## PMA Monthly approvals from 5/1/2017 to 5/31/2017

## Original

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P160015 | 05/26/2017 | PMAO - PMA Origi | AED PLUS AND FULLY AUTOMATIC AED PLUS | ZOLL MEDICAL CORPORATIO N | Approval for the AED Plus and Fully Automatic AED Plus. These devices are indicated for use when a suspected cardiac arrest victim has an apparent lack of circulation as indicated by:<br><br>1) Unconsciousness;<br>2) Absence of normal breathing; and<br>3) Absence of a pulse or signs of circulation<br><br>These devices are intended for use by personnel who have been trained in their operation. Users should have received training in basic life support/AED, advanced life support or a physician-authorized emergency medical response training program.<br><br>When a victim is less than 8 years of age, or weighs less than 55 lbs. (25kg), the ZOLL AED Plus® and Fully Automatic AED Plus® should be used with the ZOLL AED Plus and Fully Automatic AED Plus® Pediatric Electrodes. Therapy should not be delayed to determine the patients exact age or weight. |
| P160044 | 05/18/2017 | PMAO - PMA Origi | ABBOTT REALTIME CMV | ABBOTT MOLECULAR | Approval for the Abbott RealTime CMV test is an in vitro polymerase chain reaction (PCR) assay for the quantitation of cytomegalovirus (CMV) DNA in human EDTA plasma. The Abbott RealTime CMV test is intended for use as an aid in the management of Hematopoietic Stem Cell Transplant patients who are undergoing anti-cytomegalovirus therapy. In this population, serial DNA measurement can be used to assess virological response to anti-cytomegalovirus therapy. The results from the RealTime CMV test must be interpreted within the context of all relevant clinical and laboratory findings. The RealTime CMV test is not intended as a screening test for the presence of CMV DNA in blood or blood products. |

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| P160046 | 05/01/2017 | PMAO - PMA Origi | VENTANA PD-L1 (SP263) ASSAY | VENTANA MEDICAL SYSTEMS, INC. | Approval for the VENTANA PD-L1 (SP263) Assay is a qualitative immunohistochemical assay using rabbit monoclonal anti-PD-L1 clone SP263 intended for use in the assessment of the PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) urothelial carcinoma tissue stained with OptiView DAB IHC Detection Kit on a VENTANA BenchMark ULTRA instrument.<br>PD-L1 status is determined by the percentage of tumor cells with any membrane staining above background or by the percentage of tumor-associated immune cells with staining (IC +) at any intensity above background. The percent of tumor area occupied by any tumor-associated immune cells (Immune Cells Present, ICP) is used to determine IC+, which is the percent area of ICP exhibiting PD-L1 positive immune cell staining. PD-L1 status is considered High if any of the following are met:<br><br>1) >= 25% of tumor cells exhibit membrane staining; or,<br>2) ICP > 1% and IC+ ? 25%; or,<br>3) ICP = 1% and IC+ = 100%.<br><br>PD-L1 High status as determined by VENTANA PD-L1 (SP263) Assay was associated with increased objective response rate (ORR) in a single arm study of IMFINZI (durvalumab). |

**Total: 3**

## Supplements

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
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| N12159/S036 | 05/26/2017 | N - Normal 180 Day | SURGICEL POWDER ABSORBABLE HEMOSTATIC POWDER | ETHICON, INC. | Approval or the Surgicel Powder Absorbable Hemostatic Powder as an additional device form of the Surgicel original device. |
| N970012/S131 | 05/08/2017 | R - Real-Time Proc | AMS 700 IMPLANTABLE PENILE PROSTHESIS WITH AND WITHOUT INHIBIZONE TREATMENT | BOSTON SCIENTIFIC CORP. | Approval for placing the Keith Needle inside a cartridge in the sterile barrier of the Accessory Kit. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
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| P830061/S140 | 05/06/2017 | N - Normal 180 Day | CAPSURE SENSE MRI SURESCAN LEAD | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Approval for the Astra SR and DR Implantable Pulse Generators. |
| P830061/S141 | 05/06/2017 | N - Normal 180 Day | CAPSURE SENSE MRI SURESCAN LEAD | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Approval for the Percepta/Percepta Quad, Serena/Serena Quad and Solara/Solara Quad CRT-P MRI SureScan Implantable Pulse Generators with Cardiac Resynchronization Therapy. |
| P840064/S066 | 05/18/2017 | R - Real-Time Proc | OPHTHALMIC VISCOSURGICAL DEVICES | ALCON LABORATORIES | Approval to include a 0.85 mL volume of ProVisc OVD and make labeling changes accordingly. |
| P860057/S154 | 05/01/2017 | Y - 135 Review Tra | EDWARDS LIFESCIENCES PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES | EDWARDS LIFESCIENCES, LLC. | Approval for the addition of the Edwards Singapore facility for manufacturing components used in Edwards surgical and transcatheter heart valves. |
| P890047/S051 | 05/18/2017 | R - Real-Time Proc | PROVISC OVD | ALCON RESEARCH, LTD. | Approval to include a 0.85 mL volume of ProVisc OVD and make labeling changes accordingly. |
| P910018/S022 | 05/23/2017 | N - Normal 180 Day | LIPOSORBER(R) LA-15 SYSTEM | KANEKA PHARMA AMERICA CORP. | Approval for changes to the housing of adsorption column LA-15 and connector parts of tubing system NK-M3R(U), plus components of the LIPOSORBER® LA-15 System. |
| P910056/S024 | 05/23/2017 | N - Normal 180 Day | ENVISTA IOL | BAUSCH & LOMB, INC. | Approval of the enVista® One Piece Hydrophobic Acrylic IOL, Model MX60E, which includes a modification to the intraocular lens (IOL) material formulation of the approved parent lens, enVista® Model MX60. |
| P920015/S191 | 05/06/2017 | N - Normal 180 Day | MODEL 6725 IS-1 PIN PLUG | MEDTRONIC INC. | Approval for the Percepta/Percepta Quad, Serena/Serena Quad and Solara/Solara Quad CRT-P MRI SureScan Implantable Pulse Generators with Cardiac Resynchronization Therapy. |
| P920046/S010 | 05/26/2017 | R - Real-Time Proc | STERISHOT II MINI FLISHIE CLIP APPLICATOR | FEMCARE LTD. | Approval for a variant of the tubal occlusion device introducer, Sterishot II Mini Filshie Clip Applicator. |
| P930038/S083 | 05/19/2017 | Y - 135 Review Tra | ANGIO SEAL VASCULAR CLOSURE DEVICE | TERUMO MEDICAL CORPORATION | Approval to implement alternate automated inspection equipment for the AngioSeal puncture locator component. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
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| P930039/S165 | 05/06/2017 | N - Normal 180 Day | CAPSUREFIX NOVUS MRI SURESCAN LEAD | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Approval for the Astra SR and DR Implantable Pulse Generators. |
| P930039/S166 | 05/06/2017 | N - Normal 180 Day | CAPSUREFIX NOVUS MRI SURESCAN LEAD | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Approval for the Percepta/Percepta Quad, Serena/Serena Quad and Solara/Solara Quad CRT-P MRI SureScan Implantable Pulse Generators with Cardiac Resynchronization Therapy. |
| P950037/S166 | 05/03/2017 | N - Normal 180 Day | PACEMAKER/ICD/CRT NON IMPLANTED COMPONENTS PSW 1602.U, HMSC 3.34.0 | BIOTRONIK, INC. | Approval for the Ilivia, Intica and Inlexa families of ICDs and CRT-Ds, BS IS4 Blind Plug, as well as associated software updates PSW 1602.U and HMSC 3.34.0. |
| P950037/S171 | 05/04/2017 | N - Normal 180 Day | PACEMAKER/ICD/CRT NON IMPLANTED COMPONENTS | BIOTRONIK, INC. | Approval for the Sentus ProMRI OTW QP L/S family of left ventricular pacing leads. |
| P950037/S173 | 05/06/2017 | N - Normal 180 Day | PULSE GENERATOR, PERMANENT IMPLANTABLE | BIOTRONIK, INC. | Approval for PSW 1702.U programmer software including support for Multi-Pole Pacing (MPP). |
| P950037/S174 | 05/24/2017 | R - Real-Time Proc | SOLIA S | BIOTRONIK, INC. | Approval for shelf life extension to 24 months. |
| P950037/S175 | 05/06/2017 | R - Real-Time Proc | EDORA / ENITRA / ENTICOS / EVITY PSW 1701.U | BIOTRONIK, INC. | Approval for inclusion of the AV Opt. test in PSW 1701.U. |
| P960040/S385 | 05/02/2017 | N - Normal 180 Day | NG4 FAMILY OF PULSE GENERATORS ICDS. | BOSTON SCIENTIFIC | Approval for NG4 models of ICD and CRT-D devices with new therapy and diagnostic features. |
| P960040/S390 | 05/18/2017 | R - Real-Time Proc | IMPLANTABLE CARDIOVERTER DEFIBRILLLATOR/ DYNAGEN, INOGEN, ORIGEN AND AUTOGEN ICD'S. | BOSTON SCIENTIFIC | Approval for addition of alternate bondply adhesive suppliers for pulse generator Super Output Module (SOM) and High Voltage Charge (HVC) module substrates. |
| P960058/S120 | 05/17/2017 | N - Normal 180 Day | HIRESOLUTION BIONIC EAR SYSTEM | ADVANCED BIONICS | Approval for the Sound Wave Professional Suite Software 3. 1, model number CI-6055-011. |

