PMA Monthly approvals from 4/1/2018 to 4/30/2018

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150009	04/09/2018	PMAO - PMA Origi	ANGELMED GUARDIAN SYSTEM	ANGEL MEDICAL SYSTEMS INC.	Approval of the AngelMed Guardian System. This device is indicated for use in patients who have had prior acute coronary syndrome (ACS) events and who remain at high risk for recurrent ACS events.The Guardian System is indicated as an adjunct to patient recognized symptoms. The Guardian System detects potential ongoing ACS events, characterized by sustained ST segment changes, and alerts the patient to seek medical attention for those potential ACS events. A Guardian System alert is a more accurate predictor of ACS events when compared to patient recognized symptoms alone and demonstrates a reduced rate over time of patient presentations without ACS events (false positives) when compared to patient recognized symptoms alone. In the absence of symptoms, the Guardian System may identify asymptomatic ACS events and prompt the patient to seek medical attention.
P160052	04/11/2018	PMAO - PMA Origi	PARTOSURE TEST	PARSAGEN DIAGNOSTICS , INC	Approval for the PartoSure test. The device is a rapid, qualitative test for detecting the presence of placental alpha microglobulin 1 (PAMG-1) in cervicovaginal secretions. The device is indicated as an aid to rapidly assess the risk of spontaneous preterm delivery in <= 7 days from the time of cervicovaginal sample collection in pregnant women with signs and symptoms of early preterm labor, intact amniotic membranes and minimal cervical dilatation (<3 cm), sampled between 24 weeks, 0 days and 34 weeks, 6 days gestation in women with a singleton gestation.

Data as of 05/03/2018 03:00 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170035	04/30/2018	PMAO - PMA Origi	BAUSCH + LOMB ULTRA (SAMFILCON A) CONTACT LENSES	BAUSCH AND LOMB, INC.	Approval for the Bausch + Lomb Ultra (samfilcon A) Contact Lenses. These devices are indicated for: Single Vision Spherical (SVS) Vision Correction The BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens is indicated for extended wear for up to 7 days between removals for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. Presbyopia Vision Correction The BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens for Presbyopia is indicated for extended wear for up to 7 days between removals for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia, hyperopia and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed for add powers ranging from +0.75D to +5.00D. Astigmatism Vision Correction The BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens for Astigmatism is indicated for extended wear for up to 7 days between removals for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism up to 5.00 diopters.

Total: 3

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N18286/S030	04/13/2018	O - Normal 180 Day	GEL-FLOW NT	PFIZER, INC.	Approval for a change in the device name from Flostat NT to Gel-Flow NT.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970012/S145	04/06/2018	S - Special CBE	AMBICOR INFLATABLE PENILE PROSTHESIS (IPP), AMS 700 IPP	BOSTON SCIENTIFIC CORP.	Approval for the addition to the labeling of adverse events (bleeding, exposure to biohazardous material, hemorrhage, improper size, pain, perforation, injury, prolonged procedure, supersonic transporter, unretrieved device fragment).
P830055/S196	04/23/2018	R - Real-Time Proc	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for an update to the ATTUNE Intuition Instruments CAS Knee 2.6 surgical technique guide, a new surgical technique guide for use with BrainLAB KNEE3 CAS 3.1 software, and a third document for guidance on the software differences between BrainLAB KNEE3 3.1 and KNEE3 ClearLens¿ 3.2.
P840001/S311	04/26/2018	R - Real-Time Proc	ITREL SPINAL CORD STIMULATION SYSTEMS	MEDTRONIC NEUROMODULATION	approval for the removal of the Parylene Coating from Itrel 4 Implantable Neurostimulators Models 37703 and 37704
P840001/S377	04/13/2018	O - Normal 180 Day	MASTER RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES SPECIFY AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Approval for a manufacturing site located at Road 31, Km. 24, Hm 4, Ceiba Norte Industrial Park, Juncos, Puerto Rico 00777, for kitting activities including Sterile Packaging, Sterilization, Final Pack & Label, and Final QA Inspection.
P840001/S393	04/13/2018	S - Special CBE	RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Approval for clarifying instructions for the safe use of the Specify SureScan surgical leads (models 977C165, 977C190, 977C265 and 977C290).
P850064/S036	04/27/2018	R - Real-Time Proc	LIFEPULSE HIGH FREQUENCY VENTILATOR	BUNNELL, INC.	Approval for adding a Funnel shape to the machine end of the 5.5 mm LifePort Adapter via the molding process. The disposable LifePort Adapters were approved for use with the LifePulse High Frequency Ventilator Model 204 in 1995.
P860004/S290	04/13/2018	O - Normal 180 Day	SYNCHROMED INFUSION SYSTEM ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Approval for a manufacturing site located at Road 31, Km. 24, Hm 4, Ceiba Norte Industrial Park, Juncos, Puerto Rico 00777, for kitting activities including Sterile Packaging, Sterilization, Final Pack & Label, and Final QA Inspection.
P860004/S297	04/25/2018	R - Real-Time Proc	SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Approval for a design change to the SynchroMed® II Infusion Pump suture loop length tolerance and updates to the measurement system used to inspect the suture loop component.
P880086/S293	04/11/2018	N - Normal 180 Day	ASSURITY, ASSURITY+, ENDURITY, ACCENT FAMILY OF PACEMAKERS	ST. JUDE MEDICAL, INC.	Approval for cybersecurity updates and implementation of a Battery Performance Alert in the firmware of ICDs and CRT-Ds.
P890003/S385	04/24/2018	R - Real-Time Proc	MYCARELINK MONITOR	MEDTRONIC, INC.	Approval for stability enhancements, security updates, and error mitigation for the MyCareLink Patient Monitor Model 24950 firmware.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P910023/S400	04/11/2018	N - Normal 180 Day	CURRENT, CURRENT ACCEL, CURRENT+, ELLIPSE, FORTIFY, FORTIFY ASSURA, EPIC/ EPIC+, ATLAS/II/+FAMILY OF ICDS	ST. JUDE MEDICAL	Approval for cybersecurity updates and implementation of a Battery Performance Alert in the firmware of ICDs and CRT-Ds.
P910073/S146	04/19/2018	N - Normal 180 Day	LEAD CAP KIT (MODEL 7007)	BOSTON SCIENTIFIC	Approval for a new S-ICD kit of tunneling tools, called EMBLEM S-ICD Electrode Delivery System (EDS), Model 4712.
P920015/S206	04/19/2018	R - Real-Time Proc	SPRINT QUATTRO LEAD (6935M), SPRINT QUATTRO LEAD (6935)	MEDTRONIC INC.	Approval for minor design changes to the multi-lumen tubing and insulated conductor cables of the Sprint Quattro Secure S/MRI SureScan Model 6935/6935M defibrillator leads.
P930014/S110	04/26/2018	R - Real-Time Proc	ACRYSOF IQ ASPHERIC UV ABSORBING IOL WITH THE ULTRASERT PRE-LOADED DELIVERY SYSTEM	ALCON RESEARCH, LTD.	Approval for preloading the AcrySof® Aspheric UV Absorbing Intraocular Lens (IOL) Model SA60WF in the UltraSert Delivery System.
P930027/S019	04/16/2018	S - Special CBE	IMMULITE/IMMULITE 1000 PSA/IMMULITE 2000 PSA	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Approval for an update to the Instructions for Use (IFU) High-Dose Hook Effect claim on IMMULITE / IMMULITE 1000 and IMMULITE 2000 platforms with values obtained for complex PSA (PSA-ACT) high dose effect.
P930036/S006	04/13/2018	N - Normal 180 Day	ADVIA CENTAUR AFP ASSAY	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Approval for the migration of the ADVIA Centaur AFP assay to the ADVIA Centaur XPT system.
P950022/S102	04/02/2018	Y - 135 Review Tra	DURATA AND OPTISURE LEADS (HV ACTIVE AND PASSIVE)	ST. JUDE MEDICAL, INC.	Approval for an alternate supplier for material used for lead insulation tubing.
P950039/S036	04/18/2018	P - Panel Track	THINPREP INTEGRATED IMAGER	HOLOGIC, INC.	Approval of the Hologic ThinPrep® Integrated Imager. The device uses computer imaging technology to assist in primary cervical cancer screening of ThinPrep® Pap Test slides for the presence of atypical cells, cervical neoplasia, including its precursor lesions (Low Grade Squamous Intraepithelial Lesions, High Grade Squamous Intraepithelial Lesions), and carcinoma as well as all other cytologic criteria as defined by the Bethesda System: Terminology for Reporting Results of Cervical Cytology.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960009/S219	04/27/2018	P - Panel Track	MEDTRONIC DBS THERAPY FOR EPILEPSY	MEDTRONIC INC.	Approval to expand the indications for the Medtronic DBS system to include Epilepsy. Bilateral stimulation of the anterior nucleus of the thalamus (ANT) using the Medtronic DBS System for Epilepsy is indicated as an adjunctive therapy for reducing the frequency of seizures in individuals 18 years of age or older diagnosed with epilepsy characterized by partial-onset seizures, with or without secondary generalization, that are refractory to three or more antiepileptic medications. The Medtronic DBS System for Epilepsy has demonstrated safety and effectiveness for patients who average six or more seizures per month over the three most recent months prior to implant of the DBS system (with no more than 30 days between seizures). The Medtronic DBS System for Epilepsy has not been evaluated in patients with less frequent seizures.
P960009/S294	04/13/2018	O - Normal 180 Day	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Approval for a manufacturing site located at Road 31, Km. 24, Hm 4, Ceiba Norte Industrial Park, Juncos, Puerto Rico 00777, for kitting activities including Sterile Packaging, Sterilization, Final Pack & Label, and Final QA Inspection.
P960013/S090	04/02/2018	Y - 135 Review Tra	TENDRIL SDX/ST/STS AND OPTISENSE LEADS (LV ACTIVE)	ST JUDE MEDICAL	Approval for an alternate supplier for material used for lead insulation tubing.
P960030/S052	04/02/2018	Y - 135 Review Tra	ISOFLEX OPTIM LEADS (LV PASSIVE)	ST. JUDE MEDICAL	Approval for an alternate supplier for material used for lead insulation tubing.
P970004/S256	04/13/2018	O - Normal 180 Day	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Approval for a manufacturing site located at Road 31, Km. 24, Hm 4, Ceiba Norte Industrial Park, Juncos, Puerto Rico 00777, for kitting activities including Sterile Packaging, Sterilization, Final Pack & Label, and Final QA Inspection.
