## PMA Monthly approvals from 2/1/2019 to 2/28/2019

## Original

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P160050 | 02/08/2019 | PMAO - PMA Origi | BARRICAID ANULAR CLOSURE DEVICE (ACD) | INTRINSIC THERAPEUTICS | Approval for the Barricaid Anular Closure Device (ACD). The device is indicated for reducing the incidence of reherniation, and reoperation in skeletally mature patients with radiculopathy (with or without back pain) attributed to a posterior or posterolateral herniation, and confirmed by history, physical examination and imaging studies which demonstrate neural compression using MRI to treat a large anular defect (between 4-6 mm tall and between 6-10 mm wide) following a primary discectomy procedure (excision of herniated intervertebral disc) at a single level between L4 and S1. |
| P170030 | 02/22/2019 | PMAO - PMA Origi | ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM | BIOTRONIK, INC | Approval of the Orsiro Sirolimus Eluting Coronary Stent System. This device is indicated for improving coronary luminal diameter in patients, including those with diabetes mellitus, with symptomatic heart disease, stable angina, unstable angina, non-ST elevation myocardial infarction or documented silent ischemia due to atherosclerotic lesions in the native coronary arteries with a reference vessel diameter of 2.25 mm to 4.0 mm and a lesion length of < 36 mm. |
| P170036 | 02/06/2019 | PMAO - PMA Origi | M6-C ARTIFICIAL CERVICAL DISC | SPINAL KINETICS LLC | Approval for the M6-C Artificial Cervical Disc. The M6-C Artificial Cervical Disc is indicated for reconstruction of the disc following single level discectomy in skeletally mature patients with intractable degenerative cervical radiculopathy with or without spinal cord compression at one level from C3 to C7. Degenerative cervical radiculopathy is defined as arm pain and/or a neurological deficit (numbness, weakness, deep tendon reflexes changes) with or without neck pain due to disc herniation and/or osteophyte formation and confirmed by radiographic imaging (CT, MRI, x-rays). The M6-C Artificial Cervical Disc is implanted via an anterior approach. Patients should have failed at least 6 weeks of conservative treatment or exhibit progressive neurological symptoms which could lead to permanent impairment prior to implantation of the M6-C Artificial Cervical Disc. |
| P180025 | 02/01/2019 | PMAO - PMA Origi | MANTA VASCULAR CLOSURE DEVICE | ESSENTIAL MEDICAL, INC. | Approval for the 14F MANTA Vascular Closure Device. The device is indicated for closure of femoral arterial access sites following the use of 10-14F devices or sheaths (maximum OD/profile of 18F), and the 18F MANTA Vascular Closure Device is indicated for closure of femoral arterial access sites following the use of 15-18F devices or sheaths (maximum OD/profile of 25F). |

**Total: 4**



Data as of 03/03/2019 03:39 AM

## Supplements

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| N970003/S233 | 02/22/2019 | R - Real-Time Proc | ADVANTIO, INGENIO, VITALIO, FORMIO, ESSENTIO, ACCOLADE, PROPONENT, (INSIGNIA AND ALTRUA 2 SUPPORTED BY LATITUDE CONSULT ONLY) PACEMAKER DEVICES | BOSTON SCIENTIFIC CORP. | Approval for changes to the Server and Communicator software updates necessary for LATITUDE NXT Release. |
| P820076/S027 | 02/12/2019 | Y - 135 Review Tra | EFH-16; S 60-K; S 60-J; S 60-S | BIOTRONIK, INC. | Approval for the implementation of new biological indicators and reduction of incubation time for the bioindicators for the sterilization process, the use of sterilization process P02 as an alternate sterilization process for cables and adaptors, and parametric release for the sterilization processes. |
| P840062/S068 | 02/22/2019 | O - Normal 180 Day | ABSORBABLE COLLAGEN PLUG FOR DENTAL SURGERY, ABSORBABLE COLLAGEN TAPE FOR DENTAL SURGERY | INTEGRA LIFESCIENCES CORP. | Approval for additional trade names: Absorbable Collagen Tape for Dental Surgery and Absorbable Collagen Plug for Dental Surgery. |
| P860004/S321 | 02/12/2019 | R - Real-Time Proc | SYNCHROMED INFUSION SYSTEM | MEDTRONIC INC. | Approval for a minor design and related minor manufacturing changes to the pumphead roller arm assembly of the SynchroMed® II Drug Infusion Pump. |
| P890003/S386 | 02/28/2019 | N - Normal 180 Day | CARELINK SMARTSYNC BASE, PATIENT CONNECTOR, HOST APP, PSA APP, COMMON APP, AND CARELINK SMARTSYNC PLATFORM APP | MEDTRONIC, INC. | Approval for changes to the Medtronic CareLink SmartSync Device Manager and an additional application intended to be used for programming Azure and Astra implantable devices. |
