# PMA Monthly approvals from 7/1/2018 to 7/31/2018

## Original

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P160026 | 07/02/2018 | PMAO - PMA Origi | LIFEPAK 1000 DEFIBRILLATOR, LIFEPAK 20 DEFIBRILLATOR/ MONITOR, LIFEPAK 20E DEFIBRILLATOR/ MONITOR, LIFEPAK 15 MONITOR/DEFIBRILLATOR, LIFEPAK 12 DEFIBRILLATOR/ MONITOR | PHYSIOCONTROL. INC. | Approval for the LIFEPAK® 1000 Defibrillator, LIFEPAK® 1000 Defibrillator Lithium-ion Rechargeable Battery, LIFEPAK® 20 Defibrillator/ Monitor (Refurbished), LIFEPAK® 20e Defibrillator/ Monitor, LIFEPAK® 15 Monitor/Defibrillator, and LIFEPAK® Lithium-ion Rechargeable Battery (for use with the LIFEPAK® 15 Monitor/Defibrillator) These devices are indicated for use as follows:<br><br>LIFEPAK® 1000 Defibrillator<br>The defibrillator is to be used in AED mode only on patients who are in cardiopulmonary arrest. The patient must be unresponsive, not breathing normally, and showing no signs of circulation. The defibrillator may be used with standard defibrillation pads only on adults and children who are 8 years old or more or who weigh more than 25 kg (55 lbs). The defibrillator may be used on children who are less than 8 years old or weigh less than 25 kg (55 lbs) with Infant/Child Reduced Energy Defibrillation Electrodes.<br><br>LIFEPAK® 20/20e Defibrillator/Monitors<br>The AED mode is to be used only on patients in cardiopulmonary arrest. The patient must be unconscious, pulseless, and not breathing normally before using the defibrillator to analyze the patient¿s ECG rhythm. In AED mode, the LIFEPAK® 20 and LIFEPAK® 20e defibrillator/monitor is not intended for use on pediatric patients less than 8 years old.<br><br>LIFEPAK® 15 Defibrillator/Monitors<br>AED mode is to be used only on patients in cardiopulmonary arrest. The patient must be unconscious, pulseless, and not breathing normally before using the defibrillator to analyze the patients ECG rhythm. In AED mode, the LIFEPAK® 15 monitor/defibrillator is not intended for use on pediatric patients less than 8 years old. |
| P160053 | 07/24/2018 | PMAO - PMA Origi | MAGTRACETM AND SENTIMAG(R) MAGNETIC LOCATIZATION SYSTEM | ENDOMAGNETICS LTD. | Approval for the MagtraceTM and Sentimag® Magnetic Localization System. The MagtraceTM and Sentimag® Magnetic Localization System is indicated to assist in localizing lymph nodes draining a tumor site, as part of a sentinel lymph node biopsy procedure, in patients with breast cancer undergoing a mastectomy. MagtraceTM is intended and calibrated for use ONLY with the Sentimag® system. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P170024 | 07/13/2018 | PMAO - PMA Origi | SURPASS STREAMLINE FLOW DIVERTER | STRYKER NEUROVASCULAR | Approval for The Surpass Streamline Flow Diverter. The Surpass Streamline Flow Diverter is indicated for use in the endovascular treatment of patients (18 years of age and older) with unruptured large or giant saccular wide-neck (neck width >= 4 mm or dome-toneck ratio < 2) or fusiform intracranial aneurysms in the internal carotid artery from the petrous segment to the terminus arising from a parent vessel with a diameter >= 2.5 mm and <= 5.3 mm. |
| P170041 | 07/20/2018 | PMAO - PMA Origi | ABBOTT REALTIME IDH1 | ABBOTT MOLECULAR, INC. | Approval for the Abbott RealTime IDH1. Abbott RealTime IDH1 is an in vitro polymerase chain reaction (PCR) assay for the qualitative detection of single nucleotide variants (SNVs) coding five IDH1 R132 mutations (R132C, R132H, R132G, R132S, and R132L) in DNA extracted from human blood (EDTA) or bone marrow (EDTA). Abbott RealTime IDH1 is for use with the Abbott m2000rt System.<br>Abbott RealTime IDH1 is indicated as an aid in identifying acute myeloid leukemia (AML) patients with an isocitrate dehydrogenase-1 (IDH1) mutation for treatment with TIBSOVO® (ivosidenib). This test is for prescription use only. |
| P170042 | 07/30/2018 | PMAO - PMA Origi | COVERA¿ VASCULAR COVERED STENT | C.R. BARD, INC | Approval of the Covera¿ Vascular Covered Stent. This device is indicated for use in the treatment of stenoses at the venous anastomosis of ePTFE and other synthetic arteriovenous (AV) access grafts. |

