X - 30-Day Notice	HEARTMATE LL LEFT VENTRICULAR ASSIST SYSTEM (LVAS)	THORATEC CORP.	Add an alternative second tier supplier of a component used to manufacture the Sealed Outflow Graft and to add a new cleanroom for manufacturing the graft.
P070008/S093	06/13/2018	X - 30-Day Notice	EVIA HF /HF-T; ENTOVIS HF/ HF-T ; EDORA 8 HF-T; ENTIRA 8 HF-1; ETRINSA 8 HF-T; EPYRA 8 HF-T; ELUNA 8 HF-T; EDORA 8HF-T QP; ENITRA 8 HF-T QP; ENTICOS 8 HF-T QP	BIOTRONIK, INC.	Changes to the visual inspection of polishing residuals on the header surface.
P070014/S056	06/20/2018	X - 30-Day Notice	LIFESTENT 5MM VASCULAR STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	Implementation of a reloading process for 5mm diameter stents.
P080006/S122	06/11/2018	X - 30-Day Notice	ATTAIN ABILITY LEAD, ATTAIN PERFORMA LEAD	MEDTRONIC INC.	Add a blood or tissue contacting component endotoxin assessment/monitoring program.
P080006/S123	06/28/2018	X - 30-Day Notice	ATTAIN ABILITY LEAD AND ATTAIN PERFORMA LEAD	MEDTRONIC INC.	Reduction in frequency of environmental monitoring testing in manufacturing areas.
P080006/S124	06/27/2018	X - 30-Day Notice	ATTAIN ABILITY LEAD / ATTAIN PERFORMA LEAD	MEDTRONIC INC.	Add a new alternate supplier for the Attain Performa coils.
P080011/S075	06/01/2018	X - 30-Day Notice	COMFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES, BIOFINITY SPHERE/ BIOFINITY XR SPHERE, BIOFINITY ENERGYS, BIOFINITY TORIC/ BIOFINITY XR TORIC, BIOFINITY MULTIFOCAL	COOPERVISION MANUFACTURING, LTD.	Addition of a secondary supplier of a critical raw material.
P080025/S167	06/01/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS BOWEL)	MEDTRONIC NEUROMODULATION	Update of the software used to apply, collect, and record data from the Helium Leak Test on batteries and capacitors, and a change in the platform used to execute FACTORYworks transactions for the leak test systems.

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P080025/S168	06/15/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM AND VERIFY EVALUATION SYSTEM (SNS BOWEL NEUROSTIMULATORS IMPLANTABLE INTERSTIM)	MEDTRONIC NEUROMODULATION	Changes in component material, associated equipment, process sequence, and supplier of Ethylene tetrafluoroethylene used for insulating battery headers of the impacted devices.
P080025/S169	06/15/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM AND VERIFY EVALUATION SYSTEM (SNS BOWEL SCREENING)	MEDTRONIC NEUROMODULATION	Removal of endotoxin testing requirement for external cables, external pin connectors, and external stimulators or programmers.
P090013/S285	06/08/2018	X - 30-Day Notice	REVO MRI SURESCAN IPG	MEDTRONIC, INC	Manufacturing updates to the battery header subassemblies for medium rate batteries.
P090013/S286	06/11/2018	X - 30-Day Notice	CAPSUREFIX MRI LEAD, REVO MRI SURESCAN IPG	MEDTRONIC, INC	Add a blood or tissue contacting component endotoxin assessment/monitoring program.
P100017/S021	06/21/2018	X - 30-Day Notice	ABBOTT REALTIME HCV ASSAY	ABBOTT MOLECULAR, INC.	Modify the manufacturing and QC testing for a kit component and tighten an incoming reagent specification.
P100020/S031	06/01/2018	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Removal of non-critical pretreatment process for component containers and vials.
P100020/S033	06/12/2018	X - 30-Day Notice	COBAS HPV TEST, 240/960 TESTS	ROCHE MOLECULAR SYSTEMS, INC.	Add a supplementary analytical HPLC column for QC of a critical manufactured material.
P100025/S013	06/05/2018	X - 30-Day Notice	BREATHTEK UBT FOR H.PYLORI KIT (BREATHTEK UBT KIT), PEDIATRIC UREA HYDROLYSIS RATE CALCULATION APPLICATION (PUHR-CA)	OTSUKA AMERICA PHARMACEUTICAL, INC.	Changes to testing methods for raw materials and kit reagents.