| P910073/S153 | 02/28/2019 | R - Real-Time Proc | RELIANCE 4-FRONT, 4-SITE IS-1 DEFIBRILLATION | BOSTON SCIENTIFIC | Approval for sales packaging and label changes. |
| P910077/S168 | 02/22/2019 | R - Real-Time Proc | LATITUDE NXT PATIENT MANAGEMENT SYSTEM, LATITUDE WAVE COMMUNICATOR, LATITUDE CONSULT COMMUNICATOR AND LATITUDE NXT SYSTEM SERVER SOFTWARE | BOSTON SCIENTIFIC | Approval for changes to the Server and Communicator software updates necessary for LATITUDE NXT Release 6.1. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
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| P950037/S192 | 02/12/2019 | Y - 135 Review Tra | EVIA DR/SR; EVIA DR-T/SR-T; ENTOVIS DR/SR, ENTOVIS DR-T/SR-T; ESTELLA DR/SR; ESTELLA DR-T/SR-T; EFFECTA D/S; EDORA 8 DR/ 8 SR; ENITRA 6 DR-T; ENITRA 8 SR-T; ENITRA 6 SR; ENTICOS 4 DR/ 4 S; ENTICOS 8 SR-T; EVITY 6 DR-T/ 6 SR-T; ETRINSA 8 DR-T/ 8 SR-T, ETRINSA 6 DR/SR; ETRINSA 6 SR-T; EPYRA 8 DR-T/ 8 SR-T; EPYRA 6 DR-T/ 6 SR-T; ELUNA 8 DR-T/ 8 SR-T; ELUNA 8 SR/ 8 DR; EDORA 8 DR-T/ 8 SR-T; ENITRA 8 DR-T; ENITRA 6 DR; ENITRA 6 SR-T; ENTICOS 8 DR-T; ENTICOS 4 D; ENTICOS 4 SR; EVITY 8 DR-T/ 8 SR-T; S53-K; S45-K; DH; DH IS-1/DF4; EFH-6F-W; SELOX ST/JT; SIELLO S; SOLIA S; SETROX S, SAFIO S; S 45-S; S 53-F; S 53-S; S 45-F; S 45-J; S 53-J; S 60-F; S 58-K; S 45-JL; S 53-JL; BS IS-1; PK-141; PK-67-S; PK-67-L; PK-155; MPK-4-R; MPK-10-R; PK-82; PK-83; PK-83-B; PK-175; PA-1-C; PK-128; PK-142; PK-185; PK-111; PK-112; PA-1-B; KRG | BIOTRONIK, INC. | Approval for the implementation of new biological indicators and reduction of incubation time for the bioindicators for the sterilization process, the use of sterilization process P02 as an alternate sterilization process for cables and adaptors, and parametric release for the sterilization processes. |
| P960004/S088 | 02/28/2019 | R - Real-Time Proc | FINELINE II STEROX, EZ. | BOSTON SCIENTIFIC | Approval for the sales packaging and label changes being made to BSC lead families. |
| P960009/S332 | 02/12/2019 | R - Real-Time Proc | ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM | MEDTRONIC INC. | Approval for the Maintenance Release 1 Update to the Model A610 Activa DBS Clinician Programmer Application which updated the impedance measurement workflow, enabled interleaving programming in both hemispheres, and updated reports. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
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| P960040/S431 | 02/22/2019 | R - Real-Time Proc | TELIGEN, ENERGEN, PUNCTUA, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN, RESONATE, MOMENTUM, VIGILANT, AND PERCIVA (ICD DEVICES) | BOSTON SCIENTIFIC | Approval for changes to the Server and Communicator software updates necessary for LATITUDE NXT Release. |
| P960043/S102 | 02/21/2019 | O - Normal 180 Day | PERCLOSE PROGLIDE SUTURE-MEDIATED CLOSURE SYSTEM/ PROSTAR XL PERCUTANEOUS VASCULAR SURGICAL SYSTEM | ABBOTT VASCULAR INC. | Approval for an alternate sterilization site located at Sterigenics UK Limited Cotes Park Lane Somercotes, Alfreton DE55 4NJ United Kingdom. |
| P970003/S219 | 02/01/2019 | Y - 135 Review Tra | VNS THERAPY SYSTEM | LIVANOVA USA, INC. | Approval for updating the component qualification test method. |
| P970003/S222 | 02/14/2019 | S - Special CBE | VNS THERAPY SYSTEM | LIVANOVA USA, INC. | Approval for the following labeling updates:<br>1) Model 1000 (SN < 100,000) High Impedance Warning - the addition of a warning to the VNS Therapy Physicians Manuals for both Epilepsy and Depression regarding the potential for erroneous high impedance warning messages that can be received in certain Model 1000 Generators (i.e. Serial Number (SN) < 100,000); and<br>2) Model 1000 (SN < 100,000) Package Insert: the creation of a package insert, containing the same warning information described above, that will be placed within the sales packaging of every Model 1000 Generator (SN < 100,000). |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P980023/S085 | 02/12/2019 | Y - 135 Review Tra | PROTEGO SD/TD; PROTEGO DF-1 SD; PROTEGO PROMRI SDX; PROTEGO DF-1 PROMRI SD; PLEXA SD; PLEXA PROMRI SD; PLEXA DF-1 SD; PLEXA PROMRI DF-1 SD BK-IS4/DF4; IS4/DF4-ADAPTER; PROTEGO S/T; PROTEGO DF-1 S; PROTEGO DF-1 PROMRI SDX; PROTEGO DF-1 PROMRI S; PLEXA S; PLEXA PROMRI S; PLEXA DF-1 S; PLEXA PROMRI DF-1 S DX; PLEXA PROMRI DF-1 S; DH DF4; DH IS-1/ DF4; EFH-30; VL; SI-2; TW; EFH-35; EFH-7F-W; EFH-8F-W; S 72-A/C/E; S 65-C/E/K; S 75-K; S 65-A; S 60-C | BIOTRONIK, INC. | Approval for the implementation of new biological indicators and reduction of incubation time for the bioindicators for the sterilization process, the use of sterilization process P02 as an alternate sterilization process for cables and adaptors, and parametric release for the sterilization processes. |
