# PMA Monthly approvals from 10/1/2019 to 10/31/2019

## Original

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P190011 | 10/18/2019 | PMAO - PMA Origir | LIAISON XL MUREX HCV AB; LIAISON XL MUREX CONTROL HCV AB | DIASORIN INC. | Approval for the LIAISON XL MUREX HCV Ab. The LIAISON XL MUREX HCV Ab is an in vitro chemiluminescent immunoassay for the qualitative determination of specific antibodies to hepatitis C virus (anti-HCV) in human adult and pediatric serum and plasma (lithium and sodium heparin, sodium citrate and potassium EDTA) samples including separator tubes, on the LIAISON XL Analyzer. It is intended to be used as an aid in the diagnosis of HCV infection. The assay may also be used as an aid in the diagnosis of HCV infection in pediatric subjects and in pregnant women. The test does not determine the state of infection or associated disease.<br>The assay is not intended for use in screening blood, plasma, or tissue donors.<br><br>The LIAISON XL MUREX Control HCV Ab (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON XL Murex HCV AB assay. The performance characteristics of LIAISON Controls have not been established for any other assays or instrument platforms different from LIAISON XL. |
| P190014 | 10/23/2019 | PMAO - PMA Origir | MYCHOICE HRD CDX | MYRIAD GENETIC LABORATORIES, INC | Approval of Myriad myChoice® CDx. Myriad myChoice® CDx is a next generation sequencing-based in vitro diagnostic test that assesses the qualitative detection and classification of single nucleotide variants, insertions and deletions, and large rearrangement variants in protein coding regions and intron/exon boundaries of the BRCA1 and BRCA2 genes and the determination of Genomic Instability Score (GIS) which is an algorithmic measurement of Loss of Heterozygosity (LOH), Telomeric Allelic Imbalance (TAI), and Large-scale State Transitions (LST) using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens. The results of the test are used as an aid in identifying ovarian cancer patients with positive homologous recombination deficiency (HRD) status for treatment with the targeted therapy listed in Table 1 in accordance with the approved therapeutic product labeling.<br>Table1---Tumor Type: Ovarian Cancer, Biomarker: Myriad HRD (defined as deleterious or suspected deleterious mutations in BRCA1 and BRCA2 genes and/or positive Genomic Instability Score), Therapy: Zejula® (niraparib) |

**Total: 2**

## Supplements

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
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| N12159/S063 | 10/24/2019 | R - Real-Time Proc | SURGICEL ABSORBABLE HEMOSTATS | ETHICON, INC. | Approval for packaging changes related to the automated process change from manual to automated foiling and cartoning at the Ethicon SARL, Neuchatel Switzerland site. In addition, Ethicon will harmonize SURGICEL NU-KNIT and SURGICEL® Original packaging components. |
| N970003/S242 | 10/18/2019 | R - Real-Time Proc | PACEMAKER DEVICES: ADVANTIO, INGENIO, VITALIO, FORMIO, ESSENTIO, ACCOLADE, AND PROPONENT | BOSTON SCIENTIFIC CORP. | Approval for modifying the Model 3300 LATITUDE Programming System software components to update the Brady device application code base, add support for 4G cellular communications, and add an integrated Heart Connect application. |
| P790005/S065 | 10/24/2019 | Y - 135 Review Tra | OSTEOSTIM(R) | EBI, LLC | Approval to qualify and place into service an upgraded and redesigned Reverse Osmosis, Deionized (RO/DI) Water System along with its ancillary equipment and components at Zimmer Biomets, EBI Patient Care, Guaynabo, Puerto Rico Manufacturing and Distribution Facility. |
| P840001/S445 | 10/23/2019 | S - Special CBE | RESTORE, ITREL, SYNERGY, AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULAITON LEADS | MEDTRONIC NEUROMODULATION | Approval for labeling changes to update existing Notes to Cautions and minor editorial changes for clarification and cross-therapy alignment purposes to the labeling for the; Spinal Cord Stimulation (SCS) Leads 1x8 Family, Injex Anchor Accessory Kits, Intellis Implantable Neurostimulation System for SCS, and SCS Screening Trial Leads. |
| P850035/S054 | 10/24/2019 | Y - 135 Review Tra | EBI SPF IMPLANTABLE SPINAL FUSION STIMULATOR | EBI, LLC | Approval to qualify and place into service an upgraded and redesigned Reverse Osmosis, Deionized (RO/DI) Water System along with its ancillary equipment and components at Zimmer Biomets, EBI Patient Care, Guaynabo, Puerto Rico Manufacturing and Distribution Facility. |
| P850068/S013 | 10/10/2019 | R - Real-Time Proc | SILSOFT (ELASTOFILCON A) CONTACT LENSES | BAUSCH & LOMB, INC. | Approval to remove the prismatic error test method and acceptance criteria from the finished product specifications. |
| P850079/S081 | 10/25/2019 | Y - 135 Review Tra | HYDRASOFT (METHAFILCON B) CONTACT LENS | COOPERVISION, INC. | Approval for the use of autoclave Getinge C to provide back up autoclave capacity for lathing produced products in the MTO (Made to Order) Business Unit at the CooperVision Manufacturing, Ltd. facility in Hamble, United Kingdom. |
| P860004/S330 | 10/16/2019 | Y - 135 Review Tra | MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM | MEDTRONIC INC. | Approval for the manufacturing change of the bi-wing anchor from transfer molding technology to liquid injection molding technology. |
| P860004/S336 | 10/08/2019 | Y - 135 Review Tra | SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS | MEDTRONIC INC. | Approval for manufacturing changes and final quality control inspection methods to a device component of the SynchroMed II Infusion System, Ascenda Intrathecal Catheters. |
| P880086/S299 | 10/18/2019 | N - Normal 180 Day | ACCENT, IDENTITY, | ST. JUDE | Approval for an alternate pre-molded header and a sterile barrier inner package tray |

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| P890003/S418 | 10/01/2019 | R - Real-Time Proc | SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071 | MEDTRONIC, INC. | Approval for the Model 5242 Integrated Diagnostics Data Calculation Module to enable alert notifications. |
| P910077/S173 | 10/18/2019 | R - Real-Time Proc | VENTAK(R) PRX (TM) MODEL 1700,1705 PULSE GENERATOR | BOSTON SCIENTIFIC | Approval to modify the Model 3300 LATITUDE Programming System software components to update the Brady device application code base, add support for 4G cellular communications, and add an integrated Heart Connect application. |
| P920046/S011 | 10/09/2019 | O - Normal 180 Day | FILSHIE CLIP (MARK VI) SYSTEM | FEMCARE LTD. | Approval for a manufacturing site change for the Filshie Clip System Classic Applicator. |
| P950037/S204 | 10/04/2019 | R - Real-Time Proc | DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS | BIOTRONIK, INC. | Approval for programmer software version 1902.U. |
| P960013/S108 | 10/25/2019 | Y - 135 Review Tra | TENDRIL ST/STS STEROID ELUTING CARDIAC LEADS | ST JUDE MEDICAL | Approval to update the in vitro elution methods. |
| P960040/S441 | 10/18/2019 | R - Real-Time Proc | VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM | BOSTON SCIENTIFIC | Approval for modifying the Model 3300 LATITUDE Programming System software components to update the Brady device application code base, add support for 4G cellular communications, and add an integrated Heart Connect application. |
| P970004/S300 | 10/10/2019 | S - Special CBE | INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM | MEDTRONIC NEUROMODULATION | Approval to modify the Verify External Neurostimulator User Manual by 1) adding a warning regarding making connections outside the sterile field; and 2) adding a caution regarding battery depletion and replacement. |
| P980006/S029 | 10/10/2019 | R - Real-Time Proc | PURE VISION VISIBILITY TINTED CONTACT LENS FOR EXTENDED WEAR | BAUSCH & LOMB, INC. | Approval to remove the prismatic error test method and acceptance criteria from the finished product specifications. |
| P980023/S094 | 10/04/2019 | R - Real-Time Proc | PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM | BIOTRONIK, INC. | Approval for programmer software version PSW 1902.U. |
| P980035/S601 | 10/01/2019 | O - Normal 180 Day | MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE | MEDTRONIC INC. | Approval for labeling updates. |
| P980040/S098 | 10/01/2019 | N - Normal 180 Day | SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS | JOHNSON & JOHNSON SURGICAL VISION, INC. | Approval for an additional packaging configuration for TECNIS®, TECNIS® OptiBlue, TECNIS® Multifocal, TECNIS® Toric, TECNIS® Symfony and TECNIS® Symfony Toric one-piece IOLs into the new Simplicity Delivery System. |