P100029/S034	06/12/2018	X - 30-Day Notice	TRIFECTA VALVE, TRIFECTA VALVE WITH GLIDE TECHNOLOGY (TRIFECTA GT)	ST. JUDE MEDICAL, INC.	Addition of an alternate porcine tissue supplier.
P100044/S032	06/01/2018	X - 30-Day Notice	PROPEL, PROPEL MINI AND PROPEL CONTOUR SINUS IMPLANTS	INTERSECT ENT	Modification of the pneumatic crimper used in the manufacturing of the delivery systems for the Propel, Propel mini and Propel Contour Sinus Implants.
P100044/S033	06/28/2018	X - 30-Day Notice	PROPEL CONTOUR SINUS IMPLANT	INTERSECT ENT	Modify the handle tensile strength specification for the delivery system for the Propel Contour Sinus Implant.

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P100047/S123	06/27/2018	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Modify the Acceptance Quality Limits for the inspection procedure of the impellers used in the HeartWare Ventricular Assist Device (HVAD).
P110004/S030	06/14/2018	X - 30-Day Notice	NIRXCELL COCR CORONARY STENT ON RX SYSTEM	MEDINOL LTD.	Add two alternative suppliers of Water For Irrigation (WFI).
P110010/S157	06/21/2018	X - 30-Day Notice	PROMUS ELEMENT PLUS/ PROMUS PREMIER EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Extension in the expiry of the drug coating solution used for PROMUS products.
P110035/S046	06/28/2018	X - 30-Day Notice	EPIC VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Add cycle S756 to Chamber 2 at BSC Coventry Rhode Island facility.
P110042/S108	06/01/2018	X - 30-Day Notice	S-ICD PULSE GENERATOR, EMBLEM S-ICD, EMBLEM MRI S-ICD	BOSTON SCIENTIFIC CORPORATION	Add an additional supplier for the raw stainless steel material for battery interconnect tabs used in Tachy and Subcutaneous Implantable Cardioverter Defibrillator pulse generator devices.
P110042/S110	06/19/2018	X - 30-Day Notice	EMBLEM S-ICD PULSE GENERATOR (PG), EMBLEM MRI S-ICD PULSE GENERATOR (PG)	BOSTON SCIENTIFIC CORPORATION	Introduction of new Encapsulation and Curing Steps and modified inspection steps for S-ICD manufacturing.
P120005/S074	06/13/2018	X - 30-Day Notice	DEXCOM G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Addition of an alternate speaker supplier for the G5 Mobile Receiver. The G5 Mobile Receiver is part of the Dexcom G5 Continuous Glucose Monitoring System.
P120005/S075	06/15/2018	X - 30-Day Notice	DEXCOM G4 PLATINUM/G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Addition of a new supplier of glucose oxidase for manufacture of glucose sensors for G4 Platinum and G5 Mobile Continuous Glucose Monitoring Systems.
P120005/S076	06/22/2018	X - 30-Day Notice	G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEMS	DEXCOM, INC.	Add an additional contract manufacturer for touchscreen components used in the manufacturing of the G5 Mobile Continuous Glucose Monitoring (CGM) System.
P120011/S011	06/28/2018	X - 30-Day Notice	IDEAL IMPLANT STRUCTURED BREAST IMPLANT	IDEALIMPLANT	Change to the bubble specification for the inner and outer shell to increase the allowable number of microscopic bubbles less than or equal to 0.020 inches in size from 5 bubbles to 10 bubbles.
P120012/S017	06/21/2018	X - 30-Day Notice	ABBOTT REALTIME HCV GENOTYPE II ASSAY	ABBOTT MOLECULAR	Modify the manufacturing and QC testing for a kit component and tighten an incoming reagent specification.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P120017/S013	06/11/2018	X - 30-Day Notice	MYOCARDIAL PACING LEAD	MEDTRONIC INC.	Add a blood or tissue contacting component endotoxin assessment/monitoring program.
P130006/S053	06/01/2018	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS, GORE VIABAHN ENDOPROSTHESIS WITH HEAPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Supplier and processing change to coating raw material.
P130006/S054	06/14/2018	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Implementation of new supplier equipment.
P130024/S023	06/28/2018	X - 30-Day Notice	LUTONIX DRUG COATED BALLON	LUTONIX	Change in the frequency of endotoxin monitoring.
