PMA Monthly approvals from 8/1/2017 to 8/31/2017

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160042	08/04/2017	PMAO - PMA Origi	REVANESSE ULTRA	PROLLENIUM MEDICAL TECHNOLOGIES INC.	Approval for the Revanesse Ultra. The device is indicated for injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds, such as nasolabial folds, in adults 22 years of age or more.
P160054	08/23/2017	PMAO - PMA Origi	HEARTMATE 3 LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATION	Approval for the HeartMate 3 Left Ventricular Assist System. This device is indicated for providing short-term hemodynamic support (e.g., bridge to transplant or bridge to myocardial recovery) in patients with advanced refractory left ventricular heart failure.
P170003	08/25/2017	PMAO - PMA Origi	LUTONIX® 035 DRUG COATED BALLOON PTA CATHETER, MODEL 9010	LUTONIX	Approval for the LUTONIX® 035 Drug Coated Balloon PTA Catheter. This device is indicated for percutaneous transluminal angioplasty (PTA), after pre-dilatation, for the treatment of stenotic lesions in dysfunctional native arteriovenous dialysis fistulae that are 4 mm to 12 mm in diameter and up to 80 mm in length.
P170005	08/01/2017	PMAO - PMA Origi	ABBOTT REALTIME IDH2	ABBOTT MOLECULAR INC.	Approval for the Abbott RealTime IDH2. The device is an in vitro polymerase chain reaction (PCR) assay for the qualitative detection of single nucleotide variants (SNVs) coding nine IDH2 mutations (R140Q, R140L, R140G, R140W, R172K, R172M, R172G, R172S, and R172W) in DNA extracted from blood (EDTA) or human bone marrow (EDTA). Abbott RealTime IDH2 is for use with the Abbott m2000rt System. Abbott RealTime IDH2 is indicated as an aid in identifying acute myeloid leukemia (AML) patients with an isocitrate dehydrogenase-2 (IDH2) mutation for treatment with IDHIFA® (enasidenib).
P170007	08/29/2017	PMAO - PMA Origi	DUROLANE	BIOVENTUS LLC	APPROVAL FOR DUROLANE. THIS DEVICE IS INDICATED FOR THE TREATMENT OF PAIN IN OSTEOARTHRITIS OF THE KNEE IN PATIENTS WHO HAVE FAILED TO RESPOND ADEQUATELY TO CONSERVATIVE NON-PHARMACOLOGICAL THERAPY OR SIMPLE ANALGESICS, E.G., ACETAMINOPHEN.

Total: 5

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S207	08/07/2017	R - Real-Time Proc	ADVANTIO, INGENIO, VITALO, FORMIO, ESSENTO, ACCOLADE, PROPONENT FAMILIES OF PACEMAKER DEVICES	BOSTON SCIENTIFIC CORP.	Approval for the LATITUDE NXT Release 5.0.1 Communicator software to add support for an alternative cellular adapter.
P830061/S144	08/03/2017	N - Normal 180 Day	CAPSUREFIX NOVUS MRI SURESCAN LEAD (4074 AND 4574)	MEDTRONIC, INC.	Approval for Attesta and Sphera devices.
P830061/S145	08/16/2017	N - Normal 180 Day	CAPSURE SENSE MRI SURESCAN LEAD	MEDTRONIC, INC.	Approval for the Azure SR and DR MRI SureScan Implantable Pulse Generators.
P860003/S092	08/17/2017	R - Real-Time Proc	THERAKOS CELLEX PHOTOPHERESIS PROCEDURAL KIT	THERAKOS, INC.	Approval for a design change to the pressure dome assembly.
P880086/S283	08/23/2017	N - Normal 180 Day	ASSURITY, ASSURITY+, ENDURITY, ACCENT FAMILY OF PACEMAKERS	ST. JUDE MEDICAL, INC.	Approval for cybersecurity updates to the firmware of low voltage devices, cybersecurity updates to the clinician programmer, and updates to the programmer and Merlin.net server to detect rapid battery depletion in high voltage devices.
P890003/S374	08/16/2017	N - Normal 180 Day	DEVICE COMMAND LIBRARY (DCL), CARELINE EXPRESS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the Azure SR and DR MRI SureScan Implantable Pulse Generators.
P890055/S067	08/14/2017	R - Real-Time Proc	CODMAN 3000 REFILL KIT	CODMAN	Approval for a material change to components of the Cadman 3000 Refill Kit.
P910001/S095	08/22/2017	S - Special CBE	ELCA CATHETERS	SPECTRANETICS CORP.	Approval for adding in-process visual inspections for the Distal Marker Band on the Excimer Laser Coronary Atherectomy (ELCA) catheters.
P910023/S386	08/23/2017	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 to the firmware of low voltage devices, cybersecurity updates to the clinician programmer, and updates to the programmer and Merlin.net server to detect rapid battery depletion in high voltage devices.
P910077/S160	08/07/2017	R - Real-Time Proc	LATITUDE NXT RELEASE PATIENT MANAGEMENT SYSTEM	BOSTON SCIENTIFIC	Approval for the LATITUDE NXT Release 5.0.1 Communicator software to add support for an alternative cellular adapter.
P930039/S169	08/03/2017	N - Normal 180 Day	CAPSUREFIX NOVUS MRI SURESCAN LEAD	MEDTRONIC, INC.	Approval for Attesta and Sphera devices.
P930039/S170	08/16/2017	N - Normal 180 Day	CAPSUREFIX NOVUS MRI SURESCAN LEAD	MEDTRONIC, INC.	Approval for the Azure SR and DR MRI SureScan Implantable Pulse Generators.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P950005/S061	08/10/2017	N - Normal 180 Day	WEBSTER DIAG./ABLATION DEFLECTABLE TIP CATHETER	CORDIS CORP.	Approval for a material change to the adhesive mixture used in the manufacture of BWI catheters and cables.
P950037/S176	08/02/2017	R - Real-Time Proc	EDORA, EVITY, ENITRA, ENTICOS 8SR/ SR-T/ DR/ DR-T	BIOTRONIK, INC.	Approval for minor updates to the RF Transceiver Integrated Circuit.
P950037/S177	08/16/2017	R - Real-Time Proc	SETROX S53, S60, SAFIO S 53, S 60, SOLIA S 45, S 53, S 60, SIELLO S 45, S 53, S 60, BLIND PLUG BS IS-1	BIOTRONIK, INC.	Approval for the Edora, Evity and Enitra ProMRI CRT-P Systems.
P950037/S179	08/31/2017	R - Real-Time Proc	PSW 1703.U	BIOTRONIK, INC.	Approval for PSW 1703.U/1 programmer software update.
P960040/S393	08/07/2017	R - Real-Time Proc	TELIGEN, ENERGEN, PUNCTUA, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN, PERCIVA, RESONATE, MOMENTUM, VIGILANT	BOSTON SCIENTIFIC	Approval for the LATITUDE NXT Release 5.0.1 Communicator software to add support for an alternative cellular adapter.
P960040/S400	08/07/2017	O - Normal 180 Day	NG3 IMPLANTABLE CARDIAC DEFIBRILLATORS, AUTOGEN, DYNAGEN, INOGEN, ORIGEN ICD'S; NG4 ICDS- MOMENTUM, VIGILANT, PERCIVA,RESONATE ICD'S	BOSTON SCIENTIFIC	Approval of the protocol for the post-approval study (PAS) protocol.
P970013/S071	08/23/2017	N - Normal 180 Day	MICRONY FAMILY OF PACEMAKERS	ST. JUDE MEDICAL, INC.	Approval for cybersecurity updates to the firmware of low voltage devices, cybersecurity updates to the clinician programmer, and updates to the programmer and Merlin.net server to detect rapid battery depletion in high voltage devices.
P970029/S033	08/07/2017	N - Normal 180 Day	CARDIOGENESIS TMR SYSTEM	CRYOLIFE, INC.	Approval for a change in material used in the construction of the Handpieces.
P970029/S034	08/31/2017	R - Real-Time Proc	TMR HOLMIUM LASER SYSTEM	CRYOLIFE, INC.	Approval for modifications to the high voltage power supply.
P980022/S200	08/11/2017	R - Real-Time Proc	IPRO2 CONTINUOUS GLUCOSE MONITORING (CGM) SYSTEM	MEDTRONIC MINIMED	Approval for design changes to the battery component of the GSR2 recorder. The GSR2 recorder is a component of the iPro2 Continuous Glucose Monitoring System and the iPro2 Professional Continuous Glucose Monitoring System.
P980035/S495	08/03/2017	N - Normal 180 Day	ATTESTA DR MRI SURESCAN	MEDTRONIC INC.	Approval for Attesta and Sphera devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980035/S506	08/16/2017	N - Normal 180 Day	AZURE XT SR / DR MRI SURESCAN, AZURE S SR / S DR MRI SURESCAN , SOFTWARE MODEL	MEDTRONIC INC.	Approval for the Azure SR and DR MRI SureScan Implantable Pulse Generators.
P980035/S513	08/29/2017	R - Real-Time Proc	ASTRA XT DR/SR/MRI/IPG	MEDTRONIC INC.	Approval for minor design changes and manufacturing documentation changes related to the hybrid integrated circuits.
P990025/S049	08/10/2017	N - Normal 180 Day	NAVI-STAR DIAGNOSTIC/ ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC.	Approval for a material change to the adhesive mixture used in the manufacture of BWI catheters and cables.
P990071/S034	08/10/2017	N - Normal 180 Day	BIOSENSE WEBSTER CABLES	BIOSENSE WEBSTER, INC.	Approval for a material change to the adhesive mixture used in the manufacture of BWI catheters and cables.
P990071/S036	08/23/2017	R - Real-Time Proc	SMARTABLATE SYSTEM FOOT PEDAL.	BIOSENSE WEBSTER, INC.	Approval for a design change to the SmartAblate System Foot Pedal.
P990074/S037	08/28/2017	N - Normal 180 Day	NATRELLE SALINE-FILLED BREAST IMPLANTS	ALLERGAN	Approval for changes to the labeling including 1) the removal of the Betadine warning against breast implant exposure to Betadine brand povidone-iodine 10% (applicable to generic versions as well) from the patient and physician labeling, and 2) modifications to the language in the physician and patient labeling regarding the potential risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL).
P000009/S074	08/31/2017	R - Real-Time Proc	PSW 1703.U	BIOTRONIK, INC.	Approval for PSW 1703.U/1 programmer software update.
P000057/S009	08/04/2017	R - Real-Time Proc	ASCENSION MCP	INTEGRA LIFESCIENCES CORPORATION	Approval for labeling changes to the surgical technique, patient brochure, and post-operative therapy protocol.
P010003/S027	08/21/2017	S - Special CBE	BIOGLUE SURGICAL ADHESIVE	CRYOLIFE, INC.	Approval to establish a minimum seal width specification for the outer-most pouches of BioGlue and BioGlue accessories.
P010012/S450	08/07/2017	R - Real-Time Proc	CRT-D RESYNCHRONIZATION DEVICES COGNIS, ENERGEN, PUNCTUA, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN, RESONATE, MOMENTUM, VIGILANT	BOSTON SCIENTIFIC CORP.	Approval for the LATITUDE NXT Release 5.0.1 Communicator software to add support for an alternative cellular adapter.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010012/S452	08/07/2017	O - Normal 180 Day	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Approval of the protocol for the post-approval study (PAS) protocol.
P010015/S338	08/29/2017	R - Real-Time Proc	PERCEPTA, SERENA, SOLARA BIPOLAR/ QUADRIPOLAR CRT-P	MEDTRONIC INC.	Approval for minor design changes and manufacturing documentation changes related to the hybrid integrated circuits.
P010030/S090	08/29/2017	N - Normal 180 Day	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Approval for new software version (V07.7M) for the LifeVest WCD 4000 Monitor; new software version (V07.2C3) for the LifeVest WCD 4000 Charger; and hardware changes to the LCD display flex tail used in both the WCD 4000 Monitor and WCD 4000 Charger.
P010030/S097	08/03/2017	R - Real-Time Proc	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Approval for an alternate shipping container for the LifeVest 4000.
P010068/S051	08/10/2017	N - Normal 180 Day	NAVISTAR/CELSIUS DS DIAGNOSTIC/ABLATION DEFLECTABLE 8MM TIP CATHETER	BIOSENSE WEBSTER, INC.	Approval for a material change to the adhesive mixture used in the manufacture of BWI catheters and cables.
P020056/S040	08/28/2017	N - Normal 180 Day	NATRELLE SILICON-FILLED BREAST IMPLANTS	ALLERGAN	Approval for changes to the labeling including 1) the removal of the Betadine warning against breast implant exposure to Betadine brand povidone-iodine 10% (applicable to generic versions as well) from the patient and physician labeling; and 2) modifications to the language in the physician and patient labeling regarding the potential risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL).
P030005/S155	08/07/2017	R - Real-Time Proc	CRT-P RESYNCHRONIZATION DEVICES INVIVE, INTUA, VISIONIST, VALITUDE	GUIDANT CORP.	Approval for the LATITUDE NXT Release 5.0.1 Communicator software to add support for an alternative cellular adapter.
P030017/S270	08/30/2017	N - Normal 180 Day	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a labeling change to designate Nevro Senza SCS System percutaneous leads and extensions as compatible to Boston Scientific Precision SCS devices (Implantable Pulse Generator, OR cable and extension/external trial stimulator (ETS), lead extensions, and tunneling tool) in the Directions for Use.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030017/S275	08/11/2017	P - Panel Track	PRECISIONTM AND SPECTRA WAVEWRITERTM SPINAL CORD STIMULATION (SCS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Approval for expanding indications to include Complex Regional Pain Syndrome (CRPS) Types I and II and the following associated conditions and etiologies: radicular pain syndrome, radiculopathies resulting in pain secondary to failed back syndrome or herniated disc, epidural fibrosis, degenerative disc disease (herniated disc pain refractory to conservative and surgical interventions), arachnoiditis, and multiple back surgeries.
P030017/S291	08/03/2017	R - Real-Time Proc	PRECISION SPECTRA WAVEWRITER SPINAL CORD STIMULATROR (SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for an update to the flash memory component used on the Printed Circuit Board Assembly (PCBA) in the Precision Spectra Wavewriter IPG because the current flash memory component is no longer available and needs to be replaced. BSN also indicated that the change will replace the current flash memory component with a new flash memory component from the same supplier and that the functionality of the IPG is unchanged.
P030031/S074	08/10/2017	N - Normal 180 Day	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Approval for a material change to the adhesive mixture used in the manufacture of BWI catheters and cables.
P030035/S157	08/23/2017	N - Normal 180 Day	ANTHEM, ALLURE/RF, ALLURE QUADRA/RF FAMILY OF CRT-PS	ST. JUDE MEDICAL, INC.	Approval for cybersecurity updates to the firmware of low voltage devices, cybersecurity updates to the clinician programmer, and updates to the programmer and Merlin.net server to detect rapid battery depletion in high voltage devices.
P030036/S094	08/03/2017	N - Normal 180 Day	SELECTSECURE MRI SURESCAN LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for Attesta and Sphera devices.
P030036/S095	08/16/2017	N - Normal 180 Day	SELECTSECURE MRI SURESCAN LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the Azure SR and DR MRI SureScan Implantable Pulse Generators.
P030054/S329	08/23/2017	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 to the firmware of low voltage devices, cybersecurity updates to the clinician programmer, and updates to the programmer and Merlin.net server to detect rapid battery depletion in high voltage devices.