P970013/S076	04/11/2018	N - Normal 180 Day	MICRONY FAMILY OF PACEMAKERS	ST. JUDE MEDICAL, INC.	Approval for cybersecurity updates and implementation of a Battery Performance Alert in the firmware of ICDs and CRT-Ds.
P980016/S658	04/24/2018	R - Real-Time Proc	EVERA MRI ICD, EVERA S DR ICD, EVERA S VR ICD, EVERA XT DR ICD, EVERA XT VR ICD, INTRINSIC 30 ICD, MARQUIS VR ICD, MAXIMO II ICD, PROTECTA XT ICD, PROTECTA ICD, SECURA ICD, VIRTUOSO II DR/VR ICD, VISIA AF AND VISIA AF MRI SURESCAN	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for stability enhancements, security updates, and error mitigation for the MyCareLink Patient Monitor Model 24950 firmware.
P980035/S532	04/02/2018	R - Real-Time Proc	ADVISA DR IPG, ADVISA DR MIR IPG AND ADVISA SR MRI IPG	MEDTRONIC INC.	Approval for an update to the epoxy resin to catalyst mix ratio and pattern weight.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980035/S534	04/24/2018	R - Real-Time Proc	ADAPTA, VERSA, SENSIA IPG, ADVISA DR IPG, ADVISA DR MRI IPG, ADVISA SR MRI IPG, ENPULSE EI IPG, ENPULSE E2 IPG, KAPPA D IPG, KAPPA DR IPG, KAPPA SR IPG, KAPPA VDD IPG	MEDTRONIC INC.	Approval for stability enhancements, security updates, and error mitigation for the MyCareLink Patient Monitor Model 24950 firmware.
P980040/S086	04/23/2018	O - Normal 180 Day	TECNIS TORIC1-PIECE INTRAOCULAR LENSES (IOLS) MODELS ZCT300 AND ZCT400	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P990012/S031	04/20/2018	R - Real-Time Proc	ELECSYS HBSAG IMMUNOASSAY	ROCHE DIAGNOSTICS CORP.	Approval for a software update (version 02-07) to the cobas e 411 immunoassay analyzer
P990056/S031	04/20/2018	R - Real-Time Proc	ELECSYS TOTAL PSA	ROCHE DIAGNOSTICS CORP.	Approval for a software update (version 02-07) to the cobas e 411 immunoassay analyzer
P000021/S033	04/13/2018	O - Normal 180 Day	DIMENSION TPSA FLEX REAGENT CARTRIDGE	SIEMENS HEALTHCARE DIAGNOSTICS	Approval of the instrument manufacturing site change for the Dimension® EXL integrated systems to the Siemens instrument manufacturing facility located in Flanders, New Jersey.
P000025/S098	04/20/2018	R - Real-Time Proc	MED-EL COCHLEAR IMPLANTS	MED-EL CORP.	Approval for the following changes to the Medical Procedures Manual (MPM) AW33290 EN US of the labeling: 1) Change to allow diagnostic ultrasound exposure for MED-EL Cochlear Implants; 2) Changes related to MRI (MPM section "Magnetic Resonance Imaging (MRI) Safety Information"); 3) Addition of some introductory text; 4) Correction of MRI condition for SONATA and Mi1000 CONCERT (PIN); and 5) Editorial changes.
P000027/S030	04/20/2018	R - Real-Time Proc	ELECSYS FREE PSA	ROCHE DIAGNOSTICS CORP.	Approval for a software update (version 02-07) to the cobas e 411 immunoassay analyzer.
P000039/S060	04/26/2018	O - Normal 180 Day	THE AMPLATZER(R) SEPTAL OCCLUDER (ASO) AND THE AMPLATZER EXCHANGE SYSTEM	AGA MEDICAL CORPORATIO N	Approval for updates made to the AMPLATZER Septal Occluder Instructions for Use.
P010014/S074	04/11/2018	S - Special CBE	OXFORD PARTIAL KNEE SYSTEM	BIOMET MANUFACTUR ING CORP.	Approval for updates to compression molding work instructions including replacement of cotton socks with polyethylene bags, reduction in mold agent, and addition of mold presses.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S353	04/02/2018	R - Real-Time Proc	CONSULTA , SYNCRA AND VIVA CRT-P	MEDTRONIC INC.	Approval for an update to the epoxy resin to catalyst mix ratio and pattern weight.
P010015/S355	04/24/2018	R - Real-Time Proc	CONSULTA CRT-P, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	Approval for stability enhancements, security updates, and error mitigation for the MyCareLink Patient Monitor Model 24950 firmware.
P010030/S102	04/17/2018	R - Real-Time Proc	LIFE VEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Approval for design changes to the LCD glass display and the injection molded display enclosure.
P010031/S618	04/24/2018	R - Real-Time Proc	BRAVA CRT-D, BRAVA QUAD CRT-D, CONCERTO ICD, CONCERTO II CRT-D, CONSULTA CRT-D, INSYNC II PROTECT ICD, MAXIMO II CRT-D, PROTECTA CRT-D, PROTECTA XT CRT-D, VIVA QUAD S CRT-D, VIVA QUAD XT CRT-D, VIVA S CRT-D, VIVA XT CRT-D, AMPLIA MRI CRT-D SURESCAN, AMPLIA MRI QUAD CRT-D SURESCAN, COMPIA MRI CRT-D SURESCAN, COMPIA MRI QUAD CRT-D SURESCAN	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for stability enhancements, security updates, and error mitigation for the MyCareLink Patient Monitor Model 24950 firmware.
P010054/S035	04/20/2018	R - Real-Time Proc	ELECSYS ANTI-HBS IMMUNOASSAY	ROCHE DIAGNOSTICS CORP.	Approval for a software update (version 02-07) to the cobas e 411 immunoassay analyzer.
P020014/S051	04/09/2018	S - Special CBE	ESSURE SYSTEM FOR PERMANENT BIRTH CONTROL	BAYER PHARMA AG	Approval for a change in the title of the “Patient-Doctor Discussion Checklist" to "Patient-Doctor Discussion Checklist - Acceptance of Risk and Informed Decision Acknowledgement, and for revisions to the patient insert card.
P020027/S028	04/13/2018	O - Normal 180 Day	DIMENSION FPSA FLEX REAGENT CARTRIDGE	SIEMENS HEALTHCARE DIAGNOSTICS	Approval of the instrument manufacturing site change for the Dimension® EXL integrated systems to the Siemens instrument manufacturing facility located in Flanders, New Jersey.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P020045/S086	04/17/2018	R - Real-Time Proc	FREEZOR CARDIAC CRYOABLATION CATHETER, FREEZOR XTRA CARDIAC CRYOABLATION CATHETER AND FREEZOR MAX CARDIAC CRYOABLATION	MEDTRONIC CRYOCATH LP	Approval for the implementation of a change to the product requirement specification documents related to the external surface of the effective length of the catheter, as well as associated changes to the manufacturing process and process planning matrix.
P020050/S028	04/09/2018	R - Real-Time Proc	WAVE LIGHT EX500 LASER	ALCON LABORATORIES, INC.	Approval for modification of the electronic circuit of VSE (Versorgungseinheit or supply unit) board in the WaveLight EX500 system by adding resistor-capacitor circuits to the switch transistors to reduce the starting currents and improve the reliability and life of the board.
P030008/S024	04/09/2018	R - Real-Time Proc	WAVE LIGHT EX500 LASER	ALCON LABORATORIES, INC.	Approval for modification of the electronic circuit of VSE (Versorgungseinheit or supply unit) board in the WaveLight EX500 system by adding resistor-capacitor circuits to the switch transistors to reduce the starting currents and improve the reliability and life of the board.
P030035/S164	04/11/2018	N - Normal 180 Day	ANTHEM, ALLURE/RF, ALLURE QUADRA/RF FAMILY OF CRT-PS	ST. JUDE MEDICAL, INC.	Approval for cybersecurity updates and implementation of a Battery Performance Alert in the firmware of ICDs and CRT-Ds.
P030054/S323	04/02/2018	Y - 135 Review Tra	QUICKFLEX U AND QUARTET LEADS	ST. JUDE MEDICAL	Approval for an alternate supplier for material used for lead insulation tubing.
P030054/S344	04/11/2018	N - Normal 180 Day	PROMOTE/+/RF/Q, PROMOTE ACCEL, PROMOTE QUADRA, UNIFY, UNIFY ASSURA, UNIFY QUADRA, QUADRA ASSURA, EPIC+/HF/HF+/II HF/II+ HF, ATLAS+HF/II HH/II+ HF FAMILY OF CRT-DS	ST. JUDE MEDICAL	Approval for cybersecurity updates and implementation of a Battery Performance Alert in the firmware of ICDs and CRT-Ds.
P070004/S013	04/17/2018	Y - 135 Review Tra	SIENTRA OPUS SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Approval for dimethyl silicone dispersion solvent from perchloroethylene to xylene.
P080011/S066	04/10/2018	O - Normal 180 Day	NATURAL EYES HYDRA WEAR XW AND NATURAL EYES XW FOR ASTIGMATISM	COOPERVISION MANUFACTURING, LTD.	Approval to add a new private label brand name, Natural Eyes Hydra Wear XW and Natural Eyes Hydra Wear for Astagmatism.
P080011/S067	04/09/2018	O - Normal 180 Day	AQUACLEAR PREMIUM	COOPERVISION MANUFACTURING, LTD.	Approval for the addition of a new private label brand name, AquaClear Premium.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P080011/S068	04/25/2018	O - Normal 180 Day	SOFMED BRETHABLES XW, SOFMED BREATHABLES XW PREMIUM, SOFMED BREATHABLES XW TORIC, SOFMED BREATHABLES XW MULTIFOCAL	COOPERVISION MANUFACTURING, LTD.	Approved for the addition of a new private label brand name Sofmed breathables XW (comfilcon A), Sofmed breathables XW premium (comfilcon A), Sofmed breathables XW toric (comfilcon A) and Sofmed breathables XW multifocal (comfilcon A) Soft Extended Wear Contact Lenses.
P080025/S151	04/13/2018	O - Normal 180 Day	INTERSTIM THERAPY SYSTEM. VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Approval for a manufacturing site located at Road 31, Km. 24, Hm 4, Ceiba Norte Industrial Park, Juncos, Puerto Rico 00777, for kitting activities including Sterile Packaging, Sterilization, Final Pack & Label, and Final QA Inspection.