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| P980040/S103 | 10/23/2019 | N - Normal 180 Day | SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS | JOHNSON & JOHNSON SURGICAL VISION, INC. | Approval for modification of the manufacturing resulting in squared and frosted haptics. |
| P990004/S036 | 10/30/2019 | S - Special CBE | SURGIFOAM ABSORBABLE GELATIN SPONGE, U.S.P. | FERROSAN MEDICAL DEVICES A/S | Approval for an update to the labeling within the Adverse Events section to strengthen information on adverse reactions related to unapproved uses for catheter embolization. |
| P000009/S081 | 10/04/2019 | R - Real-Time Proc | PHYLAX AV ICD SYSTEM | BIOTRONIK, INC. | Approval for programmer software version PSW 1902.U. |
| P000025/S113 | 10/15/2019 | O - Normal 180 Day | COMBI 40+ COCHLEAR IMPLANT SYSTEM | MED-EL CORP. | Approval of the Single-Sided Deafness and Asymmetric Hearing Loss Post-Approval Study protocol. |
| P010012/S508 | 10/18/2019 | R - Real-Time Proc | CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL | BOSTON SCIENTIFIC CORP. | Approval for modifying the Model 3300 LATITUDE Programming System software components to update the Brady device application code base, add support for 4G cellular communications, and add an integrated Heart Connect application. |
| P010030/S124 | 10/11/2019 | R - Real-Time Proc | LIFEVEST WEARABLE DEFIBRILLATOR | ZOLL MANUFACTURING CORPORATION | Approval for an alternate Velcro Loop Fastener on the LifeVest Wearable Defibrillator. |
| P020004/S164 | 10/02/2019 | Y - 135 Review Tra | EXCLUDER BIFURCATED ENDOPROSTHESIS | W.L. GORE & ASSOCIATES,INC | Approval to implement changes to the divisional bacterial endotoxin test parameters using the Limulus Amebocyte Lysate test methodology. |
| P020050/S033 | 10/03/2019 | R - Real-Time Proc | WAVELIGHT ALLEGRETTO WAVE EXCIMER LASER SYSTEM | ALCON LABORATORIES, INC. | Approval for a minor design change (software bugfix) to the WaveLight® EX500 Laser System and the associated WaveNet Planning Software (WPS). |
| P030005/S188 | 10/18/2019 | R - Real-Time Proc | CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE | GUIDANT CORP. | Approval for modifying the Model 3300 LATITUDE Programming System software components to update the Brady device application code base, add support for 4G cellular communications, and add an integrated Heart Connect application. |
| P030008/S029 | 10/03/2019 | R - Real-Time Proc | WAVELIGHT ALLEGRETTO WAVE EXCIMER LASER SYSTEM | ALCON LABORATORIES, INC. | Approval for a minor design change (software bugfix) to the WaveLight® EX500 Laser System and the associated WaveNet Planning Software (WPS). |
| P030017/S328 | 10/20/2019 | R - Real-Time Proc | PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM | BOSTON SCIENTIFIC CORP. | Approval for minor design changes to the IPG Header in the Precision Spectra, Spectra WaveWriter, Precision Novi, Precision Montage and Precision Montage MRI Spinal Cord Stimulator (SCS) Systems. |

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| P040002/S062 | 10/08/2019 | R - Real-Time Proc | ENDOLOGIX POWERLINK SYSTEM | ENDOLOGIX, INC. | Approval for a shelf-life extension for the AFX2 device system. |
| P040024/S116 | 10/08/2019 | R - Real-Time Proc | RESTYLANE INJECTABLE GEL | Q-MED AB | Approval for reclassification of Impurity C in Lidocaine (HCl) of RESTYLANE Injectable Gels from a Specified Unidentified Impurity to an Unspecified Unidentified Impurity. |
| P040027/S072 | 10/02/2019 | Y - 135 Review Tra | GORE VIATORR TIPS | W. L. GORE & ASSOCIATES, INC. | Approval to implement changes to the divisional bacterial endotoxin test parameters using the Limulus Amebocyte Lysate test methodology. |
| P040029/S009 | 10/24/2019 | N - Normal 180 Day | EUCLID SYSTEMS ORTHOKERATOLOGY (TISILFOCON A) CONTACT LENSES FOR OVERNIGHT WEAR | EUCLID SYSTEMS CORPORATION | Approval for the addition of an alternate lens blank supplier, with a change to the contact angle specification, for the manufacture of the Euclid Systems Orthokeratology (tisilfocon A) Contact Lenses for Overnight Wear. |
| P040037/S130 | 10/02/2019 | Y - 135 Review Tra | VIABAHN ENDOPROSTHESIS | W.L. GORE & ASSOCIATES,INC | Approval to implement changes to the divisional bacterial endotoxin test parameters using the Limulus Amebocyte Lysate test methodology. |
| P040037/S133 | 10/15/2019 | R - Real-Time Proc | GORE VIABAHN ENDOPROSTHESIS | W.L. GORE & ASSOCIATES,INC | Approval a modification to a tolerance value within the device design specification |
| P040043/S110 | 10/02/2019 | Y - 135 Review Tra | GORE TAG THORACIC ENDOPROSTHESIS | W. L. GORE & ASSOCIATES, INC. | Approval to implement changes to the divisional bacterial endotoxin test parameters using the Limulus Amebocyte Lysate test methodology. |
| P050006/S075 | 10/02/2019 | Y - 135 Review Tra | GORE HELEX SEPTAL OCCLUDER | W.L. GORE & ASSOCIATES,INC | Approval to implement changes to the divisional bacterial endotoxin test parameters using the Limulus Amebocyte Lysate test methodology. |
| P050023/S134 | 10/04/2019 | R - Real-Time Proc | TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD | BIOTRONIK, INC. | Approval for programmer software version PSW 1902.U. |
| P050050/S012 | 10/21/2019 | R - Real-Time Proc | SCANDINAVIAN TOTAL ANKLE REPLACEMENT SYSTEM (S.T.A.R.ANKLE) | STRYKER CORPORATION | Approval for a change in sealing to the packaging for the existing STAR implants. |
| P070008/S106 | 10/04/2019 | R - Real-Time Proc | STRATOS LV CRT-P AND STRATOS LV-T CRT-P, COROX OTW BP LEAD AND COROX OTW-S BP LEAD | BIOTRONIK, INC. | Approval for programmer software version PSW 1902.U. |
| P070008/S107 | 10/04/2019 | O - Normal 180 Day | COROX OTW BP | BIOTRONIK, INC. | Approval for labeling updates to the clinical study summary for the post approval study. |
| P070026/S061 | 10/27/2019 | O - Normal 180 Day | CERAMAX CERAMIC HIP SYSTEM | DEPUY ORTHOPAEDICS, INC. | Approval for a manufacturing site located at for a manufacturing site located at Synergy Health Westport Ltd., Lodge Road, Westport Mayo, Ireland for the for terminal gamma irradiation sterilization of the Summit Hip Stems |

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| P070026/S062 | 10/27/2019 | O - Normal 180 Day | CERAMAX CERAMIC HIP SYSTEM | DEPUY ORTHOPAEDICS, INC. | Approval for a manufacturing site located at Synergy Health Reading Ltd. Marcus Close Thilehurst, Reading, Bershire, UK for the for terminal gamma irradiation sterilization of the Summit Hip Stems. |
| P080003/S008 | 10/24/2019 | N - Normal 180 Day | SELENIA DIMENSIONS FULL FIELD DIGITAL MAMMOGRAPHY SYSTEM | HOLOGIC, INC. | Approval for software option 3DQuoromTM technology, which generates thicker 6 mm slices (also referred as SmartSlices or slabs) and change to the indications for use statement as a result of this update. |
| P080004/S023 | 10/25/2019 | Y - 135 Review Tra | HOYA ISPHERIC MODEL YA-60BB INTRAOCULAR LENS | HOYA SURGICAL OPTICS, INC. | Approval for an alternate supplier for the PSC24 preset tips and to use a new mold. |
| P080011/S087 | 10/25/2019 | Y - 135 Review Tra | BIOFINITY (COMFILCON A) | COOPERVISION, INC. | Approval for the use of autoclave Getinge C to provide back up autoclave capacity for lathing produced products in the MTO (Made to Order) Business Unit at the CooperVision Manufacturing, Ltd. facility in Hamble, United Kingdom. |
| P080012/S062 | 10/22/2019 | R - Real-Time Proc | PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM, PUMP FIRMWARE PATCH 0.28 | FLOWONIX MEDICAL, INC. | Approval for introducing Software Version 0.28 for the Prometra II Pumps (REF 13827, 20 mL Pump and Ref 16827, 40 mL Pump). |
| P080020/S035 | 10/30/2019 | R - Real-Time Proc | GEL-ONE | SEIKAGAKU CORP. | Approval for a change to the design of the Finger Grip of the Gel-One container closure system. |
| P080025/S195 | 10/10/2019 | S - Special CBE | INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM | MEDTRONIC NEUROMODULATION | Approval to modify the Verify External Neurostimulator User Manual by 1) adding a warning regarding making connections outside the sterile field; and 2) adding a caution regarding battery depletion and replacement. |
| P100047/S139 | 10/21/2019 | O - Normal 180 Day | HEARTWARE HVAD SYSTEM | MEDTRONIC | Approval for revisions to the Instructions for Use to include findings from the Bridge-to-Transplant PAS03 study and data from longer term follow-up of ENDURANCE Supplemental study subjects. |
| P110013/S095 | 10/17/2019 | Y - 135 Review Tra | RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM | MEDTRONIC VASCULAR | Approval to automated the stent pre-clean manufacturing processes for the Resolute Integrity and Resolute Onyx Drug Eluting Stents. |
| P110013/S096 | 10/22/2019 | Y - 135 Review Tra | RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM | MEDTRONIC VASCULAR | Approval for implementing the option of a reusable polypropylene sterilization tote for the transportation of the product to the contract sterilization supplier, during sterilization and return from the contract sterilization supplier. |
| P110013/S098 | 10/17/2019 | R - Real-Time Proc | RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM | MEDTRONIC VASCULAR | Approval for introducing changes to the material of the desiccant (molecular sieve material) added to the product packaging post sterilization of the Resolute Integrity product. |