**Total: 5**

## Supplements

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| N970003/S229 | 07/27/2018 | N - Normal 180 Day | ADVANTIO, INGENIO, VITALIO, FORMIO, ALTRUA 2, ESSENTIO, PROPONENT AND ACCOLADE PACEMAKER AND PROGRAMMER SOFTWARE APPLICATION | BOSTON SCIENTIFIC CORP. | Approval for firmware modifications for the Ingenio and Accolade families of pacemaker and cardiac resynchronization therapy-pacemaker pulse generators and the associated Programmer Software Applications to support the addition of features including Signal Artifact Monitor, Automatic Lead Recognition, MRI Protection Mode, and RightRate pacing. |
| N970003/S231 | 07/17/2018 | R - Real-Time Proc | ALTRUA 2, ESSENTIO, PROPONENT AND ACCOLADE | BOSTON SCIENTIFIC CORP. | Approval of an inner tray redesign for the packaging used for the standard life (SL) Accolade pacemakers. |
| P840062/S063 | 07/03/2018 | Y - 135 Review Tra | COLLACOTE, COLLATAPE, COLLAPLUG, ABSORBABLE COLLAGEN WOUND DRESSINGS FOR DENTAL SURGERY | COLLA-TEC, INC. | Approval for verification of a temporary ethylene oxide sterilization cycle for the collagen products manufactured and released from the Integra Neurosciences, Anasco, Puerto Rico facility. |
| P860004/S291 | 07/31/2018 | N - Normal 180 Day | SYNCHROMED INFUSION SYSTEM | MEDTRONIC INC. | Approval for the Model A820 myPTM Application (myPTM App) and its labeling which is part of the new Model TH90 Personal Therapy Manager (PTM) system intended for use with the SynchroMed II infusion pump. |
| P890055/S069 | 07/06/2018 | S - Special CBE | CODMAN 3000 SERIES CONSTANT FLOW IMPLANTABLE INFUSION PUMP | CODMAN | Approval for an updated MRI labeling for the Codman 3000 pump. |
| P910001/S089 | 07/27/2018 | R - Real-Time Proc | CVX-300 AND CVX-300-P EXCIMER LASER SYSTEM | SPECTRANETICS CORP. | Approval to modify the coating applied to the optics of the laser and minor design changes to accommodate the change in coating. |
| P930014/S112 | 07/31/2018 | R - Real-Time Proc | ACRYSOF POSTERIIOR CHAMBER SINGLE PIECE INTRAOCULAR LENSES | ALCON RESEARCH, LTD. | Approval for a second alternate sterilization chamber at the contract sterilization site for the AcrySof® and AcrySof® IQ ReSTOR® Posterior Chamber Intraocular Lenses. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P960004/S085 | 07/27/2018 | N - Normal 180 Day | FINELINE II STEROX LEAD, FINELINE II STEROX EZ LEAD ABND SUTURE SLEEVE ACCESSORY (FOR FINELINE II LEADS) | BOSTON SCIENTIFIC | Approval for firmware modifications for the Ingenio and Accolade families of pacemaker and cardiac resynchronization therapy-pacemaker pulse generators and the associa ted Programmer Software Applications to support the addition of features including Signal Artifact Monitor, Automatic Lead Recognition, MRI Protection Mode , and RightRate pacing. The device, as modified, will be marketed under the trade names listed for pacemakers and CRT P devices.. Adaptive rate pacing is indicated for patients exhibiting chronotropic incompetence and who would benefit from increased pacing rates concurrent with increases in minute ventilation and/or physical activity. |
| P970003/S218 | 07/27/2018 | R - Real-Time Proc | VNS THERAPY SENTIVA MODEL 1000 GENERATOR, VNS THERAPY MODEL 2000 PROGRAMMING WAND, VNS THERAPY MODEL 3000 PROGRAMMER | LIVANOVA USA, INC. | Approval for updates to the Model1000 SenTiva Generator, Model2000 Programming Wand, and Model3000 Programmer; the updates are referred to as Version 1.5. These changes spanned new outer packaging for leads, generators, and accessory packs, Model1000 Generator firmware corrections, Model1000 Heart Rate Sensing requirement updates, Model2000 Wand Firmware Corrections, Model2000 Wand Label Cover Addition, and Model3000 Programmer Software Enhancements and Corrections. |
| P970004/S268 | 07/03/2018 | N - Normal 180 Day | MASTER INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM | MEDTRONIC NEUROMODU LATION | Approval of new models A510 and A520 programmer applications and TH90 kit for INS; update of programming software for models A511 and A521 programmer applications for ENS; labeling revisions. |
| P970051/S180 | 07/11/2018 | S - Special CBE | NUCLEUS C1532 COCHLEAR IMPLANT | COCHLEAR AMERICAS | Approval for labeling enhancements for the Nucleus CI532 Cochlear Implant. |
| P980016/S678 | 07/23/2018 | R - Real-Time Proc | EVERA MRI DF-I ICD / EVERA MRI ICD/ S DR ICD / S VR ICD / XT DR ICD /XT VR ICD ; MIRRO MRI DR ICD / MRI VR ICD; PRIMO MRI DR ICD/ MRI VR ICD; VISIA AF MRI DFI ICD / AF MRI VR ICD / AF VR ICD | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T | Approval for an alternate transformer component used in the high voltage charging circuit. |
| P980040/S072 | 07/10/2018 | O - Normal 180 Day | TECNIS SYMFONY TORIC EXTENDED RANGE OF VISION INTRAOCULAR LENSES (IOLS), MODELS ZXT150, ZXT225,ZXT300, AND ZT375 | JOHNSON & JOHNSON SURGICAL VISION, INC. | Approval of the protocol for the post-approval study (PAS) protocol. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P990056/S028 | 07/09/2018 | N - Normal 180 Day | ELECSYS TOTAL PSA AND TOTAL PSA CALSET II | ROCHE DIAGNOSTICS CORP. | Approval for the migration of Elecsys total PSA and total PSA CalSet II on the cobas e 801 immunoassay analyzer. |
| P000014/S032 | 07/02/2018 | O - Normal 180 Day | VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBS QUANTITATIVE REAGENT PACK AND CALIBRATOR | ORTHOCLINICAL DIAGNOSTICS , INC. | Approval for an additional manufacturing site located at NPA de México S.A. de C.V. dba Nypro, at Sor Juana Ines de la Cruz #20150, Parque Industrial Chilpancingo, 22509 Tijuana, Baja California, Mexico, limited to manufacturing of the Ortho-Clinical Diagnostics VITROS 3600 Immunodiagnostic System. |
| P000014/S033 | 07/02/2018 | O - Normal 180 Day | VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBS QUANTITATIVE REAGENT PACK AND CALIBRATOR | ORTHOCLINICAL DIAGNOSTICS , INC. | Approval for an additional contract manufacturing site located at NPA de México S.A. de C.V. dba Nypro, at Sor Juana Ines de la Cruz #20150, Parque Industrial Chilpancingo, 22509 Tijuana, Baja California, Mexico, limited to manufacturing of the Ortho-Clinical Diagnostics VITROS 5600 Immunodiagnostic System. |
| P000025/S097 | 07/24/2018 | N - Normal 180 Day | MAESTRO SYSTEM SOFTWARE 7.0 | MED-EL CORP. | Approval for the Maestro System Software 7.0. |
| P000027/S027 | 07/27/2018 | N - Normal 180 Day | ELECSYS FREE PSA, FREE PSA CALSET, AND FREE PSA CALCHECK | ROCHE DIAGNOSTICS CORP. | Approval for the migration of Elecsys free PSA, free PSA CalSet and free PSA CalCheck on the cobas e 801 immunoassay analyzer |
| P000032/S043 | 07/11/2018 | N - Normal 180 Day | HER OPTION OFFICE CRYOABLATION THERAPY SYSTEM | COOPERSURGICAL, INC. | Approval for changes to device materials included in the Disposable Probe of the Her Option® Office Cryoablation Therapy System. |
| P000044/S037 | 07/02/2018 | O - Normal 180 Day | VITROS IMMUNODIAGNOSTIC PRODUCTS HBSAG REAGENT PACK, CALIBRATOR AND CONFIRMATORY KIT | ORTHOCLINICAL DIAGNOSTICS , INC. | Approval for an additional manufacturing site located at NPA de México S.A. de C.V. dba Nypro, at Sor Juana Ines de la Cruz #20150, Parque Industrial Chilpancingo, 22509 Tijuana, Baja California, Mexico, limited to manufacturing of the Ortho-Clinical Diagnostics VITROS 3600 Immunodiagnostic System. |
| P000044/S038 | 07/02/2018 | O - Normal 180 Day | VITROS IMMUNODIAGNOSTIC PRODUCTS HBSAG REAGENT PACK, CALIBRATOR AND CONFIRMATORY KIT | ORTHOCLINICAL DIAGNOSTICS , INC. | Approval for an additional contract manufacturing site located at NPA de México S.A. de C.V. dba Nypro, at Sor Juana Ines de la Cruz #20150, Parque Industrial Chilpancingo, 22509 Tijuana, Baja California, Mexico, limited to manufacturing of the Ortho-Clinical Diagnostics VITROS 5600 Immunodiagnostic System. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P010012/S484 | 07/27/2018 | N - Normal 180 Day | ACUITYX4 LEAD STRAIGHT, ACUITY X4 LEAD SPIRAL S, ACUITY X4 LEAD SPIRAL L AND SUTURE SLEEVE ACCESSORY | BOSTON SCIENTIFIC CORP. | Approval for firmware modifications for the Ingenio and Accolade families of pacemaker and cardiac resynchronization therapy-pacemaker pulse generators and the associa ted Programmer Software Applications to support the addition of features including Signal Artifact Monitor, Automatic Lead Recognition, MRI Protection Mode , and RightRate pacing. The device, as modified, will be marketed under the trade names listed for pacemakers and CRT P devices.. Adaptive rate pacing is indicated for patients exhibiting chronotropic incompetence and who would benefit from increased pacing rates concurrent with increases in minute ventilation and/or physical activity. |
| P010014/S071 | 07/03/2018 | R - Real-Time Proc | OXFORD PARTIAL KNEE SYSTEM | BIOMET MANUFACTURING CORP. | Approval for change in UHMWPE DCM specification to a range of 0.925-0.944 g/cc. |
| P010021/S029 | 07/02/2018 | O - Normal 180 Day | VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HCV REAGENT PACK AND CALIBRATOR | ORTHOCLINICAL DIAGNOSTICS , INC. | Approval for an additional manufacturing site located at NPA de México S.A. de C.V. dba Nypro, at Sor Juana Ines de la Cruz #20150, Parque Industrial Chilpancingo, 22509 Tijuana, Baja California, Mexico, limited to manufacturing of the Ortho-Clinical Diagnostics VITROS 3600 Immunodiagnostic System. |
| P010021/S030 | 07/02/2018 | O - Normal 180 Day | VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HCV REAGENT PACK AND CALIBRATOR | ORTHOCLINICAL DIAGNOSTICS , INC. | Approval for an additional contract manufacturing site located at NPA de México S.A. de C.V. dba Nypro, at Sor Juana Ines de la Cruz #20150, Parque Industrial Chilpancingo, 22509 Tijuana, Baja California, Mexico, limited to manufacturing of the Ortho-Clinical Diagnostics VITROS 5600 Immunodiagnostic System. |
| P010030/S100 | 07/05/2018 | N - Normal 180 Day | LIFEVEST WEARABLE DEFIBRILLATOR (MODEL 4000) | ZOLL MANUFACTURING CORPORATION | Approval for the inclusion of the Advanced Arrhythmia Discrimination (AAD) algorithm into the subject device. |
| P010030/S106 | 07/16/2018 | Y - 135 Review Tra | LIFEVEST WEARABLE DEFIBRILLATOR | ZOLL MANUFACTURING CORPORATION | Approval to move the manufacturing site of two transformers in the high voltage printed circuit board from Butler, Pennsylvania, to Gowanda, New York. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P010031/S636 | 07/23/2018 | R - Real-Time Proc | AMPLIA MRI CRT-D / QUAD CRT-D; BRAVA CRT-D / QUAD CRT-D; CLARIA MRI CRT-D / QUAD CRT-D ; COMPIA MRI CRT-D / QUAD CRT-D; VIVA QUAD S CRT-D / S CRT-D / XT CRT-D | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Approval for an alternate transformer component used in the high voltage charging circuit. |
| P010032/S141 | 07/19/2018 | N - Normal 180 Day | SPINAL CORD STIMULATION (SCS) EXTERNAL PROGRAMMER APPS | ST. JUDE MEDICAL | Approval for:<br><br>1) P140009/S037: MR Conditional labeling, Firmware version 1.3, and ClinicianProgrammer and Patient Controller Apps version 3.7 (DBS MRI mode, DBS shared frequency mode, DBS Multistim Programming, DBS Monopolar Survey Mode, and minor software changes); and<br><br>2) P010032/S141 and P150004/S20: Firmware version 1.3 and Clinician Programmer andPatient Controller Apps version 3.7 (minor software changes). |
| P010047/S046 | 07/03/2018 | Y - 135 Review Tra | PROGEL PLEURAL AIR LEAK SEALANT (PALS) | NEOMEND, INC. | Approval for manufacturing changes regarding the silicone concentration and application methods to the glass cartridges containing the chemical pre-gel components of the PROGEL Pleural Air Leak Sealant (PALS) device. |
| P010054/S037 | 07/13/2018 | R - Real-Time Proc | ELECSYS ANI-HBS, PRECICONTROL ANTI-HBS AND ANTI-HBS CALCHECK | ROCHE DIAGNOSTICS CORP. | Approval for the addition of K2-EDTA plasma as a matrix. |
| P010062/S011 | 07/19/2018 | R - Real-Time Proc | BOSTON ORTHOKERATOLOGY (OPRIFOCON A) SHAPING LENS FOR OVERNIGHT WEAR FOR BAUSCH & LOMB, VISION SHAPING TREATMENT | BAUSCH & LOMB | Approval to update the contact lens labeling to remove references to a tap water rinse and replace with a saline rinse, and update warnings related to use of water |
| P020018/S058 | 07/20/2018 | S - Special CBE | ZENITH AAA ENDOVASCULAR GRAFT | COOK, INC. | Approval for modifications to the manufacturing instructions for the delivery systems for the Zenith AAA Endovascular Graft. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P030005/S176 | 07/27/2018 | N - Normal 180 Day | INVIVE CRT-P, INTUA CRT-P, VALITUDE CRT-P, VISIONIST CRT-P, VALITUDE X4 CRT-P, VISIONIST X4 CRT-P, AND PROGRAMMER SOFTWARE APPLICATION | GUIDANT CORP. | Approval for firmware modifications for the Ingenio and Accolade families of pacemaker and cardiac resynchronization therapy-pacemaker pulse generators and the associa ted Programmer Software Applications to support the addition of features including Signal Artifact Monitor, Automatic Lead Recognition, MRI Protection Mode , and RightRate pacing. The device, as modified, will be marketed under the trade names listed for pacemakers and CRT P devices.. Adaptive rate pacing is indicated for patients exhibiting chronotropic incompetence and who would benefit from increased pacing rates concurrent with increases in minute ventilation and/or physical activity. |
| P030024/S025 | 07/02/2018 | O - Normal 180 Day | VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBC REAGENT PACK AND CALIBRATOR | ORTHOCLINICAL DIAGNOSTICS | Approval for an additional manufacturing site located at NPA de México S.A. de C.V. dba Nypro, at Sor Juana Ines de la Cruz #20150, Parque Industrial Chilpancingo, 22509 Tijuana, Baja California, Mexico, limited to manufacturing of the Ortho-Clinical Diagnostics VITROS 3600 Immunodiagnostic System. |
| P030024/S026 | 07/02/2018 | O - Normal 180 Day | VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBC REAGENT PACK AND CALIBRATOR | ORTHOCLINICAL DIAGNOSTICS | Approval for an additional contract manufacturing site located at NPA de México S.A. de C.V. dba Nypro, at Sor Juana Ines de la Cruz #20150, Parque Industrial Chilpancingo, 22509 Tijuana, Baja California, Mexico, limited to manufacturing of the Ortho-Clinical Diagnostics VITROS 5600 Immunodiagnostic System. |
| P030026/S032 | 07/02/2018 | O - Normal 180 Day | VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBC IGM REAGENT PACK AND CALIBRATOR | ORTHOCLINICAL DIAGNOSTICS , INC. | Approval for an additional manufacturing site located at NPA de México S.A. de C.V. dba Nypro, at Sor Juana Ines de la Cruz #20150, Parque Industrial Chilpancingo, 22509 Tijuana, Baja California, Mexico, limited to manufacturing of the Ortho-Clinical Diagnostics VITROS 3600 Immunodiagnostic System. |
| P030026/S034 | 07/02/2018 | O - Normal 180 Day | VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBC IGM REAGENT PACK AND CALIBRATOR | ORTHOCLINICAL DIAGNOSTICS , INC. | Approval for an additional contract manufacturing site located at NPA de México S.A. de C.V. dba Nypro, at Sor Juana Ines de la Cruz #20150, Parque Industrial Chilpancingo, 22509 Tijuana, Baja California, Mexico, limited to manufacturing of the Ortho-Clinical Diagnostics VITROS 5600 Immunodiagnostic System. |
| P030039/S023 | 07/26/2018 | R - Real-Time Proc | COSEAL SURGICAL SEALANT, COSEAL SPRAY SET, COSEAL REPLACEMENT APPLICATOR, COSEAL EXTENDED APPLICATOR | BAXTER BIO SCIENCE | Approval for implementing a new sterilization chamber and cycle for the Coseal Spray Set. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P040002/S060 | 07/03/2018 | R - Real-Time Proc | AFX ENDOVASCULAR AAA SYSTEM | ENDOLOGIX, INC. | Approval for modifications to the Instructions for Use regarding general information for interventions through or re-interventions on an existing AFX device, as well as patienttailored surveillance recommendations. |
| P040004/S013 | 07/06/2018 | N - Normal 180 Day | ATELLICA IM ANTI-HEPATITIS B CORE TOTAL (HBCT), ATELLICA IM ANTI-HEPATITIS B CORE TOTAL QUALITY CONTROL (HBCT QC) | SIEMENS HEALTHCARE DIAGNOSTICS | Approval for migration of the ADVIA Centaur HBc Total assay (HBcT) and the ADVIA Centaur HBc Total (HBcT) Quality Control onto the Atellica IM analyzer. |