P090007/S019	04/20/2018	R - Real-Time Proc	ELECSYS ANBTI-HCV IMMUNOASSAY	ROCHE DIAGNOSTICS CORP.	Approval for a software update (version 02-07) to the cobas e 411 immunoassay analyzer.
P090013/S270	04/24/2018	R - Real-Time Proc	REVO MRI SURESCAN IPG	MEDTRONIC, INC	Approval for stability enhancements, security updates, and error mitigation for the MyCareLink Patient Monitor Model 24950 firmware.
P100010/S073	04/17/2018	R - Real-Time Proc	ARCTIC FRONT CARDIAC CRYOABLATION CATHETER AND ARCTIC FRONT ADVANCE CARDIAC CRYOABLATION CATHETER	MEDTRONIC CRYOCATH LP	Approval for the implementation of a change to the product requirement specification documents related to the external surface of the effective length of the catheter, as well as associated changes to the manufacturing process and process planning matrix.
P100031/S023	04/20/2018	R - Real-Time Proc	ELECSYS ANTI-HBC II	ROCHE DIAGNOSTICS CORP.	Approval for a software update (version 02-07) to the cobas e 411 immunoassay analyzer.
P100032/S018	04/20/2018	R - Real-Time Proc	ELECSYS ANTI-HBC II	ROCHE DIAGNOSTICS CORP.	Approval for a software update (version 02-07) to the cobas e 411 immunoassay analyzer.
P100045/S023	04/04/2018	R - Real-Time Proc	CARDIOMEMS HF SYSTEM	ST. JUDE MEDICAL	Approval for a change the tolerance for the hydrophilic coated length along the distal end of the catheter.
P100047/S118	04/13/2018	S - Special CBE	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for the addition of 100% visual inspection of the HeartWare Ventricular Assist System Controller at final packaging.
P110004/S028	04/17/2018	Y - 135 Review Tra	NIRXCELL COCR CORONARY STENT ON RX SYSTEM	MEDINOL LTD.	Approval for the addition of two new balloon manufacturing machines.
P110008/S008	04/25/2018	N - Normal 180 Day	COFLEX® INTERLAMINAR TECHNOLOGY	PARADIGM SPINE, LLC	Approval for introducing a set of disposable instruments for the coflex® and for Otto Klumpp to manufacture these disposable instruments at Burgstraße 18, 72336, Balingen-Ostdorf, Germany.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110008/S010	04/20/2018	O - Normal 180 Day	COFLEX® INTERLAMINAR TECHNOLOGY	PARADIGM SPINE, LLC	Approval for a manufacturing site located at Diener Implants GmbH, Rudolf-Diesel-Strasse: 18, Tuttllingen, Germany.
P110013/S086	04/18/2018	O - Normal 180 Day	RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval to update the device labeling with the most currently available long-term clinical data from the Post-Approval Study.
P110031/S022	04/20/2018	R - Real-Time Proc	ELECSYS ANTI-HBC IGM	ROCHE DIAGNOSTICS CORP.	Approval for a software update (version 02-07) to the cobas e 411 immunoassay analyzer
P110041/S004	04/19/2018	N - Normal 180 Day	ADVIA CENTAUR HBSAGII (HBSII), ADVIA CENTAUR HBSAG CONFIRMATORY, ADVIA CENTAUR HBSAG QUALITY CONTROL	SIEMENS CORP.	Approval for migration of the ADVIA Centaur HBsAgII (HBsII), the ADVIA Centaur HBsAg Confirmatory, and the ADVIA Centaur HBsAg Quality Control Material onto the Atellica IM analyzer.
P110042/S102	04/19/2018	N - Normal 180 Day	EMBLEM S-ICD ELECTRODE DELIVERY SYSTEM (MODEL 4712)	BOSTON SCIENTIFIC CORPORATION	Approval for a new S-ICD kit of tunneling tools, called EMBLEM S-ICD Electrode Delivery System (EDS), Model 4712.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P120019/S016	04/18/2018	N - Normal 180 Day	COBAS EGFR MUTATION TEST V2	ROCHE	Approval of the cobas® EGFR Mutation Test v2. The device is a real-time PCR test for the qualitative detection of defined mutations of the epidermal growth factor receptor (EGFR) gene in non-small cell lung cancer (NSCLC) patients. Defined EGFR mutations are detected using DNA isolated from formalin-fixed paraffin-embedded tumor tissue (FFPET) or circulating-free tumor DNA (cfDNA) from plasma derived from EDTA anti-coagulated peripheral whole blood. The test is indicated as a companion diagnostic to aid in selecting NSCLC patients for treatment with the targeted therapies listed in Table 1 below in accordance with the approved therapeutic product labeling: Table 1 Drug FFPET Plasma TARCEVA® (erlotinib) Exon 19 deletions and L858R Exon 19 deletions and L858R TAGRISSO® (osimertinib) Exon 19 deletions, L858R, and T790M T790M* Patients with positive cobas® EGFR Mutation Test v2 test results using plasma specimens for the presence of the EGFR mutations listed above are eligible for treatment with the corresponding drug as indicated in Table 1 (see Note* for T790M). Patients who are negative for these mutations by this test using plasma specimens should be reflexed to routine biopsy and testing for EGFR mutations with the FFPET sample type. *The efficacy of TAGRISSO (osimertinib) has not been established in the EGFR T790M plasma-positive, tissue-negative or unknown population and clinical data for T790M plasma-positive patients are limited; therefore testing using plasma specimens is most appropriate for consideration in patients from whom a tumor biopsy cannot be obtained. Drug safety and efficacy have not been established for the following EGFR mutations also detected by the cobas® EGFR Mutation Test v2. Table 2 Drug FFPET Plasma TARCEVA® (erlotinib) G719X, Exon 20 insertions, T790M, S768I, and L861Q G719X, Exon 20 insertions, T790M, S768I, and L861Q TAGRISSO® (osimertinib) G719X, Exon 20 insertions, S768I, and L861Q G719X, Exon 19 deletions, L858R, Exon 20 insertions, S768I, and L861Q For manual sample preparation, FFPET specimens are processed using the cobas® DNA Sample Preparation Kit and plasma specimens are processed using the cobas® cfDNA Sample Preparation Kit. The cobas z 480 analyzer is used for automated amplification and detection.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P120019/S018	04/18/2018	N - Normal 180 Day	COBAS EGFR MUTATION TEST V2	ROCHE	The cobas® EGFR Mutation Test v2 is a real-time PCR test for the qualitative detection of defined mutations of the epidermal growth factor receptor (EGFR) gene in non-small cell lung cancer (NSCLC) patients. Defined EGFR mutations are detected using DNA isolated from formalin-fixed paraffin-embedded tumor tissue (FFPET) or circulating-free tumor DNA (cfDNA) from plasma derived from EDTA anti-coagulated peripheral whole blood. The test is indicated as a companion diagnostic to aid in selecting NSCLC patients for treatment with the targeted therapies listed in Table 1 below in accordance with the approved therapeutic product labeling: Table 1 Drug FFPET Plasma TARCEVA® (erlotinib) Exon 19 deletions and L858R Exon 19 deletions and L858R TAGRISSO® (osimertinib) Exon 19 deletions, L858R and T790M Exon 19 deletions, L858R and T790M* Patients with positive cobas® EGFR Mutation Test v2 test results using plasma specimens for the presence of the EGFR mutations listed above are eligible for treatment with the corresponding drug as indicated in Table 1 (see Note* for T790M). Patients who are negative for these mutations by this test using plasma specimens should be reflexed to routine biopsy and testing for EGFR mutations with the FFPET sample type. *The efficacy of TAGRISSO® (osimertinib) has not been established in the EGFR T790M plasma-positive, tissue-negative or unknown population and clinical data for T790M plasma-positive patients are limited; therefore testing using plasma specimens is most appropriate for consideration in patients from whom a tumor biopsy cannot be obtained. Drug safety and efficacy have not been established for the following EGFR mutations also detected by the cobas® EGFR Mutation Test v2: Table 2 Drug FFPET Plasma TARCEVA® (erlotinib) G719X, Exon 20 insertions, T790M, S768I and L861Q G719X, Exon 20 insertions, T790M, S768I and L861Q TAGRISSO® (osimertinib) G719X, Exon 20 insertions, S768I, and L861Q G719X, Exon 20 insertions, S768I, and L861Q For manual sample preparation, FFPET specimens are processed using the cobas® DNA Sample Preparation Kit and plasma specimens are processed using the cobas® cfDNA Sample Preparation Kit. The cobas z 480 analyzer is used for automated amplification and detection.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130021/S041	04/06/2018	O - Normal 180 Day	MEDTRONIC COREVALVE SYSTEM / MEDTRONIC COREVALVE EVOLUT R SYSTEM/ MEDTRONIC COREVALVE EVOLUT PRO SYSTEM	MEDTRONIC COREVALVE LLC	Approval of the protocol for the post-approval study (PAS) protocol.
P140003/S029	04/30/2018	R - Real-Time Proc	IMPELLA 2.5 SYSTEM, IMPELLA CP SYSTEM, IMPELLA CP OPTICAL SYSTEM, IMPELLA 5.0 SYSTEM, AND IMPELLA LD SYSTEM	ABIOMED, INC.	Approval for a design change to the EEPROM component of the Impella catheters.
P140004/S011	04/09/2018	O - Normal 180 Day	SUPERION INDIRECT DECOMPRESSION SYSTEM	VERTIFLEX (R), INCORPORATED	Approval of the revised protocol for the post-approval study (PAS) protocol.
P140010/S037	04/19/2018	P - Panel Track	IN.PACT ADMIRAL PACLITAXEL-COATED PERCUTANEOUS-TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Approval for the IN.PACT Admiral Paclitaxel-Coated Percutaneous-Transluminal Angioplasty Balloon Catheter. This device is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo, restenotic, or in-stent restenotic lesions with lengths up to 360 mm in superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm.
P140015/S024	04/17/2018	R - Real-Time Proc	T:SLIM G4 INSULIN PUMP WITH DEXCOM G4 PLATINUM CGM (T:SLIM G4 SYSTEM); T:SLIM X2 INSULIN PUMP WITH DEXCOM G5 MOBILE CGM SYSTEM	TANDEM DIABETES CARE, INC.	Approval for minor design changes to the pump housing and patient line port of the t:slim X2 Insulin Pump. The t:slim X2 Insulin Pump is a part of the t:slim X2 Insulin Pump with Dexcom G5 Mobile CGM System.