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| P110016/S064 | 10/09/2019 | S - Special CBE | FLEXABILITY ABLATION CATHETER AND FLEXABILITY ABLATION CATHETER, SENSOR ENABLED | ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL) | Approval for the addition of a warning statement to the instructions for use regarding atrioesophageal fistulas. |
| P110033/S040 | 10/22/2019 | N - Normal 180 Day | JUVEDERM VOLUMA XC | ALLERGAN | Approval for the use of an additional supplier of hyaluronic acid raw material in the manufacture of Juvéderm Voluma XC, Vollure XC and Volbella XC. |
| P130005/S027 | 10/09/2019 | N - Normal 180 Day | DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM | CARDIOVASCULAR SYSTEMS, INC. | Approval for changes to the Orbital Atherectomy Device Component for the Coronary Classic Crown Diamondback 360 Coronary OAS. |
| P130006/S069 | 10/02/2019 | Y - 135 Review Tra | GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE | W.L. GORE & ASSOCIATES,INC | Approval to implement changes to the divisional bacterial endotoxin test parameters using the Limulus Amebocyte Lysate test methodology. |
| P130006/S072 | 10/15/2019 | R - Real-Time Proc | GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE | W.L. GORE & ASSOCIATES,INC | Approval for a modification to a tolerance value within the device design specification. |
| P130013/S033 | 10/18/2019 | R - Real-Time Proc | WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY | BOSTON SCIENTIFIC CORP. | Approval to update the clinical data in the directions for use with the currently available data and make minor changes to the language in the directions for use and patient brochure. |
| P130022/S021 | 10/15/2019 | N - Normal 180 Day | NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM | NEVRO CORPORATION | Approval for changes made to MRI Guidelines Manual for the Senza System by adding a new MRI claim for IPG1000/1500/2000. |
| P130022/S026 | 10/25/2019 | R - Real-Time Proc | SENZA SPINAL CORD STIMULATION (SCS) SYSTEM | NEVRO CORPORATION | Approval to make changes to the software for the Clinical Programmer, model CLPG2000/ CLPG2500 upgrading the software from version 1.7 to 2.0. |
| P130026/S051 | 10/09/2019 | S - Special CBE | TACTICATH CONTACT FORCE ABLATION CATHETER, SENSOR ENABLED | ST. JUDE MEDICAL | Approval for the addition of a warning statement to the instructions for use regarding atrioesophageal fistulas. |
| P130026/S053 | 10/22/2019 | S - Special CBE | TACTICATH QUARTZ CATHETER CONTACT FORCE ABLATION CATHETER | ST. JUDE MEDICAL | Approval for manufacturing modifications to sulfuric acid immersion times for the TactiCath Quartz Contact Force Ablation Catheter |
| P140019/S003 | 10/11/2019 | O - Normal 180 Day | I-FACTOR PEPTIDE ENHANCED BONE GRAFT | CERAPEDICS, LLC | Approval for an updated package insert that incorporates the 24-month follow-up data from all subjects enrolled in the original clinical study. |

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| P140032/S036 | 10/02/2019 | R - Real-Time Proc | IMPLANTABLE SYSTEM FOR REMODULIN | MEDTRONIC, INC. | Approval for a shelf life extension of the Model 845PAH Catheter Patency Kit shelf life from 24 months to 48 months. |
| P140033/S031 | 10/18/2019 | N - Normal 180 Day | ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE | ST. JUDE MEDICAL, INC. | Approval for an alternate pre-molded header and a sterile barrier inner package tray modification. |
| P150012/S081 | 10/18/2019 | R - Real-Time Proc | IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD | BOSTONSCIENTIFIC | Approval for modifying the Model 3300 LATITUDE Programming System software components to update the Brady device application code base, add support for 4G cellular communications, and add an integrated Heart Connect application. |
| P150021/S039 | 10/07/2019 | Y - 135 Review Tra | FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM | ABBOTT DIABETES CARE INC. | Approval for an alternate supplier for the PCB of the reader component of the FreeStyle Libre, FreeStyle Libre 14-day, and FreeStyle Libre Pro Flash Continuous Glucose Monitoring Systems. |
| P150031/S021 | 10/20/2019 | R - Real-Time Proc | VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM | BOSTON SCIENTIFIC CORP. | Approval for minor design changes to the IPG Header in the Vercise PC and Vercise Gevia Deep Brain Stimulation (DBS) systems. |
| P150034/S008 | 10/09/2019 | O - Normal 180 Day | RAINDROP NEAR VISION INLAY | RVO 2.0, INC. (D.B.A. OPTICS MEDICAL) | Approval to temporarily suspend the New Enrollment PAS due to not distributing or marketing of the device. |
| P160001/S033 | 10/18/2019 | O - Normal 180 Day | OBALON BALLOON SYSTEM | OBALON THERAPEUTICS, INC. | Approval for the revised protocol for the post-approval study (PAS) protocol. |
| P160004/S027 | 10/02/2019 | Y - 135 Review Tra | GORE TIGRIS VASCULAR STENT | W. L. GORE & ASSOCIATES, INC. | Approval to implement changes to the divisional bacterial endotoxin test parameters using the Limulus Amebocyte Lysate test methodology. |
| P160014/S011 | 10/15/2019 | R - Real-Time Proc | COBRA PZF NANOCOATED CORONARY STENT SYSTEM | CELONOVA BIOSCIENCES, INC. | Approval for changes to the polycarbonate resin used in the luer component of the delivery system. |
| P160021/S020 | 10/02/2019 | Y - 135 Review Tra | GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS | W. L. GORE & ASSOCIATES, INC. | Approval to implement changes to the divisional bacterial endotoxin test parameters using the Limulus Amebocyte Lysate test methodology. |