| P040020/S079 | 07/31/2018 | R - Real-Time Proc | ACRYSOF IQ RESTOR POSTERIOR CHAMBER INTRAOCULAR LENSES | ALCON RESEARCH, LTD. | Approval for a second alternate sterilization chamber at the contract sterilization site for the AcrySof® and AcrySof® IQ ReSTOR® Posterior Chamber Intraocular Lenses. |
| P040044/S081 | 07/10/2018 | O - Normal 180 Day | MYNXGRIP VASCULAR CLOSURE DEVICE | ACCESS CLOSURE, INC. | Approval to add Steri-Tek (Smart World LLC) located at 48225 Lakeview Boulevard, Fremont, California 94538, as a new E-beam sterilization site for the MynxGrip Vascular Closure Device (5F/6F/7F). |
| P060011/S012 | 07/05/2018 | O - Normal 180 Day | RAYNER C-FLEX 570C, CFLEX ASPHERIC 970C AND 600C ASPHERIC INTRAOCULAR LENSES | RAYNER INTRAOCULAR LENSES LTD. | Approval for a manufacturing site located at The Ridley Innovation Centre, 10 Dominion Way, Worthing, West Sussex, GB BN14 8AQ. |
| P080025/S163 | 07/03/2018 | N - Normal 180 Day | INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM | MEDTRONIC NEUROMODULATION | Approval of new models A510 and A520 programmer applications and TH90 kit for INS; update of programming software for models A511 and A521 programmer applications for ENS; labeling revisions. |
| P090018/S037 | 07/31/2018 | R - Real-Time Proc | ESTEEM TOTALLY IMPLANTABLE HEARING DEVICE | ENVOY MEDICAL CORPORATION | Approval for MR Conditional Labeling for the Esteem System. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P090024/S004 | 07/12/2018 | N - Normal 180 Day | ATELLICA IM HEPATITIS B E ANTIGEN (HBEAG) | SIEMENS HEALTHCARE DIAGNOSTICS | Approval for migration of the ADVIA Centaur Hepatitis B e Antigen and the ADVIA Centaur Hepatitis B e Antigen Quality Control onto the Atellica IM analyzer. The device, as modified, will be marketed under the trade name Atellica IM Hepatitis B e Antigen (HBeAg) and Atellica IM Hepatitis B e Antigen Quality Control (HBeAg QC) and is indicated for:<br>Atellica IM Hepatitis Be Antigen (HBeAg)<br>The Atellica IM Hepatitis Be Antigen (HBeAg) assay is an in vitro diagnostic immunoassay for use in the qualitative determination of the hepatitis B e antigen (HBeAg) in human serum and plasma (potassium EDTA, lithium heparin, and sodium heparin) from individuals who have signs and symptoms of hepatitis or who may be at risk for hepatitis B virus (HBV) infection using the Atellica¿ IM Analyzer. This assay, in conjunction with other serological and clinical information, is intended only for the determination of chronic infection with hepatitis B virus.<br>Atellica IM Hepatitis B e Antigen Quality Control (HBeAg QC)<br>The Atellica® IM Hepatitis B e Antigen Quality Control (HBeAg QC) is for use in monitoring the performance of the Atellica IM HBeAg assay using the Atellica® IM Analyzer. The performance of the Atellica IM HBeAg quality control material has not been established with any other HBeAg assay. |
| P090028/S013 | 07/02/2018 | O - Normal 180 Day | VITROS IMMUNODIAGNOSTIC PRODUCTS HBEAG REAGENT PACK AND CALIBRATOR | ORTHOCLINICAL DIAGNOSTICS, INC. | Approval for an additional manufacturing site located at NPA de México S.A. de C.V. dba Nypro, at Sor Juana Ines de la Cruz #20150, Parque Industrial Chilpancingo, 22509 Tijuana, Baja California, Mexico, limited to manufacturing of the Ortho-Clinical Diagnostics VITROS 3600 Immunodiagnostic System. |
| P090028/S015 | 07/02/2018 | O - Normal 180 Day | VITROS IMMUNODIAGNOSTIC PRODUCTS HBEAG REAGENT PACK AND CALIBRATOR | ORTHOCLINICAL DIAGNOSTICS, INC. | Approval for an additional contract manufacturing site located at NPA de México S.A. de C.V. dba Nypro, at Sor Juana Ines de la Cruz #20150, Parque Industrial Chilpancingo, 22509 Tijuana, Baja California, Mexico, limited to manufacturing of the Ortho-Clinical Diagnostics VITROS 5600 Immunodiagnostic System. |
| P100001/S012 | 07/02/2018 | O - Normal 180 Day | VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBE REAGENT PACK AND CALIBRATOR | ORTHOCLINICAL DIAGNOSTICS | Approval for an additional manufacturing site located at NPA de México S.A. de C.V. dba Nypro, at Sor Juana Ines de la Cruz #20150, Parque Industrial Chilpancingo, 22509 Tijuana, Baja California, Mexico, limited to manufacturing of the Ortho-Clinical Diagnostics VITROS 3600 Immunodiagnostic System. |
| P100001/S014 | 07/02/2018 | O - Normal 180 Day | VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBE REAGENT PACK AND CALIBRATOR | ORTHOCLINICAL DIAGNOSTICS | Approval for an additional contract manufacturing site located at NPA de México S.A. de C.V. dba Nypro, at Sor Juana Ines de la Cruz #20150, Parque Industrial Chilpancingo, 22509 Tijuana, Baja California, Mexico, limited to manufacturing of the Ortho-Clinical Diagnostics VITROS 5600 Immunodiagnostic System. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P100020/S025 | 07/02/2018 | N - Normal 180 Day | COBAS HPV TEST, 240 TESTS | ROCHE MOLECULAR SYSTEMS, INC. | Approval for an expansion of the intended use for the FDA-approved cobas HPV Test to include cervical specimens collected in SurePath Preservative Fluid as a specimen type |
| P100047/S112 | 07/10/2018 | N - Normal 180 Day | HEARTWARE HVAD SYSTEM | MEDTRONIC | Approval for a label expansion to include the thoracotomy surgical procedure. |
| P100047/S115 | 07/26/2018 | O - Normal 180 Day | HEARTWARE HVAD SYSTEM | MEDTRONIC | Approval for the HeartWare™ HVAD™ System This device is indicated for hemodynamic support in patients with advanced, refractory left ventricular heart failure; either as a bridge to cardiac transplantation (BTT), myocardial recovery, or as destination therapy (DT) in patients for whom subsequent transplantation is not planned. |
| P120005/S073 | 07/03/2018 | R - Real-Time Proc | G5 MOBILE TRANSMITTER HARDWARE AND FIRMWARE, G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM | DEXCOM, INC. | Approval for minor design changes to the Dexcom G5 transmitter hardware and firmware. The Dexcom G5 transmitter is part of the Dexcom G5 Mobile Continuous Glucose Monitoring System (CGM). |
| P120020/S018 | 07/26/2018 | N - Normal 180 Day | SUPERA PERIPHERAL STENT SYSTEM | ABBOTT VASCULAR (IDEF TECHNOLOGIES INC) | Approval for changes to the design of your delivery system. |
| P130014/S005 | 07/31/2018 | O - Normal 180 Day | ADHERUS AUTOSPRAY DURAL AND ET DURAL SEALANT | HYPERBRANCH MEDICAL TECHNOLOGY, INC. | Approval for manufacturing sites located at STERIS Applied Sterilization Technologies (AST) dba Synergy Health AST, LLC, 7225 North Noah Drive, Saxonburg, Pennsylvania 16056 and STERIS Applied Sterilization Technologies (AST) dba Synergy Health AST, LLC, 3200 Lakeville Hwy, Suite 120, Petaluma, California 94954, as contract sterilizers. |
| P130026/S035 | 07/31/2018 | S - Special CBE | TACTICATH QUARTZ CONTACT FORCE ABLATION CATHETER | ST. JUDE MEDICAL | Approval for manufacturing modifications to the irrigation lumen subassembly process and includes updates to the polyimide tube cutting fixture and placement of polyimide tube over adhesive covered Inox irrigation tube. |
| P140003/S033 | 07/10/2018 | R - Real-Time Proc | IMPELLA CP/LD, IMPELLA 2.5/5.0 | ABIOMED, INC. | Approval for revision of the Automated Impella Controller (AIC) software version V7. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P140009/S037 | 07/19/2018 | N - Normal 180 Day | SJM INFINITY DEEP BRAIN STIMULATION (DBS) NEUROSTIMULATION SYSTEM | ST. JUDE MEDICAL NEUROMODULATION | Approval for:<br><br>1) P140009/S037: MR Conditional labeling, Firmware version 1.3, and ClinicianProgrammer and Patient Controller Apps version 3.7 (DBS MRI mode, DBS shared frequency mode, DBS Multistim Programming, DBS Monopolar Survey Mode, and minor software changes); and<br><br>2) P010032/S141 and P150004/S20: Firmware version 1.3 and Clinician Programmer and Patient Controller Apps version 3.7 (minor software changes). |
| P140029/S007 | 07/25/2018 | R - Real-Time Proc | RESTYLANE REFYNE, RESTYLANE DEFYNE | Q-MED AB | Approval for the addition of a new tool for molding the plastic prefillable syringe. |
| P140031/S064 | 07/26/2018 | N - Normal 180 Day | SAPIEN 3 TRANSCATHETER HEART VALVE | EDWARDS LIFESCIENCES, LLC. | Approval to remove the precaution regarding patients with a congenital bicuspid aortic valve from the labeling. |
| P140031/S067 | 07/23/2018 | O - Normal 180 Day | EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE | EDWARDS LIFESCIENCES, LLC. | Approval for various modifications to the protocols for the "ODE Lead PMA PAS Continued follow-up of the premarket cohort" of the PIIS3HR and PIIS3i trials. |
| P140032/S001 | 07/27/2018 | O - Normal 180 Day | REMODULIN | MEDTRONIC, INC. | Post-Approval Study protocol as a condition of approval for P140032 of the Medtronic Implantable System for Remodulin (ISR) for the post-approval study (PAS) referenced above. The PAS protocol has been submitted to comply with the conditions of approval outlined in our approval order for P140032. |
| P150004/S020 | 07/19/2018 | N - Normal 180 Day | PROCLAIM DORSAL ROOT GANGLION (DRG) EXTERNAL PROGRAMMER APPS | ST. JUDE MEDICAL | Approval for:<br><br>1) P140009/S037: MR Conditional labeling, Firmware version 1.3, and ClinicianProgrammer and Patient Controller Apps version 3.7 (DBS MRI mode, DBS shared frequency mode, DBS Multistim Programming, DBS Monopolar Survey Mode, and minor software changes); and<br><br>2) P010032/S141 and P150004/S20: Firmware version 1.3 and Clinician Programmer andPatient Controller Apps version 3.7 (minor software changes). |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P150012/S060 | 07/27/2018 | N - Normal 180 Day | INGENIO MRI, VITALIO MRI, FORMIO MRI, ESSENTIO MRI, PROPONENT MRI, ACCOLADE MRI PACEMAKERS, INGEVITY MRI LEAD, SLIT SUTURE SLEEVE ACCESSORY AND PROGRAMMER SOFTWARE APPLICATION | BOSTONSCIENTIFIC | Approval for firmware modifications for the Ingenio and Accolade families of pacemaker and cardiac resynchronization therapy-pacemaker pulse generators and the associa ted Programmer Software Applications to support the addition of features including Signal Artifact Monitor, Automatic Lead Recognition, MRI Protection Mode , and RightRate pacing. The device, as modified, will be marketed under the trade names listed for pacemakers and CRT P devices.. Adaptive rate pacing is indicated for patients exhibiting chronotropic incompetence and who would benefit from increased pacing rates concurrent with increases in minute ventilation and/or physical activity. |
| P150012/S062 | 07/17/2018 | R - Real-Time Proc | ESSENTIO MRI, PROPONENT MRI, AND ACCOLADE MRI | BOSTONSCIENTIFIC | Approval for an inner tray redesign for the packaging used for the standard life (SL) Accolade pacemakers.. |
| P150021/S024 | 07/23/2018 | N - Normal 180 Day | FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM | ABBOTT DIABETES CARE INC. | Approval for design changes to the adhesive pad used in the sensor of the FreeStyle Libre Pro Flash Glucose Monitoring System and FreeStyle Libre Flash Glucose Monitoring System. |
| P150021/S027 | 07/27/2018 | R - Real-Time Proc | FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM | ABBOTT DIABETES CARE INC. | Approval for a change to the adhesive visual inspection criteria for the sensor puck assembly. The sensor puck assembly is a component of both the FreeStyle Libre and the FreeStyle Libre Pro Flash Glucose Monitoring Systems. |
| P150021/S031 | 07/03/2018 | R - Real-Time Proc | FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM | ABBOTT DIABETES CARE INC. | Approval for alternate electrostatic discharge (ESD) suppressor components for the Reader of the FreeStyle Libre Flash Glucose Monitoring System and the Reader of the FreeStyle Libre Pro Flash Glucose Monitoring System, to support higher manufacturing capacity. |
| P150022/S005 | 07/10/2018 | R - Real-Time Proc | CLOSER VASCULAR SEALING SYSTEM (VSS) | REX MEDICAL, L.P. | Approval for a change to the maximum tightening force exerted by the delivery system during device deployment. |
| P150028/S003 | 07/20/2018 | S - Special CBE | CHEATHAM PLATINUM (CP) STENT SYSTEM (COVERED CP STENT, COVERED MOUNTED CP STENT, CP STENT, MOUNTED CP STENT) | NUMED, INC. | Approval for the addition of a quality control inspection step to the Mounted CP Stent manufacturing process. |
| P150046/S001 | 07/13/2018 | R - Real-Time Proc | NEVISENSE | SCIBASE AB | Approval for addition of a patient labeling for the Nevisense Device. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P160002/S006 | 07/02/2018 | N - Normal 180 Day | VENTANA PD-L1(SP142) CDX ASSAY | VENTANA MEDICAL SYSTEMS, INC. | Approval for modifying the intended use of the VENTANA PD-L1(SP142). The VENTANA PD-L1 (SP142) Assay is a qualitative immunohistochemical assay using rabbit monoclonal anti-PD-L1 clone SP142 intended for use in the assessment of the PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) urothelial carcinoma and non-small cell lung cancer (NSCLC) tissue stained with OptiView DAB IHC Detection Kit and OptiView Amplification Kit on a VENTANA BenchMark ULTRA instrument. Determination of PD-L1 status is indication-specific, and evaluation is based on either the proportion of tumor area occupied by PD-L1 expressing tumor-infiltrating immune cells (% IC) of any intensity or the percentage of PD-L1 expressing tumor cells (% TC) of any intensity.<br>PD-L1 expression in >= 5% IC determined by VENTANA PD-L1 (SP142) Assay in urothelial carcinoma tissue is indicated as an aid in identifying urothelial carcinoma patients for treatment with TECENTRIQ (atezolizumab).<br>PD-L1 expression in >= 50% TC or >= 10% IC determined by VENTANA PD-L1 (SP142) Assay in NSCLC tissue may be associated with enhanced overall survival from TECENTRIQ (atezolizumab).<br>See the TECENTRIQ® product label for PD-L1 expression cutoff values guiding therapy in specific clinical circumstances.<br>This product is intended for in vitro diagnostic (IVD) use. |
| P160004/S015 | 07/25/2018 | S - Special CBE | GORE TIGRIS VASCULAR STENT | W. L. GORE & ASSOCIATES, INC. | Approval for additional visual inspection and modification to the mandrels. |
| P160030/S014 | 07/23/2018 | N - Normal 180 Day | FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM | ABBOTT DIABETES CARE INC. | Approval for design changes to the adhesive pad used in the sensor of the FreeStyle Libre Pro Flash Glucose Monitoring System and FreeStyle Libre Flash Glucose Monitoring System. |
| P160030/S017 | 07/23/2018 | P - Panel Track | FREESTYLE LIBRE 14 DAY FLASH GLUCOSE MONITORING SYSTEM | ABBOTT DIABETES CARE INC. | Approval for the FreeStyle Libre 14 Day Flash Glucose Monitoring System. The FreeStyle Libre 14 Day Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device indicated for the management of diabetes in persons age 18 and older. It is designed to replace blood glucose testing for diabetes treatment decisions. The System detects trends and tracks patterns aiding in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time. The System is intended for single patient use and requires a prescription. |
| P160030/S018 | 07/27/2018 | R - Real-Time Proc | FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM | ABBOTT DIABETES CARE INC. | This supplement requested approval for a change to the adhesive visual inspection criteria for the sensor puck assembly. The sensor puck assembly is a component of both the FreeStyle Libre and the FreeStyle Libre Pro Flash Glucose Monitoring Systems. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P160030/S023 | 07/03/2018 | R - Real-Time Proc | FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM | ABBOTT DIABETES CARE INC. | Approval for alternate electrostatic discharge (ESD) suppressor components for the Reader of the FreeStyle Libre Flash Glucose Monitoring System and the Reader of the FreeStyle Libre Pro Flash Glucose Monitoring System, to support higher manufacturing capacity |
| P160054/S007 | 07/05/2018 | N - Normal 180 Day | HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM (LVAS) | THORATEC CORPORATIO N | Approval for introducing: 1) various design modifications to the Tunneling Adapter and Tunneling Lance; 2) various design modifications to the HeartMate 3 LVAD inner tray; and 3) a standalone packaging configuration for the modified Tunneling Adapter, with a shelf life of 3 years. |
| P170012/S006 | 07/16/2018 | S - Special CBE | HEMOBLAST¿ BELLOWS | BIOM'UP SA | Approval for a change in the sample size for the moisture content determination method. |