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P040024/S095	08/28/2017	Y - 135 Review Tra	RESTYLANE-L, RESTYLANE LYFT WITH LIDOCAINE, AND RESTYLANE SILK	Q-MED AB	Approval for pooling of samples in the analytical method for particle size measurement.
P040036/S055	08/10/2017	N - Normal 180 Day	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Approval for a material change to the adhesive mixture used in the manufacture of BWI catheters and cables.
P040046/S021	08/28/2017	N - Normal 180 Day	NATRELLE HIGHLY COHESIVE ANATOMICALLY SHAPED SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Approval for changes to the labeling including 1) the removal of the Betadine warning against breast implant exposure to Betadine brand povidone-iodine 10%; (applicable to generic versions as well) from the patient and physician labeling, and 2) modifications to the language in the physician and patient labeling regarding the potential risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL).
P050023/S109	08/02/2017	R - Real-Time Proc	LLIVIA, INLEXA, INTICA 7/5, VR-T/ DR-T DF4	BIOTRONIK, INC.	Approval for minor updates to the RF Transceiver Integrated Circuit.
P050023/S111	08/16/2017	R - Real-Time Proc	BLIND PLUG BS IS4	BIOTRONIK, INC.	Approval for the Edora, Evity and Enitra ProMRI CRT-P Systems.
P050023/S112	08/31/2017	R - Real-Time Proc	PSW 1703.U	BIOTRONIK, INC.	Approval for PSW 1703.U/1 programmer software update.
P050047/S058	08/25/2017	Y - 135 Review Tra	JUVÉDERM ULTRA, ULTRA XC, ULTRA, JUVÉDERM ULTRA XC	ALLERGAN	Approval for an additional syringe assembly and packaging line.
P070008/S083	08/02/2017	R - Real-Time Proc	EDORA, EVITY, ENITRA, ENTICOS 8 HF-T/ QP	BIOTRONIK, INC.	Approval for minor updates to the RF Transceiver Integrated Circuit.
P070008/S084	08/16/2017	R - Real-Time Proc	EDORA 8 HF-T QP, EDORA 8 HF-T/QP, EVITY 8 HF-T/ QP,EVITY 8 HF-T/QP, COROX (PROMRI) OTW 85 BP, L85 BP, S 85 BP, SENTUS (PROMRI) OTW QP S-75, S-85 BP, S-75, S-85, S-95, L-75, L-85, L-95, S-75/49, S-85/49, S95/49, L-75/49, L-85/49, L-95/49	BIOTRONIK, INC.	Approval for the Edora, Evity and Enitra ProMRI CRT-P Systems.
P070008/S085	08/31/2017	R - Real-Time Proc	PSW 1703.U	BIOTRONIK, INC.	Approval for PSW 1703.U/1 programmer software update.
P070026/S040	08/18/2017	O - Normal 180 Day	CERAMAX CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Approval of the manufacturing site.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P080012/S045	08/21/2017	O - Normal 180 Day	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Approval for revised protocol for the post-approval study (PAS) protocol.
P090013/S254	08/03/2017	N - Normal 180 Day	CAPSUREFIX NOVUS MRI SURESCAN LEAD	MEDTRONIC, INC	Approval for Attesta and Sphera devices.
P090013/S256	08/16/2017	N - Normal 180 Day	CAPSUREFIX MRI SURESCAN LEAD	MEDTRONIC, INC	Approval for the Azure SR and DR MRI SureScan Implantable Pulse Generators.
P090031/S008	08/21/2017	R - Real-Time Proc	MONOVISC HIGH MOLECULAR WEIGHT HYALURONAN	ANIKA THERAPEUTICS, INC.	Approval for the addition of an alternative syringe stopper made with a different chemical formulation of rubber.
P100003/S007	08/18/2017	O - Normal 180 Day	SECURE-C CERVICAL ARTIFICIAL DISC	GLOBUS MEDICAL INC.	Approval for updated labeling to reflect seven (7) year data.
P100010/S066	08/31/2017	R - Real-Time Proc	ARCTIC FRONT ADVANCE CATHETERS	MEDTRONIC CRYOCATH LP	Approval for minor labeling modifications to Arctic Front Advance Catheters.
P100013/S014	08/07/2017	Y - 135 Review Tra	EXOSEAL VASCULAR CLOSURE DEVICE	CORDIS CORPORATION	Approval for the addition of Cordis Corporation, Miami Lakes, Florida as an alternate supplier for the Delivery Shaft component of the 6F EXOSEAL Vascular Closure Device.
P100016/S004	08/09/2017	O - Normal 180 Day	CT LUCIA 202 IOL AND CT LUCIA 602 IOL	CARL ZEISS MEDITEC PRODUCTION LLC	Approval for change in product name from Aaris® EC-3 and Aaris® EC-3 PAL to CT LUCIA 202 and CT LUCIA 602 respectively; minor product labeling changes to include the unit container box, adhesive label, Instructions for Use and patient card; and a new contact/manufacturing address.
P100026/S047	08/14/2017	N - Normal 180 Day	NEUROPACE RNS SYSTEM	NEUROPACE INC	Approval for the Neurostimulator (model RNS-320), NeuroPace Programmer (model 5000), Patient Data Management System (PDMS, model 4340), and Remote Monitor (model 5100).
P100030/S007	08/25/2017	R - Real-Time Proc	PREVELEAK SURGICAL SEALANT	MALLINCKRODT PHARMA IP TRADING DAC	Approval for changes to the pH specification and the ratio of salts for the crosslinker solution component
P100031/S017	08/16/2017	N - Normal 180 Day	ELECSYS ANTI-HBC IMMUNOASSAY TEST SYSTEM	ROCHE DIAGNOSTICS CORP.	Approval for 1) the inclusion of a second antigen source for the recombinant hepatitis B core antigen used in Reagent 1 of the test kit;, 2) an update in the device by changing the standardization traceability to the World Health Organization Standard NIBSC 95/522; 3) extension of the reagent rackpack onboard stability from 4 weeks to 8 weeks, 4) addition of K3-EDTA plasma as a specimen type, and 5) modification of the device name.
P100032/S014	08/16/2017	N - Normal 180 Day	ELECSYS ANTI-HBC IMMUNOASSAY TEST SYSTEM	ROCHE DIAGNOSTICS CORP.	Approval for 1) the inclusion of a second antigen source for the recombinant hepatitis B core antigen used in Reagent 1 of the test kit; 2) an update in the device by changing the standardization traceability to the World Health Organization Standard NIBSC 95/522; 3) extension of the reagent rackpack onboard stability from 4 weeks to 8 weeks; 4) addition of K3-EDTA plasma as a specimen type; and 5) modification of the device name.