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| P160026/S010 | 10/25/2019 | N - Normal 180 Day | LIFEPAK 1000 DEFIBRILLATOR, LIFEPAK 20 DEFIBRILLATOR/ MONITOR, LIFEPAK 20E DEFIBRILLATOR/ MONITOR, LIFEPAK 15 MONITOR/DEFIBRILLATOR, LIFEPAK 12 DEFIBRILLATOR/ MONITOR | PHYSIO-CONTROL. INC. | Approval for minor design changes to several Printed Circuit Board Assemblies (PCBA) and a printer assembly component. |
| P160030/S030 | 10/07/2019 | Y - 135 Review Tra | FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM | ABBOTT DIABETES CARE INC. | Approval for an alternate supplier for the PCB of the reader component of the FreeStyle Libre, FreeStyle Libre 14-day, and FreeStyle Libre Pro Flash Continuous Glucose Monitoring Systems. |
| P160031/S002 | 10/25/2019 | N - Normal 180 Day | ASPIRE CRISTALLE DIGITAL BREAST TOMOSYNTHESIS OPTION | FUJIFILM MEDICAL SYSTEMS U.S.A., INC. | Approval for changing the image processing in DBT reconstruction to Iterative Super-Resolution Reconstruction (ISR) and applying new image processing, Dynamic Visualization II for mammography (DVIIm), to the DBT and the FFDM images. |
| P160043/S024 | 10/17/2019 | Y - 135 Review Tra | RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM | MEDTRONIC VASCULAR | Approval to automated the stent pre-clean manufacturing processes for the Resolute Integrity and Resolute Onyx Drug Eluting Stents. |
| P160043/S025 | 10/22/2019 | Y - 135 Review Tra | RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM | MEDTRONIC VASCULAR | Approval for implementing the option of a reusable polypropylene sterilization tote for the transportation of the product to the contract sterilization supplier, during sterilization and return from the contract sterilization supplier. |
| P160048/S014 | 10/29/2019 | O - Normal 180 Day | EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM | SENSEONICS, INCORPORATED | Approval for a manufacturing site located at Steris Isomedix Services, 3459 South Clinton Ave., South Plainfield, NJ 07080 for use as a sterilization site for the sensor insertion tools of the Eversense Continuous Glucose Monitoring System. |
| P160049/S004 | 10/11/2019 | N - Normal 180 Day | STELLAREX 0.035 OTW DRUG-COATED ANGIOPLASTY BALLOON | THE SPECTRANETICS CORP. | Approval for 150 mm and 200 mm balloon lengths for the Stellarex 0.035 OTW Drug-coated Angioplasty Balloon. |
| P160052/S001 | 10/11/2019 | O - Normal 180 Day | PARTOSURE TEST | QIAGEN INC | Approval of the revised protocol for the post-approval study (PAS) protocol |
| P170002/S005 | 10/29/2019 | R - Real-Time Proc | RHA 2, RHA 3, RHA 4 | TEOXANE S.A. | Approval for extension of products¿ shelf-life from 17 months to 36 months. |
| P170003/S007 | 10/04/2019 | O - Normal 180 Day | LUTONIX® 035 DRUG COATED BALLOON PTA CATHETER, MODEL 9010 | LUTONIX | Approval for updates to the Instructions for Use for the Lutonix 035 Model 9010 to reflect the 24-month data from the AV IDE Cohort Post-Approval Study. |
| P170003/S012 | 10/02/2019 | S - Special CBE | LUTONIX 035 DRUG COATED BALLOON PTA CATHETER | LUTONIX | Approval for updates to the device labeling to communicate safety information regarding paclitaxel-coated devices for treatment of femoropopliteal arterial disease. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P170018/S004 | 10/23/2019 | R - Real-Time Proc | LIFEPAK® CR2 DEFIBRILLATOR | PHYSIO-CONTROL, INC | Approval for a labeling change to support a different configuration of the LIFEPAK CR2 defibrillator. |
| P170019/S007 | 10/11/2019 | R - Real-Time Proc | FOUNDATIONONE CDX | FOUNDATION MEDICINE, INC. | Approval for implementation of FoundationOne CDx (F1CDx) QSR pipeline v3.2.0. |
| P170032/S002 | 10/01/2019 | O - Normal 180 Day | WOVEN ENDOBRIDGE (WEB) ANEURYSM EMBOLIZATION SYSTEM | SEQUENT MEDICAL, INC | Approval for a manufacturing site located at MicroVention Inc. 35 Enterprise, Aliso Viejo, California, for the Woven EndoBridge (WEB) Aneurysm Embolization System. |
| P170034/S001 | 10/08/2019 | O - Normal 180 Day | HYDRUS MICROSTENT | IVANTIS, INC. | Approval of the revised protocol for the post-approval study (PAS) protocol. |
| P170035/S005 | 10/10/2019 | R - Real-Time Proc | BAUSCH + LOMB ULTRA (SAMFILCON A) CONTACT LENSES | BAUSCH AND LOMB, INC. | Approval to remove the prismatic error test method and acceptance criteria from the finished product specifications. |
| P170039/S002 | 10/03/2019 | O - Normal 180 Day | CUSTOMFLEX ARTIFICIAL IRIS | CLINICAL RESEARCH CONSULTANTS, INC. | Approval of the protocol for the post-approval study (PAS) protocol. |
| P170042/S003 | 10/31/2019 | O - Normal 180 Day | COVERA¿ VASCULAR COVERED STENT | C.R. BARD, INC | Approval of the protocols for the post-approval studies (PAS) protocol. |
| P180001/S001 | 10/31/2019 | O - Normal 180 Day | ZENITH DISSECTION ENDOVASCULAR SYSTEM | WILLIAM COOK EUROPE APS | Approval of the charter for the surveillance project. |
| P180002/S009 | 10/02/2019 | O - Normal 180 Day | ZEPHYR VALVE REGISTRY (ZEVR) | PULMONX CORPORATION | Approval for the enrollment of at least 20 patients with the new sized Zephyr valve (5.5 LP EBV). |
| P180014/S001 | 10/29/2019 | O - Normal 180 Day | XPS¿ WITH STEEN SOLUTION¿ PERFUSATE | XVIVO PERFUSION, INC. | Approval of the protocol for the post-approval study (PAS) protocol. |
| P180029/S008 | 10/30/2019 | R - Real-Time Proc | LOTUS EDGE VALVE SYSTEM | BOSTON SCIENTIFIC CORPORATION | Approval for replacement of the current luer-activated valve component on the LOTUS Edge delivery system. |
| P180036/S003 | 10/23/2019 | N - Normal 180 Day | OPTIMIZER SMART SYSTEM | IMPULSE DYNAMICS (USA), INC. | Approval for the 2-lead OPTIMIZER Smart Cardiac Contractility Modulation System. |

**Total: 100**

## 30-Day Notice

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| N12159/S064 | 10/08/2019 | X - 30-Day Notice | SURGICEL ORIGINAL ABSORBABLE HEMOSTAT | ETHICON, INC. | Mechanical and system upgrades on the automated Foiling Line G11719 for the inspection of hermetically sealed SURGICEL original foil pouches to add cameras to image the bottom of the foil pouch and a modification of the vision conveyor to accommodate the added cameras. |
| N12159/S065 | 10/30/2019 | X - 30-Day Notice | SURGICEL POWDER | ETHICON, INC. | Change in the sampling plan utilized in the manufacturing process of SURGICEL Powder. |
| N970003/S244 | 10/29/2019 | X - 30-Day Notice | NON-MRI PACEMAKERS | BOSTON SCIENTIFIC CORP. | Revert to previously approved controlled environment area specifications for feedthrough component and sputter coating manufacturing lines, eliminate use of booties, and change the hand sanitization method. |
| P840001/S444 | 10/13/2019 | X - 30-Day Notice | ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS | MEDTRONIC NEUROMODULATION | Add a new qualified laboratory for bioburden and endotoxin testing and lower the endotoxin testing limit for two components. |
| P840001/S446 | 10/24/2019 | X - 30-Day Notice | RESTORE, ITREL, SYNERGY, AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS | MEDTRONIC NEUROMODULATION | Update several manufacturing process changes for the XT097 and XT116 TAZ Series tantalum capacitors. |
| P850007/S043 | 10/08/2019 | X - 30-Day Notice | PHYSIOSTIM AND SPINALSTIM | ORTHOFIX, INC. | Modify the manufacturing process for sewing the garment assembly for the Orthofix SpinalStim Model 5212 and modify the manufacturing process to cut, split, and strip the ribbon cable for the Orthofix CervicalStim Model 5505 and Orthofix PhysioStim Models 53XX. |
| P860004/S342 | 10/01/2019 | X - 30-Day Notice | SYNCHROMED (SM) INFUSION SYSTEM | MEDTRONIC INC. | Alternate receiving inspection site to perform incoming inspection activities of the SynchroMed II pump tubing for tensile strength and elongation. |
| P860004/S343 | 10/13/2019 | X - 30-Day Notice | SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS | MEDTRONIC INC. | Add a new qualified laboratory for bioburden and endotoxin testing and lower the endotoxin testing limit for two components. |
| P860004/S344 | 10/24/2019 | X - 30-Day Notice | SYNCHROMED INFUSION | MEDTRONIC | Update several manufacturing process changes for the XT097 and XT116 TAZ Series |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P860057/S192 | 10/28/2019 | X - 30-Day Notice | PERIMOUNT BIOPROSTHESIS, PERIMOUNT MAGNA AORTIC BIOPROSTHESIS, PERIMOUNT MAGNA EASE BIOPROSTHESIS, AND PERIMOUNT PLUS BIOPROSTHESIS | EDWARDS LIFESCIENCES, LLC. | Modifications to the final assembly cleanroom and the associated gowning room. |
| P910001/S110 | 10/21/2019 | X - 30-Day Notice | CVX-3000 EXCIMER LASERT SYSTEM AND ELCA CORONARY ATHERECTOMY CATHETERS | SPECTRANETICS CORP. | Implement additional fiber production equipment. |
| P910023/S419 | 10/15/2019 | X - 30-Day Notice | ELLIPSE, FORTIFY, FORTIFY ASSURA AND QUADRA ASSURA MP ICD | ST. JUDE MEDICAL | Modify the temperature range utilized for the temperature cycling of hybrid assemblies with organic substrates. |
| P910023/S420 | 10/18/2019 | X - 30-Day Notice | ELLIPSE HYBRID | ST. JUDE MEDICAL | Alternate supplier for a telemetry coil component used on the Ellipse ICD hybrid. |
| P930014/S128 | 10/10/2019 | X - 30-Day Notice | ACRYSOF POSTERIOR CHAMBER INTRAOCULAR LENS | ALCON RESEARCH, LTD. | Implement new welding operating parameters with a modified welding method. |
| P930031/S066 | 10/07/2019 | X - 30-Day Notice | WALLSTENT ENDOPROSTHEIS TIPS WITH UNISTEP PLUS | BOSTON SCIENTIFIC CORP. | Expansion of the manufacturing clean room. |
| P940019/S057 | 10/07/2019 | X - 30-Day Notice | WALLSTENT RP ENDOPROSTHESIS ILIAC | BOSTON SCIENTIFIC SCIMED, INC. | Expansion of the manufacturing clean room. |
| P950022/S128 | 10/24/2019 | X - 30-Day Notice | DURATA AND OPTISURE HV ACTIVE STEROID ELUTING CARDIAC LEADS | ST. JUDE MEDICAL, INC. | Update the in vitro elution methods for high voltage active fixation leads. |