| P980023/S089 | 02/21/2019 | R - Real-Time Proc | PLEXA PROMRI S DX ICD LEADS | BIOTRONIK, INC. | Approval for Plexa ProMRI S DX ICD leads. |
| P980035/S536 | 02/28/2019 | N - Normal 180 Day | CARELINK SMARTSYNC AZURE ASTRA APP AND AZURE ASTRA DR/SR/XT MRI SURESCAN IPGS | MEDTRONIC INC. | Approval for changes to the Medtronic CareLink SmartSync Device Manager and an additional application intended to be used for programming Azure and Astra implantable devices. |
| P990004/S033 | 02/20/2019 | Y - 135 Review Tra | SURGIFLO HEMOSTATIC MATRIX KIT W/THROMBIN | FERROSAN MEDICAL DEVICES A/S | Approval for a change to the pallet configuration for the Ethylene Oxide sterilization of the Thrombin Kit Package which is a part of the SURGIFLO Hemostatic Matrix Kit with Thrombin. |
| P010012/S492 | 02/22/2019 | R - Real-Time Proc | COGNIS, ENERGEN, PUNCTUA, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN, RESONATE, MOMENTUM AND VIGILIANT (CRT-D RESYNCHRONIZATION DEVICES) | BOSTON SCIENTIFIC CORP. | Approval for changes to the Server and Communicator software updates necessary for LATITUDE NXT Release. |
| P010012/S494 | 02/28/2019 | R - Real-Time Proc | ACUITY X4 LEADS, ACUITY SPIRAL LEADS | BOSTON SCIENTIFIC CORP. | Approval for the sales packaging and label changes being made to BSC lead families. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
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| P010030/S107 | 02/27/2019 | Y - 135 Review Tra | LIFEVEST WEARABLE DEFIBRILATOR | ZOLL MANUFACTURING CORPORATION | Approval for an alternate gel supplier. |
| P010030/S111 | 02/28/2019 | R - Real-Time Proc | LIFEVEST WEARABLE DEFIBRILLATOR | ZOLL MANUFACTURING CORPORATION | Approval for a material change to the flex tail used in the monitor response button and minor dimensional changes to the enclosure cover. |
| P030005/S179 | 02/22/2019 | R - Real-Time Proc | INVIVE, INTUA, VISIONIST AND VALITUDE (CRT-P RESYNCHRONIZATION DEVICES) | GUIDANT CORP. | Approval for changes to the Server and Communicator software updates necessary for LATITUDE NXT Release. |
| P050007/S037 | 02/21/2019 | O - Normal 180 Day | STARCLOSE SE VASCULAR SURGICAL SYSTEM | ABBOTT VASCULAR DEVICES | Approval for an alternate sterilization site located at Sterigenics UK Limited Cotes Park Lane Somercotes, Alfreton DE55 4NJ United Kingdom. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
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| P050023/S121 | 02/12/2019 | Y - 135 Review Tra | ILESTO 7 VR-T; IFORIA 7 VR-T; ILESTO 5 VR-T; IFORIA 5 VR-T; ILESTO 7 VR T DX; IFORIA 7 VR-T DX; ILESTO 5 VR-T DX; IFORIA 5 VR-T DX; ITREVIA 7 VR-T; IPERIA 7 VR-T; ILIVIA 7 VR-T DX (GB/LI); INTICA 7 VR-T DX (GB/LI); INTICA 5 VR-T DX (GB/LI); ILIVIA 7 VR-T (GB/LI); ILIVIA 7 DF4 VR-T (GB/LI); INTICA 7 VR-T (GB/LI); INLEXA 3 VR-T (GB/LI); INVENTRA 7 VR-T; ITREVIA 5 VR-T; IPERIA 5 VR-T; INVENTRA 7 VR-T; ITREVIA 7 VR-T DX; IPERIA 7 VR-T DX; INVENTRA 7 VR T DX; ITREVIA 5 VR-T DX; IPERIA 5 VR-T DX; INVENTRA 5 VR-T DX; INTICA 7 DF4 VR-T (GB/LI); INTICA 5 VR-T (GB/LI); INTICA 5 DF4 VR-T (GB/LI); INLEXA 7 VR-T (GB/LI); INLEXA 7 VR-T DF4 (GB/LI); INLEXA 7 VR-T DX (GB/LI); INLEXA 3 VR-T DF4 (GB/LI); ILESTO 7 DR-T, IFORIA 7 DR-T; ILESTO 5 DR-T; IFORIA 5 DR-T; ITREVIA 7 DR-T; ILIVIA 7 DR-T (GB/LI); ILIVIA 7 DR-T DF4 (GB/LI); INTICA 7 DR-T (GB/LI); INTICA 7 DR-T DF4 (GB/LI); INTICA 5 DR-T (GB/LI); IPERIA 7 DR-T; IVENTRA 7 DR-T; ITREVIA 5 DR-T; IPERIA 5 DR-T; IVENTRA 5 DR-T; INLEXA 7 DR-T (GB/LI) | BIOTRONIK, INC. | Approval for the implementation of new biological indicators and reduction of incubation time for the bioindicators for the sterilization process, the use of sterilization process P02 as an alternate sterilization process for cables and adaptors, and parametric release for the sterilization processes. |

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|---|---|---|---|---|---|
