

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 Orig | 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 Orig | 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 Orig | 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 Orig | 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 Orig | 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/III+ 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. |

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|-------------------|---------------------|--------------------|---|------------------------|--|
| 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. |

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|-------------------|---------------------|--------------------|---|-----------------------------------|---|
| 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 LIFESCIENCE S 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. |

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| P010012/S452 | 08/07/2017 | O - Normal 180 Day | CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILL | 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. |

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| 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 ORTHOPAEDI CS, INC. | Approval of the manufacturing site. |

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|-------------------|---------------------|--------------------|--|------------------------------------|--|
| 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 GENERATOR | 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. |

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| 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. | <p>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:</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> |
| 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. |

Total: 97

30-Day Notice

| 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 LIFESCIENCE S 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 LIFESCIENCE S, 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. |

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|-------------------|---------------------|-------------------|--|-------------------------|---|
| 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. | 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. |
| 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, VIGILANT 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. |

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|-------------------|---------------------|-------------------|--|-------------------------|---|
| 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, ADDR1, 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 | RESTITLANE, PERLANE, RESTITLANE-L, RESTITLANE LYFT (FORMERLY PERLANE-L), RESTITLANE 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 | RESTITLANE 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 LIFESCIENCE S CORPORATIO N | 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, I NC | 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 CORPORATIO N | 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) |

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

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|-------------------|---------------------|-------------------|--|-------------------------------|---|
| 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 CORPORATION | Additional suppliers for low voltage capacitors. |
| P110042/S091 | 08/30/2017 | X - 30-Day Notice | ICD; S-ICD, EMBLEM S-ICD MRI | BOSTON SCIENTIFIC CORPORATION | 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 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. |

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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 LIFESCIENCE S, 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. |

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

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|-------------------|---------------------|-------------------|--|-------------------------------|---|
| 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 LIFESCIENCE S, LLC. | Transfer the polyester band component manufacturing process. |
| P150036/S017 | 08/31/2017 | X - 30-Day Notice | EDWARDS INTUITY ELITE VALVE SYSTEM | EDWARDS LIFESCIENCE S, 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 LIFESCIENCE S, 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. |

Total: 203