P140021/S013	04/20/2018	R - Real-Time Proc	ELECSYS ANTI-HCV II	ROCHE DIAGNOSTICS OPERATIONS INC	Approval for a software update (version 02-07) to the cobas e 411 immunoassay analyzer.
P140030/S004	04/25/2018	Y - 135 Review Tra	ASTRON PERIPHERAL SELF-EXPANDING NITINOL STENT SYSTEM	BIOTRONIK, INC.	Approval for modifications to the incubation conditions used during bioburden testing of the product and environment.
P140032/S002	04/17/2018	N - Normal 180 Day	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Approval for changes made to the design history file and device master record of the motor component of the SynchroMed II Implantable System for Remodulin, (Model 8637P), the associated parts of the motor (i.e. assemblies, subassemblies, components, subcomponents, and materials used in the manufacturing of the motor assembly), and the pumphead assembly material specifications.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140033/S002	04/02/2018	Y - 135 Review Tra	TENDRIL MRI LEADS (MRI)	ST. JUDE MEDICAL, INC.	Approval for an alternate supplier for material used for lead insulation tubing.
P140033/S022	04/11/2018	N - Normal 180 Day	ASSURITY MRI ENDURITY MRI FAMILY OF PACEMAKERS	ST. JUDE MEDICAL, INC.	Approval for cybersecurity updates and implementation of a Battery Performance Alert in the firmware of ICDs and CRT-Ds.
P150016/S012	04/20/2018	R - Real-Time Proc	TRIDYNE VASCULAR SEALANT	NEOMEND, INC.	Approval for updates to the performance specifications for Tridyne Vascular Sealant.
P150031/S003	04/24/2018	O - Normal 180 Day	VERCISE DBS SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for manufacturing sites located at Boston Scientific Limited, Cashel Road, Clonmel, Ireland (Vercise DBS IPG packaging, sterilization, and distribution operations); Guidant Puerto Rico B.V., No. 12, Road 698, Dorado, Puerto Rico (Vercise Leads, Extension, M8 Adaptor, and Physician¿s Spare Kit manufacturing and sterilization operations); and Boston Scientific Corporation, 4100 Hamline Avenue North, St. Paul, Minnesota (Vercise external devices and surgical accessories manufacturing and sterilization operations).
P150033/S032	04/24/2018	R - Real-Time Proc	MICRA	MEDTRONIC INC.	Approval for stability enhancements, security updates, and error mitigation for the MyCareLink Patient Monitor Model 24950 firmware.
P160003/S002	04/25/2018	Y - 135 Review Tra	PRO-KINETIC ENERGY CORONARY STENT SYSTEM	BIOTRONIK, INC.	Approval for modifications to the incubation conditions used during bioburden testing of the product and environment.
P160004/S008	04/13/2018	O - Normal 180 Day	GORE TIGRIS VASCULAR STENT	W. L. GORE & ASSOCIATES, INC.	Approval for updated labeling with post-approval study results.
P160018/S001	04/06/2018	P - Panel Track	FOUNDATIONFOCUS CDX BRCA HRD	FOUNDATION MEDICINE, INC	Approval for the FoundationFocus¿ CDx BRCA LOH. The device is an assay that uses next-generation sequencing (NGS) for qualitative detection of BRCA1 and BRCA2 sequence alterations and genomic loss of heterozygosity (LOH) from formalin-fixed, paraffin-embedded (FFPE) ovarian tumor tissue. Results of the test are used as an aid in identifying ovarian cancer patients with deleterious tumor BRCA variants (tBRCA-positive), who may be eligible for treatment with Rubraca (rucaparib). Positive homologous recombination deficiency (HRD) status (defined as tBRCA-positive or LOH high) in ovarian cancer patients is associated with improved progression-free survival (PFS) from Rubraca (rucaparib) maintenance therapy. See the RUBRACA product label for information about guiding therapy in specific clinical circumstances. This test is to be performed at Foundation Medicine, Inc., a single laboratory site, located at 150 Second Street, Cambridge, Massachusetts.
P160025/S001	04/25/2018	Y - 135 Review Tra	ASTRON PULSAR/ PULSAR-18 STENT SYSTEM	BIOTRONIK, INC.	Approval for modifications to the incubation conditions used during bioburden testing of the product and environment.
P170008/S002	04/17/2018	Y - 135 Review Tra	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Approval for the addition of two new balloon manufacturing machines.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170011/S005	04/30/2018	R - Real-Time Proc	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval for a design change to the EEPROM component of the Impella catheters.

Total: 89

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N18286/S031	04/09/2018	X - 30-Day Notice	GELFOAM STERILE SPONGE	PFIZER, INC.	Change in the Gelfoam crosslinking time range.
N970003/S227	04/11/2018	X - 30-Day Notice	ACCOLADE, ALTRUA 2, ESSENTIO, PROPONENT	BOSTON SCIENTIFIC CORP.	Additional inspection criteria for pulse generator case halves with minor blemishes.
N970003/S228	04/25/2018	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Updates to the BET test method.
P790005/S061	04/26/2018	X - 30-Day Notice	EBI OSTEOGEN IMPLANTABLE BONE GROWTH STIMULATORS	EBI, LLC	Qualification and implementation of digitally-controlled vacuum sealing equipment to replace the analog vacuum sealing equipment.
P790007/S056	04/19/2018	X - 30-Day Notice	HANCOCK MODIFIED ORIFICE VALVED CONDUIT	MEDTRONIC HEART VALVES	Addition of a new porcine tissue supplier.
P810006/S081	04/25/2018	X - 30-Day Notice	COLLASTAT, ABSORABLE COLLAGEN, HEMOSTATIC SPONGE COLLASTAT, ABSORBABLE COLLAGEN HEMOSTATIC AGENT, MICROFIBRILLAR FORM	INTEGRA LIFESCIENCES CORPORATION	Replacement of two Air Handler Units.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830060/S082	04/25/2018	X - 30-Day Notice	VENTAK AND AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (AICD) SYSTEMS	BOSTON SCIENTIFIC	Updates to the BET test method.
P830061/S155	04/23/2018	X - 30-Day Notice	CAPSURE SENSE LEAD, CAPSURE SP NOVUS LEAD, VITATRON CRYSTALLINE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer the extrusion process of stylet tubing.
P830061/S156	04/23/2018	X - 30-Day Notice	CAPSURE SENSE LEAD, CAPSURE SP NOVUS LEAD, AND VITATRON CRYSTALLINE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Automate certain manufacturing processes for stylet assemblies.
P840001/S391	04/09/2018	X - 30-Day Notice	MASTER RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Implementation of updated hardware and software for battery testing for production use.
P840001/S392	04/13/2018	X - 30-Day Notice	RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Addition of an alternate printed circuit board supplier.
P840001/S394	04/20/2018	X - 30-Day Notice	MASTER RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Update the electrical resistance test equipment to allow for storing/transferring measurement data and for restarting the test using the same or different model or return to the main menu.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840062/S065	04/25/2018	X - 30-Day Notice	COLLACOTE, COLLATAPE, COLLAPLUG, ABSORBABLE COLLAGEN WOUND DRESSINGS	COLLA-TEC, INC.	Replacement of two Air Handler Units.
P840064/S068	04/24/2018	X - 30-Day Notice	VISCOAT OPTHALMIC VISCOELASTIC SYSTEM, DUOVISC OPTHALMIC VISCOELASTIC SYSTEM	ALCON LABORATORIES	Use of a compounding isolator for sterile incorporation of Sodium Hyaluronate during production of PROVISC and PROVISC as part of DUOVISC, and for additional formulation rooms 4 and 5 for manufacture of PROVISC, PROVISC as part of DUOVISC, VISCOAT, and VISCOAT as part of DUOVISC.
P850010/S080	04/25/2018	X - 30-Day Notice	HILISTAT, HELITENE, ABSORBABLE COLLAGEN HEMOSTATIC AGENTS	INTEGRA LIFESCIENCES CORPORATION	Replacement of two Air Handler Units.
P850035/S050	04/26/2018	X - 30-Day Notice	SPF IMPLANTABLE SPINAL FUSION STIMULATORS	EBI, LLC	Qualification and implementation of digitally-controlled vacuum sealing equipment to replace the analog vacuum sealing equipment.
P850089/S131	04/23/2018	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	Transfer the extrusion process of stylet tubing.
P850089/S132	04/23/2018	X - 30-Day Notice	CAPSURE SP NOVUS LEAD, CAPSURE SP Z LEAD, CAPSURE Z NOVUS LEAD AND VITATRON IMPULSE II LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Automate certain manufacturing processes for stylet assemblies.
P860004/S299	04/09/2018	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Implementation of updated hardware and software for battery testing for production use.
P860004/S301	04/25/2018	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	Addition of an additional manufacturing site for the laser etch operation of selected components associated with the Medtronic SynchroMed® Infusion System.
P860004/S302	04/27/2018	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Manufacturing site change for the SynchoMed II Infusion System pump tube component assembly.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860057/S177	04/12/2018	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT PERICARDIAL AORTIC BIOPROSTHESIS, PERIMOUNT THEON PERICARDIAL AORTIC BIOPROTHESIS WITH THERMAFIX TISSUE PROCESS, PERIMOUNT RSR PERICARDIAL AORTIC BIOPROTHESIS, PERIMOUNT THEON RSR PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, PERIMOUNT MAGNA PERICARDIAL AORTIC BIOPROSTHESIS, PERIMOUNT MAGNA PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, PERIMOUNT MAGNA EASE PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, PERIMOUNT PLUS PERICARDIAL MITRAL BIOPROSTHESIS, PERIMOUNT THEON PERICARDIAL MITRAL EASE PERICARDIAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS,	EDWARDS LIFESCIENCE S, LLC.	Transfer receiving and inspection to a new cleanroom within the same facility.
P870078/S041	04/19/2018	X - 30-Day Notice	HANCOCK LOW POROSITY VALVED CONDUIT	MEDTRONIC, INC.	Addition of a new porcine tissue supplier.
P880086/S297	04/25/2018	X - 30-Day Notice	ASSURITY, ASSURITY +, ENDURITY, ENDURITY CORE	ST. JUDE MEDICAL, INC.	Incorporate 2D barcode laser marking.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P890003/S388	04/23/2018	X - 30-Day Notice	CAPSURE VDD 2 LEAD, VITATRON BRILLIANT S+ VDD LEAD	MEDTRONIC, INC.	Transfer the extrusion process of stylet tubing.