**Total: 81**

## 30-DAY NOTICE

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| N16837/S025 | 07/12/2018 | X - 30-Day Notice | ARTEGRAFT COLLAGEN VASCULAR GRAFT | ARTEGRAFT, INC. | Addition of an alternate supplier for a raw material used in processing of the Artegraft. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| N18033/S099 | 07/10/2018 | X - 30-Day Notice | VISTAKON (ETAFILCON A) BRAND CONTACT LENSES | VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC. | Modification of the heat seal mechanism used to seal the foil lidstock onto the primary package during the manufacturing process of VISTAKON® (etafilcon A) Brand Contact Lenses. |
| N970012/S147 | 07/23/2018 | X - 30-Day Notice | AMS 700 IMPLANTABLE PENILE PROSTHESIS WITH AND WITHOUT INHIBIZONE | BOSTON SCIENTIFIC CORP. | New supplier for tubing plug component with dimension inspection step. |
| P830061/S161 | 07/12/2018 | X - 30-Day Notice | CAPSURE SENSE LEAD; CAPSURE SP NOVUS LEAD; VITATRON CRYSTALLINE LEAD | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Process improvement at the supplier to automate the ball tipping process of the stylet wires. |
| P840001/S402 | 07/18/2018 | X - 30-Day Notice | RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEM AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS | MEDTRONIC NEUROMODULATION | Change in manufacturing site for parts cleaning. |
| P850089/S135 | 07/12/2018 | X - 30-Day Notice | CAPSURE SP NOVUS LEAD; CAPSURE SP Z LEAD; CAPSURE SP Z NOVUS; CAPSURE SP Z LEAD; CAPSURE Z NOVUS LEAD; VITATRON IMPULSE II LEAD | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Process improvement at the supplier to automate the ball tipping process of the stylet wires. |
| P860004/S312 | 07/18/2018 | X - 30-Day Notice | SYNCHROMED INFUSION SYSTEM | MEDTRONIC INC. | Change in manufacturing site for parts cleaning. |
| P860004/S313 | 07/30/2018 | X - 30-Day Notice | SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS | MEDTRONIC INC. | Changes to the surface treatment used on select components of the SynchroMed II motor assembly. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P860004/S314 | 07/24/2018 | X - 30-Day Notice | SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS | MEDTRONIC INC. | Additional molding and testing equipment to be added to the manufacturing process and updates to the equipment cleaning and maintenance for the SynchroMed Infusion System, Ascenda Intrathecal Catheters. |
| P860057/S180 | 07/18/2018 | X - 30-Day Notice | CARPENTIER-EDWARDS PERIMOUNT PERICARDIAL AORTIC BIOPROSTHESIS, PERIMOUNT THEON/ MAGNA PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, PERIMOUNT RSR PERICARDIAL AORTIC BIOPROSTHESIS, PERIMOUNT THEON RSR PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, PERIMOUNT MAGNA PERICARDIAL AORTIC BIOPROSTHESIS, PERIMOUNT MAGNA EASE PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, PERIMOUNT PLUS PERICARDIAL MITRAL BIOPROSTHESIS, PERIMOUNT THEON PERICARDIAL MITRAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS AND CARPENTIER-EDWARDS PERIMOUNT MAGNA MITRAL EASE PERICARDIAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS | EDWARDS LIFESCIENCES, LLC. | Addition of an Optical Character Verification (OCV) system during the preliminary valve packaging process. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P860057/S181 | 07/27/2018 | X - 30-Day Notice | CARPENTIER-EDWARDS PERIMOUNT MAGNA PERICARDIAL AORTIC BIOPROSTHESIS, PERIMOUNT MAGNA PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, PERIMOUNT MAGNA EASE PERICARIDAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, PERIMOUNT PLUS PERICARIDIAL MITRAL BIOPROSTHESIS, PERIMOUNT THEON PERICARDIAL MITRAL BIOPORSTHESIS WITH THERMAFIX TISSUE PROCESS AND PERIMOUNT MAGNA MITRAL EASE PERICARDIAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS | EDWARDS LIFESCIENCES, LLC. | Increase in the number of frames and valve holders ultrasonically cleaned per load. |

| | | | | | |
|---|---|---|---|---|---|
| P860057/S182 | 07/26/2018 | X - 30-Day Notice | CARPENTIER-EDWARDS PERIMOUNT PERICARDIAL AORTIC BIOPROSTHESIS; THEON PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS; RSR PERICARDIAL AORTIC BIOPROSTHESIS;THEON RSR PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS; MAGNA PERICARDIAL AORTIC BIOPROSTHESIS; MAGNA PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS; MAGNA EASE PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS; PLUS PERICARDIAL MITRAL BIOPROSTHESIS; THEON PERICARDIAL MITRAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS; MAGNA MITRAL EASE PERICARDIAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS | EDWARDS LIFESCIENCE S, LLC. | Addition of a new cleaning process utilizing an ultrasonic cleaner for surgical heart valve polyester support bands. |
| P890003/S393 | 07/12/2018 | X - 30-Day Notice | CAPSURE VDD 2 LEAD; VITATRON BRILLIANT S+ VDD LEAD | MEDTRONIC, INC. | Process improvement at the supplier to automate the ball tipping process of the stylet wires. |