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|---|---|---|---|---|---|
| P950037/S205 | 10/18/2019 | X - 30-Day Notice | PULSE GENERATOR, PERMANENT IMPLANTABLE, PULSE-GERERATOR, PACEMAKER EXTERNAL, ADAPTER AND DRUG ELUTING PERMANENT RIGHT VENTRICULAR/RIGHT ATRIAL PACEMAKER ELECTRODES, STYLET, CATHETER AND BLIND PLUG ACCESSORY | BIOTRONIK, INC. | Replacement of the sterilization chamber corpus. |
| P960009/S359 | 10/13/2019 | X - 30-Day Notice | ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM | MEDTRONIC INC. | Add a new qualified laboratory for bioburden and endotoxin testing and lower the endotoxin testing limit for two components. |
| P960009/S360 | 10/24/2019 | X - 30-Day Notice | ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM | MEDTRONIC INC. | Update several manufacturing process changes for the XT097 and XT116 TAZ Series tantalum capacitors. |
| P960013/S109 | 10/24/2019 | X - 30-Day Notice | TENDRIL, OPTISENSE | ST JUDE MEDICAL | Adjust the sterilization load configuration at the Abbott Penang Malaysia manufacturing facility. |
| P960016/S080 | 10/25/2019 | X - 30-Day Notice | LIVEWIRE TC ABLATION, LIVEWIRE TC CABLES, SAFIRE ABLATION CATHETER AND SAFIRE CABLES | ST. JUDE MEDICAL | Add an additional sterilization chamber at Midwest Sterilization Corporation in Jackson, Missouri. |
| P960030/S067 | 10/24/2019 | X - 30-Day Notice | ISOFLEX | ST. JUDE MEDICAL | Adjust the sterilization load configuration at the Abbott Penang Malaysia manufacturing facility. |
| P960040/S443 | 10/29/2019 | X - 30-Day Notice | IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) | BOSTON SCIENTIFIC | Revert to previously approved controlled environment area specifications for feedthrough component and sputter coating manufacturing lines, eliminate use of booties, and change the hand sanitization method. |
| P960042/S067 | 10/07/2019 | X - 30-Day Notice | SLS/GLIDELIGHT | SPECTRANETICS CORP. | Change in supplier of an extruder outer jacket tubing component. |
| P960042/S068 | 10/21/2019 | X - 30-Day Notice | SPECTRANETICS LASER SHEATHS SLS | SPECTRANETICS CORP. | Implement additional fiber production equipment. |
| P960058/S143 | 10/25/2019 | X - 30-Day Notice | HIRESOLUTION BIONIC EAR SYSTEM | ADVANCED BIONICS | Change of manufacturing location for the RF Coil Manufacturing Process. |
| P970003/S227 | 10/24/2019 | X - 30-Day Notice | VNS THERAPY SYSTEM | LIVANOVA USA, INC. | Changes to the Surface Mount Technology Process for different generator models of the VNS Therapy Systems. |

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|---|---|---|---|---|---|
| P970004/S301 | 10/13/2019 | X - 30-Day Notice | INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS URINARY) | MEDTRONIC NEUROMODULATION | Add a new qualified laboratory for bioburden and endotoxin testing and lower the endotoxin testing limit for two components. |
| P970051/S192 | 10/08/2019 | X - 30-Day Notice | NUCLEUS 24 COCHLEAR IMPLANT SYSTEM (EA22 STIFFENER) | COCHLEAR AMERICAS | Proposes the addition of a secondary supplier for the EA22 Stiffener. |
| P980016/S719 | 10/04/2019 | X - 30-Day Notice | EVERA MRI DF1 ICD, EVERA MRI ICD, EVERA S DR ICD, EVERA S VR ICD, EVERA XT DR/VR ICD, MIRRO MRI DR/VR ICD, PRIMO MRI DR/VR ICD, VISIA AF MRI DF1/VR ICD AND VISIA AF VR ICD | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Implement new leak test stations and fixtures to be used for the CAPLEAKTEST process. |
| P980023/S095 | 10/18/2019 | X - 30-Day Notice | PERMANENT DEFIBRILLATOR ELECTRODES, ACCESSORIES TO PERMANENT PACEMAKER ELECTRODE AND STYLEY CATHETER | BIOTRONIK, INC. | Replacement of the sterilization chamber corpus. |
| P980033/S056 | 10/07/2019 | X - 30-Day Notice | WALLSTENT VENOUS RP & ENDOPROSTHESIS WITH UNISTEP PLUS | BOSTON SCIENTIFIC CORPORATION | Expansion of the manufacturing clean room. |
| P980040/S108 | 10/15/2019 | X - 30-Day Notice | SENSAR 1-PIECE IOL, TECNIS 1-PIECE IOL, OPTIBLUE 1-PIECE IOL, ITEC PRELOADED DELIVERY SYSTEM, MULTIFOCAL 1-PIECE IOL, MULTIFOCAL 1-PIECE IOL, AND TORIC 1-PIECE IOL, TECNIS SYMFONY EXTENDED RANGE OF VISION, SYMFONY TORIC EXTENDED RANGE OF VISION OF IOL, AND SENSAR 3-PIECE MONOFOCAL | JOHNSON & JOHNSON SURGICAL VISION, INC. | Consolidation of the cosmetic inspection step of the one-piece and three-piece intraocular lenses. |

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|---|---|---|---|---|---|
| P990080/S051 | 10/15/2019 | X - 30-Day Notice | TECNIS 3-PIECE ACRYLIC MONOFOCAL | JOHNSON & JOHNSON SURGICAL VISION, INC. | Consolidation of the cosmetic inspection step of the one-piece and three-piece intraocular lenses. |
| P000006/S053 | 10/25/2019 | X - 30-Day Notice | TITAN INFLATABLE PENILE PROSTHESIS (IPP) | COLOPLAST CORP. | Change to add an additional laser marker to the manufacturing process. |
| P000039/S068 | 10/25/2019 | X - 30-Day Notice | AMPLATZER SEPTAL OCCLUDER AND AMPLATZER MULTI-FENESTRATED SEPTAL OCCLUDER | ABBOTT MEDICAL | Add an additional sterilization chamber at Midwest Sterilization Corporation in Jackson, Missouri. |
| P010012/S510 | 10/29/2019 | X - 30-Day Notice | CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR (CRT-D) | BOSTON SCIENTIFIC CORP. | Revert to previously approved controlled environment area specifications for feedthrough component and sputter coating manufacturing lines, eliminate use of booties, and change the hand sanitization method. |
| P010013/S078 | 10/01/2019 | X - 30-Day Notice | NOVASURE IMPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM | HOLOGIC, INC. | Replace a Stoll CMS 340 knitting machine with a Stoll CMS 822 knitting machine. |
| P010014/S094 | 10/09/2019 | X - 30-Day Notice | OXFORD PARTIAL KNEE SYSTEM | BIOMET MANUFACTURING CORP. | Addition of a pneumatic-powered press in the post-casting forming process. |
| P010030/S126 | 10/21/2019 | X - 30-Day Notice | LIFEVEST WEARABLE DEFIBRILLATOR | ZOLL MANUFACTURING CORPORATION | Implement a fixture to screen the fastener used in the LifeVest 4000 Electrode Belt. |
| P010031/S680 | 10/04/2019 | X - 30-Day Notice | AMPLIA MRI CRT-D, AMPLIA MRI QUAD CRT-D,BRAVA CRT-D, BRAVA QUAD CRT-D, CLARIA MRI CRT-D, CLARIA MRI QUAD CRT-D, COMPIA MRI CRT-D, COMPIA MRI QUADCRT-D, VIVA QUAD S, XT CRT-D AND VIVA S/XT CRT-D | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Implement new leak test stations and fixtures to be used for the CAPLEAKTEST process. |
| P020003/S009 | 10/25/2019 | X - 30-Day Notice | TOROSA SALINE FILLED TESTICULAR PROSTHESIS | COLOPLAST CORP. | Change to add an additional laser marker to the manufacturing process. |