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P100045/S015	08/03/2017	Y - 135 Review Tra	CARDIOMEMS HF SYSTEM	ST. JUDE MEDICAL	Approval for removal of a chemical processing agent from production of their coating used on the delivery system tether wire of the CardioMEMS HF System.
P110004/S015	08/07/2017	O - Normal 180 Day	NIRXCELL COCR CORONARYSTENT ON RX SYSTEM	MEDINOL LTD.	Approval for labeling updates to the Instructions for Use (IFU) to reflect the long-term data from the Post-Approval BLAST Placebo Cohort study.
P110033/S028	08/25/2017	Y - 135 Review Tra	VOLUMA XC, VOLLURE XC, VOLBELLA XC	ALLERGAN	Approval for an additional syringe assembly and packaging line.
P110042/S086	08/07/2017	R - Real-Time Proc	SUBCUTANEOUS ICD DEVICES EMBLEM	BOSTON SCIENTIFIC CORPORATION	Approval for the LATITUDE NXT Release 5.0.1 Communicator software to add support for an alternative cellular adapter.
P110042/S087	08/08/2017	R - Real-Time Proc	EMBLEM SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATOR PULSE GERATOR	BOSTON SCIENTIFIC CORPORATION	Approval for a higher density insulation paper in the high voltage capacitors and associated manufacturing process changes.
P110042/S089	08/16/2017	R - Real-Time Proc	SQ-RX, EMBLEM, EMBLEM MRI S-ICD	BOSTON SCIENTIFIC CORPORATION	Approval for changes to the EMBLEM Programmer software and the SQ-RX, EMBLEM, and EMBLEM MRI S-ICD device firmware.
P120005/S064	08/11/2017	R - Real-Time Proc	DEXCOM G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Approval for minor design changes to the firmware installed on the receiver component of the Dexcom G5 Continuous Glucose Monitoring System.
P130005/S017	08/02/2017	R - Real-Time Proc	DIAMONDBACK 360 ORBITAL ATHERECTOMY SYSTEM	CARDIOVASCULAR SYSTEMS, INC.	Approval for design and material changes to the Saline Line.
P130008/S020	08/02/2017	N - Normal 180 Day	MODEL 2740 INSPIRE PROGRAMMER SYSTEM	INSPIRE MEDICAL SYSTEMS	Approval for an update to the telemetry head of the Model 2740 Programmer.
P130030/S040	08/01/2017	R - Real-Time Proc	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM (MONORAIL) AND (OVER-THE-WIRE).	BOSTON SCIENTIFIC CORP.	Approval for modifications to the carton locking tab and tuck flap.
P140003/S017	08/22/2017	O - Normal 180 Day	IMPELLA 2.5, IMPELLA CP SYSTEMS	ABIOMED, INC.	Approval for the protocol for the post-approval study (PAS) protocol.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140008/S007	08/21/2017	O - Normal 180 Day	ORBERA INTRAGASTRIC BALLOON	APOLLO ENDOSURGERY INC	Approval for revised protocol for the post-approval study (PAS) protocol.
P140013/S006	08/07/2017	O - Normal 180 Day	MINERVA ENDOMETRIAL ABLATION SYSTEM	MINERVA SURGICAL	Approval for labeling changes to update the clinical study results to reflect the final 2- and 3-year follow-up results from the Minerva Single-Arm study, as well as the 1-year follow-up results from the Minerva Randomized Control Trial.
P140015/S020	08/25/2017	P - Panel Track	T:SLIM X2 INSULIN PUMP WITH DEXCOM G5 MOBILE CGM	TANDEM DIABETES CARE, INC.	Approval for the use of the t:slim X2 Insulin Pump with the Dexcom G5 Mobile CGM and for modifying the indications for use to include pediatric patients ages 6-11 years and replace adjunctive with non-adjunctive CGM use (i.e., replace fingerstick blood glucose testing for diabetes treatment decisions). This device is indicated as follows: The t:slim X2 Insulin Pump with Dexcom G5 Mobile CGM (¿t:slim X2 System¿) consists of the t:slim X2 Insulin Pump paired with the Dexcom G5 Mobile Sensor and Transmitter. 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 System to receive and display continuous glucose measurements from the Dexcom G5 Mobile Sensor and Transmitter. The t:slim X2 System also includes continuous glucose monitoring (CGM) indicated for the management of diabetes. The Dexcom G5 Mobile CGM is designed to replace fingerstick blood glucose testing for diabetes treatment decisions. The t:slim X2 System aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of the t:slim X2 System results should be based on the trends and patterns seen with several sequential readings over time. The t:slim X2 System is indicated for use in individuals 6 years of age and greater. The t:slim X2 System is intended for single patient use and requires a prescription. The device is indicated for use with NovoLog or Humalog U-100 insulin.
P140018/S006	08/22/2017	O - Normal 180 Day	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Approval for a manufacturing site located at Medtronic Ireland Parkmore Business Park West Galway, Ireland for manufacturing activities and final release of product.
P140021/S008	08/10/2017	N - Normal 180 Day	ELECSYS ANTI-HCV II TEST SYSTEM	ROCHE DIAGNOSTICS OPERATIONS INC	Approval for 1) the migration of claims from the FDA approved Elecsys Anti-HCV II Immunoassay and Elecsys PreciControl Anti-HCV on the cobas e 601 immunoassay analyzer to the cobas e 411 immunoassay analyzer and 2) a modification to the proprietary device name.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140031/S041	08/15/2017	R - Real-Time Proc	EDWARDS CRIMPER MODEL 9600CR	EDWARDS LIFESCIENCE S, LLC.	Approval for design modifications to the Edwards Crimper and for extending the shelf life of the Crimper to 2 years.
P140033/S008	08/23/2017	N - Normal 180 Day	ASSURITY MRI, ENDURITY MRI FAMILY OF PACEMAKERS	ST. JUDE MEDICAL, INC.	Approval for cybersecurity updates to the firmware of low voltage devices, cybersecurity updates to the clinician programmer, and updates to the programmer and Merlin.net server to detect rapid battery depletion in high voltage devices.
P150004/S007	08/25/2017	O - Normal 180 Day	AXIUM NEUROSTIMULATOR SYSTEM	ST. JUDE MEDICAL	Approval of the revised protocol for the post-approval study (PAS) protocol.
P150005/S017	08/22/2017	N - Normal 180 Day	INTELLANAV MIFI OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval for the IntellaNav MiFi Open-Irrigated Ablation Catheter, which represents design, manufacturing, and labeling changes to the IntellaTip MiFi Open-Irrigated Ablation Catheter
P150021/S011	08/21/2017	R - Real-Time Proc	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval for removal of the acetaminophen interference statement from all FreeStyle Libre Pro labeling, including the Sensor Insert and User Manual.
P150023/S007	08/07/2017	Y - 135 Review Tra	ABSORB GT1 BIORESORBABLE VASCULAR SCAFFOLD (BVS) SYSTEM.	ABBOTT VASCULAR INC.	Approval to change the finished goods molecular weight testing sampling plan and molecular weight stability testing plan.
P150026/S001	08/03/2017	R - Real-Time Proc	HEARTLIGHT ENDOSCOPIC ABLATION SYSTEM	CARDIOFOCUS, INC.	Approval to add an alternative supplier and an alternative sterilization process for the Balloon Fill Media.
P150029/S010	08/11/2017	R - Real-Time Proc	IPRO2 PROFESSIONAL CONTINUOUS GLUCOSE MONITORING (CGM) SYSTEM	MEDTRONIC MINIMED	Approval for design changes to the battery component of the GSR2 recorder. The GSR2 recorder is a component of the iPro2 Continuous Glucose Monitoring System and the iPro2 Professional Continuous Glucose Monitoring System.
P150037/S006	08/18/2017	O - Normal 180 Day	CYPASS MICRO-STENT	ALCON RESEARCH, LTD	Approval of the revised protocol for the post-approval study (PAS) protocol.
P160025/S002	08/07/2017	O - Normal 180 Day	ASTRON PULSAR/ PULSAR-18 STENT SYSTEM	BIOTRONIK, INC.	Approval for the final PMA PAS Protocol Administrative Addendum (dated June 6, 2017) containing the PAS long-term data analysis plan and for extending the Post-Approval Study (PAS) reporting frequency from 6 months to 12 months.