| P050027/S014 | 02/21/2019 | R - Real-Time Proc | KARL STORZ PHOTODYNAMIC DIAGNOSTIC D-LIGHT C (PDD) SYSTEM | KARL STORZ ENDOSCOPY-AMERICA, INC. | Approval for the following alternate sterilization methods for the Flexible PDD Video Cystoscopes (P/N: 11272VNIA and 11272VNIUA): STERRAD NX Advanced Cycle, STERRAD 100 NX Flex and Duo Cycles, STERIS V-PRO maX Flexible Cycle and Steris V-PRO 60 Flexible Cycle. |
| P070008/S094 | 02/12/2019 | Y - 135 Review Tra | EVIA HF/ HF-T; ENTOVIS HF/ HF-T; EDORA 8 HF-T; ENITRA 8 HF-T; ENTICOS 8 HF-T; EVITY 8 HF-T; ETRINSA 8 HF T; EPYRA 8 HF-T; ELUNA 8 HF-T; EDORA 8 HF-T QP; ENITRA 8 HF-T QP; ENTICOS 8 HF-T QP; EVITY 8 HF-T QP; COROX OTW BP; COROX OTW-L BP; COROX PROMRI OTW BP; SENTUS PROMRI OTW QP S; SENTUS PROMRI OTW QP S-XX/49; COROX OTW-S BP; COROX PROMRI OTW-L BP; COROX PROMRI OTW-S BP; SENTUS PROMRI OTW QP L; SENTUS PROMRI OTW QP L-XX/49 | BIOTRONIK, INC. | Approval for the implementation of new biological indicators and reduction of incubation time for the bioindicators for the sterilization process, the use of sterilization process P02 as an alternate sterilization process for cables and adaptors, and parametric release for the sterilization processes. |
| P100034/S022 | 02/28/2019 | R - Real-Time Proc | OPTUNE SYSTEM | NOVOCURE, LTD. | Approval for a color change to the INE Transducer Array medical tape from white to tan, and a change to the release liner of the INE Transducer Array from a paper-based material to polyester. |
| P100042/S020 | 02/28/2019 | R - Real-Time Proc | APTIMA HPV ASSAY | GEN-PROBE INCORPORATED | Approval for an alternate cleaning method for the samples racks used on the Panther, Panther Fusion, and Tigris instruments. |
| P100044/S037 | 02/28/2019 | R - Real-Time Proc | PROPEL CONTOUR SINUS IMPLANT | INTERSECT ENT | Approval for modifications to the design and manufacturing of the delivery system, including the implementation of mechanical press fit bond joints, new dimensional specifications, revisions to the tip molding process, and a redefined tensile strength specification for the applicator. |
| P100047/S133 | 02/21/2019 | O - Normal 180 Day | HEARTWARE VENTRICULAR ASSIST SYSTEM | MEDTRONIC | Approval of the protocol changes for the post-approval study (PAS) protocol. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P110042/S119 | 02/22/2019 | R - Real-Time Proc | EMBLEM (SUBCUTANEOUS ICD DEVICES) | BOSTON SCIENTIFIC CORPORATION | Approval for changes to the Server and Communicator software updates necessary for LATITUDE NXT Release. |
| P110042/S120 | 02/28/2019 | R - Real-Time Proc | EMBLEM S-ICD, ELECTRODE | BOSTON SCIENTIFIC CORPORATION | Approval for the sales packaging and label changes being made to BSC lead families. |
| P120007/S018 | 02/28/2019 | R - Real-Time Proc | APTIMA HPV 16 18/45 GENOTYPE ASSAY | GEN-PROBE INCORPORATED | Approval for an alternate cleaning method for the samples racks used on the Panther, Panther Fusion, and Tigris instruments. |
| P120016/S026 | 02/05/2019 | O - Normal 180 Day | CARDIVA VASCADE VASCULAR CLOSURE SYSTEM (VCS) | CARDIVA MEDICAL, INC. | Approval for changing your California headquarters facility to 1615 Wyatt Dr., Santa Clara, California, for the VASCADE Vascular Closure System (VCS) 700-500DX, 70-580I, 800-612C devices. |
| P130012/S006 | 02/21/2019 | S - Special CBE | MYOPORE SUTURELESS MYOCARDIAL PACING LEAD | GREATBATCH MEDICAL | Approval for revisions and enhancements to the content in the Myopore lead Instructions for Use. |
| P130019/S019 | 02/15/2019 | O - Normal 180 Day | MAESTRO RECHARGEABLE SYSTEM | RESHAPE LIFESCIENCES, INC. | Approval of the revised protocol which includes modification to the follow-up schedule for the post-approval study (PAS) protocol. |
| P130022/S019 | 02/08/2019 | N - Normal 180 Day | SENZA SPINAL CORD STIMULATION (SCS) SYSTEM | NEVRO CORPORATION | Approval for conditional Magnetic Resonance labeling for the Senza Implantable Pulse Generator (IPG) model IPG2000. |
| P130024/S026 | 02/14/2019 | R - Real-Time Proc | LUTONIX 035 DRUG COATED BALLOON PTA CATHETER | LUTONIX | Approval for a shelf life extension to 24 months for devices with balloon sizes 4 x 220 mm and 5 x 220 mm (standard balloon) and 6 x 220 mm (low profile balloon). |
| P130026/S038 | 02/11/2019 | O - Normal 180 Day | TACTICATH CONTACT FORCE ABLATION CATHETER, SENSOR ENABLED | ST. JUDE MEDICAL | Approval to add additional manufacturing site and additional sterilization site in Costa Rica for the TactiCath SE. |