P890003/S389	04/23/2018	X - 30-Day Notice	CAPSURE VDD 2 LEAD AND VITATRON BRILLIANT S+ VDD LEAD	MEDTRONIC, INC.	Automate certain manufacturing processes for stylet assemblies.
P890047/S053	04/24/2018	X - 30-Day Notice	PROVISC OPTHALMIC VISCOELASTIC DEVICE	ALCON RESEARCH, LTD.	Use of a compounding isolator for sterile incorporation of Sodium Hyaluronate during production of PROVISC and PROVISC as part of DUOVISC, and for additional formulation rooms 4 and 5 for manufacture of PROVISC, PROVISC as part of DUOVISC, VISCOAT, and VISCOAT as part of DUOVISC.
P900033/S068	04/05/2018	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Qualification of two new computers that will be used for conducting Pore Size Image Analysis in the Quality Control Analytical Laboratory located at Integra LifeSciences Collagen Manufacturing Center.
P900033/S069	04/25/2018	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE, INTEGRA MESHED DERMAL REGENERATION TEMPLATE INTERGRA, OMINIGRAFT DERMAL REGENERATION MATRIX	INTEGRA LIFESCIENCES CORP.	Replacement of two Air Handler Units.
P910018/S025	04/12/2018	X - 30-Day Notice	LIPOSORBER LA-15 SYSTEM	KANEKA PHARMA AMERICA CORP.	Change to the bioburden recovery procedure of the sterilization process used for the SULFLUX® KP-05 plasma filter device, a component of the LIPOSORBER® LA-15 System.
P910023/S406	04/04/2018	X - 30-Day Notice	FORTIFY MODELS CD1231-40, CD1231-40Q, CD2231-40, CD2231-40Q; FORTIFY ASSURA MODELS CD1257-40, CD1257-40Q, CD2257-40, CD2257-40Q, CD1357-40, CD1357-40Q, CD1357-40C, CD1357-40QC, CD2357-40, CD2357-40Q, CD2357-40C, CD2357-40QC	ST. JUDE MEDICAL	Add an alternate supplier for the metal ring frame used in the hybrid.
P910023/S407	04/03/2018	X - 30-Day Notice	FORIFY, FORTIFY ASSURA	ST. JUDE MEDICAL	Use of a plastic ring frame as an alternative to a ceramic frame in hybrids.
P910023/S408	04/25/2018	X - 30-Day Notice	ELLIPSE VR, ELLIPSE DR, FORTIFY, FORTIFY ASSURA	ST. JUDE MEDICAL	Incorporate 2D barcode laser marking.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P910073/S148	04/25/2018	X - 30-Day Notice	ENDOTAK LEAD SYSTEM	BOSTON SCIENTIFIC	Updates to the BET test method.
P910077/S166	04/25/2018	X - 30-Day Notice	VENTAK(R) PRX (TM) MODEL 1700,1705 PULSE GENERATOR	BOSTON SCIENTIFIC	Updates to the BET test method.
P920015/S210	04/23/2018	X - 30-Day Notice	SPRINT QUATTRO LEAD, TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Transfer the extrusion process of stylet tubing.
P920015/S211	04/23/2018	X - 30-Day Notice	SPRINT QUATTRO LEAD	MEDTRONIC INC.	Minor manufacturing process update to an IS-1 fixation tool.
P920015/S212	04/23/2018	X - 30-Day Notice	SPRINT QUATTRO LEAD, SUBCUTANEOUS LEAD AND TRANSVENE CS/SVS LEAD	MEDTRONIC INC.	Automate certain manufacturing processes for stylet assemblies.
P930014/S111	04/11/2018	X - 30-Day Notice	ACRYSOF POSTERIOR CHAMBER SINGLE PIECE INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Implementation of an automated dimensional inspection system as an alternate process for dimensional inspection of AcrySof Intraocular Lenses at the Alcon Ireland manufacturing site.
P930035/S029	04/25/2018	X - 30-Day Notice	VENTAK(R) P2 SYSTEM	BOSTON SCIENTIFIC	Updates to the BET test method.
P930038/S087	04/03/2018	X - 30-Day Notice	ANGIO SEAL VASCULAR CLOSURE DEVICES	TERUMO MEDICAL CORPORATION	Modification to the sterilizer isotope for the AngioSeal Evolution, STS Plus, and VIP devices and a change to the AngioSeal STS Plus and VIP load configuration.
P930038/S088	04/26/2018	X - 30-Day Notice	ANGIO-SEAL VASCULAR CLOSURE DEVICES	TERUMO MEDICAL CORPORATION	Add alternate printing equipment for the handle marker.
P930039/S181	04/03/2018	X - 30-Day Notice	CAPSURE FIX NOVUS LEAD; VITATRON CRYSTALLINE ACTIVE FIXATION LEAD	MEDTRONIC, INC.	Implementation of new dry chamber time and temperature settings, elimination of a wash and air dry operations, an update to inspection methods, and standardization of process operations description.
P930039/S182	04/12/2018	X - 30-Day Notice	CAPSUREFIX NOVUS LEAD, VITATRON CRYSTALLINE ACTIVE FIXATION LEAD	MEDTRONIC, INC.	New laser welding machine, modified program for an existing laser welding machine, and modified inspection criteria.
P930039/S183	04/23/2018	X - 30-Day Notice	CAPSUREFIX LEAD, CAPSUREFIX NOVUS LEAD, VITATRON CRYSTALLINE ACTIVE FIXATION LEAD	MEDTRONIC, INC.	Transfer the extrusion process of stylet tubing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P930039/S184	04/23/2018	X - 30-Day Notice	CAPSUREFIX LEAD, CAPSUREFIX NOVUS LEAD, VITATRON CRYSTALLINE ACTIVE FIXATION LEAD	MEDTRONIC, INC.	Minor manufacturing process update to an IS-1 fixation tool.
P930039/S185	04/23/2018	X - 30-Day Notice	CAPSUREFIX LEAD, CAPSUREFIX NOVUS LEAD AND VITATRON CRYSTALLINE ACTIVE FIXATION LEAD	MEDTRONIC, INC.	Automate certain manufacturing processes for stylet assemblies.
P950029/S121	04/25/2018	X - 30-Day Notice	REPLY SR, REPLY DR, ESPRIT SR, ESPRIT DR	LIVANOVA USA, INC.	Minor sterilization cycle and sterilization equipment changes.
P960004/S083	04/25/2018	X - 30-Day Notice	THINLINE ENDOCARDIAL PACING LEADS	BOSTON SCIENTIFIC	Updates to the BET test method.
P960006/S047	04/25/2018	X - 30-Day Notice	SWEET TIP(R) RX STEROID ELUTING LEAD	BOSTON SCIENTIFIC	Updates to the BET test method.
P960009/S310	04/09/2018	X - 30-Day Notice	ACTIVE DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Implementation of updated hardware and software for battery testing for production use.
P960009/S311	04/20/2018	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Update the electrical resistance test equipment to allow for storing/transferring measurement data and for restarting the test using the same or different model or return to the main menu.
P960011/S030	04/23/2018	X - 30-Day Notice	BIOLON	AMRING PHARMACEUTICALS	Changes to the purification of sodium hyaluronate.
P960016/S074	04/02/2018	X - 30-Day Notice	LIVEWIRE TC STEERABLE ELECTROPHYSIOLOGY CATHETER	ST. JUDE MEDICAL	Modify the epoxy application process used for the tip to shaft assembly.
P960040/S423	04/25/2018	X - 30-Day Notice	VENTAK AV ACID VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Updates to the BET test method.
P960040/S424	04/10/2018	X - 30-Day Notice	NG2.5 (DYNAGEN MINI/ INOGEN MINI/ ORIGEN MINI), PERVICA ICD PULSE GENERATOR	BOSTON SCIENTIFIC	Additional facility for manufacturing battery case halves.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960043/S100	04/24/2018	X - 30-Day Notice	PROSTAR XL PERCUTANEOUS VASCULAR SURGICAL SYSTEM AND PERCLOSE PROGLIDE SUTURE-MEDIATED CLOSURE SYSTEM	ABBOTT VASCULAR INC.	Reduction in the frequency of bacterial endotoxin testing.
P970004/S266	04/09/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Implementation of updated hardware and software for battery testing for production use.
P970004/S267	04/13/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Addition of an alternate printed circuit board supplier.
P970031/S063	04/19/2018	X - 30-Day Notice	FREESTYLE AORTIC ROOT BIOPROSTHESIS	MEDTRONIC, INC.	Addition of a new porcine tissue supplier.
P980006/S027	04/10/2018	X - 30-Day Notice	BAUSCH & LOMB PUREVISION (BALAFILCON A) CONTACT LENSES	BAUSCH & LOMB, INC.	Add an alternate supplier for a raw material for the PureVision® (balafilcon A) product line.
P980016/S660	04/03/2018	X - 30-Day Notice	PROTECTA ICD, PROTECTA VR ICD, PROTECTAXT ICD, SECURA DR ICD, SECURA ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Additional mold machine for use during hybrid component manufacturing.
P980016/S661	04/10/2018	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; VISIA AF MRI DF1/VR ICD; VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Additional universal burn-in load station during battery manufacturing.
P980016/S662	04/09/2018	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 DF1 ICD, VISIA AF MRI VR ICD, VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	New upper limit for room temperature final functional charge time testing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S664	04/25/2018	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, 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 MANAGEMENT	Implementation of a collaborative robot.
P980035/S538	04/03/2018	X - 30-Day Notice	ADVISA DR IPG, ADVISA DR MRI IPG, ADVISA SR MRI IPG	MEDTRONIC INC.	Additional mold machine for use during hybrid component manufacturing.
P980035/S539	04/09/2018	X - 30-Day Notice	AZURE S DR MRI IPG, AZURE S SR MRI IPG, AZURE XT DR MRI IPG, AZURE XT SR MRI IPG	MEDTRONIC INC.	Implementation of additional models on the Unitek welder station.
P980035/S540	04/10/2018	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG; ADVISA DR IPG; ADVISA DR/SR MRI IPG; ASTRA XT DR MRI IPG; ASTRA S DR/SR MRI IPG; ASTRA XT SR MRI IPG; ATTESTA DR/SR MRI IPG; AZURE S DR/SR MRI IPG; AZURE XT DR/SR MRI IPG; RELIA IPG; SPHERA DR/SR MRI IPG	MEDTRONIC INC.	Additional universal burn-in load station during battery manufacturing.