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Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N16895/S100	08/11/2017	X - 30-Day Notice	SOFLENS (POLYMACON) VISIBILITY TINTED CONTACT LENS	BAUSCH & LOMB, INC.	Blister packaging mold tool modification.
N18033/S094	08/30/2017	X - 30-Day Notice	VISTAKON (ETAFILCON A) BRAND CONTACT LENSES	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Change to the raw material specification of a visibility tint used in the VISTAKON® (senofilcon A) and (etafilcon A) Brand Contact Lenses.
N970003/S210	08/30/2017	X - 30-Day Notice	ACCOLADE NON-MRI PACEMAKERS , ALTRUA, ESSENTIO, PROPONENT, ACCOLADE	BOSTON SCIENTIFIC CORP.	Modify test software used in the wafer fabrication process.
N970003/S211	08/30/2017	X - 30-Day Notice	PACEMAKERS: ESSENTIO, PROPONENT, ACCOLADE, ALTRUA 2	BOSTON SCIENTIFIC CORP.	Modifications to the manufacturing process for the spring contact housing components.
N970012/S137	08/11/2017	X - 30-Day Notice	AMS 700 INFLATABLE PENILE PROSTHESIS (IPP) WITH AND WITHOUT INHIBIZONE TREATMENT	BOSTON SCIENTIFIC CORP.	Use of new molding equipment and changes to the milling and molding process of the pump bulb component.
P790007/S051	08/09/2017	X - 30-Day Notice	HANCOCK MODIFIED ORIFICE (MO) VALVED CONDUIT, MODEL 150	MEDTRONIC HEART VALVES	Implement additional test samples for solution chemistry and sterility as part of the routine monitoring and lot release performed for terminal liquid sterilization.
P810002/S103	08/10/2017	X - 30-Day Notice	ST. JUDE MEDICAL MECHANICAL HEART VALVES	ST. JUDE MEDICAL, INC.	Modifications to the cleanroom area including introduction of new equipment.
P810006/S077	08/31/2017	X - 30-Day Notice	COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC SPONGE AND AGENT-MICROFIBRILLAR FORM	INTEGRA LIFESCIENCES CORPORATION	New Shrink Temperature Test Equipment to reduce the equipment footprint as well as to reduce background and electrical noise.
P830061/S149	08/16/2017	X - 30-Day Notice	CAPSURE SENSE LEAD/ CAPSURE SP NOVUS LEAD/CAPSURESENSE LEAD/VITATRON CRYSTALLINE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer of the incoming inspection activities for select components.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840001/S366	08/16/2017	X - 30-Day Notice	RESTORE, ITREL, AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Replace a capacitor due to obsolescence and to implement a redesigned back half of the programmer case in order to accommodate the capacitor change.
P840001/S368	08/08/2017	X - 30-Day Notice	RESTORE ITREL AND SYNERGY SPINAL CORD STIMULATION SYSTEM AND PISCES, SPECIFY AND VECTRIS SPINAL CORD STIMULATION LEADS.	MEDTRONIC NEUROMODULATION	Transfer of and revision to receiving and incoming inspection activities.
P840001/S369	08/24/2017	X - 30-Day Notice	RESTORE, ITREL, SYNERGY AND INTELLIS SPRINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY,ADN VECTRIS SPRINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Transfer of receiving and incoming inspection activities for device components (i.e., Screw-Conn Set, Crimp Block 7495, and Block- Connector, Set Screw) used in the manufacture of Medtronic Neuromodulation therapy delivery products, from the Medtronic Rice Creek facility to the Medtronic Puerto Rico Operations Company (MPROC)-Villalba, MPROC-Juncos, and the FedEx/3PL (Third Party Logistics) facility in Guaynabo, Puerto Rico.
P840001/S370	08/31/2017	X - 30-Day Notice	RESTORE, ITREL, SYNERGY AND INTELLIS SPRINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY,ADN VECTRIS SPRINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Addition of a new supplier of polysulfone resin.
P840001/S371	08/31/2017	X - 30-Day Notice	MASTER RESTORE, ITREL AND SYNERGY SPINAL CORD STIMULATION SYSTEMS, INTELLIS IMPLANTABLE NEUROSTIMULATION SYSTEM AND PISCES, SPECIFY AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Qualify an alternate BalSeal manufacturing site facility for the spring coil components (Colorado Springs) and to update the tooling used for the insertion testing of the contact assembly from a uni-directional test pin to a bi-directional test pin.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840001/S372	08/31/2017	X - 30-Day Notice	MASTER RESTORE, ITREL AND SYNERGY SPINAL CORD STIMULATION SYSTEMS, INTELLIS IMPLANTABLE NEUROSTIMULATION SYSTEM AND PISCES, SPECIFY AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Several changes to the stacked chip scale package (SCSP) process flow and modified visual inspection requirements.
P850010/S076	08/31/2017	X - 30-Day Notice	HELISTAT, HELITENE ABSORBABLE COLLAGEN HEMOSTATIC AGENTS	INTEGRA LIFESCIENCES CORPORATION	New Shrink Temperature Test Equipment to reduce the equipment footprint as well as to reduce background and electrical noise.
P850079/S074	08/14/2017	X - 30-Day Notice	METHAFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION, INC.	Validation of a new wet line.
P850089/S127	08/16/2017	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 of the incoming inspection activities for select components.
P860003/S094	08/18/2017	X - 30-Day Notice	THERAKOS CELLEX PROCEDURAL KIT	THERAKOS, INC.	Addition of a new mold tool for the CELLEX Procedural Kit.
P860004/S283	08/16/2017	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	Replace a capacitor due to obsolescence and to implement a redesigned back half of the programmer case in order to accommodate the capacitor change.
P860004/S285	08/08/2017	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Transfer of and revision to receiving and incoming inspection activities.
P860004/S286	08/16/2017	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	Modification of the manufacturing processes window parameters and the clarifications to the manufacturing operating procedures for the Model 8637 SynchroMed II Pump.
P860004/S287	08/24/2017	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	Addition of an alternate manufacturing site (ProMed) for silicone molded components.
P860004/S288	08/31/2017	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Change to the supplier of the Lithium Anode Pre-Cut Foil, for the SynchroMed® Infusion System, Ascenda® Intrathecal Catheters, Models 8637-20 and 8637-40.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860057/S167	08/24/2017	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT THEON/RSR/ MAGNA/MAGNA EASE PERICARDIAL AORTIC BIOPROTHESIS / THERMAFIX TISSUE PROCESS	EDWARDS LIFESCIENCES, LLC.	Transfer the polyester band component manufacturing process.
P870078/S036	08/09/2017	X - 30-Day Notice	HANCOCK VALVED CONDUIT, MODEL 105	MEDTRONIC, INC.	Implement additional test samples for solution chemistry and sterility as part of the routine monitoring and lot release performed for terminal liquid sterilization.
P880086/S284	08/22/2017	X - 30-Day Notice	ASSURITY, ASSURITY+, ENDURITY FAMILIES OF ICD DEVICES	ST. JUDE MEDICAL, INC.	Addition of an alternate supplier for header molds.
P880086/S285	08/14/2017	X - 30-Day Notice	ENDURITY, ENDURITY CORE, ASSURITY, ASSURITY+	ST. JUDE MEDICAL, INC.	Alternate supplier of the 5-pin filtered feedthrough (FFT) assembly.
P890003/S379	08/16/2017	X - 30-Day Notice	CAPSURE VDD 2 LEAD/ VITATRON BRILLIANT S+ VDD LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer of the incoming inspection activities for select components.
P900056/S163	08/17/2017	X - 30-Day Notice	ROTABLATOR ROTATIONAL ATHERECTOMY SYSTEM	BOSTON SCIENTIFIC CORP.	Sterilize the devices within the scope of this bundled submission by the optimized BSC2000-2 cycle in Chambers 1, 2, 3, 6, 8, 9 and 10 at BSC Coventry, Rhode, Island.
P900056/S164	08/31/2017	X - 30-Day Notice	ROTABLATOR ROTATIONAL ANGIOPLASTY SYSTEM GUIDEWIRE	BOSTON SCIENTIFIC CORP.	Update the BSC2000-2 cycle conducted in Chamber 2 at the BSC Coventry, RI facility with new Programmable Logic Controller (PLC) software, an additional vacuum pump booster, and a new validation documentation structure used to support the system.
P910001/S096	08/25/2017	X - 30-Day Notice	ELCA LASER CATHETERS	SPECTRANETICS CORP.	Implement a semi-automated dimensional verification for the radiopaque markers.
P910023/S391	08/23/2017	X - 30-Day Notice	CURRENT+ / FORTIFY / FORTIFY ASSURA / ELLIPSE.	ST. JUDE MEDICAL	Changes to the foil etching manufacturing process for high voltage capacitors.
P920015/S201	08/16/2017	X - 30-Day Notice	"Y" ADAPTOR/EXTENDER KIT/SPRINT QUATTRO LEAD/SUBCUTANEOUS LEAD	MEDTRONIC INC.	Transfer of the incoming inspection activities for select components.
P920047/S100	08/17/2017	X - 30-Day Notice	BLAZER II CARDIAC ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC CORP.	Sterilize the devices within the scope of this bundled submission by the optimized BSC2000-2 cycle in Chambers 1, 2, 3, 6, 8, 9 and 10 at BSC Coventry, Rhode, Island.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P920047/S101	08/31/2017	X - 30-Day Notice	BLAZER II CARDIAC ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Update the BSC2000-2 cycle conducted in Chamber 2 at the BSC Coventry, RI facility with new Programmable Logic Controller (PLC) software, an additional vacuum pump booster, and a new validation documentation structure used to support the system.
P930039/S175	08/16/2017	X - 30-Day Notice	CAPSUREFIX LEAD/ CAPSUREFIX NOVUS LEAD/VITATRON CRYSTALLINE ACTIVE FIXATION LEAD	MEDTRONIC, INC.	Transfer of the incoming inspection activities for select components.
P950020/S081	08/18/2017	X - 30-Day Notice	FLEXTOME CUTTING BALLOON MICROSURGICAL DILATATION DEVICE/ WOLVERINE CORONARY CUTTING BALLOON MONORAIL (MR) / WOLVERINE CORONARY CUTTING BALLON OVER-THE-WIRE (OTW)	BOSTON SCIENTIFIC CORP.	Alternate degreaser used in the cleaning process for the cutting blades (atherotomes).
P950020/S082	08/31/2017	X - 30-Day Notice	WOLVERINE CORONARY CUTTING BALLOON (MONORAIL AND OVER-THE-WIRE)	BOSTON SCIENTIFIC CORP.	Update the BSC2000-2 cycle conducted in Chamber 2 at the BSC Coventry, RI facility with new Programmable Logic Controller (PLC) software, an additional vacuum pump booster, and a new validation documentation structure used to support the system.
P950024/S075	08/16/2017	X - 30-Day Notice	CAPSURE EPICARDIAL PACING LEAD	MEDTRONIC INC.	Transfer of the incoming inspection activities for select components.
P950029/S114	08/03/2017	X - 30-Day Notice	REPLY SR, REPLY DR, ESPRIT SR, ESPRIT DR (2ND GENERATION , I.E. V2) & (5TH GENERATION I.E.V5)	LIVANOVA USA, INC.	Update to the manufacturing flow sequence and gluing curing temperature.
P950034/S048	08/29/2017	X - 30-Day Notice	SEPRAFILM ADHESION BARRIER	GENZYME CORP.	Use of die cutting to produce seprafilm quarter sheets.
P960009/S285	08/16/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Replace a capacitor due to obsolescence and to implement a redesigned back half of the programmer case in order to accommodate the capacitor change.
P960009/S287	08/08/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Transfer of and revision to receiving and incoming inspection activities.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960009/S288	08/24/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Ttransfer of receiving and incoming inspection activities for device components (i.e., Screw-Conn Set, Crimp Block 7495, and Block- Connector, Set Screw) used in the manufacture of Medtronic Neuromodulation therapy delivery products, from the Medtronic Rice Creek facility to the Medtronic Puerto Rico Operations Company (MPROC)-Villalba, MPROC-Juncos, and the FedEx/3PL (Third Party Logistics) facility in Guaynabo, Puerto Rico.
P960009/S290	08/24/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Addition of an alternate manufacturing site (ProMed) for silicone molded components.
P960040/S399	08/30/2017	X - 30-Day Notice	NG3 IMPLANTABLE CARDIAC DEFIBRILLATORS, AUTOGEN, DYNAGEN, INOGEN, ORIGEN ICD'S; NG4 ICDS- MOMENTUM, VIGILANT, PERCIVA,RESONATE ICD'S	BOSTON SCIENTIFIC	Modify test software used in the wafer fabrication process.
P960040/S401	08/30/2017	X - 30-Day Notice	ICDS: ORIGEN, INOGEN, DYNAGEN, AUTOGEN, RESONATE HF ICD, RESONATE EL ICD, MOMENTUM EL ICD, VIGILIANT EL ICD, PERCIVA HF ICD, PERCIVA ICD	BOSTON SCIENTIFIC	Modifications to the manufacturing process for the spring contact housing components.
P970003/S213	08/11/2017	X - 30-Day Notice	VNS THERAPY SYSTEM	LIVANOVA USA, INC.	Removal of a redundant generator interrogation inspection and a redundant sterilization inspection from the shipping process.
P970004/S248	08/16/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM (SNS URINARY PROGRAMMING SYSTEMS)	MEDTRONIC NEUROMODULATION	Replace a capacitor due to obsolescence and to implement a redesigned back half of the programmer case in order to accommodate the capacitor change.
P970004/S250	08/08/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUTION SYSTEM	MEDTRONIC NEUROMODULATION	Transfer of and revision to receiving and incoming inspection activities.
P970004/S251	08/24/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Transfer of receiving and incoming inspection activities for device components (i.e., Screw-Conn Set, Crimp Block 7495, and Block- Connector, Set Screw) used in the manufacture of Medtronic Neuromodulation therapy delivery products, from the Medtronic Rice Creek facility to the Medtronic Puerto Rico Operations Company (MPROC)-Villalba, MPROC-Juncos, and the FedEx/3PL (Third Party Logistics) facility in Guaynabo, Puerto Rico.
P970031/S057	08/09/2017	X - 30-Day Notice	FREESTYLE BIOPROSTHESIS, MODEL 995, 995SC AND 995MS	MEDTRONIC, INC.	Implement additional test samples for solution chemistry and sterility as part of the routine monitoring and lot release performed for terminal liquid sterilization.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970051/S167	08/16/2017	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Addition of new molding equipment to manufacture the CP900 Series Sound Processors.
P970051/S168	08/23/2017	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Move the manufacturing of the CI500 series Sterile Replacement Magnet and the Non-Magnetic Plug to the Macquarie site where similar manufacturing processes occur.
P980003/S077	08/17/2017	X - 30-Day Notice	CHILLI II COOLE DABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC CORP.	Sterilize the devices within the scope of this bundled submission by the optimized BSC2000-2 cycle in Chambers 1, 2, 3, 6, 8, 9 and 10 at BSC Coventry, Rhode, Island.
P980003/S078	08/31/2017	X - 30-Day Notice	CHILLI II COOLED RF ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Update the BSC2000-2 cycle conducted in Chamber 2 at the BSC Coventry, RI facility with new Programmable Logic Controller (PLC) software, an additional vacuum pump booster, and a new validation documentation structure used to support the system.
P980035/S514	08/10/2017	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, RELIA IPG	MEDTRONIC INC.	Additional laser welder for use in manufacturing of the battery header subassembly.
P980035/S515	08/17/2017	X - 30-Day Notice	ASTRA S DR MRI IPG/ ASTRA S SR MRI IPG / ASTRA XT DR MRI IPG / ASTRA XT SR MRI IPG	MEDTRONIC INC.	Changes to a manufacturing visual inspection specification used for hybrid production.
P980035/S516	08/14/2017	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPGS ADSR01, ADDR01, ADDR06, ADDRL1, ADDRS1, VEDR01, ADD01, SEDRL1, SED01, SES01, ADDR03, SEDR01, ADSR03, ADSR06, ADVDD01, SESR01; RELIA IPGS RED01, REDR01, RES01, RESR01, REVDD01	MEDTRONIC INC.	Update to the software used in the final functional device tester.
P980035/S517	08/25/2017	X - 30-Day Notice	ASTRA S DR MRI IPG X3DR01; ASTRA S SR MRI IPG X3SR01; ASTRA XT DR MRI IPG X1DR01; ASTRA XT SR MRI IPG X1SR01	MEDTRONIC INC.	New laser tack weld station for the Electronic Module Assembly manufacturing line.
P980043/S061	08/09/2017	X - 30-Day Notice	HANCOCK II BIOPROSTHESIS, MODELS T505 AND T510	MEDTRONIC, INC.	Implement additional test samples for solution chemistry and sterility as part of the routine monitoring and lot release performed for terminal liquid sterilization.
P990012/S028	08/31/2017	X - 30-Day Notice	ELECSYS HBSAG	ROCHE DIAGNOSTICS CORP.	Install an additional bead coating apparatus.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P990013/S036	08/02/2017	X - 30-Day Notice	COLLAMER UV ABSORBING POSTERIOR CHAMBER THREE AND ONE PIECE FOLDABLE INTRAOCULAR LENS	STARR SURGICAL CO.	Add an alternate instrument to measure the optical properties of the Collamer IOL at the Monrovia, California facility.
P990013/S037	08/04/2017	X - 30-Day Notice	COLLAMER UV ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	STARR SURGICAL CO.	Addition of an autoclave for use in the sterilization of the Visian Implantable Collamer Lens (ICL) and the Collamer Intraocular Lens (CIOL) at the Monrovia, California facility.
P990046/S049	08/22/2017	X - 30-Day Notice	OPEN PIVOT HEART VALVE, OPEN PIVOT AORTIC VALVED GRAFT	MEDTRONIC ATS MEDICAL, INC.	implementation of a continuous monitoring system for controlled environment areas
P990056/S027	08/31/2017	X - 30-Day Notice	ELESYS TOTAL PSA IMMUNOASSAY	ROCHE DIAGNOSTICS CORP.	Install an additional bead coating apparatus.
P990064/S069	08/09/2017	X - 30-Day Notice	MOSAIC BIOPROSTHESIS, MODELS 305 AND 310	MEDTRONIC, INC.	Implement additional test samples for solution chemistry and sterility as part of the routine monitoring and lot release performed for terminal liquid sterilization.
P990074/S040	08/21/2017	X - 30-Day Notice	NATRELLE SALINE-FILLED BREAST IMPLANTS	ALLERGAN	Change to Limulous Amoebocyte Lysate (LAL) reagent sensitivity
P990075/S042	08/09/2017	X - 30-Day Notice	SPECTRUM SALINE BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Supplier change for Room Temperature Vulcanization (RTV) adhesive that is used in the assembly of Mentor® Spectrum® Saline Breast Implants with a kink valve. The current supplier location is Applied Silicone Corporation (ASC) located in Santa Paula, California. The new supplier location will be the Nusil Technology facility located in Carpinteria, California.
P990081/S036	08/04/2017	X - 30-Day Notice	PATHWAY ANTI-HER-2/NEU (4B) RABBIT MONOCLONAL PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Current suppliers new manufacturing site for a device component.
P000015/S024	08/23/2017	X - 30-Day Notice	NUCLEUS AUDITORY BRAINSTEM IMPLANT	COCHLEAR AMERICAS	Move the manufacturing of the CI500 series Sterile Replacement Magnet and the Non-Magnetic Plug to the Macquarie site where similar manufacturing processes occur.
P000027/S026	08/31/2017	X - 30-Day Notice	ELECSYS FREE PSA IMMUNOASSAY	ROCHE DIAGNOSTICS CORP.	Install an additional bead coating apparatus.
P000039/S058	08/03/2017	X - 30-Day Notice	AMPLATZER SEPTAL DEFECT OCCLUDER (AND CRIBRIFORM OCCLUDER)	AGA MEDICAL CORPORATION	Change to laser parameters on the laser used to weld the occluder braid.
P010012/S457	08/08/2017	X - 30-Day Notice	TERMINAL PIN WELD PROCESS MONITORING PLAN	BOSTON SCIENTIFIC CORP.	Modification of the Terminal Pin Weld Process Monitoring Plan.