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| P020004/S170 | 10/08/2019 | X - 30-Day Notice | GORE EXCLUDER AAA ENDOPROSTHESIS | W.L. GORE & ASSOCIATES,INC | Addition of an Oven Monitoring System to be used on ovens within the manufacturing processes for Excluder and Iliac Branch devices. |
| P020004/S171 | 10/24/2019 | X - 30-Day Notice | GORE EXCLUDER AAA ENDOPROSTHESIS | W.L. GORE & ASSOCIATES,INC | Implementation of performance qualifications and updates to the sampling plan for the GORE EXCLUDER AAA Endoprosthesis and GORE EXCLUDER Iliac Branch Endoprosthesis. |
| P020012/S034 | 10/01/2019 | X - 30-Day Notice | BELLAFILL DERMAL FILLER | SUNEVA MEDICAL, INC. | Implement a change on the Sampling and Monitoring plan for the USP Purified Water and Pure Steam WFI in the Suneva Medical facility at San Diego, California. |
| P020012/S035 | 10/25/2019 | X - 30-Day Notice | BELLAFILL DERMAL FILLER | SUNEVA MEDICAL, INC. | Alternative Quality Control test method for PMMA microspheres. |
| P020024/S058 | 10/25/2019 | X - 30-Day Notice | AMPLATZER DUCT OCCLUDER, AMPLATZER DUCT OCCLUDER II AND AMPLATZER SEPTAL OCCLUDER | ABBOTT MEDICAL | Add an additional sterilization chamber at Midwest Sterilization Corporation in Jackson, Missouri. |
| P020045/S090 | 10/09/2019 | X - 30-Day Notice | FREEZOR CARDIAC CRYOABLATION SYSTEM | MEDTRONIC CRYOCATH LP | Modification of an inspection test specific to check valve (CV6) in the CryoConsole. |
| P030005/S190 | 10/29/2019 | X - 30-Day Notice | CARDIAC RESYNCHRONIZATION THERAPY - PACEMAKER (CRT-P) | GUIDANT CORP. | Revert to previously approved controlled environment area specifications for feedthrough component and sputter coating manufacturing lines, eliminate use of booties, and change the hand sanitization method. |
| P030034/S015 | 10/08/2019 | X - 30-Day Notice | CERVICALSTIM | ORTHOFIX, INC. | Modify the manufacturing process for sewing the garment assembly for the Orthofix SpinalStim Model 5212 and modify the manufacturing process to cut, split, and strip the ribbon cable for the Orthofix CervicalStim Model 5505 and Orthofix PhysioStim Models 53XX. |
| P030049/S013 | 10/25/2019 | X - 30-Day Notice | ADVIA CENTAUR HBSAG | SIEMENS HEALTHCARE DIAGNOSTICS | Implement two additional tiers of standards identical to the approved standard used in manufacturing. |
| P030054/S371 | 10/15/2019 | X - 30-Day Notice | QUADRA ASSURA, UNIFY, UNIFY ASSURA AND UNIFY QUADRA CRT-D | ST. JUDE MEDICAL | Modify the temperature range utilized for the temperature cycling of hybrid assemblies with organic substrates. |
| P040020/S092 | 10/10/2019 | X - 30-Day Notice | ACRYSOF IQ RESTOR POSTERIOR CHAMBER INTRAOCULAR LENSES | ALCON RESEARCH, LTD. | Implement new welding operating parameters with a modified welding method. |
| P040040/S038 | 10/25/2019 | X - 30-Day Notice | AMPLATZER MUSCULAR VSD OCCLUDER | ABBOTT MEDICAL | Add an additional sterilization chamber at Midwest Sterilization Corporation in Jackson, Missouri. |

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| P040043/S113 | 10/31/2019 | X - 30-Day Notice | GORE TAG THORACIC ENDOPROSTHESIS, GORE TAG CONFORMABLE THORACIC STENT GRAFT WITH ACTIVE CONTROL SYSTEM | W. L. GORE & ASSOCIATES, INC. | Use of an alternate coating on mandrels used as manufacturing aids. |
| P040044/S085 | 10/03/2019 | X - 30-Day Notice | MYNXGRIP, MYNX ACE, AND MYNX CONTROL VASCULAR CLOSURE DEVICE (VCD) | ACCESS CLOSURE, INC. | Automate the hub sub-assembly process. |
| P050006/S080 | 10/31/2019 | X - 30-Day Notice | GORE CARDIOFORM ASD OCCLUDER AND SEPTAL OCCLUDER | W.L. GORE & ASSOCIATES,INC | Use of an alternate coating on mandrels used as manufacturing aids. |
| P050023/S136 | 10/18/2019 | X - 30-Day Notice | IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (NON-CRT), DEFIBRILLATOR, IMPLANTABLE, DUAL CHAMBER, DEFIBRILLATOR, AUTOMATIC IMPLANTABLE CARDIOVERTER, WITH CARDIAC RESYNCHRONIZATION (CT-D) AND STYLET, CATHETER | BIOTRONIK, INC. | Replacement of the sterilization chamber corpus. |
| P050028/S079 | 10/10/2019 | X - 30-Day Notice | COBAS TAQMAN HBV TEST FOR USE WITH THE HIGH PURE SYSTEM AND COBAS AMPLIPREP, COBASTAQMAN HBV TEST, V2.0 | ROCHE MOLECULAR SYSTEMS, INC. | Implement an alternate spectrophotometer for in-process QC testing. |
| P050038/S033 | 10/04/2019 | X - 30-Day Notice | ARISTA AH ABSORBABLE HEMOSTAT | C.R. BARD, INC. | Qualification of a new manufacturing equipment related to the drying, milling and sieving processes used to produce Arista AH Absorbable Hemostat. |
| P050047/S073 | 10/15/2019 | X - 30-Day Notice | JUVÉDERM ULTRA, ULTRA XC, ULTRA PLUS, AND ULTRA PLUS XC | ALLERGAN | Implement a change in the manual cleaning procedure for equipment used in the manufacturing of Juvederm injectable gel products in the Pringy I building in France. |