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|---|---|---|---|---|---|
| P980023/S081 | 05/24/2017 | R - Real-Time Proc | PLEXA S 60/PLEXA SD 60/16/PLEXA PROMRI S/ PLEXA PROMRI SD/PLEXA DF-1 S/PLEXA DF-1 SD/ PLEXA PROMRI DF-1 SD/ PLEXA PROMRI DF-1 S DX | BIOTRONIK, INC. | Approval for shelf life extension of Plexa leads to 24 months and Siello steroid collars to 12 months.. |
| P980035/S486 | 05/06/2017 | N - Normal 180 Day | ASTRA XT SR MRI SURESCAN, ASTRA XT DR MRI SURESCAN, ASTRA S SR MRI SURESCAN, ASTRA S DR MRI SURESCAN, SOFTWARE MODEL | MEDTRONIC INC. | Approval for the Astra SR and DR Implantable Pulse Generators. |
| P990040/S024 | 05/11/2017 | N - Normal 180 Day | TRUFILL N-BUTYL CYANOACRYLATE LIQUID EMBOLIC SYSTEM | CODMAN & SHURTLEFF, INC. | Approval for a modified specification to the dimer control limit of the n-BCA purity testing. |
| P000006/S046 | 05/17/2017 | R - Real-Time Proc | TITAN INFLATABLE PENILE PROSTHESIS | COLOPLAST CORP. | Approval for addition of a new insertion tool; update of pusher tool design; addition of shods supplied with kit; modification of package layout and material; use of new package denesting agent; and 2 year and 5 year shelf-life protocol. |
| P000009/S068 | 05/03/2017 | N - Normal 180 Day | PACEMAKER/ICD/CRT NON IMPLANTED COMPONENTS; PSW 1602.U; HMSC 3.34.0 | BIOTRONIK, INC. | Approval for the Ilivia, Intica and Inlexa families of ICDs and CRT-Ds, BS IS4 Blind Plug, as well as associated software updates PSW 1602.U and HMSC 3.34.0. |
| P000009/S070 | 05/04/2017 | N - Normal 180 Day | PACEMAKER ICD CRT NON IMPLANTED COMPONENTS | BIOTRONIK, INC. | Approval for the Sentus ProMRI OTW QP L/S family of left ventricular pacing leads. |
| P000009/S071 | 05/06/2017 | N - Normal 180 Day | PACEMAKER ICD CRT NON IMPLANTED COMPONENTS. | BIOTRONIK, INC. | Approval for PSW 1702.U programmer software including support for Multi-Pole Pacing (MPP.) |
| P000009/S072 | 05/06/2017 | R - Real-Time Proc | LUMOS DR-T/VR-T | BIOTRONIK, INC. | Approval for inclusion of the AV Opt. test in PSW 1701.U. |
| P010012/S436 | 05/02/2017 | N - Normal 180 Day | NG4 FAMILY OF PULSE GENERATORS CRT-DS | BOSTON SCIENTIFIC CORP. | Approval for NG4 models of ICD and CRT-D devices with new therapy and diagnostic features. |
| P010012/S446 | 05/18/2017 | R - Real-Time Proc | CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR; DYNAGEN, INOGEN, ORIGEN, AUTOGEN CRT-D'S | BOSTON SCIENTIFIC CORP. | Approval for addition of alternate bondply adhesive suppliers for pulse generator Super Output Module (SOM) and High Voltage Charge (HVC) module substrates. |

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|---|---|---|---|---|---|
| P010015/S317 | 05/06/2017 | N - Normal 180 Day | PERCEPTA QUAD CRT-P MRI SURESCAN, SERENA QUAD CRT-P MRI SURESCAN, SOLARA QUAD CRT-P MRI SURESCAN, IMPLANTABLE PULSE GENERATORS WITH CARDIAC RESYNCHRONIZATION THERAPY, PROGRAMMER SOFTWARE | MEDTRONIC INC. | Approval for the Percepta/Percepta Quad, Serena/Serena Quad and Solara/Solara Quad CRT-P MRI SureScan Implantable Pulse Generators with Cardiac Resynchronization Therapy. |
| P020025/S096 | 05/08/2017 | R - Real-Time Proc | INTELLANAV XP, NAV MIFI XP | BOSTON SCIENTIFIC | Approval to change the ablation connection box design, IntellaNav Ablation Connection Box, to the Rhythmia HDx Ablation Connection Box, for the family of IntellaNav Ablation Catheters. |
| P030011/S048 | 05/24/2017 | R - Real-Time Proc | SYNCARDIA TEMPORARY TOTAL ARTIFICIAL HEART (TAH-T) SYSTEM | SYNCARDIA SYSTEMS, LLC | Approval for a change in the length of screw used in the Freedom Driver. |
| P030011/S054 | 05/12/2017 | Y - 135 Review Tra | SYNCARDIA TEMPORARY TOTAL ARTIFICIAL HEART (TAH-T) SYSTEM | SYNCARDIA SYSTEMS, LLC | Approval for a change of supplier for the Freedom Driver main Printed Circuit Board Assembly (PCBA). |
| P030017/S269 | 05/31/2017 | N - Normal 180 Day | PRECISION MONTAGE MRI SPINAL CORD STIMULATOR SYSTEM | BOSTON SCIENTIFIC CORP. | Approval for expanding magnetic conditional labeling for the Precision Montage MRI Spinal Cord Stimulation System to include existing BSN SCS Leads. |
| P030017/S273 | 05/12/2017 | R - Real-Time Proc | PRECISION SPECTRA SPINAL CORD STIMULATION(SCS) SYSTEM | BOSTON SCIENTIFIC CORP. | Approval for an update to the flash memory component used on the PCBA in the Precision Spectra IPG. The current flash memory component is no longer available and needs to be replaced. The change will replace the current flash memory component with a new flash memory component from the same supplier. The functionality of the IPG is unchanged. |
| P030017/S281 | 05/08/2017 | R - Real-Time Proc | PRECISION MONTAGE MRI AND PRECISION MONTAGE SPINAL CORD STIMULATOR (SCS) SYSTEMS | BOSTON SCIENTIFIC CORP. | Approval for an update to the flash memory component used on the PCBA in the Precision Montage IPG. |
| P030036/S091 | 05/06/2017 | N - Normal 180 Day | SELECTSECURE LEAD MODEL 3830 | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Approval for the Astra SR and DR Implantable Pulse Generators. |

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|---|---|---|---|---|---|
| P030036/S092 | 05/06/2017 | N - Normal 180 Day | SELECTSECURE MRI SURESCAN LEAD | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Approval for the Percepta/Percepta Quad, Serena/Serena Quad and Solara/Solara Quad CRT-P MRI SureScan Implantable Pulse Generators with Cardiac Resynchronization Therapy. |
| P030053/S036 | 05/08/2017 | Y - 135 Review Tra | MEMORYGEL BREAST IMPLANTS | MENTOR CORP. | Approval for implementation of a CO2 shell soaking process as an alternative to the current isopropyl alcohol (IPA) shell soaking process for removal of primarily low molecular weight (LMW) siloxanes from high temperature vulcanized (HTV) round and shaped breast implant shells. |
| P040002/S059 | 05/02/2017 | S - Special CBE | AFX ENDOVASCULAR AAA SYSTEM | ENDOLOGIX, INC. | Approval for updates to the in-process inspection of the AFX2 Endovascular AAA System. |
| P050023/S103 | 05/03/2017 | N - Normal 180 Day | VARIOUS MODELS OF DUAL CHAMBER ICDS IN THE ILIVIA, INTICA, INLEXA FAMILIES, VARIOUS MODELS OF CRT-DS AND NON- CRT-DS IN ILIVIA, INTICA, INLEXA FAMILIES;BS IS4 BLIND PLUG, 1 AND 5PACK; PSW 1602.U, HMSC 3.34.0 | BIOTRONIK, INC. | Approval for the Ilivia, Intica and Inlexa families of ICDs and CRT-Ds, BS IS4 Blind Plug, as well as associated software updates PSW 1602.U and HMSC 3.34.0. |
| P050023/S105 | 05/04/2017 | N - Normal 180 Day | PACEMAKER ICD CRT NON IMPLANTED COMPONENTS | BIOTRONIK, INC. | Approval for the Sentus ProMRI OTW QP L/S family of left ventricular pacing leads. |
| P050023/S107 | 05/06/2017 | N - Normal 180 Day | DEFIBRILLATOR, IMPLANTABLE, DUAL CHAMBER, AUTOMATIC IMPLANTABLE CARDIOVERTER WITH CARDIAC RESYNCHRONIZATION | BIOTRONIK, INC. | Approval for PSW 1702.U programmer software including support for Multi-Pole Pacing (MPP). |
| P050023/S108 | 05/06/2017 | R - Real-Time Proc | INVENTRA / IPERIA / ITREVIA | BIOTRONIK, INC. | Approval for inclusion of the AV Opt. test in PSW 1701.U. |
| P050028/S055 | 05/10/2017 | S - Special CBE | COBAS TAQMAN HBV TEST, FOR USE WITH HIGH PURE SYSTEM | ROCHE MOLECULAR SYSTEMS, INC. | Approval for labeling changes to the package inserts and product information cards for the devices identified. |
| P050047/S056 | 05/12/2017 | Y - 135 Review Tra | JUVEDERM® HYALURONATE GEL IMPLANTS | ALLERGAN | Approval for a change in the cleaning procedure for some equipment used in the manufacturing of injectable gel products |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P060028/S019 | 05/08/2017 | Y - 135 Review Tra | MENTOR MEMORYSHAPE BREAST IMPLANTS | MENTOR WORLDWIDE LLC | Approval for implementation of a CO2 shell soaking process as an alternative to the current isopropyl alcohol (IPA) shell soaking process for removal of primarily low molecular weight (LMW) siloxanes from high temperature vulcanized (HTV) round and shaped breast implant shells. |
| P060030/S056 | 05/10/2017 | S - Special CBE | COBAS TAQMAN HCV TEST V2.0, FOR USE WITH HIGH PURE SYSTEM | ROCHE MOLECULAR SYSTEMS, INC. | Approval for labeling changes to the package inserts and product information cards for the devices identified. |
| P070008/S075 | 05/03/2017 | N - Normal 180 Day | PACEMAKER/ICD/CRT NON IMPLANTED COMPONENTS; PSW 1602.U; HMSC 3.34.0 | BIOTRONIK, INC. | Approval for the Ilivia, Intica and Inlexa families of ICDs and CRT-Ds, BS IS4 Blind Plug, as well as associated software updates PSW 1602.U and HMSC 3.34.0. |
| P070008/S079 | 05/04/2017 | N - Normal 180 Day | PACEMAKER ICD CRT NON IMPLANTED COMPONENTS | BIOTRONIK, INC. | Approval for the Sentus ProMRI OTW QP L/S family of left ventricular pacing leads. |
| P070008/S081 | 05/05/2017 | N - Normal 180 Day | PULSE GENERATOR, PACEMAKER, IMPLANTABLE WITH CARDIAC RESYNCHRONIZATION (CRT_P) | BIOTRONIK, INC. | Approval for PSW 1702.U programmer software including support for Multi-Pole Pacing (MPP). |
| P070008/S082 | 05/06/2017 | R - Real-Time Proc | ELUNA / EPYRA / ETRINSA | BIOTRONIK, INC. | Approval for inclusion of the AV Opt. test in PSW 1701.U. |
| P080003/S005 | 05/23/2017 | S - Special CBE | SELENIA DIMENSIONS 3D SYSTEM. | HOLOGIC, INC. | Approval for a change to the Physician Labeling of the Selenia Dimensions 3D System and the Selenia Dimensions 3D System with C-View Software Module, to claim superior screening accuracy of 3D plus 2D imaging, where the 2D image can be either a synthesized 2D or a Full Field Digital Mammography (FFDM) image, as compared to FFDM alone, for women with dense breasts. |
| P080006/S105 | 05/06/2017 | N - Normal 180 Day | MEDTRONIC ATTAIN ABILITY MRI SURESCAN, ATTAIN PERFORMA MRI SURESCAN LEAD | MEDTRONIC INC. | Approval for the Percepta/Percepta Quad, Serena/Serena Quad and Solara/Solara Quad CRT-P MRI SureScan Implantable Pulse Generators with Cardiac Resynchronization Therapy. |
| P080011/S058 | 05/05/2017 | O - Normal 180 Day | IWEAR OXYGEN AND IWEAR OXYGEN ASTIGMATISM | COOPERVISION MANUFACTURING, LTD. | Approval for labeling change to add new private label brand name, iWear oxygen and iWear oxygen astigmatism. The name iWear oxygen is intended for the spherical lenses and iWear oxygen astigmatism for the toric lenses. |
| P080012/S041 | 05/31/2017 | S - Special CBE | PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM | FLOWONIX MEDICAL, INC. | Approval for the addition of a dimensional measurement to the current inspection procedure for the Flow Activated Safety Valve (FAV) Access Port Body component to measure the counter-sink depth of the O-ring sealing surface, as specified in change ECO 16-80. |