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P010012/S459	08/30/2017	X - 30-Day Notice	NG3 CARDIAC RESYNCHRONIZATION THERAPY- DEFIBRILLATOR DEVICES , AUTOGEN DYNAGEN, INOGEN, ORIGEN , MOMENTUM, VIGILANT, RESONATE CRT D'S	BOSTON SCIENTIFIC CORP.	Modify test software used in the wafer fabrication process.
P010012/S460	08/30/2017	X - 30-Day Notice	CRT-DS: ORIGEN, INOGEN, DYNAGEN, AUTOGEN, VIGILANT, MOMENTUM, RESONATE, PUNCTUA, ENERGEN, INCEPTA	BOSTON SCIENTIFIC CORP.	Modifications to the manufacturing process for the spring contact housing components.
P010015/S339	08/17/2017	X - 30-Day Notice	PERCEPTA BIPOLAR CRT-P/ PERCEPTA QUADRIPOLAR CRT-P/ SERENA BIPOLAR CRT-P/ SERENA QUADRIPOLAR CRT-P/ SOLAR BIPOLAR CRT-P/ SOLAR QUADRIPOLAR CRT-P	MEDTRONIC INC.	Changes to a manufacturing visual inspection specification used for hybrid production.
P010015/S341	08/25/2017	X - 30-Day Notice	PERCEPTA BIPOLAR CRT-P W1TR01; PERCEPTA QUADRIPOLAR CRT-P W4TR01; SERENA BIPOLAR CRT-P W1TR02; SERENA QUADRIPOLAR CRT-P W4TR02; SOLARA BIPOLAR CRT-P W1TR03; SOLARA QUADRIPOLAR CRT-P W4TR03	MEDTRONIC INC.	New laser tack weld station for the Electronic Module Assembly manufacturing line.
P010015/S342	08/16/2017	X - 30-Day Notice	ATTAIN OTW LV LEAD	MEDTRONIC INC.	Transfer of the incoming inspection activities for select components.
P010054/S031	08/31/2017	X - 30-Day Notice	ELECSYS ANIT-HBS	ROCHE DIAGNOSTICS CORP.	Install an additional bead coating apparatus.
P020004/S146	08/18/2017	X - 30-Day Notice	GORE EXCLUDER AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Expand oven loading conditions for the sealing cuff of the GORE EXCLUDER AAA Endoprosthesis and the GORE TAG Thoracic Endoprosthesis.
P020024/S049	08/03/2017	X - 30-Day Notice	AMPLATZER DUCT OCCLUDER	AGA MEDICAL CORP.	Change to laser parameters on the laser used to weld the occluder braid.