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

| | | | | | |
|---|---|---|---|---|---|
| P900033/S071 | 07/19/2018 | X - 30-Day Notice | INTEGRA DERMAL REGENERATION TEMPLATE, INTEGRA MESHED DERMAL REGENERATION TEMPLATE AND INTEGRA OMNIGRAFT DERMAL REGENERATION MATRIX | INTEGRA LIFESCIENCES CORP. | Change to the site that will conduct the E-Beam dose verification audits for the Collagen Glycosaminonglycan (GAG) Matrix and Omnigraft sterilization product families. |
| P900056/S171 | 07/02/2018 | X - 30-Day Notice | ROTAPRO ROTATIONAL ATHERECTOMY SYSTEM | BOSTON SCIENTIFIC CORP. | Implement additional controls and performance tests for the ROTAPRO console. |
| P900056/S172 | 07/11/2018 | X - 30-Day Notice | ROTABLATOR ROTATIONAL ATHERECTOMY SYSTEM | BOSTON SCIENTIFIC CORP. | Parametric release of product sterilized in the BSC2000-2 cycle. |
| P900060/S058 | 07/11/2018 | X - 30-Day Notice | CARBOMEDICS PROSTHETIC HEART VALVE | SORIN GROUP ITALIA S.R.L | Alternate gelatin supplier for use in the Carbo-Seal and Mitroflow devices. |
| P910056/S030 | 07/10/2018 | X - 30-Day Notice | ENHANCED ENVISTA HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) | BAUSCH & LOMB, INC. | Modification of the extraction process from single manual extraction to bulk extraction for the enVista® Hydrophobic Acrylic Intraocular Lens, Model MX60E. |
| P910073/S150 | 07/26/2018 | X - 30-Day Notice | ENDOTAK RELIANCE, RELIANCE 4-FRONT | BOSTON SCIENTIFIC | Implement the Central Monitoring System for the monitoring of environmental conditions at the Dorado facility. |
| P920015/S216 | 07/12/2018 | X - 30-Day Notice | SPRINT QUATTRO LEAD; SUBCUTANEOUS LEAD; TRANSVENE CS/SVC LEAD | MEDTRONIC INC. | Process improvement at the supplier to automate the ball tipping process of the stylet wires. |
| P920047/S109 | 07/11/2018 | X - 30-Day Notice | BLAZER II CARDIAC ABLATION CATHETER AND CABLE | BOSTON SCIENTIFIC CORP. | Parametric release of product sterilized in the BSC2000-2 cycle. |
| P930021/S020 | 07/09/2018 | X - 30-Day Notice | STRAUMANN EMDOGAIN | THE STRAUMANN COMPANY | Process change for alternative location for tertiary packaging. |
| P930039/S190 | 07/12/2018 | X - 30-Day Notice | CAPSUREFIX LEAD; CAPSUREFIX NOVUS LEAD; VITATRON CRYSTALLINE ACTIVE FIXATION LEAD | MEDTRONIC, INC. | Process improvement at the supplier to automate the ball tipping process of the stylet wires. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P950005/S070 | 07/30/2018 | X - 30-Day Notice | WEBSTER ELECTROPHYSIOLOGY CATHETER, CELSIUS ELECTROPHYSIOLOGY CATHETER, ELECTROPHYSIOLOGY CATHETER DEFLECTABLE BRAIDED TIP, ELECTROHPYSIOLOGY CATHETER-DEFLECTABLE TIP AND CELSIUS RMT ELECTROPHYSIOLOGY CATHETER | CORDIS CORP. | Addition of a new sealer for the sterile pouch. |
| P950022/S120 | 07/19/2018 | X - 30-Day Notice | DURATA AND OPTISURE | ST. JUDE MEDICAL, INC. | Change the cleaning agent and cleaning process on the incoming tools used in the manufacture of MCRDs. |
| P960004/S086 | 07/26/2018 | X - 30-Day Notice | FINELINE II | BOSTON SCIENTIFIC | Implement the Central Monitoring System for the monitoring of environmental conditions at the Dorado facility. |
| P960006/S048 | 07/26/2018 | X - 30-Day Notice | FLEXTEND | BOSTON SCIENTIFIC | Implement the Central Monitoring System for the monitoring of environmental conditions at the Dorado facility. |
| P960009/S319 | 07/18/2018 | X - 30-Day Notice | ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM | MEDTRONIC INC. | Change in manufacturing site for parts cleaning. |
| P960013/S100 | 07/19/2018 | X - 30-Day Notice | TENDRIL SDX, OPTISENSE, TENDRIL STS AND TENDRIL ST | ST JUDE MEDICAL | Change the cleaning agent and cleaning process on the incoming tools used in the manufacture of MCRDs. |
| P960030/S059 | 07/19/2018 | X - 30-Day Notice | ISOFLEX | ST. JUDE MEDICAL | Change the cleaning agent and cleaning process on the incoming tools used in the manufacture of MCRDs. |
| P960040/S427 | 07/11/2018 | X - 30-Day Notice | DYNAGEN MINI, INOGEN MINI, ORIGEN MINI AND PERCIVA MINI | BOSTON SCIENTIFIC | Vertical integration for the Mini high voltage capacitor can manufacturing process. |
| P970004/S275 | 07/18/2018 | X - 30-Day Notice | INTERSTIM THERAPY SYSTEM (URINARY) | MEDTRONIC NEUROMODULATION | Change in manufacturing site for parts cleaning. |

| | | | | | |
|---|---|---|---|---|---|
| P970020/S083 | 07/10/2018 | X - 30-Day Notice | MULTI-LINK ULTRA CORONARY STENT SYSTEM | ABBOTT VASCULAR INC. | Change the product bioburden sampling plan for coronary stent systems. |
| P970029/S037 | 07/10/2018 | X - 30-Day Notice | TMR HOLMIUM LASER SYSTEM | CRYOLIFE, INC. | New seal strength specification for the CardioGenesis handpiece pouch. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P970054/S014 | 07/31/2018 | X - 30-Day Notice | PARVOVIRUS B19 IGG ENZYME IMMUNOASSAY (V519IGUS) | DIASORIN | Transferring distribution site of assay kits for U.S. customers to a new location and minor labeling changes. |
| P970055/S016 | 07/31/2018 | X - 30-Day Notice | PARVOVIRUS B19 IGM ENZYME IMMUNOASSAY (V619IMUS) | DIASORIN | Transferring distribution site of assay kits for U.S. customers to a new location and minor labeling changes. |
| P980003/S086 | 07/11/2018 | X - 30-Day Notice | CHILLI II COOLED ABLATION CATHETER AND CABLE | BOSTON SCIENTIFIC CORP. | Parametric release of product sterilized in the BSC2000-2 cycle. |
| P980016/S679 | 07/13/2018 | X - 30-Day Notice | EVERA MRI DF-1 ICD, EVERA MRI ICD, EVERA S DR/ S VR ICD, EVERA XT DR/ XT VR ICD, PRIMO MRI DR/VR ICD, VISIA AF MRI DF1 ICD, VISIA AF MRI VR ICD, VISIA AF VR ICD | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Implementation of Nitrogen content process monitoring. |
| P980024/S018 | 07/11/2018 | X - 30-Day Notice | PATH VYSION HER-2 DNA PROBE KIT | ABBOTT MOLECULAR, INC. | Manufacturing process scale ranges. |
| P980040/S092 | 07/24/2018 | X - 30-Day Notice | TECNIS 1-PIECE IOL WITH TECNIS ITEC PRELOADED DELIVERY SYSTEM (PCB00), TECNIS MULTIFOCAL 1-PIECE IOL WITH TECNIS ITEC PRELOADED DELIVERY SYSTEM (PMB00) | JOHNSON & JOHNSON SURGICAL VISION, INC. | Alternate microbiology laboratory for media preparation and growth promotion test. |
| P980050/S119 | 07/12/2018 | X - 30-Day Notice | TRANSVENE CS/SVC LEAD | MEDTRONIC INC. | Process improvement at the supplier to automate the ball tipping process of the stylet wires. |

| | | | | | |
|---|---|---|---|---|---|
| P990025/S056 | 07/30/2018 | X - 30-Day Notice | NAVISTAR RMT ELECTROPHYSIOLOGY CATHETER | BIOSENSE WEBSTER, INC. | Addition of a new sealer for the sterile pouch. |
| P990046/S054 | 07/11/2018 | X - 30-Day Notice | OPEN PIVOT MECHANICAL HEART VALVE; OPEN PIVOT AORTIC VALVED GRAFT | MEDTRONIC ATS MEDICAL, INC. | Transfer of manufacturing operations to a different building within the same manufacturing site. |
| P990071/S041 | 07/30/2018 | X - 30-Day Notice | SMARTABLATE CABLE | BIOSENSE WEBSTER, INC. | Addition of a new sealer for the sterile pouch. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P000006/S049 | 07/27/2018 | X - 30-Day Notice | TITAN INFLATABLE PENILE PROSTHESIS (IPP) | COLOPLAST CORP. | New mixer equipment, new mixing process, and larger capacity filter during mixing process for Bioflex silicone cylinders and reservoirs. |
| P000008/S043 | 07/20/2018 | X - 30-Day Notice | LAP-BAND ADJUSTABLE GASTRIC BANDING SYSTEM | APOLLO ENDOSURGERY INC | Change in manufacturing site for the contract manufacturer of a critical device component. |
| P000021/S038 | 07/05/2018 | X - 30-Day Notice | DIMENSION VISTA TPSA FLEX REAGENT CARTRIDGE (K6451) | SIEMENS HEALTHCARE DIAGNOSTICS | Transfer to a contract service provider the manufacture of subassembly components and service spare parts, which are used in the Dimension Vista® System manufacturing process. |
| P000025/S101 | 07/25/2018 | X - 30-Day Notice | MED-EL COCHLEAR IMPLANT SYSTEM | MED-EL CORP. | Removal of the AETA (Automated Electrode Test Application) as a mandatory test to be performed on all standard CI electrodes. |
| P000053/S091 | 07/23/2018 | X - 30-Day Notice | AMS 800 URINARY CONTROL SYSTEM WITH AND WITHOUT INHIBIZONE | BOSTON SCIENTIFIC CORP. | New supplier for tubing plug component with dimension inspection step. |
| P010012/S488 | 07/26/2018 | X - 30-Day Notice | EASYTRAK 2, EASYTRACK 3, ACUITY SPRIAL, ACUITY X4 | BOSTON SCIENTIFIC CORP. | Implement the Central Monitoring System for the monitoring of environmental conditions at the Dorado facility. |
| P010013/S071 | 07/25/2018 | X - 30-Day Notice | NOVASURE IMPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM | HOLOGIC, INC. | Addition of a supplier. |
| P010014/S079 | 07/17/2018 | X - 30-Day Notice | OXFORD PARTIAL KNEE SYSTEM | BIOMET MANUFACTURING CORP. | Transfer testing of tensile mechanical properties of Oxford Partial Knee UHMWPE bearing test specimens to ATS Labs, Zimmer Inc. |