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| P090013/S244 | 05/06/2017 | N - Normal 180 Day | CAPSUREFIX MRI SURESCAN LEAD | MEDTRONIC, INC | Approval for the Astra SR and DR Implantable Pulse Generators. |
| P090013/S245 | 05/06/2017 | N - Normal 180 Day | CAPSUREFIX MRI SURESCAN LEAD | MEDTRONIC, INC | Approval for the Percepta/Percepta Quad, Serena/Serena Quad and Solara/Solara Quad CRT-P MRI SureScan Implantable Pulse Generators with Cardiac Resynchronization Therapy. |
| P090018/S034 | 05/24/2017 | Y - 135 Review Tra | ESTEEM | ENVOY MEDICAL CORPORATION | Approval for relocation and requalification of the supplier for the seam welding and laser marking processes for the Esteem System Sound Processor, Model 2001. |
| P100009/S021 | 05/11/2017 | Y - 135 Review Tra | MITRACLIP NT CLIP DELIVER SYSTEM | ABBOTT VASCULAR INC. | Approval to modify acceptance criteria for the surface inspection performed on the clip arm component. |
| P100022/S022 | 05/02/2017 | R - Real-Time Proc | ZILVER PTX DRUG-ELUTING PERIPHERAL STENT | COOK MEDICAL INCORPORATED | Approval for the extension of the shelf life of the Zilver PTX Drug-Eluting Peripheral Stent to 24 months. |
| P100042/S012 | 05/04/2017 | R - Real-Time Proc | APTIMA HPV ASSAY | GEN-PROBE INCORPORATED | Approval for minor design changes to the Tigris instrument and System software. |
| P100044/S027 | 05/30/2017 | R - Real-Time Proc | PROPEL SINUS IMPLANT & PROPEL MINI SINUS IMPLANT | INTERSECT ENT | Approval for the implementation of mechanically interlocking bond joints for the Propel and Propel Mini delivery systems, as well as a redefined tensile strength specification for the Propel applicator. |
| P100045/S019 | 05/19/2017 | Y - 135 Review Tra | CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM | ST. JUDE MEDICAL | Approval for hardware and software updates to equipment used to measure atmospheric and device parameters used in-process during production. |
| P100047/S089 | 05/12/2017 | Y - 135 Review Tra | HEARTWARE VENTRICULAR ASSIST SYSTEM | MEDTRONIC | Approval for the addition of an alternate supplier for a component of the HeartWare Ventricular Assist System Pump. |
| P110002/S015 | 05/05/2017 | O - Normal 180 Day | MOBI-C CERVICAL DISC PROSTHESIS (ONE-LEVEL INDICATION) | LDR SPINE USA | Approval for manufacturing sites located at: 1) SAS Etablissements Maurice, MARLE, Zi Rue Lavoisier, Bp 46, Nogent France; 2)Marle Finishing SAS, 22 Rue de la Mollanche Sorbiers, Loire 42290, France; and 3) Marie Sferic SAS, Zone Artisanale, Rue du Courtois Prolongee 41500 MENARS France, for polishing endplates and machining the mobile insert of the device. |
| P110006/S007 | 05/01/2017 | N - Normal 180 Day | INVENIA ABUS - AUTOMATED BREAST ULTRASOUND SYSTEM | U-SYSTEMS, INC. | Approval for a change to the labeling to allow the use of ultrasound gel in addition to currently required ultrasound lotion with the system |

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| P110009/S015 | 05/05/2017 | O - Normal 180 Day | MOBI-C CERVICAL DISC PROSTHESIS (TWO-LEVEL INDICATION) | LDR SPINE USA INC. | Approval for manufacturing sites located at: 1) SAS Etablissements Maurice, MARLE, Zi Rue Lavoisier, Bp 46, Nogent France; 2) Marie Finishing SAS, 22 Rue de Ia Mollanche Sorbiers, Loire 42290, France; and 3) Marie Sferic SAS, Zone Artisanale, Rue du Courtois Prolongee 41500 MENARS France, for polishing endplates and machining the mobile insert of the device. |
| P110033/S026 | 05/12/2017 | Y - 135 Review Tra | JUVEDERM VOLUMA® XC AND JUVEDERM VOLBELLA® XC | ALLERGAN | Approval for a change in the cleaning procedure for some equipment used in the manufacturing of injectable gel products |
| P110042/S080 | 05/19/2017 | R - Real-Time Proc | MODEL A219 EMBLEM MRI S-ICD PULSE GENERATOR; MODEL A209 EMBLEM S-ICD PULSE GENERATOR; MODEL 2877 PROGRAMMER SOFTWARE APPLICATION; | BOSTON SCIENTIFIC CORPORATION | Approval for a firmware update to version 3.1.536 on the EMBLEM S-ICD Model A209 and EMBLEM MRI S-ICD Model A219 devices, and software version 4.03 for the Model 2877 Programmer Software. |
| P120005/S059 | 05/22/2017 | O - Normal 180 Day | DEXCOM G4 PLATINUM CONTIUOUS GLUCOSE MONITORING SYSTEM | DEXCOM, INC. | Approval of the revised protocol for the post-approval study (PAS) protocol. |
| P120007/S010 | 05/04/2017 | R - Real-Time Proc | APTIMA HPV 16 18/45 GENOTYPE ASSAY. | GEN-PROBE INCORPORATED | Approval for minor design changes to the Tigris instrument and System software. |
| P120022/S014 | 05/19/2017 | N - Normal 180 Day | THERASCREEN EGFR RGQ PCR KIT | QIAGEN MANCHESTER LTD | Approval for changes to the Instructions for Use. |
| P120023/S004 | 05/16/2017 | O - Normal 180 Day | KAMRA INLAY | ACUFOCUS, INC. | Approval of the protocol for the post-approval study (PAS) protocol. |
| P130005/S016 | 05/03/2017 | R - Real-Time Proc | DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY DEVICE (OAD) | CARDIOVASCULAR SYSTEMS, INC. | Approval to revert to manufacturing a previously approved design of the saline pump used as part of CSIs diamondback 360 Orbital Atherectomy System. |
| P130008/S016 | 05/05/2017 | N - Normal 180 Day | INSPIRE UPPER AIRWAY STIMULATION (UAS) SYSTEM, MODEL 3028 IPG | INSPIRE MEDICAL SYSTEMS | Approval for the Model 3028 MR Conditional Implantable Pulse Generator (IPG). |
| P130009/S066 | 05/01/2017 | Y - 135 Review Tra | EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE | EDWARDS LIFESCIENCES, LLC. | Approval for the addition of the Edwards Singapore facility for manufacturing components used in Edwards surgical and transcatheter heart valves. |
| P130017/S015 | 05/24/2017 | R - Real-Time Proc | COLOGUARD | EXACT SCIENCES CORPORATION | Approval for the changes to the EXACT System Software for Cologuard. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
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| P130019/S014 | 05/24/2017 | R - Real-Time Proc | MAESTRO RECHARGEABLE SYSTEM | ENTEROMEDICS INC. | Approval for the inclusion of the Patient Transmit Coil in the Model 2504 Clinician Programmer Kit for the Maestro Rechargeable System. |
| P130021/S031 | 05/16/2017 | Y - 135 Review Tra | MEDTRONIC COREVALVE (TM) EVOLUT (TM) R SYSTEM | MEDTRONIC COREVALVE LLC | Approval for an additional supplier for the EnVeo R delivery system spindle component. |
| P130021/S034 | 05/09/2017 | O - Normal 180 Day | MEDTRONIC COREVALVE SYSTEM | MEDTRONIC COREVALVE LLC | Approval for changes to the protocol for the post-approval study (PAS) protocol. |
| P130028/S014 | 05/12/2017 | R - Real-Time Proc | ALGOVITA SPINAL CORD STIMULATION SYSTEM | NUVECTRA CORPORATION | Approval for the removal of sleep mode functionality and the modification of the boot logo branding for the device. |
| P140009/S023 | 05/01/2017 | R - Real-Time Proc | INFINITY NEUROSTIMULATION SYSTEM | ST. JUDE MEDICAL NEUROMODULATION | Approval for updated Firmware version 1.2. |
| P140013/S005 | 05/15/2017 | N - Normal 180 Day | MINERVA ENDOMETRIAL ABLATION SYSTEM | MINERVA SURGICAL | Approval for the addition of a CO2 extension tube and sheath marking to the Minerva Handpiece and software modifications to the gas management module in the RF controller. |
| P140017/S006 | 05/22/2017 | O - Normal 180 Day | MELODY TRANSCATHETER PULMONARY VALVE , ENSEMBLE TRANSCATHETER VALVE DELIVERY SYSTEM (DS) | MEDTRONIC INC. | Approval for updates to the Melody Transcatheter Pulmonary Valve System Instructions for Use to reflect the final results of the Long-Term Follow-up Post-Approval Study. |
| P140025/S005 | 05/26/2017 | N - Normal 180 Day | VENTANA ALK (D5F3) CDX ASSAY | VENTANA MEDICAL SYSTEMS, INC. | Approval for extending the label claim of the VENTANA ALK (D5F3) CDx Assay to include an indication for Zykadia (ceritinib) |
| P140031/S025 | 05/01/2017 | Y - 135 Review Tra | SAPIEN 3 TRANSCATHETER HEART VALVE | EDWARDS LIFESCIENCES, LLC. | Approval for the addition of the Edwards Singapore facility for manufacturing components used in Edwards surgical and transcatheter heart valves. |
| P150005/S015 | 05/08/2017 | R - Real-Time Proc | INTELLANAV OL | BOSTON SCIENTIFIC CORP. | Approval to change the ablation connection box design, IntellaNav Ablation Connection Box, to the Rhythmia HDx Ablation Connection Box, for the family of IntellaNav Ablation Catheters. |
| P150021/S004 | 05/31/2017 | Y - 135 Review Tra | FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM | ABBOTT DIABETES CARE INC. | Approval to increase the sensor manufacturing capacity, at the manufacturing facility ADC Witney, by implementing a high volume sensor manufacturing line setup. The change included updates to the printed flex circuit processing equipment, qualification of a new ISO 8 cleanroom, implementation of new manufacturing and support equipment, and introduction of a new sampling machine. The sensor is a component of the Freestyle Libre Pro Flash Glucose Monitoring System. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P150025/S005 | 05/03/2017 | O - Normal 180 Day | PD-L1 IHC 28-8 PHARMDX | DAKO NORTH AMERICA, INC. | Approval for the device which will be marketed under the trade name PD-L1 IHC 28 - 8 pharmDx and is indicated for a qualitative immunohistochemical assay using Monoclonal Rabbit Anti-PD-L1, Clone 28-8 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-squamous non-small cell lung cancer (NSCLC) and melanoma tissues using EnVision FLEX visualization system on Autostainer Link 48. PD-L1 protein expression is defined as the percentage of evaluable tumor cells exhibiting partial or complete membrane staining at any intensity. PD-L1 expression as detected by PD-L1 IHC 28-8 pharmDx in non-squamous NSCLC may be associated with enhanced survival from OPDIVO® (nivolumab). Positive PD-L1 status as determined by PD-L1 IHC 28-8 pharmDx in melanoma is correlated with the magnitude of the treatment effect on progression-free survival from OPDIVO®. |
| P150033/S015 | 05/01/2017 | N - Normal 180 Day | MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM | MEDTRONIC INC. | Approval for design changes to the delivery catheter of the Micra Transcatheter Pacing System. |
| P150033/S020 | 05/05/2017 | R - Real-Time Proc | MICRA TRANSCATHETER PACING SYSTEM | MEDTRONIC INC. | Approval for shelf life extension to 18 months. |
| P150036/S001 | 05/01/2017 | Y - 135 Review Tra | EDWARDS INTUITY VALVE SYSTEM | EDWARDS LIFESCIENCES, LLC. | Approval for the addition of the Edwards Singapore facility for manufacturing components used in Edwards surgical and transcatheter heart valves. |