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P020025/S104	08/17/2017	X - 30-Day Notice	BLAZER II XP CARDIAC ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC	Sterilize the devices within the scope of this bundled submission by the optimized BSC2000-2 cycle in Chambers 1, 2, 3, 6, 8, 9 and 10 at BSC Coventry, Rhode, Island.
P020025/S105	08/31/2017	X - 30-Day Notice	BLAZER II XP CARDIAC RF ABLATION SYSTEM	BOSTON SCIENTIFIC	Update the BSC2000-2 cycle conducted in Chamber 2 at the BSC Coventry, RI facility with new Programmable Logic Controller (PLC) software, an additional vacuum pump booster, and a new validation documentation structure used to support the system.
P020055/S020	08/04/2017	X - 30-Day Notice	PATHWAY ANTI-C-KIT (9.7) RABBIT MONOCLONAL PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Current suppliers new manufacturing site for a device component.
P020056/S043	08/01/2017	X - 30-Day Notice	NATRELLE SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Addition of two new Gruenberg gel curing ovens.
P020056/S044	08/21/2017	X - 30-Day Notice	NATRELLE SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Change to Limulous Amoebocyte Lysate (LAL) reagent sensitivity
P030005/S158	08/30/2017	X - 30-Day Notice	ACCOLADE CARDIAC RESYNCHRONIZATION THERAPY PACEMAKER DEVICES- VALITUDE, VALITUDE X4, VISIONIST AND VISIONIST X4	GUIDANT CORP.	Modify test software used in the wafer fabrication process.
P030005/S159	08/30/2017	X - 30-Day Notice	CRT-P VALITUDE, VISIONIST	GUIDANT CORP.	Modifications to the manufacturing process for the spring contact housing components.
P030016/S033	08/04/2017	X - 30-Day Notice	VISIAN IMPLANTABLE COLLAMER LENS FOR MYOPIA	STAAR SURGICAL CO.	Addition of an autoclave for use in the sterilization of the Visian Implantable Collamer Lens (ICL) and the Collamer Intraocular Lens (CIOL) at the Monrovia, California facility.
P030017/S301	08/31/2017	X - 30-Day Notice	PRECISION SPECTRA, SPECTRA WAVEWRITER, PRECISION NOVI, PRECISION MONTAGE, PRECISION MONTAGE, MRI SPINAL CORD STIMULATOR SYSTEMS, HEADER OF THE IMPLANTABLE PULSE GENERATOR	BOSTON SCIENTIFIC CORP.	Automated overmolding process for the header assembly of the Implantable Pulse Generators (IPG) of the Precision Spectra System, Spectra WaveWriter System, Precision Novi System, Precision Montage and Precision Montage MRI Systems.
P030022/S044	08/17/2017	X - 30-Day Notice	RCHS CERAMIC LINERS AND SHELLS	SMITH & NEPHEW, INC.	Change in the outer packaging carton for P030022, so that it is consistent with the approved packaging.

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P030036/S096	08/16/2017	X - 30-Day Notice	SELECTSECURE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer of the incoming inspection activities for select components.
P030054/S335	08/23/2017	X - 30-Day Notice	PROMOTE+ / UNIFY QUADRA /UNITY ASSURA/ QUADRA ASSURA / QUADRA ASSURA MP	ST. JUDE MEDICAL	Changes to the foil etching manufacturing process for high voltage capacitors.
P040024/S097	08/01/2017	X - 30-Day Notice	RESTYLANE, PERLANE, RESTYLANE-L, RESTYLANE LYFT (FORMERLY PERLANE-L), RESTYLANE SILK	Q-MED AB	Changes in the storage time and F0 limit for in-house prepared microbiological media used in the microbiological testing.
P040024/S098	08/09/2017	X - 30-Day Notice	RESTYLANE INJECTABLE GELS	Q-MED AB	Installation of a sprinkler system in the manufacturing buildings.
P040034/S026	08/17/2017	X - 30-Day Notice	DURASEAL TM DURAL SEALANT SYSTEM	INTEGRA LIFESCIENCES CORPORATION	Change in manufacturing site of one of the suppliers.
P040037/S100	08/09/2017	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Implementation of an automated deionized water fill station for use in the manufacturing of the GORE® VIABAHN® Endoprosthesis, GORE® TIGRIS® Vascular Stent and GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis.
P040040/S031	08/03/2017	X - 30-Day Notice	AMPLATZER MUSCULAR VSD OCCLUDER	AGA MEDICAL CORPORATION	Change to laser parameters on the laser used to weld the occluder braid.
P040043/S094	08/18/2017	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Expand oven loading conditions for the sealing cuff of the GORE EXCLUDER AAA Endoprosthesis and the GORE TAG Thoracic Endoprosthesis.
P040045/S078	08/11/2017	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Implementation of a new recartoning line.

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P040045/S080	08/30/2017	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Change to the raw material specification of a visibility tint used in the VISTAKON® (senofilcon A) and (etafilcon A) Brand Contact Lenses.
P040046/S024	08/01/2017	X - 30-Day Notice	NATRELLE 410 HIGHLY COHESIVE ANATOMICALLY SHAPED SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Addition of two new Gruenberg gel curing ovens.
P040046/S025	08/21/2017	X - 30-Day Notice	NATRELLE 410 HIGHLY COHESIVE ANATOMICALLY SHAPED SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Change to Limulous Amoebocyte Lysate (LAL) reagent sensitivity
P050028/S056	08/09/2017	X - 30-Day Notice	COBAS TAQMAN HBV TEST FOR USE WITH THE HIGH PURE SYSTEM/COBAS AMPLIPREP/COBAS TAQMAN HBV TEST, V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Relocation of manufacturing activities related to production of critical components.
P050028/S057	08/11/2017	X - 30-Day Notice	COBAS TAQMAN HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Process improvements to the probe synthesis process.
P050052/S097	08/29/2017	X - 30-Day Notice	RADIESSE (+) LIDOCAINE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Manufacturing process change to automate the filling and capping process for Radiesse (+) Lidocaine Injectable Implant.
P060006/S084	08/17/2017	X - 30-Day Notice	EXPRESS SD MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Sterilize the devices within the scope of this bundled submission by the optimized BSC2000-2 cycle in Chambers 1, 2, 3, 6, 8, 9 and 10 at BSC Coventry, Rhode, Island.
P060006/S085	08/31/2017	X - 30-Day Notice	EXPRESS SD MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Update the BSC2000-2 cycle conducted in Chamber 2 at the BSC Coventry, RI facility with new Programmable Logic Controller (PLC) software, an additional vacuum pump booster, and a new validation documentation structure used to support the system.
P060030/S057	08/09/2017	X - 30-Day Notice	COBAS TAQMAN HCV TEST, V2.0, FOR USE WITH THE HIGH PURE SYSTEM/ COBAS AMPLIPREP/COBAS TAQMAN HCV TEST, V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Relocation of manufacturing activities related to production of critical components.
P060030/S058	08/11/2017	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Process improvements to the probe synthesis process.