| | | | | | |
|---|---|---|---|---|---|
| P010014/S080 | 07/27/2018 | X - 30-Day Notice | OXFORD PARTIAL KNEE SYSTEM | BIOMET MANUFACTURING CORP. | Upgrade the cleaning process for the Oxford Partial Knee metal components. The new validated cleaning process consists of an in-process cleaning operation through the Elma 3-Stage Cleaning Process, a final cleaning operation through the Elma 5-Stage Final Cleaning Process and a biological upgrade in nitric acid. |
| P010015/S375 | 07/12/2018 | X - 30-Day Notice | ATTAIN BIPOLAR OTW LEAD; ATTAIN OTW LV LEAD | MEDTRONIC INC. | Process improvement at the supplier to automate the ball tipping process of the stylet wires. |
| P010019/S066 | 07/24/2018 | X - 30-Day Notice | LOTRAFILCON A AND LOTRAFILCON B SOFT CONTACT LENSES | ALCON LABORATORIES, INC. | Implementation of a Strip Blister Inspection System at the packaging lines in the production of Lotrafilcon A and Lotrafilcon B Soft Contact Lenses at Alcon's Batam, Indonesia production facility. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P010031/S638 | 07/13/2018 | X - 30-Day Notice | AMPLIA MRI CRT-D, AMPLIA MRI QUAD CRT-D, CLARIA MRI CRT-D, CLARIA MRI QUAD CRT-D, COMPIA MRI CRT-D, COMPIA MRI QUAD CRT-D, VIVA QUAD S/XT CRT-D, VIVA S/XT CRT-D | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Implementation of Nitrogen content process monitoring. |
| P010047/S059 | 07/26/2018 | X - 30-Day Notice | PROGEL PLEURAL AIR LEAK SEALANT | NEOMEND, INC. | Change to the radiation dose used for the sterile Nalgene plastic containers used to store and deliver the Polyethylene Glycol Disuccinimidyl Succinate (PEG(SS)2) raw material to Neomend. |
| P010068/S057 | 07/30/2018 | X - 30-Day Notice | CELSIUS DS ELECTROPHYSIOLOGY CATHETER | BIOSENSE WEBSTER, INC. | Addition of a new sealer for the sterile pouch. |
| P020004/S154 | 07/02/2018 | X - 30-Day Notice | GORE EXCLUDER AAA ENDOPROSTHESIS | W.L. GORE & ASSOCIATES,INC | Update for device component manufacturing equipment. |
| P020004/S155 | 07/05/2018 | X - 30-Day Notice | GORE EXCLUDER AAA ENDOPROSTHESIS | W.L. GORE & ASSOCIATES,INC | New polymer processing equipment and an alternate cleaning process. |
| P020004/S156 | 07/27/2018 | X - 30-Day Notice | GORE EXCLUDER AAA ENDOPROSTHESIS | W.L. GORE & ASSOCIATES,INC | Transferring manufacturing of raw materials, intermediate materials and manufacturing aids to an external supplier. |

| | | | | | |
|---|---|---|---|---|---|
| P020012/S026 | 07/26/2018 | X - 30-Day Notice | BELLAFILL DERMAL FILLER | SUNEVA MEDICAL, INC. | Change in the syringe labeling process from manual to automated. |
| P020025/S112 | 07/11/2018 | X - 30-Day Notice | BLAZER II XP CARDIAC ABLATION CATHETER AND CABLE | BOSTON SCIENTIFIC | Parametric release of product sterilized in the BSC2000-2 cycle. |
| P020027/S033 | 07/05/2018 | X - 30-Day Notice | DIMENSION VISTA FPSA FLEX REAGENT CARTRIDGE (K6452) | SIEMENS HEALTHCARE DIAGNOSTICS | Transfer to a contract service provider the manufacture of subassembly components and service spare parts, which are used in the Dimension Vista® System manufacturing process. |
| P020045/S088 | 07/12/2018 | X - 30-Day Notice | FREEZOR CARDIAC CRYOABLATION CATHETER; FREEZOR XTRA SURGICAL CARDIAC CRYOABLATION DEVICE; FREEZOR MAX CARDIAC CRYOABLATION CATHETER; COAXIAL UMBILICAL CABLE | MEDTRONIC CRYOCATH LP | Addition of an alternate polyimide tubing supplier. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P020047/S069 | 07/10/2018 | X - 30-Day Notice | MULTI-LINK VISION/ MULTI-LINK MINI VISION CORONARY STENT SYSTEM, MULTI-LINK 8/ 8 SV/ 8 LL CORONARY STENT SYSTEM | ABBOTT VASCULAR | Change the product bioburden sampling plan for coronary stent systems. |
| P030011/S062 | 07/04/2018 | X - 30-Day Notice | SYNCARDIA TEMPORARY TOTAL ARTIFICIAL HEART (TAH-T) SYSTEM-COMPANION 2 DRIVER SYSTEM | SYNCARDIA SYSTEMS, LLC | Change of manufacturer for the electrical assemblies for the Companion 2 Driver. |
| P030031/S088 | 07/18/2018 | X - 30-Day Notice | THERMOCOOL SMART TOUCH SF BI-DIRECTIONAL NAVIGATION CATHETER & THERMOCOOL SMART TOUCH SF UNI-DIRECIONAL NAVIGATION CATHETER | BIOSENSE WEBSTER, INC. | Additional sensor coil quality control test for ThermoCool SmartTouch SF Uni-Directional Navigation Catheters and the ThermoCool SmartTouch SF Bi-Directional Navigation Catheters. |

| | | | | | |
|---|---|---|---|---|---|
| P030031/S089 | 07/30/2018 | X - 30-Day Notice | CELSIUS THERMOCOOL ELECTROPHYSIOLOGY CATHETER, NAVISTAR RMT THERMOCOOL AND CELSIUS RMT THERMOCOOL | BIOSENSE WEBSTER, INC. | Addition of a new sealer for the sterile pouch. |
| P030031/S090 | 07/26/2018 | X - 30-Day Notice | THERMOCOOL SMARTTOUCH SF CATHETERS UNI/BIDIRECTIONAL NAVIATION CATHETER | BIOSENSE WEBSTER, INC. | Modification of the wire stripping process used during the manufacture of ThermoCool SmartTouch and ThermoCool SmartTouch SF Catheters. |
| P030052/S023 | 07/11/2018 | X - 30-Day Notice | UROVYSION BLADDER CANCER KIT | ABBOTT MOLECULAR | Manufacturing process scale ranges. |
| P030054/S357 | 07/19/2018 | X - 30-Day Notice | QUICKFLEX U AND QUARTET | ST. JUDE MEDICAL | Change the cleaning agent and cleaning process on the incoming tools used in the manufacture of MCRDs. |
| P040027/S063 | 07/02/2018 | X - 30-Day Notice | GORE VIATORR TIPS ENDOPROSTHESIS | W. L. GORE & ASSOCIATES, INC. | Update for device component manufacturing equipment. |
| P040027/S064 | 07/05/2018 | X - 30-Day Notice | GORE VIATORR TIPS ENDOPROSTHESIS | W. L. GORE & ASSOCIATES, INC. | New polymer processing equipment and an alternate cleaning process. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P040027/S065 | 07/27/2018 | X - 30-Day Notice | GORE VIATORR TIPS ENDOPROSTHESIS | W. L. GORE & ASSOCIATES, INC. | Transferring manufacturing of raw materials, intermediate materials and manufacturing aids to an external supplier. |
| P040036/S063 | 07/26/2018 | X - 30-Day Notice | THERMOCOOL SMARTTOUCH UNI-BIDIRECTIONAL NAVIGATION CATHETER | BIOSENSE WEBSTER, INC. | Modification of the wire stripping process used during the manufacture of ThermoCool SmartTouch and ThermoCool SmartTouch SF Catheters. |
| P040037/S116 | 07/02/2018 | X - 30-Day Notice | GORE VIABAHN ENDOPROSTHESIS AND GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE | W.L. GORE & ASSOCIATES,INC | Update for device component manufacturing equipment. |

| | | | | | |
|---|---|---|---|---|---|
| P040037/S117 | 07/05/2018 | X - 30-Day Notice | GORE VIABAHN ENDOPROSTHESIS AND GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE | W.L. GORE & ASSOCIATES,INC | New polymer processing equipment and an alternate cleaning process. |
| P040037/S118 | 07/27/2018 | X - 30-Day Notice | GORE VIABAHN ENDOPROSTHESIS, GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE | W.L. GORE & ASSOCIATES,INC | Transferring manufacturing of raw materials, intermediate materials and manufacturing aids to an external supplier. |
| P040043/S101 | 07/02/2018 | X - 30-Day Notice | GORE TAG THORACIC ENDOPROSTHESIS | W. L. GORE & ASSOCIATES, INC. | Update for device component manufacturing equipment. |
| P040043/S102 | 07/05/2018 | X - 30-Day Notice | GORE TAG THORACIC ENDOPROSTHESIS | W. L. GORE & ASSOCIATES, INC. | New polymer processing equipment and an alternate cleaning process. |
| P040043/S103 | 07/27/2018 | X - 30-Day Notice | GORE TAG THORACIC ENDOPROSTHESIS | W. L. GORE & ASSOCIATES, INC. | Transferring manufacturing of raw materials, intermediate materials and manufacturing aids to an external supplier. |
| P040045/S100 | 07/30/2018 | X - 30-Day Notice | VISTAKON (SENOFILCON A) BRAND CONTACT LENSES | VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR | Replacement sterilizer unit to be used in the manufacturing process of VISTAKON (senofilcon A) Brand Contact Lenses. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P050006/S070 | 07/27/2018 | X - 30-Day Notice | GORE CARDIOFORM SEPTAL OCCLUDER | W.L. GORE & ASSOCIATES,INC | Transferring manufacturing of raw materials, intermediate materials and manufacturing aids to an external supplier. |
| P050028/S066 | 07/03/2018 | X - 30-Day Notice | COBAS TAQMAN HBV TEST, HIGH PURE SYSTEM VIRAL NUCLEIC ACID KIT | ROCHE MOLECULAR SYSTEMS, INC. | Reduce Environmental Monitoring testing at a manufacturing facility. |