**Total: 96**

## 30-Day Notice

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| N18033/S090 | 05/04/2017 | X - 30-Day Notice | VISTAKON (ETAFILCON A) BRAND CONTACT LENSES | VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC. | Expansion of the deionized water system. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| N18033/S091 | 05/02/2017 | X - 30-Day Notice | VISTAKON (ETAFILCON A) BRAND CONTACT LENSES | VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC. | Raw material supplier name change to a component used in manufacture of senofilcon A and etafilcon A brand contact lenses. |
| N970003/S205 | 05/01/2017 | X - 30-Day Notice | PACEMAKER MODELS ADVANTIO & INGENIO | BOSTON SCIENTIFIC CORP. | Additional lithium supplier used in battery manufacturing. |
| N970003/S206 | 05/01/2017 | X - 30-Day Notice | ESSENTO, PROPONENT, ACCOLADE, ALTRUA | BOSTON SCIENTIFIC CORP. | Modification to the software for the Automated Optical Inspection System used during header manufacturing. |
| P840001/S357 | 05/03/2017 | X - 30-Day Notice | RESTORE AND ITREL SPINAL CORD STIMULATION SYSTEMS | MEDTRONIC NEUROMODULATION | Addition of new equipment for battery cathode mixing process. |
| P840001/S358 | 05/11/2017 | X - 30-Day Notice | RESTORE AND ITREL SPINAL CORD STIMULATION SYSTEMS | MEDTRONIC NEUROMODULATION | Notification of the intent to semi-automate the completion and confirmation of required packaging components and make changes to process steps in the final packaging assembly at Medtronic Puerto Rico Operations, Juncos. |
| P840001/S359 | 05/19/2017 | X - 30-Day Notice | RESTORE SPINAL CORD STIMULATION SYSTEMS | MEDTRONIC NEUROMODULATION | New CNC machine for Restore covers at Supplier, Hudson Technologies. |
| P840001/S360 | 05/23/2017 | X - 30-Day Notice | RESTORE, ITREL, SPINAL CORD STIMULATION SYSTEMS | MEDTRONIC NEUROMODULATION | Allow the use of an additional laser welder (BATWELDLASER040 aka Sven), for the medium rate (MR) battery case-to-cover welding process at Medtronic Energy and Component Center. |
| P840001/S361 | 05/25/2017 | X - 30-Day Notice | RESTORE, ITREL AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES SPECIFY AND VECTRIS SPINAL CORD STIMULATION LEAD | MEDTRONIC NEUROMODULATION | Manufacturing process change to add vapor degreaser cleaning to the build clean process at Medtronic Tempe Campus (MTC). |
| P840001/S362 | 05/25/2017 | X - 30-Day Notice | RESTORE, ITREL, AND SYNERGY SPINAL CORD STIMULATION 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. |
| P860003/S088 | 05/02/2017 | X - 30-Day Notice | THERAKOS CELLEX AND UVAR XTS PROCEDURAL KITS | THERAKOS, INC. | Replace the ultrasonic welder and qualify new mold tools used for cuvette assemblies. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P860003/S089 | 05/16/2017 | X - 30-Day Notice | THERAKOS UVAR XTS PHOTOPHERESIS SYSTEM PROCEDURAL KIT. | THERAKOS, INC. | Manufacturing process change to the photoactivation plate. |
| P860004/S272 | 05/03/2017 | X - 30-Day Notice | SYNCHROMED INFUSION SYSTEM | MEDTRONIC INC. | Addition of new equipment for battery cathode mixing process. |
| P860004/S274 | 05/23/2017 | X - 30-Day Notice | SYNCHROMED INFUSION SYSTEM | MEDTRONIC INC. | Allow the use of an additional laser welder (BATWELDLASER040 aka Sven), for the medium rate (MR) battery case-to-cover welding process at Medtronic Energy and Component Center. |
| P860004/S276 | 05/26/2017 | X - 30-Day Notice | SYNCHROMED II (MODEL 8637) PUMP | MEDTRONIC INC. | Removal of inspections of the Pumphead Gear at the Medtronic facility before the subcomponent is further manufactured into the Pumphead Assembly. |
| P860004/S277 | 05/25/2017 | X - 30-Day Notice | SYNCHROMED INFUSION SYSTEM | MEDTRONIC INC. | Manufacturing process change to add vapor degreaser cleaning to the build clean process at Medtronic Tempe Campus (MTC). |
| P860004/S278 | 05/31/2017 | X - 30-Day Notice | SYNCHROMED INFUSION SYSTEM | MEDTRONIC INC. | Changes made to the Gem 1000BK Ink Document M933254A to add a limitation for Use by Date (UBD) of 5 years from the date of manufacture, and add reference to ISO 10993-01:2009 standard for biocompatibility to align with current industry and Medtronic standards and practices. |
| P860057/S159 | 05/10/2017 | X - 30-Day Notice | CARPENTIER-EDWARDS PERIMOUNT PERICARDIAL AORTIC BIOPROSTHESIS | EDWARDS LIFESCIENCES, LLC. | Use of a newly installed component manufacturing cleanroom at the Edwards facility in Irvine, California. |
| P860057/S160 | 05/23/2017 | X - 30-Day Notice | CARPENTIER-EDWARDS PERIMOUNT PERICARDIAL AORTIC BIOPROSTHESIS, CARPENTIER-EDWARDS PERIMOUNT THEON PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS | EDWARDS LIFESCIENCES, LLC. | New equipment used in the manufacture of Edwards surgical and transcatheter heart valves. |
| P880086/S282 | 05/05/2017 | X - 30-Day Notice | ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS | ST. JUDE MEDICAL, INC. | Longer dwell time between plasma cleaning and wire bonding of the hybrid. |
| P900056/S159 | 05/04/2017 | X - 30-Day Notice | ROTABLATOR ROTATIONAL ATHERECTOMY SYSTEM | BOSTON SCIENTIFIC CORP. | Automate the UV Bond process on the RotaLink Advancer line. |
| P900056/S160 | 05/12/2017 | X - 30-Day Notice | ROTABLATOR® ROTATIONAL ATHERECTOMY SYSTEM | BOSTON SCIENTIFIC CORP. | Sterilization of devices within the scope of this bundled submission with the optimized BSC2000-2 cycle in Chamber 3 at the Synergy Health/Steris, Costa Rica facility. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P900056/S161 | 05/26/2017 | X - 30-Day Notice | ROTABLATOR ROTATIONAL ANGIOPLASTY SYSTEM GUIDEWIRE | BOSTON SCIENTIFIC CORP. | Remove a redundant inspection for the RotaWire Guidewire. |
| P910023/S385 | 05/05/2017 | X - 30-Day Notice | CADENCE(R) TIERED THERAPY DEFRIBILATION SYSTEM | ST. JUDE MEDICAL | Longer dwell time between plasma cleaning and wire bonding of the hybrid. |
| P920047/S097 | 05/12/2017 | X - 30-Day Notice | BLAZER II TM CARDIAC ABLATION CATHETER AND CABLE | BOSTON SCIENTIFIC CORP. | Sterilization of devices within the scope of this bundled submission with the optimized BSC2000-2 cycle in Chamber 3 at the Synergy Health/Steris, Costa Rica facility. |
| P930014/S101 | 05/03/2017 | X - 30-Day Notice | ACRYSOF® SINGLE PIECE INTRAOCULAR LENSES | ALCON RESEARCH, LTD. | Relocation of two processing steps within your approved manufacturing facility. |
| P940015/S040 | 05/11/2017 | X - 30-Day Notice | SYNVISC ONE | GENZYME CORP. | Modifications to the sterilization process of a component used to manufacture Synvisc and Synvisc-One. |
| P950020/S080 | 05/10/2017 | X - 30-Day Notice | WOLVERINE CORONARY CUTTING BALLOON | BOSTON SCIENTIFIC CORP. | Changes to the Carrier Tube Extrusion Line. |
| P960004/S080 | 05/23/2017 | X - 30-Day Notice | FINELINE II STEROX AND STEROX EZ LEAD | BOSTON SCIENTIFIC | Changes to the quality control analytical test methods used to evaluate dexamethasone acetate for passive fixation distal tip subassembly test articles. |
| P960009/S276 | 05/03/2017 | X - 30-Day Notice | ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM | MEDTRONIC INC. | Addition of new equipment for battery cathode mixing process. |
| P960009/S277 | 05/11/2017 | X - 30-Day Notice | ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM | MEDTRONIC INC. | Intent to semi-automate the completion and confirmation of required packaging components and make changes to process steps in the final packaging assembly at Medtronic Puerto Rico Operations, Juncos. |
| P960009/S278 | 05/19/2017 | X - 30-Day Notice | ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM | MEDTRONIC INC. | New CNC machine for Restore covers at Supplier, Hudson Technologies. |
| P960009/S279 | 05/23/2017 | X - 30-Day Notice | ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM | MEDTRONIC INC. | Allow the use of an additional laser welder (BATWELDLASER040 aka Sven), for the medium rate (MR) battery case-to-cover welding process at Medtronic Energy and Component Center. |
| P960009/S280 | 05/25/2017 | X - 30-Day Notice | ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM. | MEDTRONIC INC. | Manufacturing process change to add vapor degreaser cleaning to the build clean process at Medtronic Tempe Campus (MTC). |
| P960009/S281 | 05/25/2017 | X - 30-Day Notice | ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM | MEDTRONIC INC. | 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 |