P130028/S021	06/28/2018	X - 30-Day Notice	ALGOVITA SPINAL CORD STIMULATION SYSTEM (SCS), TRIAL LEAD: 8/12 ELECTRODE PERCUTANEOUS LEAD KIT	NUVECTRA CORPORATION	Changes to incorporate several process enhancements to the distal final bond and distal epoxy backfill manufacturing processes for the Percutaneous Leads and Trial Leads. The changes do not change the design of the Leads
P140003/S036	06/07/2018	X - 30-Day Notice	IMPELLA 5.0 SYSTEM	ABIOMED, INC.	Addition of a second manufacturing site for a sub-assembly in Impella 5.0.
P140028/S032	06/28/2018	X - 30-Day Notice	INNOVA SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Add cycle S756 to Chamber 2 at BSC Coventry Rhode Island facility.
P140029/S008	06/13/2018	X - 30-Day Notice	RESTYLANE REFYNE AND RESTYLANE DEFYNE INJECTABLE GELS	Q-MED AB	Change in supplier for the "puck press" used in manufacturing Restylane Refyne and Restylane Defyne.
P140029/S009	06/14/2018	X - 30-Day Notice	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Installation of new buffer tanks to increase the manufacturing capacity for Restylane Refyne and Restylane Defyne.
P140029/S010	06/22/2018	X - 30-Day Notice	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Prolonged storage of samples for bioburden analysis for Restylane Refyne and Restylane Defyne.
P140029/S011	06/21/2018	X - 30-Day Notice	RESTYLANE REYNE AND RESTYLANE DEFYNE INJECFTABLE GELS	Q-MED AB	Change to increase the syringe filling speed for Restylane Defyne.
P140029/S012	06/28/2018	X - 30-Day Notice	RESTYLANE REFYNE AND RESTYLANE DEFYNE	Q-MED AB	Change to the secondary packaging.
P140032/S008	06/06/2018	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Manufacturing facility change for a current sub-tier device component supplier.

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P140032/S009	06/01/2018	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Update of the software used to apply, collect, and record data from the Helium Leak Test on batteries and capacitors, and a change in the platform used to execute FACTORYworks transactions for the leak test systems.
P140032/S010	06/15/2018	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Changes in component material, associated equipment, process sequence, and supplier of Ethylene tetrafluoroethylene used for insulating battery headers of the impacted devices.
P140032/S011	06/15/2018	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN (ISR)	MEDTRONIC, INC.	Changes Medtronic Implantable System for Remodulin® (ISR) including changes to the manufacturing process and suppliers for the ISR pump, components and processes for the ISR catheter and changes to the number of nitrogen purges for the ISR Refill Kit.
P140032/S012	06/19/2018	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Reorganization of the resistance spot welding process (RSW) steps and a modification to the current RWS inspection process in the manufacturing line of the Synchromed II pump.
P140033/S032	06/15/2018	X - 30-Day Notice	ASSURITY MRI AND ENDURITY MRI	ST. JUDE MEDICAL, INC.	Implementation of an automated environment monitoring system.
P150001/S044	06/07/2018	X - 30-Day Notice	GUARDIAN GLUCOSE SENSOR (3)	MEDTRONIC MINIMED	Installation of additional equipment for the automation of the GOx patterning stage of Guardian Glucose Sensor (3) to increase production capacity. The Guardian Glucose Sensor is a component of the Minimed 630, Minimed 670, and the Guardian connect systems.
P150003/S040	06/28/2018	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Add cycle S756 to Chamber 2 at BSC Coventry Rhode Island facility.
P150016/S014	06/13/2018	X - 30-Day Notice	TRIDYNE VASCULAR SEALANT	NEOMEND, INC.	New supplier of the Self Contained Biological Indicator (SCBI) used to monitor sterilization of the Tridyne Vascular Sealant.
P150021/S028	06/01/2018	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Updating the foil lid sealing temperature of the assembly process for the Sensor Pack of the FreeStyle Libre Pro Flash Glucose Monitoring System and Freestyle Libre Flash Glucose Monitoring System.
P150021/S029	06/28/2018	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Introduce a new electron beam sterilization station and new Sensor Pack sterilization/ shipping trays for the FreeStyle Libre Flash and Libre Pro Flash Glucose Monitoring Systems.
P150031/S006	06/19/2018	X - 30-Day Notice	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Additional Ethylene Oxide (EO) sterilization chamber (Getinge GI) and associated sterilization process located at Boston Scientific Dorado manufacturing site (BSC-DOR) for routine sterilization of the Lead products (Lead, Lead Extension, Adapter and Physician's Spare Kit) of the Vercise Deep Brain Stimulation (DBS) System.