| P130026/S039 | 02/15/2019 | S - Special CBE | TACTICATH CONTACT FORCE ABLATION CATHETER, SENSOR ENABLED | ST. JUDE MEDICAL | Approval of a manufacturing change to add a tip adhesive fixture. |
| P140009/S038 | 02/14/2019 | Y - 135 Review Tra | 4CH & 8CH INFINITY DBS SYSTEM FLEX EXTENSION | ABBOTT MEDICAL | Approval for five changes to specific steps within the manufacturing process of the 4 and 8 Channel Infinity DBS System Flex Extensions (Models 6355, 6356, 6359, 6371, 6372, and 6373). |
| P140032/S020 | 02/15/2019 | N - Normal 180 Day | IMPLANTABLE SYSTEM FOR REMODULIN | MEDTRONIC, INC. | Approval for design and packaging changes as a result of a manufacturing site location change of the Model 8551 Refill Kit used with the Implantable System for Remodulin (ISR) |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P150011/S015 | 02/08/2019 | S - Special CBE | PERCEVAL HEART VALVE | LIVANOVA CANADA CORP. | Approval for labeling changes to instruct users on safe, future valve-in-valve implantations. |
| P150012/S067 | 02/22/2019 | R - Real-Time Proc | INGENIO MRI, VITALIO MRI, FORMIO MRI, ESSENTIO MRI, PROPONENT MRI AND ACCOLADE MRI (PACEMAKER DEVICES) | BOSTONSCIENTIFIC | Approval for changes to the Server and Communicator software updates necessary for LATITUDE NXT Release. |
| P150012/S070 | 02/28/2019 | R - Real-Time Proc | INGEVITY MRI | BOSTONSCIENTIFIC | Approval for the sales packaging and label changes being made to BSC lead families |
| P150021/S037 | 02/26/2019 | R - Real-Time Proc | FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM | ABBOTT DIABETES CARE INC. | Approval for a change to the Printed Circuit Board Assembly (PCBA) Battery Contact for the sensor puck assembly. |
| P150030/S006 | 02/19/2019 | R - Real-Time Proc | R3 DELTA CERAMIC ACETABULAR SYSTEM | SMITH & NEPHEW, INC. | Approval for an additional supplier for the Inner Packaging Tyvek lid. |
| P160001/S030 | 02/14/2019 | S - Special CBE | OBALON BALLOON SYSTEM | OBALON THERAPEUTICS, INC. | Approval for changes to physician and patient labeling in response to reported cases of gastric perforation. |
| P160008/S004 | 02/19/2019 | R - Real-Time Proc | HEARTSINE TECHNOLOGIES LLC'S SAMARITAN PUBLIC ACCESS AUTOMATED EXTERNAL DEFIBRILLATORS AND ACCESSORIES | HEARTSINE TECHNOLOGIES LLC | Approval for minor changes including the addition of EMC suppression circuitry, PCBA and membrane standardization, related manufacturing changes, and labeling updates. |
| P160023/S009 | 02/28/2019 | R - Real-Time Proc | APTIMA HCV QUANT DX ASSAY | HOLOGIC, INC. | Approval for an alternate cleaning method for the samples racks used on the Panther, Panther Fusion, and Tigris instruments. |
| P160030/S029 | 02/26/2019 | R - Real-Time Proc | FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM | ABBOTT DIABETES CARE INC. | Approval for a change to the Printed Circuit Board Assembly (PCBA) Battery Contact for the sensor puck assembly. |
| P160031/S001 | 02/08/2019 | N - Normal 180 Day | ASPIRE CRISTALLE BREAST TOMOSYNTHESIS SYSTEM | FUJIFILM MEDICAL SYSTEMS U.S.A., INC. | Approval for the implementation of the synthesized 2D (S-View) image, changing the image processing in DBT reconstruction to iterative super-resolution reconstruction (ISR), applying new image processing, Dynamic Visualization II for mammography (DVIIm), to DBT and synthesized 2D images, and related changes in the indications for use (IFU). |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P160048/S003 | 02/01/2019 | O - Normal 180 Day | EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM (CGMS-ENTIRE SYSTEM), EVERSENSE SENSOR , EVERSENSE INSERTION TOOLS, EVERSENSE SMART TRANSMITTER AND EVERSENSE ADHESIVE PATCH, EVERSENSE MOBILE MEDICAL APPLICATION | SENSEONICS, INCORPORATED | Approval to add final packaging, storage, and distribution activities for the Eversense Continuous Glucose Monitoring System at Woodfield Distribution, LLC, Boca Raton, FL. |
| P170008/S011 | 02/13/2019 | Y - 135 Review Tra | ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM | MEDINOL, LTD. | Approval for introduction of a new analytical test method for determination of the concentration of the polymers in the drug solution, and removal of certain tests for the polymer stock solutions and the drug solution. |
| P170018/S002 | 02/19/2019 | R - Real-Time Proc | LIFEPAK® CR2 DEFIBRILLATOR | PHYSIO-CONTROL, INC | Approval for software updates related to device readiness and cellular AED event transmissions. |