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P060039/S081	08/16/2017	X - 30-Day Notice	ATTAIN STARFIX LEAD	MEDTRONIC INC.	Transfer of the incoming inspection activities for select components.
P060040/S067	08/17/2017	X - 30-Day Notice	THORATEC, HEARTMATE II, VENTRICULAR ASSIST SYSTEM	THORATEC CORP.	Implement the use of a secondary supplier of three silicone components of the HeartMate II LVAS.
P080006/S113	08/16/2017	X - 30-Day Notice	ATTAIN ABILITY LEAD	MEDTRONIC INC.	Transfer of the incoming inspection activities for select components.
P080011/S061	08/07/2017	X - 30-Day Notice	COMFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION MANUFACTURING, LTD.	Change to the injection molding machine cycle time for Biofinity Sphere (comfilcon A) lenses.
P080025/S143	08/16/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM (SNS BOWEL PROGRAMMING SYSTEMS)	MEDTRONIC NEUROMODULATION	Replace a capacitor due to obsolescence and to implement a redesigned back half of the programmer case in order to accommodate the capacitor change.
P080025/S145	08/08/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUTION SYSTEM	MEDTRONIC NEUROMODULATION	Transfer of and revision to receiving and incoming inspection activities.
P080025/S146	08/24/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Transfer of receiving and incoming inspection activities for device components (i.e., Screw-Conn Set, Crimp Block 7495, and Block- Connector, Set Screw) used in the manufacture of Medtronic Neuromodulation therapy delivery products, from the Medtronic Rice Creek facility to the Medtronic Puerto Rico Operations Company (MPROC)-Villalba, MPROC-Juncos, and the FedEx/3PL (Third Party Logistics) facility in Guaynabo, Puerto Rico.
P090007/S016	08/31/2017	X - 30-Day Notice	ELECSYS ANIT-HCV	ROCHE DIAGNOSTICS CORP.	Install an additional bead coating apparatus.
P090008/S018	08/31/2017	X - 30-Day Notice	ELECSYS ANIT-HCV	ROCHE DIAGNOSTICS CORP.	Install an additional bead coating apparatus.
P090009/S016	08/31/2017	X - 30-Day Notice	ELECSYS ANIT-HCV	ROCHE DIAGNOSTICS CORP.	Install an additional bead coating apparatus.
P090013/S262	08/16/2017	X - 30-Day Notice	CAPSUREFIX MRI LEAD	MEDTRONIC, INC	Transfer of the incoming inspection activities for select components.
P100010/S067	08/22/2017	X - 30-Day Notice	VISUAL INTEGRITY INSPECTION	MEDTRONIC CRYOCATH LP	Manufacturing and inspection changes for the Guide Wire Lumen (GWL)

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P100020/S022	08/09/2017	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Relocation of manufacturing activities related to production of critical components.
P100020/S023	08/11/2017	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Process improvements to the probe synthesis process.
P100020/S024	08/15/2017	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Replacement of a camera subassembly.
P100021/S065	08/10/2017	X - 30-Day Notice	ENDURANT, ENDURANTII, ENDURANT LLS STENT GRAFT SYSTEMS	MEDTRONIC VASCULAR	Group the Endurant, Endurant II and Endurant IIs Stent Graft System; and the Valiant Thoracic Stent Graft System with Captivia Delivery System; for routine bacterial endotoxin testing (BET).
P100021/S066	08/17/2017	X - 30-Day Notice	ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Change in the resin used to manufacture the yarn for the graft fabric, as well as the use of a new yarn manufacturing facility and new yarn manufacturing equipment.
P100021/S067	08/22/2017	X - 30-Day Notice	ENDURANT, ENDURANT II AND ENDURANT IIS STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Implementation of a wall thickness specification for the mandrels used during the manufacturing of the Endurant, Endurant II and Endurant IIs Stent Graft System.
P100027/S027	08/04/2017	X - 30-Day Notice	INFORM HER2 DUAL ISH DNA PROBE COCKTAIL	VENTANA MEDICAL SYSTEMS, INC.	Current suppliers new manufacturing site for a device component.
P100030/S010	08/21/2017	X - 30-Day Notice	PREVELEAK SURGICAL SEALANT / PREVELEAK SURGICAL SEALANT 10PK APPLICATOR TIPS	MALLINCKRODT PHARMA IP TRADING DAC	Use of an alternative 10-pack shipping case.
P100030/S011	08/30/2017	X - 30-Day Notice	PREVELEAK SURGICAL SEALANT / PREVELEAK SURGICAL 10PK APPLICATOR TIPS	MALLINCKRODT PHARMA IP TRADING DAC	Use of two roller bottles for each of the syringe¿s solutions into the filler machine.
P100031/S019	08/31/2017	X - 30-Day Notice	ELECSYS ANTI-HBC	ROCHE DIAGNOSTICS CORP.	Install an additional bead coating apparatus.
P100032/S016	08/31/2017	X - 30-Day Notice	ELECSYS ANTI-HBC	ROCHE DIAGNOSTICS CORP.	Install an additional bead coating apparatus.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100040/S032	08/10/2017	X - 30-Day Notice	VALIANT THORACIC STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Group the Endurant, Endurant II and Endurant IIs Stent Graft System; and the Valiant Thoracic Stent Graft System with Captivia Delivery System; for routine bacterial endotoxin testing (BET).
P100047/S102	08/04/2017	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST DEVICE SYSTEM	MEDTRONIC	Replacement of an existing inspection method for inspection of the Inner Bearing Fastener.
P100047/S103	08/17/2017	X - 30-Day Notice	HEARTWARE LEFT VENTRICULAR ASSIST DEVICE SYSTEM	MEDTRONIC	Addition of tolerances to a specification and a revised inspection method for seal strength at the supplier of the HeartWare Ventricular Assist Device Outflow Graft.
P100047/S104	08/07/2017	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Modify drawings and receiving inspection procedures for the sterile tray packaging of the HeartWare Ventricular Assist Device Implant Kit and Surgical Tool Kit.
P100047/S105	08/07/2017	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Implement minimum bond strength specifications for existing manufacturing processes of HVAD System subassemblies.
P100047/S106	08/07/2017	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Perform additional surface finish inspections to ensure surface finish control of additional components of the HeartWare Ventricular Assist Device (HVAD) pump.
P110010/S143	08/17/2017	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING STENT SYSTEM/ PROMUS PREMIER EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Sterilize the devices within the scope of this bundled submission by the optimized BSC2000-2 cycle in Chambers 1, 2, 3, 6, 8, 9 and 10 at BSC Coventry, Rhode, Island.
P110010/S144	08/31/2017	X - 30-Day Notice	PROMUS PREMIER EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Update the BSC2000-2 cycle conducted in Chamber 2 at the BSC Coventry, RI facility with new Programmable Logic Controller (PLC) software, an additional vacuum pump booster, and a new validation documentation structure used to support the system.
P110020/S019	08/09/2017	X - 30-Day Notice	COBAS BRAF V600 MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Relocation of manufacturing activities related to production of critical components.
P110020/S020	08/11/2017	X - 30-Day Notice	COBAS 4800 BRAF V600 MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Process improvements to the probe synthesis process.

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P110020/S021	08/15/2017	X - 30-Day Notice	COBAS 4800 BRAF V600 MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Replacement of a camera subassembly .
P110022/S023	08/31/2017	X - 30-Day Notice	ELECSYS ANIT-HBC IGM	ROCHE DIAGNOSTICS CORP.	Install an additional bead coating apparatus.
P110025/S020	08/31/2017	X - 30-Day Notice	ELECSYS ANIT-HBC IGM	ROCHE DIAGNOSTICS CORP.	Install an additional bead coating apparatus.
P110031/S019	08/31/2017	X - 30-Day Notice	ELECSYS ANIT-HBC IGM	ROCHE DIAGNOSTICS CORP.	Install an additional bead coating apparatus.
P110037/S030	08/09/2017	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN CMV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Relocation of manufacturing activities related to production of critical components.
P110037/S031	08/11/2017	X - 30-Day Notice	COBAS® AMPLIPREP/ COBAS® TAQMAN® CMV TEST (CAP/CTM CMV TEST)	ROCHE MOLECULAR SYSTEMS, INC.	Process improvements to the probe synthesis process.
P110042/S090	08/18/2017	X - 30-Day Notice	VOLTAGE CERAMIC CAPACITORS	BOSTON SCIENTIFIC CORPORATIO N	Additional suppliers for low voltage capacitors.
P110042/S091	08/30/2017	X - 30-Day Notice	ICD; S-ICD, EMBLEM S-ICD MRI	BOSTON SCIENTIFIC CORPORATIO N	Modifications to the manufacturing process for the spring contact housing components.
P120010/S105	08/16/2017	X - 30-Day Notice	MINIMED 530G SYSTEM ENLITE SENSOR	MEDTRONIC INC.	Changes to the test method and acceptance criteria for the glucose layer membrane solution release testing that is performed for use of the solution in Enlite Sensor fabrication. The Enlite Sensor is a component of the MiniMed 530G System, MiniMed 630G System, Paradigm Real-Time Revel System, and iPro2 Continuous Glucose Monitoring System.
P120017/S010	08/16/2017	X - 30-Day Notice	MYOCARDIAL PACING LEAD	MEDTRONIC INC.	Transfer of the incoming inspection activities for select components.
P120019/S013	08/09/2017	X - 30-Day Notice	COBAS EGFR MUTATION TEST AND COBAS EGFR MUTATION TEST V2	ROCHE	Relocation of manufacturing activities related to production of critical components.