P150048/S021	06/20/2018	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS, INSPIRIS RESILIA AORTIC MODEL 11500A	EDWARDS LIFESCIENCES, LLC.	Modifications to the preparation, storage, and shelf life of buffer solution.
P160001/S017	06/01/2018	X - 30-Day Notice	OBALON BALLOON KIT	OBALON THERAPEUTICS, INC.	Installation and qualification of Clean Environment Room Suite J only.

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P160004/S011	06/01/2018	X - 30-Day Notice	GORE TIGRIS VASCULAR STENT	W. L. GORE & ASSOCIATES, INC.	Supplier and processing change to coating raw material.
P160004/S012	06/14/2018	X - 30-Day Notice	GORE TIGRIS VASCULAR STENT	W. L. GORE & ASSOCIATES, INC.	Implementation of new equipment at the existing pouch supplier.
P160007/S003	06/07/2018	X - 30-Day Notice	GUARDIAN GLUCOSE SENSOR (3)	MEDTRONIC MINIMED	Installation of additional equipment for the automation of the GOx patterning stage of Guardian Glucose Sensor (3) to increase production capacity. The Guardian Glucose Sensor is a component of the Minimed 630, Minimed 670, and the Guardian connect systems.
P160007/S005	06/26/2018	X - 30-Day Notice	GUARDIAN SENSOR (3) SYSTEM	MEDTRONIC MINIMED	Manufacturing changes for the Guardian Sensor (3): 1) adding a new ISO Class 8 Cleanroom for the manufacturing of Enlite Sensors and Guardian Sensors (3); 2) adding a new press, two new molds and a new quality control measurement system at the contract manufacturer; 3) adding an alternate injection molding machine and mold to produce the needle hub body component; 4) adding an alternative mask aligner; 5) adding a new electroplating machine; 6) adding a new sterilization site for the Enlite Sensor and the Guardian Sensor (3); 7) introducing an alternative press and mold to manufacture the sensor cap components of the Guardian Sensor (3) and implementing a new configuration number for parts manufactured. The Guardian Sensor (3) is a component of the Guardian Connect System
P160017/S042	06/07/2018	X - 30-Day Notice	GUARDIAN GLUCOSE SENSOR (3)	MEDTRONIC MINIMED, INC.	Installation of additional equipment for the automation of the GOx patterning stage of Guardian Glucose Sensor (3) to increase production capacity. The Guardian Glucose Sensor is a component of the Minimed 630, Minimed 670, and the Guardian connect systems.
P160021/S008	06/01/2018	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Supplier and processing change to coating raw material.
P160021/S009	06/14/2018	X - 30-Day Notice	GORE VIABAHN BALLOON EXPANDABLE VBX ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implementation of new equipment at the existing pouch supplier.
P160030/S019	06/01/2018	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Updating the foil lid sealing temperature of the assembly process for the Sensor Pack of the FreeStyle Libre Pro Flash Glucose Monitoring System and Freestyle Libre Flash Glucose Monitoring System.
P160030/S020	06/28/2018	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Introduce a new electron beam sterilization station and new Sensor Pack sterilization/ shipping trays for the FreeStyle Libre Flash and Libre Pro Flash Glucose Monitoring Systems.
P160038/S004	06/25/2018	X - 30-Day Notice	PRAXIS EXTENDED RAS PANEL	ILLUMINA, INC.	Redesign of Quality Control method that tests for cross-contamination and purity of Index Adapters which will include the obsolescence of Illuminas Genome Analyzer IIx.

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P160054/S009	06/01/2018	X - 30-Day Notice	HEARTMATE 3 LEFT VENTRICULAR ASSIST SYSTEM (LVAS)	THORATEC CORPORATION	Add an alternative second tier supplier of a component used to manufacture the Sealed Outflow Graft and to add a new cleanroom for manufacturing the graft.
P170003/S003	06/28/2018	X - 30-Day Notice	LUTONIX DRUG COATED BALLOON	LUTONIX	Change in the frequency of endotoxin monitoring.
P170008/S005	06/14/2018	X - 30-Day Notice	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Add two alternative suppliers of Water For Irrigation (WFI).
P170012/S004	06/14/2018	X - 30-Day Notice	HEMOBLAST¿ BELLOWS	BIOM'UP SA	Changes in the cryogrinding process of the collagen powder component.

Total: 164