| P170025/S007 | 02/28/2019 | R - Real-Time Proc | APTIMA HBV QUANT ASSAY | HOLOGIC, INC | Approval for an alternate cleaning method for the samples racks used on the Panther, Panther Fusion, and Tigris instruments. |

**Total: 57**

## 30-Day Notice

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
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| N970003/S235 | 02/19/2019 | X - 30-Day Notice | ACCOLADE PACEMAKERS | BOSTON SCIENTIFIC CORP. | Add a Post-Reflow inspection using 3D technology. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
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| N970012/S155 | 02/15/2019 | X - 30-Day Notice | MAS 700 INFLATABLE PENILE PROSTHESIS (IP) WITH AND WITHOUT INHIBIZONE | BOSTON SCIENTIFIC CORP. | Changes to the manufacture of the flat polyethylene terephthalate (PET) yarn. |
| N970012/S156 | 02/15/2019 | X - 30-Day Notice | AMS 700 SERIES PRODUCT LINE/INFLATABLE PENILE PROSTHESIS (IPP) WITH AND WITHOUT INHIBIZONE TREATMENT | BOSTON SCIENTIFIC CORP. | Relocation of and changes to the milling and molding process of the rear tip component. |
| P830055/S221 | 02/04/2019 | X - 30-Day Notice | LCS(R) TOTAL KNEE SYSTEM | DEPUY, INC. | Modification of repack Manufacturing Process Specification for Universal Stems. |
| P840039/S063 | 02/28/2019 | X - 30-Day Notice | PMMA POSTERIOR CHAMBER INTRAOCULAR LENSES | BAUSCH & LOMB, INC. | Ethylene oxide and ethylene chlorohydrin residual testing for the silicone and PMMA intraocular lenses be transferred to a new testing laboratory. |
| P880090/S030 | 02/28/2019 | X - 30-Day Notice | PMMA ANTERIOR CHAMBER INTRAOCULAR LENSES | BAUSCH & LOMB, INC. | Ethylene oxide and ethylene chlorohydrin residual testing for the silicone and PMMA intraocular lenses be transferred to a new testing laboratory. |
| P910061/S025 | 02/28/2019 | X - 30-Day Notice | SOFPORT POSTERIOR CHAMBER INTRAOCULAR LENSES | BAUSCH & LOMB | Ethylene oxide and ethylene chlorohydrin residual testing for the silicone and PMMA intraocular lenses be transferred to a new testing laboratory. |
| P950020/S093 | 02/19/2019 | X - 30-Day Notice | WOLVERINE CORONARY CUTTING BALLOON | BOSTON SCIENTIFIC CORP. | Addition of new equipment for the manufacture of a device component. |
| P950020/S094 | 02/14/2019 | X - 30-Day Notice | WOLVERINE CORONARY CUTTING BALLOON | BOSTON SCIENTIFIC CORP. | Removal of an incoming inspection and modification to the shelf life evaluation of a product component. |
| P950020/S095 | 02/12/2019 | X - 30-Day Notice | WOLVERINE CORONARY CUTTING BALLOON | BOSTON SCIENTIFIC CORP. | Removal of a redundant balloon inspection step. |
| P960040/S433 | 02/13/2019 | X - 30-Day Notice | NG3 DEVICES | BOSTON SCIENTIFIC | Move the supplier location for fabrication of the Zener diode wafer and to utilize an existing supplier to conduct electrical inspection and dicing of the wafer. |
| P980035/S575 | 02/13/2019 | X - 30-Day Notice | ASTRA S DR MRI IPG; ASTRA S SR MRI IPG; ASTRA XT DR MRI IPG; ASTRA XT SR MRI IPG; AZURE S DR MRI IPG; AZURE S SR MRI IPG; AZURE XT DR MRI IPG; AZURE XT SR MRI; AZURE XT SR MRI IPG | MEDTRONIC INC. | Addition of a capacitor inspection step and an updated packaging method used at an external supplier. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P000025/S107 | 02/22/2019 | X - 30-Day Notice | MED-EL COCHLEAR IMPLANT SYSTEM | MED-EL CORP. | Addition of a new supplier for a cochlear implant electrode wire. |
| P000037/S053 | 02/26/2019 | X - 30-Day Notice | ON-X PROSTHETIC HEART VALVE | ON-X LIFE TECHNOLOGIES, INC. | Implementation of new tooling and modified CNC software used to machine On-X device housing substrates. |
| P010012/S496 | 02/04/2019 | X - 30-Day Notice | ACUITY X4 E24 MOLDING NOR OPTIMIZATION | BOSTON SCIENTIFIC CORP. | New normal operating range for molding temperature and cure time during the molding process. |
| P010012/S497 | 02/13/2019 | X - 30-Day Notice | NG4 DEVICES | BOSTON SCIENTIFIC CORP. | Move the supplier location for fabrication of the Zener diode wafer and to utilize an existing supplier to conduct electrical inspection and dicing of the wafer. |
| P010015/S390 | 02/13/2019 | X - 30-Day Notice | PERCEPTA BIPOLAR CRT-P; PERCEPTA QUADRIPOLAR CRT-P; SERENA BIPOLAR CRT-P; SERENA QUADRIPOLAR CRT-P; SOLARA BIPOLAR CRT-P; SOLARA QUADRIPOLAR CRT-P | MEDTRONIC INC. | Addition of a capacitor inspection step and an updated packaging method used at an external supplier. |