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|---|---|---|---|---|---|
| P060030/S080 | 10/10/2019 | X - 30-Day Notice | COBAS TAQMAN HCV TEST, V2.0, FOR USE WITH THE HIGH PURE SYSTEM AND COBAS AMPLIPREP, COBAS TAQMAN HCV TEST, V2.0 | ROCHE MOLECULAR SYSTEMS, INC. | Implement an alternate spectrophotometer for in-process QC testing. |
| P060037/S062 | 10/24/2019 | X - 30-Day Notice | NEXGEN LPS-FLEX/LPS-MOBILE BEARING KNEE | ZIMMER, INC. | Change in the density range of gamma sterilization from 0.09 to 0.2 g/cm3 to 0.05 to 0.15 g/cm3. The density range is used in the gamma sterilization of NexGen® LPSFlex/LPS-Mobile Bearing Knee manufactured at Zimmer Orthopedics Manufacturing Limited (ZOML) Shannon Ireland facility. |
| P070004/S020 | 10/15/2019 | X - 30-Day Notice | SIENTRA OPUS SILICONE GEL BREAST IMPLANTS | SIENTRA, INC | Addition of an additional snap gauge data input tool used to collect and document shell thickness measurements in manufacturing Sientra OPUS Silicone Gel Breast Implants. |
| P070004/S021 | 10/29/2019 | X - 30-Day Notice | SIENTRA OPUS SILICONE GEL BREAST IMPLANTS | SIENTRA, INC | Standardizing the frequency of filtering and replacing isopropyl alcohol (IPA) in the manufacturing of Sientra® OPUS Silicone Gel Breast Implants. |
| P070004/S022 | 10/29/2019 | X - 30-Day Notice | SIENTRA OPUS SILICONE GEL BREAST IMPLANTS | SIENTRA, INC | Addition of a Variable Frequency Drive (VFD) to the Dipping Hood blower system used in the manufacturing of Sientra OPUS® Silicone Gel Breast Implants. |
| P070008/S108 | 10/18/2019 | X - 30-Day Notice | PULSE GENERATOR, PACEMAKER IMPLANTBLE WITH CARDIAC RESYNCHRONIZATION (CRT-P) AND DRUG ELUTING PERMANENT LEFT VENTRICULAR (LV) PACEMAKER ELECTRODE | BIOTRONIK, INC. | Replacement of the sterilization chamber corpus. |
| P080006/S141 | 10/23/2019 | X - 30-Day Notice | ATTAIN PERFORMA LEAD AND ATTAIN STABILITY QUAD MRI LEAD | MEDTRONIC INC. | Update the preventive maintenance process of the crimping process. |
| P080011/S099 | 10/09/2019 | X - 30-Day Notice | BIOFINITY TORIC | COOPERVISION, INC. | Manufacture of the Biofinity Toric (comfilcon A) Soft (hydrophilic) Contact Lens on Biofinity Line 4 at the facility in Hamble, United Kingdom. |
| P080025/S196 | 10/13/2019 | X - 30-Day Notice | INTERM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS BOWEL) | MEDTRONIC NEUROMODULATION | Add a new qualified laboratory for bioburden and endotoxin testing and lower the endotoxin testing limit for two components. |
| P090015/S009 | 10/25/2019 | X - 30-Day Notice | BOND ORACLE HER2 IHC SYSTEM | LEICA BIOSYSTEMS | Add an additional Incoming Quality Control (IQC) test for a reagent. |
| P100010/S097 | 10/18/2019 | X - 30-Day Notice | ARCTIC FRONT ADVANCE PRO AND ARCTIC FRONT ADVANCE CARDIAC CRYOABLATION CATHETERS | MEDTRONIC CRYOCATH LP | Equipment and process changes for manufacturing the balloon assembly of the Arctic Front Advance and Arctic Front Advance Pro Cryoablation catheters. |

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|---|---|---|---|---|---|
| P100020/S050 | 10/10/2019 | X - 30-Day Notice | COBAS HPV TEST | ROCHE MOLECULAR SYSTEMS, INC. | Implement an alternate spectrophotometer for in-process QC testing. |
| P100021/S078 | 10/17/2019 | X - 30-Day Notice | TALENT OCCLUDER WITH OCCLUDER DELIVERY SYSTEM | MEDTRONIC VASCULAR | Supplier change for a component of the delivery system. |
| P100040/S039 | 10/17/2019 | X - 30-Day Notice | VALIANT THORACIC STENT GRAFT WITH THE CAPTIVIA DELIVERY SYSTEM | MEDTRONIC VASCULAR | Supplier change for a component of the delivery system. |
| P100044/S044 | 10/08/2019 | X - 30-Day Notice | PROPEL, PROPEL MINI AND PROPEL CONTOUR (PROPEL FAMILLY) SINUS IMPLANTS | INTERSECT ENT | New packaging vision inspection system. |
| P100045/S040 | 10/29/2019 | X - 30-Day Notice | CARDIOMEMS HF SYSTEM | ST. JUDE MEDICAL | Change the network analyzer used for in-process frequency validation. |
| P100047/S147 | 10/07/2019 | X - 30-Day Notice | HEARTWARE VENTRICULAR ASSIST SYSTEM | MEDTRONIC | Updates to the manufacturing process for the blister sealer. |
| P100047/S148 | 10/18/2019 | X - 30-Day Notice | HEARTWARE HVAD SYSTEM | MEDTRONIC | Modifications to the assembly process for the Apical Coring Tool. |
| P110010/S169 | 10/11/2019 | X - 30-Day Notice | PROMUS PREMIER EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM AND PROMUS ELITE EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM | BOSTON SCIENTIFIC CORP. | Change to the analytical chemistry method used for material acceptance testing. |
| P110016/S065 | 10/25/2019 | X - 30-Day Notice | FLEXABILITY AND FLEXABILITY SE ABLATION CATHETER AND FLEXABILITY CABLES, SENSOR ENABLED | ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL) | Add an additional sterilization chamber at Midwest Sterilization Corporation in Jackson, Missouri. |
| P110020/S034 | 10/10/2019 | X - 30-Day Notice | COBAS BRAF V600 MUTATION TEST | ROCHE MOLECULAR SYSTEMS, INC. | Implement an alternate spectrophotometer for in-process QC testing. |

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| P110033/S050 | 10/15/2019 | X - 30-Day Notice | JUVÉDERM VOLUMA, VOLLURE, VOLBELLA XC | ALLERGAN | Implement a change in the manual cleaning procedure for equipment used in the manufacturing of Juvederm injectable gel products in the Pringy I building in France. |
| P110035/S053 | 10/07/2019 | X - 30-Day Notice | EPIC VASCULAR SELF EXPANDING STENT SYSTEM | BOSTON SCIENTIFIC CORP. | Expansion of the manufacturing clean room. |
| P110037/S050 | 10/10/2019 | X - 30-Day Notice | COBAS AMPLIPREP AND COBAS TAQMAN CMV TEST | ROCHE MOLECULAR SYSTEMS, INC. | Implement an alternate spectrophotometer for in-process QC testing. |
| P110038/S024 | 10/30/2019 | X - 30-Day Notice | RELAY THORACIC STENT-GRAFT WITH PLUS DELIVERY SYSTEM | BOLTON MEDICAL, INC. | Change to the delivery system hydrophilic coating process and test specifications. |
| P110042/S128 | 10/10/2019 | X - 30-Day Notice | EMBLEM S-ICD ELECTRODE | BOSTON SCIENTIFIC CORPORATION | Updates to inspection criteria for defects on the terminal boot of the EMBLEM S-ICD electrode. |
| P110042/S130 | 10/29/2019 | X - 30-Day Notice | SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (S-ICD) | BOSTON SCIENTIFIC CORPORATION | Revert to previously approved controlled environment area specifications for feedthrough component and sputter coating manufacturing lines, eliminate use of booties, and change the hand sanitization method. |
| P120019/S030 | 10/10/2019 | X - 30-Day Notice | COBAS EGFR MUTATION TEST AND COBAS EGFR MUTATION TEST V2 | ROCHE | Implement an alternate spectrophotometer for in-process QC testing. |
| P120021/S013 | 10/25/2019 | X - 30-Day Notice | AMPLATZER PFO OCCLUDER | ABBOTT MEDICAL | Add an additional sterilization chamber at Midwest Sterilization Corporation in Jackson, Missouri. |
| P130009/S102 | 10/17/2019 | X - 30-Day Notice | EDWARDS EXPANDABLE INTRODUCER SHEATH SET | EDWARDS LIFESCIENCES, LLC. | Addition of a new cleanroom to perform borescope inspections. |
| P130009/S103 | 10/28/2019 | X - 30-Day Notice | EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE | EDWARDS LIFESCIENCES, LLC. | Modifications to the final assembly cleanroom and the associated gowning room. |
| P130017/S033 | 10/18/2019 | X - 30-Day Notice | COLOGUARD | EXACT SCIENCES CORPORATION | New testing method. |
| P130017/S034 | 10/08/2019 | X - 30-Day Notice | COLOGAURD | EXACT SCIENCES CORPORATION | Changes to third-party supplier's manufacturing processes. |