|---|---|---|---|---|---|
| P960016/S068 | 05/19/2017 | X - 30-Day Notice | LIVEWIRE TC¿ ABLATION CATHETER AND SAFIRE ¿ BI-DIRECTIONAL ABLATION CATHETER | ST. JUDE MEDICAL | Replacement equipment for final inspection. |
| P960042/S057 | 05/10/2017 | X - 30-Day Notice | SPECTRANETICS LASER SHETH (SLS) II, GLIDEL LIGHT LASER SHEATH | SPECTRANETICS CORP. | Updates to the tubing extrusion process, including the following: an update to the process parameters, a new supplier of some tubing components, the addition of new tooling/ equipment, and an update to the inspection test method. |
| P970004/S240 | 05/03/2017 | X - 30-Day Notice | INTERSTIM THERAPY SYSTEM | MEDTRONIC NEUROMODULATION | Addition of new equipment for battery cathode mixing process. |
| P970004/S241 | 05/23/2017 | X - 30-Day Notice | INTERSTIM THERAPY SYSTEM (URINARY) | MEDTRONIC NEUROMODULATION | Allow the use of an additional laser welder (BATWELDLASER040 aka Sven) for the medium rate (MR) battery case-to-cover welding process at Medtronic Energy and Component Center. |
| P970004/S242 | 05/25/2017 | X - 30-Day Notice | INTERSTIM THERAPY SYSTEM (URINARY) | MEDTRONIC NEUROMODULATION | Manufacturing process change to add vapor degreaser cleaning to the build clean process at Medtronic Tempe Campus (MTC). |
| P970004/S243 | 05/25/2017 | X - 30-Day Notice | INTERSTIM THERAPY SYSTEM (URINARY) | 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. |
| P970004/S244 | 05/16/2017 | X - 30-Day Notice | INTERSTIM THERAPY SYSTEM (URINARY) | MEDTRONIC NEUROMODULATION | Change of the installation method for a capacitor on the Verify Patient Therapy Manager printed circuit board assembly. |
| P970051/S160 | 05/09/2017 | X - 30-Day Notice | NUCLEUS 24 COCHLEAR IMPLANT SYSTEM | COCHLEAR AMERICAS | Transfer of the Arburg 220S Molding Machine (CP800/CP900 Injection Molding Tool System) from the Lane Cove manufacturing site to the Macquarie manufacturing site. |
| P970051/S162 | 05/23/2017 | X - 30-Day Notice | NUCLEUS 24 COCHLEAR IMPLANT SYSTEM | COCHLEAR AMERICAS | Alternate Flash Memory chip and ESD Diode, both of which are components of the Printed Circuit Board Assemblies used in the CP810 and CP802 Sound Processors. |
| P980003/S073 | 05/12/2017 | X - 30-Day Notice | CHILLI II ¿ COOLED ABLATION CATHETER AND CABLE | BOSTON SCIENTIFIC CORP. | Sterilization of devices within the scope of this bundled submission with the optimized BSC2000-2 cycle in Chamber 3 at the Synergy Health/Steris, Costa Rica facility. |
| P980016/S631 | 05/15/2017 | X - 30-Day Notice | EVERA, MAXIMO, PROTECTA, SECURA, VISIA MRI VR/XT/DR/AF ICD | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Implementation of a hardness manufacturing process monitor for the backfill weld process used at final device manufacturing facilities. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P980022/S199 | 05/10/2017 | X - 30-Day Notice | PARADIGM REAL-TIME INSULIN PUMP & PARADIGN REAL-TIME REVEL INSULIN PUMP | MEDTRONIC MINIMED | Transfer equipment used for leak testing seals of the Paradigm insulin infusion pumps and Next Generation insulin infusion pumps from Medtronic MiniMed to a sub-tier supplier, as well as transferring the task of performing such testing to the sub-tier supplier. The Paradigm insulin infusion pump is component of the Paradigm REAL-Time System, the Paradigm REAL-Time Revel System, and the MiniMed 530G System. The Next Generation insulin infusion pump is a component of the MiniMed 630G System and the MiniMed 670G System. |
| P980035/S498 | 05/30/2017 | X - 30-Day Notice | ADAPTA, VERSA, SENSIA IPG ADSR01, ADDR01, ADDR06, ADDRL1, ADDRS1, VEDR01, ADD01, SEDRL1, SED01, SES01, ADDR03, SEDR01, ADSR03, ADSR06, ADVDD01, SESR01; RELIA IPG RED01*, REDR01, RES01, RESR01, REVDD01 | MEDTRONIC INC. | Software update to the distribution control sorter tool (DCST) system. |
| P980040/S081 | 05/24/2017 | X - 30-Day Notice | TECNIS 1-PIECE IOL, TECNIS OPTIBLUE 1-PIECE IOL, TECNIS MULTIFOCAL 1-PIECE IOLS, TECNIS TORIC 1-PIECE IOLS, TECNIS TORIC 1-PIECE IOL WITH THE TECNIS ITEC PRELOADED DELIVERY SYSTEM, TECNIS SYMFONY EXTENDED RANGE OF VISION IOL, TECNIS SYMFONY TORIC EXTENDED RANGE OF VISION IOLS | ABBOTT MEDICAL OPTICS INC | Expand the existing manufacturing area. |
| P990004/S031 | 05/30/2017 | X - 30-Day Notice | SURGIFOAM ABSORBABLE GELATIN SPONGE | FERROSAN MEDICAL DEVICES A/S | Update the location of the Biological Indicator used during the sterilization validation of the Thrombin Kit Package of Product Code 2994 from the current location of under the flip-top-seal to the new location of next to the Thrombin vial. |
| P990009/S046 | 05/11/2017 | X - 30-Day Notice | FLOSEAL HEMOSTATIE MATRIX | BAXTER HEALTHCARE CORP. | Modification to the in-process and final release testing of the Gelatin and Thrombin pouches. |
| P990038/S022 | 05/25/2017 | X - 30-Day Notice | DIASORIN ETI-MAK-2 PLUS | DIASORIN, INC. | Change to a test method for incoming material. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P990038/S023 | 05/23/2017 | X - 30-Day Notice | ETI MAK-2 PLUS AND HBSAG CONFIRMATORY TEST ASSAYS | DIASORIN, INC. | Change to temperature and cycle parameters on instruments used to manufacture kit subcomponents. |
| P990041/S021 | 05/25/2017 | X - 30-Day Notice | DIASORIN ETI-AB-EBK PLUS ASSAY | DIASORIN, INC. | Change to a test method for incoming material. |
| P990041/S022 | 05/23/2017 | X - 30-Day Notice | ETI-AB-EBK PLUS ASSAY | DIASORIN, INC. | Change to temperature and cycle parameters on instruments used to manufacture kit subcomponents. |
| P990042/S018 | 05/25/2017 | X - 30-Day Notice | DIASORIN ETI-AB-AUK PLUS ASSAY | DIASORIN, INC. | Change to a test method for incoming material. |
| P990042/S019 | 05/23/2017 | X - 30-Day Notice | ETI-AB-AUK PLUS ASSAY | DIASORIN, INC. | Change to temperature and cycle parameters on instruments used to manufacture kit subcomponents. |
| P990043/S022 | 05/25/2017 | X - 30-Day Notice | DIASORIN ETI-EBK PLUS ASSAY | DIASORIN, INC. | Change to a test method for incoming material. |
| P990043/S023 | 05/23/2017 | X - 30-Day Notice | ETI-EBK PLUS ASSAY | DIASORIN, INC. | Change to temperature and cycle parameters on instruments used to manufacture kit subcomponents. |
| P990044/S019 | 05/25/2017 | X - 30-Day Notice | DIASORIN ETI-CORE-IGMK PLUS ASSAY | DIASORIN, INC. | Change to a test method for incoming material. |
| P990044/S020 | 05/23/2017 | X - 30-Day Notice | ETI-CORE-IGMK PLUS ASSAY | DIASORIN, INC. | Change to temperature and cycle parameters on instruments used to manufacture kit subcomponents. |
| P990045/S019 | 05/25/2017 | X - 30-Day Notice | DIASORIN ETI-AB-COREK PLUS ASSAY | DIASORIN, INC. | Change to a test method for incoming material. |
| P990045/S020 | 05/23/2017 | X - 30-Day Notice | ETI-AB-COREK PLUS ASSAY | DIASORIN, INC. | Change to temperature and cycle parameters on instruments used to manufacture kit subcomponents. |
| P990075/S040 | 05/01/2017 | X - 30-Day Notice | MENTOR SALINE FILLED AND SPECTRUM BREAST IMPLANTS | MENTOR WORLDWIDE LLC | Information pertaining to the change allowing for use of an additional identical shrink-wrapping machine to the secondary packaging process. |
| P990075/S041 | 05/24/2017 | X - 30-Day Notice | MENTOR SALINE-FILLED AND SPECTRUM® BREAST IMPLANTS | MENTOR WORLDWIDE LLC | Conversion from the use of Biological Indicators to the use of Parametric Release for batch release of dry heat sterilized devices at the Mentor Texas facility. |
| P000015/S020 | 05/09/2017 | X - 30-Day Notice | NUCLEUS AB1541 AUDITORY BRAINSTEM IMPLANT | COCHLEAR AMERICAS | Transfer of the Arburg 220S Molding Machine (CP800/CP900 Injection Molding Tool System) from the Lane Cove manufacturing site to the Macquarie manufacturing site. |
| P000021/S031 | 05/22/2017 | X - 30-Day Notice | DIMENSION TPSA FLEX REAGENT CARTRIDGE (RF451) | SIEMENS HEALTHCARE DIAGNOSTICS | Transfer to a contract service provider for Dimension® RxL/RxL Max® and Dimension® Xpand/Xpand Plus Clinical Chemistry Systems Service Spare Parts. |
| P000040/S036 | 05/26/2017 | X - 30-Day Notice | HYDRO THERMABLATOR ENDOMETRIAL ABLATION SYSTEM | BOSTON SCIENTIFIC CORP. | Updates to the Programmable Logic Controller (PLC) software used for sterilization Chamber 3, an update to the vacuum pump system used in Chamber 3, and an update to the validation documentation structure used to support the system. |