| P010030/S113 | 02/14/2019 | X - 30-Day Notice | LIFEVEST WEARABLE DEFIBRILLATOR | ZOLL MANUFACTURING CORPORATION | Alternate supplier for the LifeVest 4000 clamshell shipping container. |
| P010047/S061 | 02/22/2019 | X - 30-Day Notice | PROGEL PLEURAL AIR LEAK SEALANT | NEOMEND, INC. | Change to implement multiple autoclaving cycles for carboys that directly contact materials used in the manufacture of approved device. |
| P020047/S071 | 02/20/2019 | X - 30-Day Notice | MULTI-LINK 8, MULTI-LINK 8 SV, AND MULTI-LINK 8 LL CORONARY STENT SYSTEM | ABBOTT VASCULAR | Add a third sterilization chamber at the contract sterilizer. |
| P030005/S181 | 02/19/2019 | X - 30-Day Notice | ACCOLADE CARDIAC RESYNCHRONIZATION THERAPY PACEMAKERS | GUIDANT CORP. | Add a Post-Reflow inspection using 3D technology. |
| P030011/S067 | 02/20/2019 | X - 30-Day Notice | SYNCARDIA TEMPORARY TOTAL ARTIFICAL HEART (TAH-T) SYSTEM | SYNCARDIA SYSTEMS, LLC | Change in supplier and changes to components of the Freedom Driver Power Adaptive Assembly. |
| P040021/S038 | 02/26/2019 | X - 30-Day Notice | BIOCOR VALVE, SUPRA VALVE; EPIC VALVE, SUPRA | ST. JUDE MEDICAL, INC. | Reduction in the concentration of glutaraldehyde in the manufacturing rinse solution. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P040037/S126 | 02/13/2019 | X - 30-Day Notice | GORE VIABAHN ENDOPROSTHESIS | W.L. GORE & ASSOCIATES,INC | Implementation of a new edge trim laser for use in the manufacture of the GORE VIABAHN Endoprosthesis and GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface. |
| P040038/S034 | 02/20/2019 | X - 30-Day Notice | XACT CAROTID STENT SYSTEM | ABBOTT VASCULAR INC. | Add a third sterilization chamber at the contract sterilizer. |
| P050023/S129 | 02/25/2019 | X - 30-Day Notice | DEFIBRILLATOR, IMPLANTABLE CARDIOVERTER, WITH CARDIAC RESYNCHRONIZATION (CRT-D); DEFIBRILLATOR, IMPLANTABLE, DUAL-CHAMBER; IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (NON-CRT) | BIOTRONIK, INC. | Automated manufacturing for the IS4/DF4 connector modules used in device headers. |
| P070008/S100 | 02/25/2019 | X - 30-Day Notice | PULSE GENERATOR, PACEMAKER, IMPLANTABLE, WITH CARDIAC RESYNCHRONIZATION (CRT-P) | BIOTRONIK, INC. | Automated manufacturing for the IS4/DF4 connector modules used in device headers. |
| P070015/S144 | 02/20/2019 | X - 30-Day Notice | XIENCE V AND XIENCE NANO EVEROLIMUS ELUTING CORONARY STENT SYSTEMS | ABBOTT VASCULAR INC. | Add a third sterilization chamber at the contract sterilizer. |
| P080006/S130 | 02/11/2019 | X - 30-Day Notice | ATTAIN ABILITY LEAD | MEDTRONIC INC. | Procure Titanium rod stock material from a different sub-tier supplier and to incorporate an additional drawing process. |
| P080011/S089 | 02/21/2019 | X - 30-Day Notice | BIOFINITY TORIC | COOPERVISION MANUFACTURING, LTD. | Implementation of the Shin Nisson DL-1000 lensmeter at Quality Control 1 testing for use in the manufacture of the Biofinity Toric (comfilcon A) Lenses at the United Kingdom manufacturing site. |
| P080011/S090 | 02/26/2019 | X - 30-Day Notice | COMFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES | COOPERVISION MANUFACTURING, LTD. | Introduction of Biofinity Line 19 in Juana Diaz, Puerto Rico to produce Biofinity Sphere and Toric Lenses. |
| P100021/S075 | 02/21/2019 | X - 30-Day Notice | ENDURANT, ENDURANT II, ENDURANT IIS STENT GRAFT SYSTEMS | MEDTRONIC VASCULAR | Modify the sampling plan of an in-process inspection of the suprarenal stent rings. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P110010/S162 | 02/14/2019 | X - 30-Day Notice | PROMUS ELEMENT PLUS EVEROLIMUS ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL (MR) AND OVER-THE-WIRE (OTW); PROMUS PREMIER EVEROLIMUS ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL (MR) AND OVER-THE-WIRE (OTW) | BOSTON SCIENTIFIC CORP. | Removal of an incoming inspection and modification to the shelf life evaluation of a product component. |
| P110019/S104 | 02/20/2019 | X - 30-Day Notice | XIENCE PRIME, SV, LL; XIENCE XPEDITION, SV, LL; EVEROLIMUS ELUTING CORONARY STENT SYSTEMS;XIENCE ALPIN AND SIERRA EVEROLIMUS ELUTING CORONARY STENT SYSTEM | ABBOTT VASCULAR | Add a third sterilization chamber at the contract sterilizer. |
| P120020/S021 | 02/20/2019 | X - 30-Day Notice | SUPERA PERIPHERAL STENT SYSTEM | ABBOTT VASCULAR (IDEF TECHNOLOGIES INC) | Add a third sterilization chamber at the contract sterilizer. |