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P120019/S014	08/15/2017	X - 30-Day Notice	COBAS EGFR MUTATION TEST V2	ROCHE	Replacement of a camera subassembly.
P120021/S004	08/03/2017	X - 30-Day Notice	AMPLATZER PFO OCCLUDER	ST. JUDE MEDICAL, INC.	Change to laser parameters on the laser used to weld the occluder braid.
P130006/S039	08/09/2017	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Implementation of an automated deionized water fill station for use in the manufacturing of the GORE® VIABAHN® Endoprosthesis, GORE® TIGRIS® Vascular Stent and GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis.
P130007/S029	08/17/2017	X - 30-Day Notice	ANIMAS VIBE SYSTEM	ANIMAS CORP.	Supplier change for the manufacturing of a Drive Housing component assembled into the Animas Vibe Insulin pump which is part of the Animas Vibe System. The Animas Vibe System consists of the Animas Vibe Insulin Pump paired with the Dexcom G4 PLATINUM Sensor and Transmitter.
P130015/S011	08/16/2017	X - 30-Day Notice	ELECSYS HBEAG AND PRECICONTROL HBEAG	ROCHE DIAGNOSTICS OPERATIONS INC	Replacement of an immunoassay analyzer used in the final QC testing.
P130015/S012	08/31/2017	X - 30-Day Notice	ELECSYS HBEAG	ROCHE DIAGNOSTICS OPERATIONS INC	Install an additional bead coating apparatus.
P130016/S031	08/16/2017	X - 30-Day Notice	NUCLEUS HYBRID COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Addition of new molding equipment to manufacture the CP900 Series Sound Processors.
P130017/S020	08/08/2017	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Addition of a storage facility used for the receiving, storage and shipping of test kit components.
P130021/S040	08/31/2017	X - 30-Day Notice	EN VEO R DELIVERY CATHETER SYSTEM	MEDTRONIC COREVALVE LLC	Addition of an alternative supplier for the Inner Slider Assembly component of the EnVeo R Delivery Catheter System.
P130022/S015	08/09/2017	X - 30-Day Notice	SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Second contract manufacturer (Sparton) conduct manufacturing activities for one of Senzas system components (called Trial Stimulator).
P130030/S042	08/17/2017	X - 30-Day Notice	REBEL PLATINUM CHROMUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Sterilize the devices within the scope of this bundled submission by the optimized BSC2000-2 cycle in Chambers 1, 2, 3, 6, 8, 9 and 10 at BSC Coventry, Rhode, Island.

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P130030/S043	08/31/2017	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM (MONORAIL AND OVER-THE-WIRE)	BOSTON SCIENTIFIC CORP.	Update the BSC2000-2 cycle conducted in Chamber 2 at the BSC Coventry, RI facility with new Programmable Logic Controller (PLC) software, an additional vacuum pump booster, and a new validation documentation structure used to support the system.
P140003/S022	08/01/2017	X - 30-Day Notice	IMPELLA 2.5 AND IMPELLA CP SYSTEMS	ABIOMED, INC.	Implement changes to the in-process testing during the manufacturing of Impella 2.5 and Impella CP Systems.
P140003/S024	08/21/2017	X - 30-Day Notice	IMPELLA VENTRICULAR SUPPORT SYSTEMS	ABIOMED, INC.	Addition of an environmentally controlled area.
P140010/S036	08/17/2017	X - 30-Day Notice	IN.PACT ADMIRAL PACLITAXEL-COATED BALLOON CATHETER	MEDTRONIC INC.	Modification to the lot release testing.
P140021/S011	08/31/2017	X - 30-Day Notice	ELECSYS ANIT-HCV II	ROCHE DIAGNOSTICS OPERATIONS INC	Install an additional bead coating apparatus.
P140023/S009	08/09/2017	X - 30-Day Notice	COBAS KRAS MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Relocation of manufacturing activities related to production of critical components.
P140023/S010	08/15/2017	X - 30-Day Notice	COBAS KRAS MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Replacement of a camera subassembly .
P140025/S007	08/04/2017	X - 30-Day Notice	VENTANA ALK (D5F3) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Current suppliers new manufacturing site for a device component.
P140028/S028	08/29/2017	X - 30-Day Notice	INNOVA SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Modifications to catheter coating process software controls.
P140031/S051	08/15/2017	X - 30-Day Notice	SAPIEN 3 - TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Implementation of an additional drying step and new visual inspection to the manufacturing process for the y-connector bond area of the Commander Delivery System.
P140033/S011	08/14/2017	X - 30-Day Notice	ENDURITY MRI, ASSURITY MRI	ST. JUDE MEDICAL, INC.	Alternate supplier of the 5-pin filtered feedthrough (FFT) assembly.

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P150001/S019	08/16/2017	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD ENLITE SENSOR	MEDTRONIC MINIMED	Changes to the test method and acceptance criteria for the glucose layer membrane solution release testing that is performed for use of the solution in Enlite Sensor fabrication. The Enlite Sensor is a component of the MiniMed 530G System, MiniMed 630G System, Paradigm Real-Time Revel System, and iPro2 Continuous Glucose Monitoring System.
P150004/S013	08/24/2017	X - 30-Day Notice	CASSETTE AND CASSETTE SPACER	ST. JUDE MEDICAL	New equipment at an alternate supplier manufacturing location for the cassette and cassette spacer components of the dorsal root ganglion (DRG) implantable pulse generators (IPGs).
P150005/S023	08/17/2017	X - 30-Day Notice	BLAZER OPEN IRRIGATED TEMPERATURE ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Sterilize the devices within the scope of this bundled submission by the optimized BSC2000-2 cycle in Chambers 1, 2, 3, 6, 8, 9 and 10 at BSC Coventry, Rhode, Island.
P150005/S024	08/31/2017	X - 30-Day Notice	BLAZER OPEN IRRIGATED CARDIAC ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Update the BSC2000-2 cycle conducted in Chamber 2 at the BSC Coventry, RI facility with new Programmable Logic Controller (PLC) software, an additional vacuum pump booster, and a new validation documentation structure used to support the system.
P150012/S035	08/30/2017	X - 30-Day Notice	ACCOLADE MRI PACEMAKERS, ESSENTIO MRI, PROPONENT MRI, ACCOLADE MRI	BOSTONSCIENTIFIC	Modify test software used in the wafer fabrication process.
P150012/S036	08/30/2017	X - 30-Day Notice	PACEMAKERS: ESSENTIO MRI, PROPONENT MRI, ACCOLADE MRI	BOSTONSCIENTIFIC	Modifications to the manufacturing process for the spring contact housing components.
P150014/S008	08/09/2017	X - 30-Day Notice	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Relocation of manufacturing activities related to production of critical components.
P150015/S007	08/09/2017	X - 30-Day Notice	COBAS HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Relocation of manufacturing activities related to production of critical components.
P150019/S031	08/16/2017	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM ENLITE SENSOR	MEDTRONIC MINIMED	Changes to the test method and acceptance criteria for the glucose layer membrane solution release testing that is performed for use of the solution in Enlite Sensor fabrication. The Enlite Sensor is a component of the MiniMed 530G System, MiniMed 630G System, Paradigm Real-Time Revel System, and iPro2 Continuous Glucose Monitoring System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150029/S011	08/16/2017	X - 30-Day Notice	IPRO2 CGM SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Changes to the test method and acceptance criteria for the glucose layer membrane solution release testing that is performed for use of the solution in Enlite Sensor fabrication. The Enlite Sensor is a component of the MiniMed 530G System, MiniMed 630G System, Paradigm Real-Time Revel System, and iPro2 Continuous Glucose Monitoring System.
P150033/S026	08/18/2017	X - 30-Day Notice	MICRA TRANSCATHETER PACING SYSTEM	MEDTRONIC INC.	Changes to the curve bake and silicone application worksteps of the Micra delivery system manufacturing process.
P150036/S016	08/24/2017	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Transfer the polyester band component manufacturing process.
P150036/S017	08/31/2017	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Change to the location of facilities for annulus frame inspections.
P150039/S002	08/10/2017	X - 30-Day Notice	TRYTON SIDE BRANCH STENT	TRYTON MEDICAL, INC.	Replace the pouch sealer equipment and to modify the sealer process parameters.
P150048/S002	08/21/2017	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS	EDWARDS LIFESCIENCES, LLC.	Implement upgrades to the temperature indicator hardware and software.
P160002/S003	08/04/2017	X - 30-Day Notice	VENTANA PD-L1 (SP142) ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Current suppliers new manufacturing site for a device component.
P160004/S005	08/09/2017	X - 30-Day Notice	GORE TIGRIS VASCULAR STENT	W. L. GORE & ASSOCIATES, INC.	Implementation of an automated deionized water fill station for use in the manufacturing of the GORE® VIABAHN® Endoprosthesis, GORE® TIGRIS® Vascular Stent and GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis.
P160019/S005	08/31/2017	X - 30-Day Notice	ELECSYS HBSAG II	ROCHE DIAGNOSTICS, INC.	Install an additional bead coating apparatus.
P160021/S003	08/09/2017	X - 30-Day Notice	GOREVIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implementation of an automated deionized water fill station for use in the manufacturing of the GORE® VIABAHN® Endoprosthesis, GORE® TIGRIS® Vascular Stent and GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis.
P160021/S004	08/15/2017	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implementation of updated equipment for device testing.
P160035/S002	08/02/2017	X - 30-Day Notice	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Manufacturing change for the cannulae used with the Berlin Heart EXCOR Pediatric VAD.

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P160041/S001	08/09/2017	X - 30-Day Notice	COBAS CMV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Relocation of manufacturing activities related to production of critical components.
P160043/S004	08/07/2017	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS ELUTING CORONARY STENT SYSTEM	MEDTRONIC INC.	Add a second production line used in the manufacturing of extruded polymer tubing.
P160045/S001	08/14/2017	X - 30-Day Notice	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Change to the storage location for raw and WIP (work in-process) materials used in the manufacture of the Oncomine Dx Target Test device.
P160046/S001	08/04/2017	X - 30-Day Notice	VENTANA PD-L1 (SP263) ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Current suppliers new manufacturing site for a device component.

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