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|---|---|---|---|---|---|
| P010014/S062 | 05/16/2017 | X - 30-Day Notice | OXFORD PARTIAL KNEE SYSTEM- MENISCAL BEARINGS | BIOMET MANUFACTURING CORP. | Harmonize device cleanliness testing methods and parameters across the global organization and change of location of residual testing. |
| P010030/S095 | 05/03/2017 | X - 30-Day Notice | WEARABLE DEFIBRILLATOR LIFE VEST | ZOLL MANUFACTURING CORPORATION | Implementation of automated battery test software to be used during servicing and reconditioning. |
| P010031/S592 | 05/15/2017 | X - 30-Day Notice | AMPLIA, BRAVA, CLARIA, COMPIA, CONSULTA, MAXIMO, PROTECTA, VIVA QUAD MRI CRT-D | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Implementation of a hardness manufacturing process monitor for the backfill weld process used at final device manufacturing facilities. |
| P010033/S033 | 05/09/2017 | X - 30-Day Notice | QUANTTFERON-TB GOLD | QIAGEN | Relocation of manufacturing activities related to production of critical raw materials. |
| P020025/S099 | 05/04/2017 | X - 30-Day Notice | MAESTRO 4000 CARDIAC ABLATION SYSTEM (CONTROLLER, REMOTE AND PODS) | BOSTON SCIENTIFIC | Alternate supplier for components used in the Maestro 4000 Cardiac Ablation System. |
| P020025/S100 | 05/12/2017 | X - 30-Day Notice | BLAZER II XP CARDIAC ABLATION CATHETER AND CABLE | BOSTON SCIENTIFIC | Sterilization of devices within the scope of this bundled submission with the optimized BSC2000-2 cycle in Chamber 3 at the Synergy Health/Steris, Costa Rica facility. |
| P020027/S026 | 05/22/2017 | X - 30-Day Notice | DIMENSION FPSA FLEX REAGENT CARTRIDGE (RF452) | SIEMENS HEALTHCARE DIAGNOSTICS | Transfer to a contract service provider for Dimension® RxL/RxL Max® and Dimension® Xpand/Xpand Plus Clinical Chemistry Systems Service Spare Parts. |
| P030005/S153 | 05/01/2017 | X - 30-Day Notice | CARDIAC RESYNCHRONIZATION THERAPY PACEMAKER MODELS INVIVE & INTUA | GUIDANT CORP. | Additional lithium supplier used in battery manufacturing. |
| P030005/S154 | 05/01/2017 | X - 30-Day Notice | VALITUDE, VISIONIST | GUIDANT CORP. | Modification to the software for the Automated Optical Inspection System used during header manufacturing. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P030017/S289 | 05/10/2017 | X - 30-Day Notice | PRECISION, PRECISION SPECTRA, PRECISION NOVI, PRECISION MONTAGE, PRECISION MONTAGE MRI AND SPECTRA WAVEWRITER SPINAL CORD STIMULATOR (SCS) SYSTEMS | BOSTON SCIENTIFIC CORP. | Alternate qualified supplier for the Tunneling Tool components of the spinal cord stimulation (SCS) systems. |
| P030017/S290 | 05/11/2017 | X - 30-Day Notice | SPECTRA WAVEWRITER SPINAL CORD STIMULATOR SYSTEM | BOSTON SCIENTIFIC CORP. | Updates to the test equipment software used for testing the Printed Circuit Board Assembly (PCBA) of the Remote Control (RC) of the Spectra WaveWriter SCS System. |
| P030035/S156 | 05/05/2017 | X - 30-Day Notice | ANTHEM AND FRONTIER II CRT-P'S | ST. JUDE MEDICAL, INC. | Longer dwell time between plasma cleaning and wire bonding of the hybrid. |
| P030044/S003 | 05/16/2017 | X - 30-Day Notice | EGFR PHARMDX | DAKO NORTH AMERICA, INC. | Changes to the relocation/ expansion of facility. |
| P030053/S041 | 05/01/2017 | X - 30-Day Notice | MENTOR, MERMORYGEL, BREAST IMPLANTS | MENTOR CORP. | Information pertaining to the change allowing for use of an additional identical shrink-wrapping machine to the secondary packaging process. |
| P030053/S042 | 05/24/2017 | X - 30-Day Notice | MENTOR MEMORYGEL® SILICONE GEL-FILLED BREAST IMPLANTS | MENTOR CORP. | Conversion from the use of Biological Indicators to the use of Parametric Release for batch release of dry heat sterilized devices at the Mentor Texas facility. |
| P030054/S328 | 05/05/2017 | X - 30-Day Notice | ST JUDE MEDICAL EPIC HF SYSTEM | ST. JUDE MEDICAL | Longer dwell time between plasma cleaning and wire bonding of the hybrid. |
| P040011/S003 | 05/16/2017 | X - 30-Day Notice | C-KIT PHARMDX | DAKO NORTH AMERICA, INC. | Changes to the relocation/ expansion of facility. |
| P040014/S032 | 05/19/2017 | X - 30-Day Notice | THERAPY ABLATION CATHETER INCLUDING BI-DIRECTIONAL CATHETER AND THERAPY 4MM THERMISTOR ABLATION CATHETER | IRVINE BIOMEDICAL, INC. | Replacement equipment for final inspection. |
| P040020/S069 | 05/03/2017 | X - 30-Day Notice | ACRYSOF® IQ RESTOR® INTRAOCULAR LENSES | ALCON RESEARCH, LTD. | Relocation of two processing steps within your approved manufacturing facility. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
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| P040042/S037 | 05/19/2017 | X - 30-Day Notice | THERAPY DUAL-8 ABLATION CATHETER, THERAPY 8MM THERMISTOR ABLATION CATHETER, SAFIRE TX ABLATION CATHETER | IRVINE BIOMEDICAL,INC.(IBI) | Replacement equipment for final inspection. |
| P040044/S076 | 05/26/2017 | X - 30-Day Notice | MYNXGRIP VASCULAR CLOSURE DEVICE | ACCESS CLOSURE, INC. | Changes related to the tamp lock to catheter shaft bonding process. |
| P040045/S070 | 05/04/2017 | X - 30-Day Notice | VISTAKON (SENOFILCON A) BRAND CONTACT LENSES | VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR | Expansion of the deionized water system. |
| P040045/S071 | 05/02/2017 | X - 30-Day Notice | VISTAKON (SENOFILCON A) BRAND CONTACT LENSES | VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR | Raw material supplier name change to a component used in manufacture of senofilcon A and etafilcon A brand contact lenses. |
| P050037/S079 | 05/05/2017 | X - 30-Day Notice | RADIESSE INJECTABLE IMPLANT | MERZ NORTH AMERICA, INC | Modification of particle manufacturing process steps to allow for an alternate particle separation process prior to sintering. |
| P050047/S059 | 05/23/2017 | X - 30-Day Notice | JUVEDERM INJECTABLE GEL IMPLANTS | ALLERGAN | Change to implement an automatic washer that will be used alongside the manual cleaning process of the manufacturing equipment and accessories. |
| P050047/S060 | 05/25/2017 | X - 30-Day Notice | JUVÉDERM INJECTABLE GEL IMPLANTS | ALLERGAN | Implementation of two additional equipment to support automated visual inspection of 1 mL syringes filled to 1.0 mL product configurations. |
| P050052/S093 | 05/05/2017 | X - 30-Day Notice | RADIESSE (+) LIDOCAINE DERMAL FILLER | MERZ NORTH AMERICA, INC | Modification of particle manufacturing process steps to allow for an alternate particle separation process prior to sintering. |
| P060006/S081 | 05/10/2017 | X - 30-Day Notice | EXPRESS SD RENAL STENT SYSTEM | BOSTON SCIENTIFIC CORP. | Changes to the Carrier Tube Extrusion Line. |
| P060006/S082 | 05/12/2017 | X - 30-Day Notice | EXPRESS SD MONORAIL® PREMOUNTED STENT SYSTEM | BOSTON SCIENTIFIC CORP. | Sterilization of devices within the scope of this bundled submission with the optimized BSC2000-2 cycle in Chamber 3 at the Synergy Health/Steris, Costa Rica facility. |
| P060011/S011 | 05/18/2017 | X - 30-Day Notice | C-FLEX 570C, C-FLEX ASPHERIC 970C AND 600C ASPHERIC INTRAOCULAR LENSES | RAYNER INTRAOCULAR LENSES LTD. | Introduction of a new method for the quantification of Aluminum Oxide residues resulting from the polishing process of intraocular lens manufacture. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P060019/S039 | 05/19/2017 | X - 30-Day Notice | THERAPY COOL PATH ABLATION CATHETERS, THERAPY COOL PATH SP ABLATION CATHETER AND SAFIRE BLU SP ABLATION CATHETER | IRVINE BIOMEDICAL, INC. | Replacement equipment for final inspection. |
| P060028/S023 | 05/01/2017 | X - 30-Day Notice | MENTOR MEMORYSHAPE, BREAST IMPLANTS | MENTOR WORLDWIDE LLC | Information pertaining to the change allowing for use of an additional identical shrink-wrapping machine to the secondary packaging process. |
| P060028/S024 | 05/24/2017 | X - 30-Day Notice | MENTOR MEMORYSHAPE ¿ BREAST IMPLANTS | MENTOR WORLDWIDE LLC | Conversion from the use of Biological Indicators to the use of Parametric Release for batch release of dry heat sterilized devices at the Mentor Texas facility. |