P980035/S541	04/06/2018	X - 30-Day Notice	ASTRA XT DR, ASTRA S DR, ASTRA S SR, ASTRA XT SR, AZURE S DR, AZURE S SR, AZURE XT DR, AZURE XT SR MRI IPG	MEDTRONIC INC.	Add Medtronic Puerto Rico Operations Center, Juncos (MPROC) as an alternate supplier for the Orion Shield assembly.
P980035/S542	04/16/2018	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ATTESTA IPG, RELIA IPG, SPHERA IPG	MEDTRONIC INC.	Alternate integrated circuit protection diode supplier.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980035/S543	04/12/2018	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 MRI IPG, AZURE XT DR MRI IPG, AZURE XT SR MRI IPG	MEDTRONIC INC.	Updates to the IC Electrical Test Requirements Specification and Automated Test Equipment software for testing Microcontroller ICs.
P980035/S544	04/25/2018	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ADVISA DR IPG, ADVISA DR MRI IPG, ADVISA SR MRI IPG, 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 MRI IPG, AZURE XT DR /SR MRI IPG, RELIA IPG	MEDTRONIC INC.	Implementation of a collaborative robot.
P980035/S545	04/30/2018	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ATTESTA DR MRI IPG, ATTESTA SR MRI IPG, RELIA IPG, SPHERA DR MRI IPG, SPHERA SR MRI IPG	MEDTRONIC INC.	New supplier for material used in battery manufacturing and minor specification changes.
P980040/S087	04/17/2018	X - 30-Day Notice	SENSAR IOL, TECNIS TORIC, TECNIS SYMFONY, TECNIS SYMFONY TORIC	JOHNSON & JOHNSON SURGICAL VISION, INC.	Supplier change for the SENSAR and TECNIS intraocular lens wheelcase packaging at the Kulim manufacturing site.
P980043/S066	04/19/2018	X - 30-Day Notice	HANCOCK II PORCINE BIOPROSTHESIS	MEDTRONIC, INC.	Addition of a new porcine tissue supplier.
P980049/S130	04/25/2018	X - 30-Day Notice	PARADYM RF VR 9250, PARADYM RF DR 9550, PLATINIUM VR 1210, PLATINIUM VR 1240, PLATINIUM DR 1510, PLATINIUM DR 1540	LIVANOVA USA, INC.	Minor sterilization cycle and sterilization equipment changes.
P980050/S115	04/23/2018	X - 30-Day Notice	TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Transfer the extrusion process of stylet tubing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980050/S116	04/23/2018	X - 30-Day Notice	TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Automate certain manufacturing processes for stylet assemblies.
P990038/S027	04/24/2018	X - 30-Day Notice	ETI-MAK-2 PLUS AND HBSAG CONFIRMATORY TEST ASSAYS	DIASORIN, INC.	Improve the process for cleaning critical manufacturing parts and equipment.
P990041/S026	04/24/2018	X - 30-Day Notice	ETI-AB-EBK PLUS ASSAY	DIASORIN, INC.	Improve the process for cleaning critical manufacturing parts and equipment.
P990042/S023	04/24/2018	X - 30-Day Notice	ETI-AB-AUK PLUS ASSAY	DIASORIN, INC.	Improve the process for cleaning critical manufacturing parts and equipment.
P990043/S027	04/24/2018	X - 30-Day Notice	ETI-EBK PLUS ASSAY	DIASORIN, INC.	Improve the process for cleaning critical manufacturing parts and equipment.
P990044/S024	04/24/2018	X - 30-Day Notice	ETI-CORE-IGMK PLUS ASSAY	DIASORIN, INC.	Improve the process for cleaning critical manufacturing parts and equipment.
P990045/S024	04/24/2018	X - 30-Day Notice	ETI-AB-COREK PLUS ASSAY	DIASORIN, INC.	Improve the process for cleaning critical manufacturing parts and equipment.
P990064/S075	04/19/2018	X - 30-Day Notice	MOSAIC PROCINE BIOPROSTHESIS	MEDTRONIC, INC.	Addition of a new porcine tissue supplier.
P010001/S018	04/20/2018	X - 30-Day Notice	TRANSCEND HIP ARTICULATION SYSTEM	CERAMTEC GMBH	Change in supplier and temperature for one of the manufacturing steps.
P010012/S482	04/25/2018	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILL	BOSTON SCIENTIFIC CORP.	Updates to the BET test method.
P010014/S072	04/13/2018	X - 30-Day Notice	OXFORD PARTIAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Upgrade the water systems used at Biomet. Water is used during the manufacturing and final cleaning processes for Oxford Partial Knee Components.
P010014/S073	04/19/2018	X - 30-Day Notice	OXFORD PATRIAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Change the laboratory that is conducting microbiology tests, change the irradiator vendor used for irradiating dose verification of test samples, and change the vendor used for testing water conductivity.
P010015/S358	04/03/2018	X - 30-Day Notice	CONSULTA CRT-P, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	Additional mold machine for use during hybrid component manufacturing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S359	04/09/2018	X - 30-Day Notice	PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P, SOLARA BIPOLAR CRT-P, SOLARA QUADRIPOLAR CRT-P	MEDTRONIC INC.	Implementation of additional models on the Unitek welder station.
P010015/S360	04/10/2018	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; VIVA CRT-P	MEDTRONIC INC.	Additional universal burn-in load station during battery manufacturing.
P010015/S361	04/12/2018	X - 30-Day Notice	PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P, SOLARA BIPOLAR CRT-P, SOLARA QUADRIPOLAR CRT-P	MEDTRONIC INC.	Updates to the IC Electrical Test Requirements Specification and Automated Test Equipment software for testing Microcontroller ICs.
P010015/S362	04/23/2018	X - 30-Day Notice	ATTAIN BIPOLAR OTW LEAD, ATTAIN OTW LV LEAD	MEDTRONIC INC.	Transfer the extrusion process of stylet tubing.
P010015/S363	04/25/2018	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, VIVA CRT-P	MEDTRONIC INC.	Implementation of a collaborative robot.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S364	04/23/2018	X - 30-Day Notice	ATTAIN BIPOLAR OTW LEAD AND ATTAIN OTW LV LEAD	MEDTRONIC INC.	Automate certain manufacturing processes for stylet assemblies.
P010019/S064	04/19/2018	X - 30-Day Notice	AIR OPTIX AQUA, AIR OPTIX PLUS HYDRAGLYDE SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Implementation of new measuring systems for power and lens dimensions.
P010029/S026	04/26/2018	X - 30-Day Notice	EUFLEXXA (1% SODIUM HYALURONATE)	FERRING PHARMACEUTICALS, INC.	Modification to a purification step for a sodium hyaluronate intermediate used to manufacture EUFLEXXA.
P010031/S619	04/03/2018	X - 30-Day Notice	CONSULTA CRT-D, PROCTECA CRT-D, PROTECTA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Additional mold machine for use during hybrid component manufacturing.
P010031/S620	04/09/2018	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, VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	New upper limit for room temperature final functional charge time testing.
P010031/S621	04/10/2018	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; VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Additional universal burn-in load station during battery manufacturing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S622	04/25/2018	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 CRT-D, VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of a collaborative robot.
P020012/S022	04/05/2018	X - 30-Day Notice	BELLAFIL DERMAL FILLER	SUNEVA MEDICAL, INC.	Revise the secondary parameters for Bubble Point Filter Testing.
P020012/S023	04/11/2018	X - 30-Day Notice	BELLAFILL DERMAL FILLER	SUNEVA MEDICAL, INC.	Resurrection and utilization of subassembly batch record, SAN 8004, 8th Purified Collagen Cake, for formulation in SAN 8005, 3.5% Atelocollagen with 0.3% Lidocaine, 20cc Syringe, on an as needed basis only.
P020012/S024	04/13/2018	X - 30-Day Notice	BELLA SKIN TEST TRAY	SUNEVA MEDICAL, INC.	Modification of the Bellafill Skin Test tray
P020012/S025	04/23/2018	X - 30-Day Notice	BELLAFILL DERMAL FILLER	SUNEVA MEDICAL, INC.	Modification to the shrink wrap process which occurs during final packaging of Bellafill Dermal Filler.
P030005/S175	04/25/2018	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Updates to the BET test method.
P030011/S061	04/25/2018	X - 30-Day Notice	SYNCARDIA TEMPORARY TOATL ARTIFICIAL HEART (TAH-T) SYSTEM - COMPANION 2 DRIVER SYSTEM	SYNCARDIA SYSTEMS, LLC	Change of location for a Companion 2 component supplier.
P030017/S312	04/02/2018	X - 30-Day Notice	PRECISION SPECTRA WAVEWRITER SPINAL CORD STIMULATOR SYSTEMS, PRECISION SPECTRA, PRE-WELD TEST EQUIPMENT SYSTEM	BOSTON SCIENTIFIC CORP.	Update to the pre-weld test equipment software used for testing the Precision Spectra and Precision Spectra Wavewriter implanted pulse generators (IPG). The update is to remove two tests (biphasic stimulation test and electrode isolation test) that duplicate upstream and downstream testing performed on the IPG.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030017/S313	04/26/2018	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATOR SYSTEM	BOSTON SCIENTIFIC CORP.	Adding an alternate qualified supplier for the cables used in the Avista MRI leads for the Precision Montage MRI and Precision Montage system.
P030035/S168	04/25/2018	X - 30-Day Notice	ALLURE RF, ALLURE QUADRA RF, ALLURE QUADRA, ALLURE, QUADRA ALLURE MP,QUADRA ALLURE MP RF	ST. JUDE MEDICAL, INC.	Incorporate 2D barcode laser marking.
P030044/S005	04/10/2018	X - 30-Day Notice	EGFR PHARMDX	DAKO NORTH AMERICA, INC.	Modification of equipment and process.
P030054/S351	04/04/2018	X - 30-Day Notice	UNIFY CD3231-40, CD3231-40Q; UNIFY QUADRA CD3249-40, CD3249-40Q; UNIFY ASSURA CD3257-40, CD3257-40Q, CD3357-40, CD3357-40Q, CD3357-40C, CD3357-40QC; QUADRA ASSURA CD3265-40, CD3265-40Q, CD3365-40, CD3365-40Q, CD3365-40C, CD3365-40QC; QUADRA ASSURA MP CD3269-40, CD3269-40C, CD3369-40, CD3369-40Q, CD3369-40C, CD3369-40QC	ST. JUDE MEDICAL	Add an alternate supplier for the metal ring frame used in the hybrid.