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| P130017/S035 | 10/24/2019 | X - 30-Day Notice | COLOGUARD | EXACT SCIENCES CORPORATION | Reagent manufacturing scale-up. |
| P130017/S036 | 10/22/2019 | X - 30-Day Notice | COLOGUARD | EXACT SCIENCES CORPORATION | Scale up manufacturing on 2 reagent components |
| P130021/S065 | 10/30/2019 | X - 30-Day Notice | ENVEO R AND ENVEO PRO DELIVERY CATHETER SYSTEM OF THE COREVALVE | MEDTRONIC COREVALVE LLC | Introduce the option of using an additional autoclave. |
| P130021/S066 | 10/29/2019 | X - 30-Day Notice | COREVALVE EVOLUT R AND EVOLUT PRO SYSTEMS | MEDTRONIC COREVALVE LLC | Addition of new equipment for the manufacturing of delivery catheter system sub-assemblies. |
| P130026/S052 | 10/25/2019 | X - 30-Day Notice | TACTICATH QUARTZ CONTACT FORCE ABLATION CATHETER AND TACTICATH CONTACT FORCE ABLATION CATHETER, SENSOR ENABLED | ST. JUDE MEDICAL | Add an additional sterilization chamber at Midwest Sterilization Corporation in Jackson, Missouri. |
| P130028/S030 | 10/25/2019 | X - 30-Day Notice | ALGOVITA SPINAL CORD STIMULATION SYSTEM | NUVECTRA CORPORATION | Addition of an alternate supplier of the silicone seals used to manufacture the header assembly of the Algovita Implantable Pulse Generators (IPGs). |
| P140003/S058 | 10/03/2019 | X - 30-Day Notice | IMPELLA 2.5, IMPELLA CP, IMPELLA CP WITH SMARTASSIST, AND IMPELLA 5.0/LD SYSTEMS | ABIOMED, INC. | Add an alternative U.S. location for the rigid packaging supplier and minor modification to the rigid packaging material. |
| P140003/S061 | 10/30/2019 | X - 30-Day Notice | IMPELLA 2.5 SYSTEM, IMPELLA CP, IMPELLA CP WITH SMARTASSIST, IMPELLA 5.0 AND IMPELLA 5.5 WITH SMARTASSIST AND IMPELLA LD SYSTEMS | ABIOMED, INC. | Relocate the coil winding step in the cannula manufacturing process. |
| P140017/S017 | 10/30/2019 | X - 30-Day Notice | EVOLUT R AND COREVALVE EVOLUT PRO SYSTEMS | MEDTRONIC INC. | Introduce the option of using an additional autoclave. |

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| P140023/S021 | 10/10/2019 | X - 30-Day Notice | COBAS KRAS MUTATION TEST | ROCHE MOLECULAR SYSTEMS, INC. | Implement an alternate spectrophotometer for in-process QC testing. |
| P140028/S044 | 10/11/2019 | X - 30-Day Notice | INNOVA VASCULAR SELF-EXPANDING STENT SYSTEM | BOSTON SCIENTIFIC CORPORATION | Automate a process used to stretch delivery system tubing. |
| P140028/S046 | 10/07/2019 | X - 30-Day Notice | INNOVA VASCULAR SELF EXPANDING STENT SYSTEM | BOSTON SCIENTIFIC CORPORATION | Expansion of the manufacturing clean room. |
| P140031/S096 | 10/03/2019 | X - 30-Day Notice | EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVES AND EDWARDS SAPIEN 3 ULTRA TRANSCATHETER HEART VALVES | EDWARDS LIFESCIENCES, LLC. | Reduce the sampling plan from 100% to 4% LTPD for visual inspection of post-cleaned valve frames. |
| P140031/S097 | 10/17/2019 | X - 30-Day Notice | EDWARDS ESHEATH INTRODUCER SET | EDWARDS LIFESCIENCES, LLC. | Addition of a new cleanroom to perform borescope inspections. |
| P140031/S098 | 10/28/2019 | X - 30-Day Notice | EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE AND EDWARD SAPIEN 3 ULTRA TRANSCATHETER HEART VALVE | EDWARDS LIFESCIENCES, LLC. | Modifications to the final assembly cleanroom and the associated gowning room. |
| P140032/S042 | 10/24/2019 | X - 30-Day Notice | IMPLANTABLE SYSTEM FOR REMODULIN | MEDTRONIC, INC. | Update several manufacturing process changes for the XT097 and XT116 TAZ Series tantalum capacitors. |
| P140033/S047 | 10/24/2019 | X - 30-Day Notice | TENDRIL MRI | ST. JUDE MEDICAL, INC. | Adjust the sterilization load configuration at the Abbott Penang Malaysia manufacturing facility. |
| P150001/S075 | 10/30/2019 | X - 30-Day Notice | MINIMED 630G SYSTEM WITH SMARTGUARD | MEDTRONIC MINIMED | Addition of a new curing process to increase production capacity of the MiniMed 630G Insulin Pump and the MiniMed670G Insulin Pump. The MiniMedi 630G Insulin pump is a component of the MiniMed 630G System with Smartguard. The MiniMed 670G Insulin Pump is a component of the MiniMed 670G System. |
| P150005/S048 | 10/07/2019 | X - 30-Day Notice | INTELLATIP MIFI OPEN IRRIGATED | BOSTON SCIENTIFIC CORP. | Expansion of the manufacturing clean room. |

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| P150012/S084 | 10/29/2019 | X - 30-Day Notice | MRI PACEMAKERS | BOSTONSCIENTIFIC | Revert to previously approved controlled environment area specifications for feedthrough component and sputter coating manufacturing lines, eliminate use of booties, and change the hand sanitization method. |
| P150014/S033 | 10/10/2019 | X - 30-Day Notice | COBAS HBV TEST | ROCHE MOLECULAR SYSTEMS, INC. | Implement an alternate spectrophotometer for in-process QC testing. |
| P150015/S035 | 10/10/2019 | X - 30-Day Notice | COBAS HCV TEST | ROCHE MOLECULAR SYSTEMS, INC. | Implement an alternate spectrophotometer for in-process QC testing. |
| P150036/S043 | 10/28/2019 | X - 30-Day Notice | EDWARDS INTUITY ELITE VALVE | EDWARDS LIFESCIENCES, LLC. | Modifications to the final assembly cleanroom and the associated gowning room. |
| P150048/S038 | 10/10/2019 | X - 30-Day Notice | EDWARDS INSPIRIS RESILIA AORTIC VALVE | EDWARDS LIFESCIENCES, LLC. | Transfer non-biological component manufacturing to the Singapore facility for the model 11500A valve. |
| P150048/S039 | 10/28/2019 | X - 30-Day Notice | EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS, INSPIRIS RESILIA AORTIC VALVE, AND EDWARDS PERICARDIAL MITRAL BIOPROSTHESIS | EDWARDS LIFESCIENCES, LLC. | Modifications to the final assembly cleanroom and the associated gowning room. |
| P160017/S073 | 10/30/2019 | X - 30-Day Notice | MINIMED 670G INSULIN SYSTEM | MEDTRONIC MINIMED, INC. | Addition of a new curing process to increase production capacity of the MiniMed 630G Insulin Pump and the MiniMed670G Insulin Pump. The MiniMedi 630G Insulin pump is a component of the MiniMed 630G System with Smartguard. The MiniMed 670G Insulin Pump is a component of the MiniMed 670G System. |
| P160035/S009 | 10/23/2019 | X - 30-Day Notice | EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE | BERLIN HEART INC. | Add an inspection for the pump membrane thickness. |
| P160041/S026 | 10/10/2019 | X - 30-Day Notice | COBAS CMV TEST | ROCHE MOLECULAR SYSTEMS, INC. | Implement an alternate spectrophotometer for in-process QC testing. |
| P170011/S016 | 10/03/2019 | X - 30-Day Notice | IMPELLA RP SYSTEM | ABIOMED, INC. | Add an alternative U.S. location for the rigid packaging supplier and minor modification to the rigid packaging material. |
| P170011/S017 | 10/30/2019 | X - 30-Day Notice | IMPELLA RP SYSTEM | ABIOMED, INC. | Relocate the coil winding step in the cannula manufacturing process. |

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| P170030/S004 | 10/25/2019 | X - 30-Day Notice | ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM | BIOTRONIK, INC | Changes to the drug-substance manufacturing process. |
| P180011/S012 | 10/11/2019 | X - 30-Day Notice | ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM | BOSTON SCIENTIFIC CORP. | Change to the analytical chemistry method used for material acceptance testing. |
| P180011/S013 | 10/11/2019 | X - 30-Day Notice | ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM | BOSTON SCIENTIFIC CORP. | Automate a process used to stretch delivery system tubing. |
| P180011/S016 | 10/07/2019 | X - 30-Day Notice | ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM | BOSTON SCIENTIFIC CORP. | Expansion of the manufacturing clean room. |
| P180013/S001 | 10/30/2019 | X - 30-Day Notice | VICI VENOUS STENT SYSTEM | BOSTON SCIENTIFIC CORPORATION | Change to the UV cure bonding step. |
| P180029/S013 | 10/07/2019 | X - 30-Day Notice | LOTUS EDGE VALVE SYSTEM | BOSTON SCIENTIFIC CORPORATION | Expansion of the manufacturing clean room. |
| P180029/S014 | 10/03/2019 | X - 30-Day Notice | LOTUS EDGE VALVE SYSTEM | BOSTON SCIENTIFIC CORPORATION | New braid manufacturing equipment. |
| P180029/S015 | 10/13/2019 | X - 30-Day Notice | LOTUS EDGE VALVE SYSTEM | BOSTON SCIENTIFIC CORPORATION | Transfer the inspection of the coiled spring pin component to an approved vendor. |
| **Total - 133** | | | | | |