| | | | | | |
|---|---|---|---|---|---|
| P050028/S067 | 07/05/2018 | X - 30-Day Notice | COBAS TAQMAN HBV TEST FOR USE WITH THE HIGH PURE SYSTEM AND COBAS AMPLIPREP/COBAS TAQMAN HBV TEST, V2.0 | ROCHE MOLECULAR SYSTEMS, INC. | Eliminate a duplicative in-process test for designated kit reagents. |
| P050028/S068 | 07/26/2018 | X - 30-Day Notice | COBAS TAQMAN HBV TEST FOR USE WITH THE HIGH PURE SYSTEM AND COBAS AMPLIPREP/COBAS TAQMAN HBV TEST, V2.0 | ROCHE MOLECULAR SYSTEMS, INC. | Scale-up a manufacturing process. |
| P050037/S090 | 07/06/2018 | X - 30-Day Notice | RADIESSE INJECTABLE IMPLANT | MERZ NORTH AMERICA, INC | Change in the supplier for a 4-way stopcock used in the manufacturing of Radiesse and Radiesse (+). |
| P050037/S092 | 07/05/2018 | X - 30-Day Notice | RADIESSE INJECTABLE IMPLANT | MERZ NORTH AMERICA, INC | Change to the transfer pin material used in the syringe barrel manufacture. |
| P050037/S093 | 07/06/2018 | X - 30-Day Notice | RADIESSE | MERZ NORTH AMERICA, INC | Replacement of the decanting drums. |
| P050046/S029 | 07/26/2018 | X - 30-Day Notice | ACUITY STEERABLE | GUIDANT CORP. | Implement the Central Monitoring System for the monitoring of environmental conditions at the Dorado facility. |
| P050052/S106 | 07/06/2018 | X - 30-Day Notice | RADIESSE (+) LIDOCAINE DERMAL FILTER | MERZ NORTH AMERICA, INC | Change in the supplier for a 4-way stopcock used in the manufacturing of Radiesse and Radiesse (+). |
| P050052/S108 | 07/05/2018 | X - 30-Day Notice | RADIESSE HANDS, RADIESSE (+) LIDOCAINE DERMAL FILLER | MERZ NORTH AMERICA, INC | Change to the transfer pin material used in the syringe barrel manufacture. |
| P050052/S109 | 07/06/2018 | X - 30-Day Notice | RADIESSE (+) | MERZ NORTH AMERICA, INC | Replacement of the decanting drums. |
| P060006/S092 | 07/11/2018 | X - 30-Day Notice | EXPRESS SD MONORAIL PREMOUNTED STENT SYSTEM | BOSTON SCIENTIFIC CORP. | Parametric release of product sterilized in the BSC2000-2 cycle. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P060030/S065 | 07/03/2018 | X - 30-Day Notice | COBAS TAQMAN HCV TEST, V2.0, FOR USE WITH THE HIGH PURE SYSTEM, HIGH PURE SYSTEM VIRAL NUCLEIC ACID KIT | ROCHE MOLECULAR SYSTEMS, INC. | Reduce Environmental Monitoring testing at a manufacturing facility. |

| | | | | | |
|---|---|---|---|---|---|
| P060030/S066 | 07/05/2018 | X - 30-Day Notice | COBAS AMPLIPREP/COBAS TAQMAN HCV TEST, V2.0 | ROCHE MOLECULAR SYSTEMS, INC. | Eliminate a duplicative in-process test for designated kit reagents. |
| P060030/S067 | 07/26/2018 | X - 30-Day Notice | COBAS AMPLIPREP/COBAS TAQMAN HCV TEST, V2.0 | ROCHE MOLECULAR SYSTEMS, INC. | Scale-up a manufacturing process. |
| P060038/S032 | 07/11/2018 | X - 30-Day Notice | MITROFLOW AORTIC PERICARDIAL HEART VALVE | LIVANOVA CANADA CORP. | Alternate gelatin supplier for use in the Carbo-Seal and Mitroflow devices. |
| P060039/S089 | 07/12/2018 | X - 30-Day Notice | ATTAIN STARFIX LEAD | MEDTRONIC INC. | Process improvement at the supplier to automate the ball tipping process of the stylet wires. |
| P080006/S125 | 07/12/2018 | X - 30-Day Notice | ATTAIN ABILITY LEAD; ATTAIN PERFORMA LEAD | MEDTRONIC INC. | Process improvement at the supplier to automate the ball tipping process of the stylet wires. |
| P080011/S076 | 07/02/2018 | X - 30-Day Notice | COMFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES | COOPERVISION MANUFACTURING, LTD. | Addition of the capability to produce Biofinity XR Toric in 5° axis increment steps on Biofinity Line 3 at the CooperVision, Inc. manufacturing facility in Hamble, UK. |
| P080025/S170 | 07/18/2018 | X - 30-Day Notice | INTERSTIM THERAPY SYSTEM (BOWEL ) | MEDTRONIC NEUROMODULATION | Change in manufacturing site for parts cleaning. |
| P090013/S287 | 07/12/2018 | X - 30-Day Notice | CAPSUREFIX MRI LEAD | MEDTRONIC, INC | Process improvement at the supplier to automate the ball tipping process of the stylet wires. |
| P090016/S030 | 07/25/2018 | X - 30-Day Notice | BELOTERO BALANCE DERMAL FILLER | MERZ NORTH AMERICA, INC | Change of analytical instrument used for determining the residual concentration of BDDE in Belotero Balance to ThermoScientific GC-MS/MS from Perkin-Elmer GC-MS. |
| P100010/S079 | 07/12/2018 | X - 30-Day Notice | FREEZOR MAX CARDIAC CRYOABLATION CATHETER | MEDTRONIC CRYOCATH LP | Addition of an alternate polyimide tubing supplier. |
| P100010/S080 | 07/26/2018 | X - 30-Day Notice | ARTIC FRONT ADVANCE CARDIAC CRYOABLATION CATHETER, 23/28MM, US | MEDTRONIC CRYOCATH LP | Addition of an alternate supplier for catheter subassemblies. |

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

| | | | | | |
|---|---|---|---|---|---|
| P100020/S034 | 07/03/2018 | X - 30-Day Notice | COBAS HPV TEST, 240/960 TESTS | ROCHE MOLECULAR SYSTEMS, INC. | Reduce Environmental Monitoring testing at a manufacturing facility. |
| P100020/S035 | 07/05/2018 | X - 30-Day Notice | COBAS HPV TEST | ROCHE MOLECULAR SYSTEMS, INC. | Eliminate a duplicative in-process test for designated kit reagents. |
| P100020/S036 | 07/26/2018 | X - 30-Day Notice | COBAS HPV TEST | ROCHE MOLECULAR SYSTEMS, INC. | Scale-up a manufacturing process. |
| P100045/S029 | 07/10/2018 | X - 30-Day Notice | CARDIOMEMS HF SYSTEM | ST. JUDE MEDICAL | Addition of incoming inspection procedures for the detection of non-conforming compact flash disks. |
| P100045/S030 | 07/24/2018 | X - 30-Day Notice | CARDIOMEMS HF SYSTEM | ST. JUDE MEDICAL | Addition of a new coil winder for production of an internal component of the CardioMEMS HF Sensor. |
| P100047/S125 | 07/11/2018 | X - 30-Day Notice | HEARTWARE VENTRICULAR ASSIST SYSTEM | MEDTRONIC | Implementation of an improved receiving process for the HVAD Controller 2.0 display. |
| P100049/S022 | 07/23/2018 | X - 30-Day Notice | LINX REFLUX MANAGEMENT SYSTEM | TORAX MEDICAL | Implementation of manufacturing process changes involving new equipment, fixtures, and inspection aids. |
| P110010/S158 | 07/11/2018 | X - 30-Day Notice | PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING STENT SYSTEM/PROMUS PREMIER EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM | BOSTON SCIENTIFIC CORP. | Parametric release of product sterilized in the BSC2000-2 cycle. |
| P110012/S016 | 07/11/2018 | X - 30-Day Notice | VYSIS ALK BREAK APART FISH PROBE KIT | ABBOTT MOLECULAR, INC. | Manufacturing process scale ranges. |
| P110015/S004 | 07/12/2018 | X - 30-Day Notice | 13 C-SPIRULINA GASTRIC EMPTYING BREATH TEST (GEBT) | ADVANCED BREATH DIAGNOSTICS | Software and system upgrade to the analytical system used to test solid samples of Cairn ¿s drug substance. The drug is a component of the 13C-Spirulina gastric emptying breath test (GEBT). |
| P110020/S025 | 07/03/2018 | X - 30-Day Notice | ROCHE COBAS DNA SAMPLE PREPARATION KIT, ROCHE COBAS 4800 BRAF V600 MUTATION TEST | ROCHE MOLECULAR SYSTEMS, INC. | Reduce Environmental Monitoring testing at a manufacturing facility. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P110020/S026 | 07/05/2018 | X - 30-Day Notice | COBAS BRAF V600 MUTATION TEST | ROCHE MOLECULAR SYSTEMS, INC. | Eliminate a duplicative in-process test for designated kit reagents. |
| P110020/S027 | 07/26/2018 | X - 30-Day Notice | COBAS BRAF V600 MUTATION TEST | ROCHE MOLECULAR SYSTEMS, INC. | Scale-up a manufacturing process. |
| P110029/S027 | 07/18/2018 | X - 30-Day Notice | ARCHITECT HBSAG QUALITATIVE REAGENT KIT (100/500 TEST), ARCHITECT HBSAG QUALITATIVE CONFIRMATORY REAGENT KIT | ABBOTT LABORATORIES | Change a quality control standard and specifications used to qualify kit subcomponents. |
| P110037/S037 | 07/03/2018 | X - 30-Day Notice | COBAS AMPLIPREP/COBAS TAQMAN CYTOMEGALOVIRUS TEST | ROCHE MOLECULAR SYSTEMS, INC. | Reduce Environmental Monitoring testing at a manufacturing facility. |
| P110037/S038 | 07/05/2018 | X - 30-Day Notice | COBAS AMPLIPREP/COBAS TAQMAN CMV TEST | ROCHE MOLECULAR SYSTEMS, INC. | Eliminate a duplicative in-process test for designated kit reagents. |
| P110037/S039 | 07/26/2018 | X - 30-Day Notice | COBAS AMPLIPREP/COBAS TAQMAN CMV TEST | ROCHE MOLECULAR SYSTEMS, INC. | Scale-up a manufacturing process. |
| P110042/S111 | 07/26/2018 | X - 30-Day Notice | EMBLEM S-ICD ELECTRODE | BOSTON SCIENTIFIC CORPORATION | Implement the Central Monitoring System for the monitoring of environmental conditions at the Dorado facility. |

| | | | | | |
|---|---|---|---|---|---|
| P120010/S118 | 07/16/2018 | X - 30-Day Notice | MINIMED 530G SYSTEM | MEDTRONIC INC. | Relocating the molding process to a new manufacturing location and adding replacement presses and new molds for the needle hub assembly parts of the Enlite 3 Sensor and the Guardian Sensor (3). The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite 3 Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P120019/S021 | 07/03/2018 | X - 30-Day Notice | ROCHE COBAS EGFR MUTATION TEST, ROCHE COBAS DNA SAMPLE PREPARATION KIT | ROCHE | Reduce Environmental Monitoring testing at a manufacturing facility. |
| P120019/S022 | 07/05/2018 | X - 30-Day Notice | COBAS EGFR MUTATION TEST, V2.0 | ROCHE | Eliminate a duplicative in-process test for designated kit reagents. |
| P130006/S055 | 07/02/2018 | X - 30-Day Notice | GORE VIABAHN ENDOPROSTHESIS AND GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE | W.L. GORE & ASSOCIATES,INC | Update for device component manufacturing equipment. |
| P130006/S056 | 07/05/2018 | X - 30-Day Notice | GORE VIABAHN ENDOPROSTHESIS AND GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE | W.L. GORE & ASSOCIATES,INC | New polymer processing equipment and an alternate cleaning process. |
| P130006/S057 | 07/27/2018 | X - 30-Day Notice | GORE VIABAHN ENDOPROSTHESIS, GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE | W.L. GORE & ASSOCIATES,INC | Transferring manufacturing of raw materials, intermediate materials and manufacturing aids to an external supplier. |
| P130007/S036 | 07/11/2018 | X - 30-Day Notice | ANIMAS VIBE SYSTEM | ANIMAS CORP. | Relocation of the incoming acceptance activities for the insulin cartridge used with the Animas Vibe Insulin Pump. The Animas Vibe Insulin pump is a component of the Animas Vibe System. |