P030054/S352	04/03/2018	X - 30-Day Notice	UNIFY, UNIFY QUADRA, UNIFY ASSURA, QUADRA ASSURA AND QUADRA ASSURA MP	ST. JUDE MEDICAL	Use of a plastic ring frame as an alternative to a ceramic frame in hybrids.
P030054/S353	04/25/2018	X - 30-Day Notice	UNIFY, UNIFY QUADRA, UNIFY ASSURA, QUADRA ASSURA, QUADRA ASSURA MP	ST. JUDE MEDICAL	Incorporate 2D barcode laser marking.
P040020/S078	04/11/2018	X - 30-Day Notice	ACRYSOF IQ RESTOR POSTERIOR CHAMBER INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Implementation of an automated dimensional inspection system as an alternate process for dimensional inspection of AcrySof Intraocular Lenses at the Alcon Ireland manufacturing site.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040021/S035	04/19/2018	X - 30-Day Notice	BIOCOR VALVE, EPIC VALVE, EPIC SUPRA VALVE	ST. JUDE MEDICAL, INC.	Installation of additional data loggers for use with the Vaisala Environmental Monitoring System in the Pampulha, Brazil manufacturing site.
P040044/S080	04/27/2018	X - 30-Day Notice	MYNXGRIP, MYNX ACE VASCULAR CLOSURE DEVICE (VCD)	ACCESS CLOSURE, INC.	Implementation of an in-process shelf life for the hydrogel component.
P040045/S096	04/03/2018	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.
P050006/S064	04/17/2018	X - 30-Day Notice	GORE CARDIOFORM SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Alternate PFTE resin for the retrieval cord.
P050007/S035	04/16/2018	X - 30-Day Notice	STARCLOSE SE VASCULAR CLOSURE SYSTEM	ABBOTT VASCULAR DEVICES	Implementation of a vision inspection system for use during the packaging process.
P050007/S036	04/24/2018	X - 30-Day Notice	STARCLOSE SE VASCULAR CLOSURE SYSTEM	ABBOTT VASCULAR DEVICES	Reduction in the frequency of bacterial endotoxin testing.
P050037/S088	04/24/2018	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT 1.5CC	MERZ NORTH AMERICA, INC	Modify the sterilization load on the autoclave cart during the sterilization process for the 1.5cc Radiesse and 1.5cc Radiesse (+) products.
P050046/S028	04/25/2018	X - 30-Day Notice	ACUITY STEERABLE LEAD SYSTEM	GUIDANT CORP.	Updates to the BET test method.
P050047/S063	04/05/2018	X - 30-Day Notice	JUVEDERM INJECTABLE GEL IMPLANTS	ALLERGAN	Addition of a new syringe assembly and packaging line, its associated cleanroom, and minor aesthetic changes to the syringe finger grip and plunger rod.
P050052/S104	04/24/2018	X - 30-Day Notice	RADIESSE (+) LIDOCAINE DERMAL FILLER 1.5CC	MERZ NORTH AMERICA, INC	Modify the sterilization load on the autoclave cart during the sterilization process for the 1.5cc Radiesse and 1.5cc Radiesse (+) products.
P060027/S095	04/25/2018	X - 30-Day Notice	PARADYM RF CRT-D 9750, PLATINIUM CRT-D 1711, PLATINIUM CRT-D 1741, PLATINIUM 4 LV CRT-D 1744	LIVANOVA USA, INC.	Minor sterilization cycle and sterilization equipment changes.
P060039/S085	04/23/2018	X - 30-Day Notice	ATTAIN STARFIX LEAD	MEDTRONIC INC.	Transfer the extrusion process of stylet tubing.
P060039/S086	04/23/2018	X - 30-Day Notice	ATTAIN STARFIX LEAD	MEDTRONIC INC.	Automate certain manufacturing processes for stylet assemblies.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P070015/S142	04/16/2018	X - 30-Day Notice	XIENCE V EVEROLIMUS ELUTING CORONARY STENT SYSTEM, XIENCE NANO EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR INC.	Addition of an alternate contract laboratory for raw material lot release tests.
P080004/S022	04/25/2018	X - 30-Day Notice	HOYA ISERT, CLARISERT INTRAOCULAR LENS	HOYA SURGICAL OPTICS, INC.	Add an additional test laboratory for endotoxin testing.
P080006/S119	04/23/2018	X - 30-Day Notice	ATTAIN ABILITY LEAD, ATTAIN PERFORMA LEAD	MEDTRONIC INC.	Transfer the extrusion process of stylet tubing.
P080006/S120	04/23/2018	X - 30-Day Notice	ATTAIN ABILITY AND PERFORMA LEAD	MEDTRONIC INC.	Automate certain manufacturing processes for stylet assemblies.
P080011/S073	04/10/2018	X - 30-Day Notice	COMFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION MANUFACTURING, LTD.	Changes in the injection molding machine processes for Biofinity Sphere XR (comfilcon A) lenses produced at the CooperVision Manufacturing, Ltd. facility in Hamble, United Kingdom.
P080025/S161	04/09/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Implementation of updated hardware and software for battery testing for production use.
P080025/S162	04/13/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Addition of an alternate printed circuit board supplier.
P080027/S033	04/12/2018	X - 30-Day Notice	ORAQUICK HCV RAPID ANTIBODY TEST	ORASURE TECHNOLOGIES INC.	Use new equipment for the filling, vialing and labeling of a kit component.
P090013/S271	04/03/2018	X - 30-Day Notice	CAPSURE FIX MRI LEAD	MEDTRONIC, INC	Implementation of new dry chamber time and temperature settings, elimination of a wash and air dry operations, an update to inspection methods, and standardization of process operations description.
P090013/S272	04/10/2018	X - 30-Day Notice	REVO MRI SURESCAN IPG	MEDTRONIC, INC	Additional universal burn-in load station during battery manufacturing.
P090013/S273	04/12/2018	X - 30-Day Notice	CAPSUREFIX MRI LEAD	MEDTRONIC, INC	New laser welding machine, modified program for an existing laser welding machine, and modified inspection criteria.
P090013/S274	04/23/2018	X - 30-Day Notice	CAPSUREFIX MRI LEAD	MEDTRONIC, INC	Transfer the extrusion process of stylet tubing.
P090013/S275	04/25/2018	X - 30-Day Notice	REVO MRI SURESCAN IPG	MEDTRONIC, INC	Implementation of a collaborative robot.
P090013/S276	04/23/2018	X - 30-Day Notice	CAPSUREFIX MRI LEAD	MEDTRONIC, INC	Minor manufacturing process update to an IS-1 fixation tool.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P090013/S277	04/23/2018	X - 30-Day Notice	CAPSUREFIX MRI LEAD	MEDTRONIC, INC	Automate certain manufacturing processes for stylet assemblies.
P090016/S026	04/02/2018	X - 30-Day Notice	BELOTERO BALANCE DERMAL FILLER	MERZ NORTH AMERICA, INC	Change in time point for buffer pH and osmolality inspection.
P090016/S027	04/03/2018	X - 30-Day Notice	BELOTERO BALANCE DERMAL FILLER	MERZ NORTH AMERICA, INC	Add the use of spracide, Steris¿ Spor-KLenz Ready to Use Cold Sterilant to clean and disinfect the PLO cleanroom facility where Belotero Balance is manufactured.
P100010/S077	04/23/2018	X - 30-Day Notice	ARTIC FRONT ADVANCE CARDIAC CRYOABLATION CATHETERS	MEDTRONIC CRYOCATH LP	Manufacturing tool change and inspection for adhesive in the Guidewire Lumen (GWL).
P100010/S078	04/25/2018	X - 30-Day Notice	ARTIC FRONT ADVANCE CARDIAC CRYOABLATION CATHETER	MEDTRONIC CRYOCATH LP	New manufacturing inspection for tubing of Arctic Front Advance cardiac cryoablation catheters.
P100029/S033	04/19/2018	X - 30-Day Notice	TRIFECTA VALVE, TRIFECTA VALVE WITH GLIDE TECHNOLOGY (TRIFECTA GT)	ST. JUDE MEDICAL, INC.	Installation of additional data loggers for use with the Vaisala Environmental Monitoring System in the Pampulha, Brazil manufacturing site.
P100042/S017	04/13/2018	X - 30-Day Notice	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Duplication for manufacture of reagent components at an approved manufacturing site.
P100047/S119	04/24/2018	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Update the inspection procedures for components with threaded features.
P110004/S029	04/05/2018	X - 30-Day Notice	NIRXCELL COCR CORONARY STENT ON RX SYSTEM	MEDINOL LTD.	Updates to quality control testing of the D-Catheter Delivery System.
P110013/S089	04/16/2018	X - 30-Day Notice	RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEMS	MEDTRONIC VASCULAR	Update to the visual standard used by the operator in the inspection of pouch seals.
P110016/S056	04/09/2018	X - 30-Day Notice	FLEXABILITY CATHETER, SENSOR ENABLED	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Additional location for contract manufacturing of the sensor enabled cable.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110019/S100	04/16/2018	X - 30-Day Notice	XIENCE PRIME, XIENCE PRIME SV, XIENCE PRIME LL, XIENCE XPEDITION, XIENCE XPEDITION SV, XIENCE XPEDITION LL, XIENCE ALPINE, XIENCE SIERRA EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Addition of an alternate contract laboratory for raw material lot release tests.
P110027/S010	04/06/2018	X - 30-Day Notice	THERASCREEN KRAS RGQ PCR KIT	QIAGEN MANCHESTER LTD	Change the supplier and the polymer used for a kit consumable.
P110033/S037	04/05/2018	X - 30-Day Notice	JUVEDERM INJECTABLE GEL IMPLANTS	ALLERGAN	Addition of a new syringe assembly and packaging line, its associated cleanroom, and minor aesthetic changes to the syringe finger grip and plunger rod.
P110035/S045	04/03/2018	X - 30-Day Notice	EPIC VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Modifications to in-process inspections.
P110042/S106	04/25/2018	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Updates to the BET test method.
P120007/S015	04/13/2018	X - 30-Day Notice	APTIMA HPV 16 18/45 GENOTYPE ASSAY	GEN-PROBE INCORPORATED	Duplication for manufacture of reagent components at an approved manufacturing site.