| P080025/S135 | 05/03/2017 | X - 30-Day Notice | INTERSTIM THERAPY SYSTEM | MEDTRONIC NEUROMODULATION | Addition of new equipment for battery cathode mixing process. |
| P080025/S136 | 05/23/2017 | X - 30-Day Notice | INTERSTIM THERAPY SYSTEM (BOWEL) | MEDTRONIC NEUROMODULATION | Allow the use of an additional laser welder (BATWELDLASER040 aka Sven) for the medium rate (MR) battery case-to-cover welding process at Medtronic Energy and Component Center. |
| P080025/S137 | 05/25/2017 | X - 30-Day Notice | INTERSTIM THERAPY SYSTEM (BOWEL) | MEDTRONIC NEUROMODULATION | Manufacturing process change to add vapor degreaser cleaning to the build clean process at Medtronic Tempe Campus (MTC). |
| P080025/S138 | 05/25/2017 | X - 30-Day Notice | INTERSTIM THERAPY SYSTEM (BOWEL) | 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. |
| P080025/S139 | 05/16/2017 | X - 30-Day Notice | INTERSTIM THERAPY SYSTEM (BOWEL) | MEDTRONIC NEUROMODULATION | Change of the installation method for a capacitor on the Verify Patient Therapy Manager printed circuit board assembly. |
| P080027/S027 | 05/11/2017 | X - 30-Day Notice | ORAQUICK HCV RAPID ANTIBODY TEST | ORASURE TECHNOLOGIES INC. | Adding a new assembly line for the OraQuick HCV Rapid Antibody Test device. |
| P100021/S064 | 05/19/2017 | X - 30-Day Notice | STENT GRAFT DRYING PROCESS AT MEDTRONIC EMPALME AND MEDTRONIC TIJUANA ENDURANT, ENDURANT II, ENDURANT II AORTO-UNI-LLIAC TALENT OCCLUDER | MEDTRONIC VASCULAR | Use of an additional, new drying oven for stent graft processing. |
| P100026/S049 | 05/02/2017 | X - 30-Day Notice | NEUROPACE RNS SYSTEM | NEUROPACE INC | Add alternate equipment for thermoforming of outer tray device packaging. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P100040/S031 | 05/19/2017 | X - 30-Day Notice | VALIANT THORACIC STENT GRAFT WITH THE CAPTIVIA DELIVERY SYSTEM, VALIANT FREEFLO TAPERED STENT GRAFT CONFIGURATIONS | MEDTRONIC VASCULAR | Use of an additional, new drying oven for stent graft processing. |
| P100044/S028 | 05/24/2017 | X - 30-Day Notice | INTERSECT ENT PROPEL CONTOUR SINUS IMPLANT COMPONENT VERIFICATION SYSTEM GENERATION II | INTERSECT ENT | Addition of a packaging inspection system for the Propel Contour Sinus Implant. |
| P110002/S018 | 05/23/2017 | X - 30-Day Notice | MOBI-C CERVICAL DISC PROSTHESIS (ONE-LEVEL INDICATION) | LDR SPINE USA | Manufacturing changes that include the addition of a Jex abrasive wheel to the cleaning (deburring) process. |
| P110009/S018 | 05/23/2017 | X - 30-Day Notice | MOBI-C CERVICAL DISC PROSTHESIS FOR USE AT ONE OR TWO LEVELS | LDR SPINE USA INC. | Manufacturing changes that include the addition of a Jex abrasive wheel to the cleaning (deburring) process. |
| P110010/S140 | 05/10/2017 | X - 30-Day Notice | PROMUS PREMIER EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM | BOSTON SCIENTIFIC CORP. | Changes to the Carrier Tube Extrusion Line. |
| P110010/S141 | 05/12/2017 | X - 30-Day Notice | PROMUS ELEMENT PLUS EVEROLIMUS-EIUTING STENT SYSTEM | BOSTON SCIENTIFIC CORP. | Sterilization of devices within the scope of this bundled submission with the optimized BSC2000-2 cycle in Chamber 3 at the Synergy Health/Steris, Costa Rica facility. |
| P110016/S043 | 05/22/2017 | X - 30-Day Notice | FLEXABILITY ABLATION CATHETER, SENSOR ENABLED | ST. JUDE MEDICAL, INC. | Add an additional sterilization site for the FlexAbility, Sensor Enabled (SE) catheters. |
| P110016/S044 | 05/26/2017 | X - 30-Day Notice | VAISALA ENVIRONMENTAL MONITORING SYSTEM | ST. JUDE MEDICAL, INC. | Changes to the environmental monitoring system for the FlexAbility Product Family. |
| P110016/S045 | 05/30/2017 | X - 30-Day Notice | FLEXABILITY ABLATION CATHETER, SENSOR ENABLED | ST. JUDE MEDICAL, INC. | Addition of a manufacturing site in for FlexAbility, Sensor Enabled (SE) ablation catheters. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P110016/S046 | 05/19/2017 | X - 30-Day Notice | THERAPY COOL PATH DUO ABLATION CATHETER, THERAPY COOL FLEX ABLATION CATHETER, THERAPY COOL PATH DUO SP ABLATION CATHETER, SAFIRE BLU DUO SP ABLATION CATHETER, COOL PATH DUO ABLATION CATHETER MEDIGUIDE ENABLED, SAFIRE DUO ABLATION CATHETER MEDIGUIDE ENABLED | ST. JUDE MEDICAL, INC. | Replacement equipment for final inspection. |
| P110033/S029 | 05/23/2017 | X - 30-Day Notice | JUVEDERM INJECTABLE GEL IMPLANTS | ALLERGAN | Change to implement an automatic washer that will be used alongside the manual cleaning process of the manufacturing equipment and accessories. |
| P110033/S030 | 05/25/2017 | X - 30-Day Notice | JUVÉDERM VOLUMA XC, JUVÉDERM VOLLURETM XC, JUVÉDERM VOLBELLA XC | ALLERGAN | Implementation of two additional equipment to support automated visual inspection of 1 mL syringes filled to 1.0 mL product configurations. |
| P110035/S039 | 05/10/2017 | X - 30-Day Notice | EPIC VASCULAR SELF-EXPANDING STENT SYSTEM | BOSTON SCIENTIFIC CORP. | Changes to the Carrier Tube Extrusion Line. |
| P110035/S040 | 05/26/2017 | X - 30-Day Notice | EPIC VASCULAR SELF-EXPANDING STENT SYSTEM | BOSTON SCIENTIFIC CORP. | Updates to the Programmable Logic Controller (PLC) software used for sterilization Chamber 3, an update to the vacuum pump system used in Chamber 3, and an update to the validation documentation structure used to support the system. |
| P110038/S015 | 05/01/2017 | X - 30-Day Notice | RELAY THORACIC STENT-GRAFT WITH PLUS DELIVERY SYSTEM | BOLTON MEDICAL, INC. | Change in frequency of the sterilization dose audit. |
| P110042/S084 | 05/23/2017 | X - 30-Day Notice | EMBLEM S-ICD PULSE GENERATOR (PG) & MRI S-ICD PULSE GENERATOR (PG) (S-ICD'S) | BOSTON SCIENTIFIC CORPORATION | Additional supplier for the anchor plug component. |
| P120005/S062 | 05/04/2017 | X - 30-Day Notice | DEXOM G4 PLATINUM CONTINUOUS GLUCOSE MONITORING SYSTEM | DEXCOM, INC. | Add a transmitter printed circuit board assembly (PCBA) reset station during manufacturing of the G5 Mobile Transmitters which is a component of Dexcom G5 Mobile Continuous Glucose Monitoring System. |
| P120005/S063 | 05/10/2017 | X - 30-Day Notice | DEXCOM G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM | DEXCOM, INC. | Add a manufacturing site for the sensor wire subassembly which is a component of the Dexcom G5 Mobile/G4 PLATINUM Continuous Glucose Monitoring Systems. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P120010/S103 | 05/10/2017 | X - 30-Day Notice | MINIMED 530G INSULIN PUMP | MEDTRONIC INC. | Transfer equipment used for leak testing seals of the Paradigm insulin infusion pumps and Next Generation insulin infusion pumps from Medtronic MiniMed to a sub-tier supplier, as well as transferring the task of performing such testing to the sub-tier supplier. The Paradigm insulin infusion pump is component of the Paradigm REAL-Time System, the Paradigm REAL-Time Revel System, and the MiniMed 530G System. The Next Generation insulin infusion pump is a component of the MiniMed 630G System and the MiniMed 670G System. |
| P130009/S073 | 05/10/2017 | X - 30-Day Notice | EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE | EDWARDS LIFESCIENCES, LLC. | Use of a newly installed component manufacturing cleanroom at the Edwards facility in Irvine, California. |
| P130009/S074 | 05/23/2017 | X - 30-Day Notice | EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE | EDWARDS LIFESCIENCES, LLC. | New equipment used in the manufacture of Edwards surgical and transcatheter heart valves. |
| P130016/S025 | 05/09/2017 | X - 30-Day Notice | NUCLEUS HYBRID COCHLEAR IMPLANT SYSTEM | COCHLEAR AMERICAS | Transfer of the Arburg 220S Molding Machine (CP800/CP900 Injection Molding Tool System) from the Lane Cove manufacturing site to the Macquarie manufacturing site. |
| P130016/S026 | 05/23/2017 | X - 30-Day Notice | NUCLEUS HYBRID COCHLEAR IMPLANT SYSTEM | COCHLEAR AMERICAS | Alternate Flash Memory chip and ESD Diode, both of which are components of the Printed Circuit Board Assemblies used in the CP810 and CP802 Sound Processors. |