| P130006/S065 | 02/13/2019 | X - 30-Day Notice | GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE | W.L. GORE & ASSOCIATES,INC | Implementation of a new edge trim laser for use in the manufacture of the GORE VIABAHN Endoprosthesis and GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface. |
| P130013/S026 | 02/20/2019 | X - 30-Day Notice | WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE (LAAC) DEVICE WITH DELIVERY SYSTEM | BOSTON SCIENTIFIC CORP. | Alternate visual inspection tool for the frame. |
| P130017/S025 | 02/20/2019 | X - 30-Day Notice | COLOGUARD | EXACT SCIENCES CORPORATION | Qualification of an alternate supplier. |
| P130026/S041 | 02/25/2019 | X - 30-Day Notice | TACTICATH QUARTZ CONTACT FORCE ABLATION CATHETER | ST. JUDE MEDICAL | Reduction in frequency of bacterial endotoxin testing for the TactiCath Quartz Catheter. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
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| P130030/S059 | 02/14/2019 | X - 30-Day Notice | REBEL STENT SYSTEM MONORAIL (MR) AND OVER-THE-WIRE (OTW) | BOSTON SCIENTIFIC CORP. | Removal of an incoming inspection and modification to the shelf life evaluation of a product component. |
| P140031/S081 | 02/18/2019 | X - 30-Day Notice | CERTITUDE INTRODUCER SHEATH SET AND CRIMPER | EDWARDS LIFESCIENCES, LLC. | Addition of a new cleanroom for the manufacture of the Certitude Introduce sheath set and Crimper. |
| P140032/S026 | 02/04/2019 | X - 30-Day Notice | IMPLANTABLE SYSTEM FOR REMODULIN | MEDTRONIC, INC. | Changes to the Implantable System for Remodulin, including the implantable catheter, implantable catheter and revision kit, and the implantable infusion pump, which includes minor changes to the specification documentation, incoming inspection, manufacturing process and manufacturing validation. |
| P150001/S058 | 02/21/2019 | X - 30-Day Notice | MINIMED 630G SYSTEM | MEDTRONIC MINIMED | Introduce a harvest/reclaim process for pump motors in the MiniMed 630G and 670G Pumps. The 630G and 670G Pumps are components of the MiniMed 630G and MiniMed 670G Systems. |
| P150003/S046 | 02/14/2019 | X - 30-Day Notice | SYNERGY EVEROLIMUS ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL (MR) AND OVER-THE-WIRE (OTW) | BOSTON SCIENTIFIC CORPORATION | Removal of an incoming inspection and modification to the shelf life evaluation of a product component. |
| P150012/S071 | 02/19/2019 | X - 30-Day Notice | ACCOLADE MRI PACEMAKERS | BOSTONSCIENTIFIC | Add a Post-Reflow inspection using 3D technology. |
| P150016/S017 | 02/22/2019 | X - 30-Day Notice | TRIDYNE VASCULAR SEALANT | NEOMEND, INC. | Change to implement multiple autoclaving cycles for carboys that directly contact materials used in the manufacture of approved device. |
| P150033/S048 | 02/13/2019 | X - 30-Day Notice | MICRA TPS | MEDTRONIC INC. | Addition of a capacitor inspection step and an updated packaging method used at an external supplier. |
| P160014/S007 | 02/20/2019 | X - 30-Day Notice | COBRA PZF NANOCOATED CORONARY STENT SYSTEM | CELONOVA BIOSCIENCES, INC. | Move in-process inspections, move the location of the lot number label on the device, and change the lot number label process. |
| P160017/S054 | 02/21/2019 | X - 30-Day Notice | MINIMED 670G SYSTEM | MEDTRONIC MINIMED, INC. | Introduce a harvest/reclaim process for pump motors in the MiniMed 630G and 670G Pumps. The 630G and 670G Pumps are components of the MiniMed 630G and MiniMed 670G Systems. |
| P160038/S008 | 02/25/2019 | X - 30-Day Notice | PRAXIS EXTENDED RAS PANEL | ILLUMINA, INC. | Remove yield as an in-process QC specification. |
| P160045/S013 | 02/13/2019 | X - 30-Day Notice | ONCOMINE DX TARGET TEST | LIFE TECHNOLOGIES CORPORATION | Addition of in-process concentration measurements of device sub-components. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P170006/S009 | 02/19/2019 | X - 30-Day Notice | AVALUS BIOPROSTHESIS | MEDTRONIC INC. | Addition of two new bovine tissue suppliers. |
| P170008/S012 | 02/15/2019 | X - 30-Day Notice | ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM | MEDINOL, LTD. | Introduction of automated stent folding and welding. |
| P170008/S013 | 02/22/2019 | X - 30-Day Notice | ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM | MEDINOL, LTD. | Reducing the sample size used for the drug impurity test. |
| P170018/S001 | 02/19/2019 | X - 30-Day Notice | LIFEPAK CR2 DEFIBRILLATOR | PHYSIO-CONTROL, INC | Changes to the end item test equipment hardware and software used in the manufacturing of the LIFEPAK CR2. |

**Total: 55**