P120010/S114	04/10/2018	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Adding an alternate injection molding machine and mold to produce the needle hub body component. The changes will apply to the Enlite Sensor and Guardian Sensor (3) which are part of the MiniMed 530G, MiniMed 630G, Paradigm Real-Time Revel, iPro2 CGM, and Medtronic 670G systems.
P120022/S019	04/06/2018	X - 30-Day Notice	THERASCREEN EGFR RGQ PCR KIT	QIAGEN MANCHESTER LTD	Change the supplier and the polymer used for a kit consumable.
P130007/S035	04/18/2018	X - 30-Day Notice	ANIMAS VIBE SYSTEM	ANIMAS CORP.	Manufacturing site change of the contract manufacturer for the Animas 2.0mL cartridge, which is part of the Animas Vibe System.
P130009/S087	04/12/2018	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Transfer receiving and inspection to a new cleanroom within the same facility.
P130026/S033	04/04/2018	X - 30-Day Notice	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Automation of a cable test performed during the manufacturing of the TactiSys Quartz Equipment.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130027/S005	04/06/2018	X - 30-Day Notice	ARTUS CMV RGQ MDX KIT AND ARTUS CMV QS_RGQ MDX KIT	QIAGEN, INC.	Change the supplier and the polymer used for a kit consumable.
P140002/S012	04/30/2018	X - 30-Day Notice	MISAGO RX SELF-EXPANDING PERIPHERAL STENT	TERUMO MEDICAL CORPORATION	Relocation of the sterility testing room within the same facility and an update to the clean room ISO classification.
P140003/S031	04/16/2018	X - 30-Day Notice	IMPELLA CP SYSTEM	ABIOMED, INC.	Implement a 2X ETO sterilization process for the Impella CP Optical catheter.
P140004/S013	04/19/2018	X - 30-Day Notice	SUPERION® INDIRECT DECOMPRESSION SYSTEM	VERTIFLEX (R), INCORPORATED	Manufacture the modified Superion implant (Superion v2.0) by the second manufacturing site, Turner Medical.
P140018/S010	04/03/2018	X - 30-Day Notice	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Implementation of a new flaring machine and a new etching machine for manufacturing of the delivery catheter of the VenaSeal Closure System.
P140018/S011	04/24/2018	X - 30-Day Notice	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Implementation of an extension to the allowable time between the sterilization cycle and the sterility testing for the VenaSeal Closure System.
P140026/S009	04/18/2018	X - 30-Day Notice	ENROUTE TRANSCAROTID STENT SYSTEM	SILK ROAD MEDICAL, INC	Modification to a supplier processing aid.
P140031/S062	04/12/2018	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Transfer receiving and inspection to a new cleanroom within the same facility.
P140032/S003	04/09/2018	X - 30-Day Notice	SYNCHROMED II INFUSION PUMP	MEDTRONIC, INC.	Implementation of updated hardware and software for battery testing for production use.
P140033/S028	04/25/2018	X - 30-Day Notice	ASSURITY MRI, ENDURITY MRI	ST. JUDE MEDICAL, INC.	Incorporate 2D barcode laser marking.
P150001/S041	04/10/2018	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED	Adding an alternate injection molding machine and mold to produce the needle hub body component. The changes will apply to the Enlite Sensor and Guardian Sensor (3) which are part of the MiniMed 530G, MiniMed 630G, Paradigm Real-Time Revel, iPro2 CGM, and Medtronic 670G systems.
P150001/S043	04/20/2018	X - 30-Day Notice	MEDTRONIC MINIMED 630G SYSTEM	MEDTRONIC MINIMED	Additional laser cutting equipment for manufacture of the Guardian Sensor (3). The Guardian Sensor (3) is a component of the MiniMed 630G System with SmartGuard, the Guardian Connect System, and the MiniMed 670G System.
P150012/S055	04/11/2018	X - 30-Day Notice	ACCOLADE MRI, ESSENTIO MRI, PROPONENT MRI	BOSTONSCIENTIFIC	Additional inspection criteria for pulse generator case halves with minor blemishes.
P150012/S056	04/05/2018	X - 30-Day Notice	INGEVITY MRI ACTIVE FIXATION LEAD MODELS	BOSTONSCIENTIFIC	Increase the batch size for drug collars used on INGEVITY active fixation leads.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150012/S058	04/25/2018	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Updates to the BET test method.
P150013/S010	04/10/2018	X - 30-Day Notice	PD-L1 IHC 22C3 PHARMDX	DAKO NORTH AMERICA, INC.	Modification of equipment and process.
P150019/S040	04/10/2018	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Adding an alternate injection molding machine and mold to produce the needle hub body component. The changes will apply to the Enlite Sensor and Guardian Sensor (3) which are part of the MiniMed 530G, MiniMed 630G, Paradigm Real-Time Revel, iPro2 CGM, and Medtronic 670G systems.
P150021/S023	04/05/2018	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Change to increase the sensor manufacturing capacity, at the manufacturing facility ADC Witney, by implementing a high volume sensor manufacturing line setup. The change included qualification of a new ISO 8 cleanroom and implementation of new manufacturing and support equipment. The sensor is a component of the Freestyle Libre Flash Pro and FreeStyle Libre Flash Glucose Monitoring System.
P150021/S025	04/17/2018	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Introduce a new mold and press used to make the Connector Body and Connector Trace components, which are a part of the FreeStyle Libre and FreeStyle Libre Pro Flash Glucose Monitoring Systems.
P150021/S026	04/25/2018	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Additional injection molding equipment in order to increase production capacity for the FreeStyle Libre sensor pack. The sensor pack is a component of the FreeStyle Libre and FreeStyle Libre Pro Flash Glucose Monitoring Systems.
P150025/S009	04/10/2018	X - 30-Day Notice	PD-L1 IHC 28-8 PHARMDX	DAKO NORTH AMERICA, INC.	Modification of manufacturing equipment and process.
P150026/S004	04/16/2018	X - 30-Day Notice	05/04/2018	CARDIOFOCUS, INC.	Implement an automated label printing system for UDI requirements.
P150029/S017	04/10/2018	X - 30-Day Notice	IPRO2 SYSTEM	MEDTRONIC MINIMED	Adding an alternate injection molding machine and mold to produce the needle hub body component. The changes will apply to the Enlite Sensor and Guardian Sensor (3) which are part of the MiniMed 530G, MiniMed 630G, Paradigm Real-Time Revel, iPro2 CGM, and Medtronic 670G systems.
P150033/S033	04/10/2018	X - 30-Day Notice	MICRA TPS	MEDTRONIC INC.	Additional universal burn-in load station during battery manufacturing.
P150036/S028	04/12/2018	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Transfer receiving and inspection to a new cleanroom within the same facility.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150048/S019	04/12/2018	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROTHESIS, INSPIRIS RESILIA AORTIC VALVE	EDWARDS LIFESCIENCES, LLC.	Transfer receiving and inspection to a new cleanroom within the same facility.
P160001/S014	04/28/2018	X - 30-Day Notice	OBALON BALLOON SYSTEM	OBALON THERAPEUTICS, INC.	Implementation of the new catheter surface preparation process prior to bonding.
P160007/S002	04/20/2018	X - 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Additional laser cutting equipment for manufacture of the Guardian Sensor (3). The Guardian Sensor (3) is a component of the MiniMed 630G System with SmartGuard, the Guardian Connect System, and the MiniMed 670G System.
P160014/S001	04/16/2018	X - 30-Day Notice	COBRA PZF NANOCOATED CORONARY STENT SYSTEM	CELONOVA BIOSCIENCES, INC.	Change to an in-process inspection step in the manufacturing process for the COBRA PzF NanoCoated Coronary Stent System.
P160017/S039	04/10/2018	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Adding an alternate injection molding machine and mold to produce the needle hub body component. The changes will apply to the Enlite Sensor and Guardian Sensor (3) which are part of the MiniMed 530G, MiniMed 630G, Paradigm Real-Time Revel, iPro2 CGM, and Medtronic 670G systems.
P160017/S041	04/20/2018	X - 30-Day Notice	MEDTRONIC MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Additional laser cutting equipment for manufacture of the Guardian Sensor (3). The Guardian Sensor (3) is a component of the MiniMed 630G System with SmartGuard, the Guardian Connect System, and the MiniMed 670G System.
P160023/S002	04/10/2018	X - 30-Day Notice	APTIMA HCV QUANT DX ASSAY	HOLOGIC, INC.	Transfer manufacturing of kit subcomponents to a new facility.
P160024/S004	04/19/2018	X - 30-Day Notice	LIFESTREAM BALLOON EXPANDABLE VASCULAR COVERED STENT	BARD PERIPHERAL VASCULAR, INC.	Modifications to tooling fixtures.
P160030/S013	04/05/2018	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Change to increase the sensor manufacturing capacity, at the manufacturing facility ADC Witney, by implementing a high volume sensor manufacturing line setup. The change included qualification of a new ISO 8 cleanroom and implementation of new manufacturing and support equipment. The sensor is a component of the Freestyle Libre Flash Pro and FreeStyle Libre Flash Glucose Monitoring System.
P160030/S015	04/17/2018	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Introduce a new mold and press used to make the Connector Body and Connector Trace components, which are a part of the FreeStyle Libre and FreeStyle Libre Pro Flash Glucose Monitoring Systems.
P160030/S016	04/25/2018	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Additional injection molding equipment in order to increase production capacity for the FreeStyle Libre sensor pack. The sensor pack is a component of the FreeStyle Libre and FreeStyle Libre Pro Flash Glucose Monitoring Systems.
P160038/S001	04/11/2018	X - 30-Day Notice	PRAXIS EXTENDED RAS PANEL	ILLUMINA, INC.	Changes in analytical test methods and removal of a redundant in-process test.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160043/S014	04/16/2018	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEMS	MEDTRONIC VASCULAR	Update to the visual standard used by the operator in the inspection of pouch seals.
P160043/S015	04/16/2018	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEMS	MEDTRONIC VASCULAR	Changes to the internal diameter inspection of the Resolute Onyx bare metal stent.
P170008/S003	04/05/2018	X - 30-Day Notice	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Updates to quality control testing of the D-Catheter Delivery System.
P170012/S002	04/10/2018	X - 30-Day Notice	HEMOBLAST BELLOWS	BIOM'UP SA	Change in the manufacturing equipment for package sealing.
P170025/S002	04/10/2018	X - 30-Day Notice	APTIMA HBV QUANT ASSAY	HOLOGIC, INC	Transfer manufacturing of kit subcomponents to a new facility.

Total: 207