| P130017/S016 | 05/17/2017 | X - 30-Day Notice | COLOGUARD | EXACT SCIENCES CORPORATION | Installation and use of manufacturing equipment. |
| P130026/S023 | 05/03/2017 | X - 30-Day Notice | TACTICATH QUARTZ SET | ST. JUDE MEDICAL | Alternate supplier for the distal optical fiber components for the TactiCath Quartz Set. |
| P130028/S017 | 05/24/2017 | X - 30-Day Notice | ALGOVITA SPINAL CORD STIMULATION SYSTEM | NUVECTRA CORPORATION | Revisions to the IPG test system software to improve system reliability and align with device performance specifications. |
| P130030/S038 | 05/10/2017 | X - 30-Day Notice | REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE | BOSTON SCIENTIFIC CORP. | Changes to the Carrier Tube Extrusion Line. |
| P130030/S039 | 05/12/2017 | X - 30-Day Notice | REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM | BOSTON SCIENTIFIC CORP. | Sterilization of devices within the scope of this bundled submission with the optimized BSC2000-2 cycle in Chamber 3 at the Synergy Health/Steris, Costa Rica facility. |
| P140008/S005 | 05/01/2017 | X - 30-Day Notice | ORBERA INTRAGASTRIC BALLOON SYSTEM | APOLLO ENDOSURGERY INC | Addition of a new supplier of a device component. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
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| P140010/S031 | 05/08/2017 | X - 30-Day Notice | IN.PACT ADMIRAL PACLITAXEL-COATED BALLOON CATHETER | MEDTRONIC INC. | Modification to a manufacturing aid material. |
| P140017/S007 | 05/19/2017 | X - 30-Day Notice | MELODY TRANSCATHETER PULMONARY VALVE SYSTEM | MEDTRONIC INC. | Changes to endotoxin and bioburden testing for the Ensemble and Ensemble II Delivery Systems. |
| P140028/S025 | 05/26/2017 | X - 30-Day Notice | INNOVA SELF-EXPANDING STENT SYSTEM | BOSTON SCIENTIFIC CORPORATION | Updates to the Programmable Logic Controller (PLC) software used for sterilization Chamber 3, an update to the vacuum pump system used in Chamber 3, and an update to the validation documentation structure used to support the system. |
| P140031/S038 | 05/10/2017 | X - 30-Day Notice | EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE | EDWARDS LIFESCIENCES, LLC. | Use of a newly installed component manufacturing cleanroom at the Edwards facility in Irvine, California. |
| P140031/S039 | 05/23/2017 | X - 30-Day Notice | EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE | EDWARDS LIFESCIENCES, LLC. | New equipment used in the manufacture of Edwards surgical and transcatheter heart valves. |
| P140033/S007 | 05/05/2017 | X - 30-Day Notice | ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE | ST. JUDE MEDICAL, INC. | Longer dwell time between plasma cleaning and wire bonding of the hybrid. |
| P150001/S014 | 05/10/2017 | X - 30-Day Notice | MINIMED 630G INSULIN PUMP | MEDTRONIC MINIMED | Transfer equipment used for leak testing seals of the Paradigm insulin infusion pumps and Next Generation insulin infusion pumps from Medtronic MiniMed to a sub-tier supplier, as well as transferring the task of performing such testing to the sub-tier supplier. The Paradigm insulin infusion pump is component of the Paradigm REAL-Time System, the Paradigm REAL-Time Revel System, and the MiniMed 530G System. The Next Generation insulin infusion pump is a component of the MiniMed 630G System and the MiniMed 670G System. |
| P150003/S029 | 05/10/2017 | X - 30-Day Notice | SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM | BOSTON SCIENTIFIC CORPORATION | Changes to the Carrier Tube Extrusion Line. |
| P150003/S030 | 05/26/2017 | X - 30-Day Notice | SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM | BOSTON SCIENTIFIC CORPORATION | Updates to the Programmable Logic Controller (PLC) software used for sterilization Chamber 3, an update to the vacuum pump system used in Chamber 3, and an update to the validation documentation structure used to support the system. |
| P150004/S009 | 05/03/2017 | X - 30-Day Notice | AXIUM NEUROSTIMULATOR SYSTEM | SPINAL MODULATION, INC | Alternate supplier site for the manufacturing of connector blocks which is a component of the Axium INS and Proclaim IPG header assembly. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P150005/S019 | 05/12/2017 | X - 30-Day Notice | BLAZER OPEN IRRIGATED TEMPERATURE ABLATION CATHETER | BOSTON SCIENTIFIC CORP. | Sterilization of devices within the scope of this bundled submission with the optimized BSC2000-2 cycle in Chamber 3 at the Synergy Health/Steris, Costa Rica facility. |
| P150012/S028 | 05/01/2017 | X - 30-Day Notice | ESSENTIO, PROPONENT, ACCOLADE MRI. | BOSTONSCIENTIFIC | Modification to the software for the Automated Optical Inspection System used during header manufacturing. |
| P150012/S029 | 05/19/2017 | X - 30-Day Notice | INGEVITY LEAD MANUFACTURING CHANGES | BOSTONSCIENTIFIC | Removal of a trimming step and updates to visual inspection criteria for silicone tubing. |
| P150012/S030 | 05/23/2017 | X - 30-Day Notice | INGEVITY LEAD | BOSTONSCIENTIFIC | Changes to the quality control analytical test methods used to evaluate dexamethasone acetate for passive fixation distal tip subassembly test articles. |
| P150013/S005 | 05/16/2017 | X - 30-Day Notice | PD-L1 IHC 22C3 PHARMDX | DAKO NORTH AMERICA, INC. | Changes to the relocation/ expansion of facility. |
| P150019/S029 | 05/10/2017 | X - 30-Day Notice | PARADIGM REAL-TIME REVEL INSULIN PUMP | MEDTRONIC MINIMED | Transfer equipment used for leak testing seals of the Paradigm insulin infusion pumps and Next Generation insulin infusion pumps from Medtronic MiniMed to a sub-tier supplier, as well as transferring the task of performing such testing to the sub-tier supplier. The Paradigm insulin infusion pump is component of the Paradigm REAL-Time System, the Paradigm REAL-Time Revel System, and the MiniMed 530G System. The Next Generation insulin infusion pump is a component of the MiniMed 630G System and the MiniMed 670G System. |
| P150023/S008 | 05/09/2017 | X - 30-Day Notice | ABSORB GT1 BIORESORBABLE VASCULAR SCAFFOLD (BVS) SYSTEM | ABBOTT VASCULAR INC. | Change to the frequency of routine bacterial endotoxin testing. |
| P150025/S006 | 05/16/2017 | X - 30-Day Notice | PD-L1 IHC 28-8 PHARMDX | DAKO NORTH AMERICA, INC. | Changes to the relocation/ expansion of facility. |
| P150036/S007 | 05/10/2017 | X - 30-Day Notice | EDWARDS INTUITY VALVE SYSTEM | EDWARDS LIFESCIENCES, LLC. | Use of a newly installed component manufacturing cleanroom at the Edwards facility in Irvine, California. |
| P150036/S008 | 05/23/2017 | X - 30-Day Notice | EDWARDS INTUITY VALVE SYSTEM | EDWARDS LIFESCIENCES, LLC. | New equipment used in the manufacture of Edwards surgical and transcatheter heart valves. |
| P150036/S010 | 05/25/2017 | X - 30-Day Notice | EDWARDS INTUITY ELITE VALVE & DELIVERY SYSTEM | EDWARDS LIFESCIENCES, LLC. | Manufacturing line change and use of APFO-free resin for manufacturing PTFE components of the INTUITY Elite valve. |
| P150037/S005 | 05/15/2017 | X - 30-Day Notice | CYPASS SYSTEM | ALCON RESEARCH, LTD | Additional supplier for the CyPass System Applier. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
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| P160017/S012 | 05/10/2017 | X - 30-Day Notice | MINIMED 670G PUMP | MEDTRONIC MINIMED | Transfer equipment used for leak testing seals of the Paradigm insulin infusion pumps and Next Generation insulin infusion pumps from Medtronic MiniMed to a sub-tier supplier, as well as transferring the task of performing such testing to the sub-tier supplier. The Paradigm insulin infusion pump is component of the Paradigm REAL-Time System, the Paradigm REAL-Time Revel System, and the MiniMed 530G System. The Next Generation insulin infusion pump is a component of the MiniMed 630G System and the MiniMed 670G System. |

**Total: 161**