| | | | | | |
|---|---|---|---|---|---|
| P130009/S091 | 07/11/2018 | X - 30-Day Notice | EDWARDS SAPIEN XT TRANSCATHETER HEART VALVES | EDWARDS LIFESCIENCES, LLC. | Addition of a verification step during final valve packaging. |
| P130009/S092 | 07/18/2018 | X - 30-Day Notice | SAPIEN XT TRANSCATHETER HEART VALVE | EDWARDS LIFESCIENCES, LLC. | Addition of an Optical Character Verification (OCV) system during the preliminary valve packaging process. |
| P130021/S050 | 07/02/2018 | X - 30-Day Notice | COREVALVE SYSTEM, COREVALVE EVOLUT R SYSTEM, COREVALVE EVOLUT PRO SYSTEM | MEDTRONIC COREVALVE LLC | Modify the number of samples used for the sterility testing prior to final release of the implants. |
| P130030/S052 | 07/11/2018 | X - 30-Day Notice | REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM | BOSTON SCIENTIFIC CORP. | Parametric release of product sterilized in the BSC2000-2 cycle. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P140023/S014 | 07/03/2018 | X - 30-Day Notice | ROCHE COBAS KRAS MUTATION TEST, ROCHE COBAS DNA SAMPLE PREPARATION KIT | ROCHE MOLECULAR SYSTEMS, INC. | Reduce Environmental Monitoring testing at a manufacturing facility. |
| P140023/S015 | 07/05/2018 | X - 30-Day Notice | COBAS KRAS MUTATION TEST | ROCHE MOLECULAR SYSTEMS, INC. | Eliminate a duplicative in-process test for designated kit reagents. |
| P140031/S068 | 07/11/2018 | X - 30-Day Notice | EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVES | EDWARDS LIFESCIENCES, LLC. | Addition of a verification step during final valve packaging. |
| P140031/S069 | 07/15/2018 | X - 30-Day Notice | EDWARDS CERTITUDE INTRODUCER SHEATH SET, MODELS 9600IS18, 9600IS21 | EDWARDS LIFESCIENCES, LLC. | Implement a change to the formulation of the mold release agent used in the production of the introducers in the Edwards Certitude introducer sheath sets. |
| P140031/S070 | 07/18/2018 | X - 30-Day Notice | SAPIEN 3 TRANSCATHETER HEART VALVE | EDWARDS LIFESCIENCES, LLC. | Addition of an Optical Character Verification (OCV) system during the preliminary valve packaging process. |

| | | | | | |
|---|---|---|---|---|---|
| P140031/S071 | 07/27/2018 | X - 30-Day Notice | SAPIEN 3 TRANSCATHETER HEART VALVE | EDWARDS LIFESCIENCES, LLC. | Increase in the number of frames and valve holders ultrasonically cleaned per load. |
| P140032/S014 | 07/18/2018 | X - 30-Day Notice | IMPLANTABLE SYSTEM FOR REMODULIN | MEDTRONIC, INC. | Change in manufacturing site for parts cleaning. |
| P140032/S015 | 07/30/2018 | X - 30-Day Notice | IMPLANTABLE SYSTEM FOR REMODULIN | MEDTRONIC, INC. | Changes to the surface treatment used on select components of the SynchroMed II motor assembly. |
| P140033/S035 | 07/19/2018 | X - 30-Day Notice | TENDRIL MRI | ST. JUDE MEDICAL, INC. | Change the cleaning agent and cleaning process on the incoming tools used in the manufacture of MCRDs. |
| P150001/S045 | 07/02/2018 | X - 30-Day Notice | MINIMED 630G INSULIN PUMP | MEDTRONIC MINIMED | Addition of a laser welding equipment for the fabrication of the drive motor assembly parts used in the MiniMed 630G Pump and the MiniMed 670G Pump, part of MiniMed 630G System with SmartGuard, and MiniMed 670G System respectively. |
| P150001/S047 | 07/16/2018 | X - 30-Day Notice | MINIMED 630G SYSTEM | MEDTRONIC MINIMED | Relocating the molding process to a new manufacturing location and adding replacement presses and new molds for the needle hub assembly parts of the Enlite 3 Sensor and the Guardian Sensor (3). The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite 3 Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems. |
| P150005/S038 | 07/11/2018 | X - 30-Day Notice | BLAZER OPEN IRRIGATED TEMPERATURE ABLATION CATHETER | BOSTON SCIENTIFIC CORP. | Parametric release of product sterilized in the BSC2000-2 cycle. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P150012/S063 | 07/05/2018 | X - 30-Day Notice | INGEVITY MRI PASSIVE FIXATION LEADS, INGEVITY NON-MRI PASSIVE FIXATION LEADS | BOSTONSCIENTIFIC | Addition of new molding preparation equipment with updated software, application of existing overmolding equipment already in use for other leads, and duplication of existing process monitoring testing to monitor output of the added equipment. |
| P150012/S064 | 07/26/2018 | X - 30-Day Notice | INGEVITY, INGEVITY MRI | BOSTONSCIENTIFIC | Implement the Central Monitoring System for the monitoring of environmental conditions at the Dorado facility. |
| P150014/S016 | 07/03/2018 | X - 30-Day Notice | COBAS HBV TEST | ROCHE MOLECULAR SYSTEMS, INC. | Reduce Environmental Monitoring testing at a manufacturing facility. |

| | | | | | |
|---|---|---|---|---|---|
| P150014/S017 | 07/05/2018 | X - 30-Day Notice | COBAS HBV | ROCHE MOLECULAR SYSTEMS, INC. | Eliminate a duplicative in-process test for designated kit reagents. |
| P150014/S018 | 07/26/2018 | X - 30-Day Notice | COBAS HBV | ROCHE MOLECULAR SYSTEMS, INC. | Scale-up a manufacturing process. |
| P150015/S015 | 07/03/2018 | X - 30-Day Notice | COBAS HCV TEST | ROCHE MOLECULAR SYSTEMS, INC. | Reduce Environmental Monitoring testing at a manufacturing facility. |
| P150015/S016 | 07/05/2018 | X - 30-Day Notice | COBAS HCV | ROCHE MOLECULAR SYSTEMS, INC. | Eliminate a duplicative in-process test for designated kit reagents. |
| P150015/S017 | 07/26/2018 | X - 30-Day Notice | COBAS HCV | ROCHE MOLECULAR SYSTEMS, INC. | Scale-up a manufacturing process. |
| P150016/S015 | 07/26/2018 | X - 30-Day Notice | TRIDYNE VASCULAR SEALENT | NEOMEND, INC. | Change to the radiation dose used for the sterile Nalgene plastic containers used to store and deliver the Polyethylene Glycol Disuccinimidyl Succinate (PEG(SS)2) raw material to Neomend. |
| P150017/S008 | 07/02/2018 | X - 30-Day Notice | CARTIVA SCI IMPLANT | CARTIVA, INC | Add an alternate raw material supplier for the manufacture of Cartiva SCI Implant. |
| P150017/S009 | 07/02/2018 | X - 30-Day Notice | CARTIVA SCI | CARTIVA, INC | Add an additional clean room for use in the manufacture of Cartiva SCI Implant. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P150019/S044 | 07/16/2018 | X - 30-Day Notice | MINIMED PARADIGM REALTIME REVEL SYSTEM | MEDTRONIC MINIMED | Relocating the molding process to a new manufacturing location and adding replacement presses and new molds for the needle hub assembly parts of the Enlite 3 Sensor and the Guardian Sensor (3). The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite 3 Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems. |

| | | | | | |
|---|---|---|---|---|---|
| P150021/S030 | 07/06/2018 | X - 30-Day Notice | FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM | ABBOTT DIABETES CARE INC. | Additional Wash/Vision System in order to increase production capacity for the FreeStyle Libre sensor pack. The sensor pack is a component of the FreeStyle Libre and FreeStyle Libre Pro Flash Glucose Monitoring Systems. |
| P150029/S020 | 07/16/2018 | X - 30-Day Notice | MINIMED IPRO2 CGM SYSTEM WITH ENLITE SENSOR | MEDTRONIC MINIMED | Relocating the molding process to a new manufacturing location and adding replacement presses and new molds for the needle hub assembly parts of the Enlite 3 Sensor and the Guardian Sensor (3). The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite 3 Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems. |
| P150031/S007 | 07/25/2018 | X - 30-Day Notice | VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM | BOSTON SCIENTIFIC CORP. | Replacement of environmental monitoring system. |
| P150036/S031 | 07/18/2018 | X - 30-Day Notice | EDWARDS INTUITY ELITE VALVE SYSTEM | EDWARDS LIFESCIENCES, LLC. | Addition of an Optical Character Verification (OCV) system during the preliminary valve packaging process. |
| P150036/S032 | 07/26/2018 | X - 30-Day Notice | EDWARDS INTUITY ELITE VALVE SYSTEM | EDWARDS LIFESCIENCES, LLC. | Addition of a new cleaning process utilizing an ultrasonic cleaner for surgical heart valve polyester support bands. |
| P150037/S010 | 07/23/2018 | X - 30-Day Notice | CYPASS ULTRA SYSTEM | ALCON RESEARCH, LTD | Addition of the Sinking Spring, PA facility as an alternative manufacturing site for the CyPass Ultra System and implement changes to the inspection test methods and acceptance criteria for the stent delivery system. |
| P150041/S003 | 07/11/2018 | X - 30-Day Notice | VYSIS CLL FISH PROBE KIT | ABBOTT MOLECULAR, INC. | Manufacturing process scale ranges. |
| P150048/S024 | 07/18/2018 | X - 30-Day Notice | EDWARDS INSPIRIS RESILIA AORTIC VALVE AND EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS | EDWARDS LIFESCIENCES, LLC. | Addition of an Optical Character Verification (OCV) system during the preliminary valve packaging process. |

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

| | | | | | |
|---|---|---|---|---|---|
| P150048/S024 | 07/18/2018 | X - 30-Day Notice | EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500) | EDWARDS LIFESCIENCES, LLC. | Addition of an Optical Character Verification (OCV) system during the preliminary valve packaging process. |
| P160001/S019 | 07/11/2018 | X - 30-Day Notice | OBALON BALLOON KIT | OBALON THERAPEUTICS, INC. | Modify four related manufacturing fixtures, and introduce a new fixture and associated process steps for the balloon film trimming process. |
| P160004/S013 | 07/02/2018 | X - 30-Day Notice | GORE TIGRIS VASCULAR STENT | W. L. GORE & ASSOCIATES, INC. | Update for device component manufacturing equipment. |
| P160004/S014 | 07/05/2018 | X - 30-Day Notice | GORE TIGRIS VASCULAR STENT | W. L. GORE & ASSOCIATES, INC. | New polymer processing equipment and an alternate cleaning process. |
| P160004/S016 | 07/27/2018 | X - 30-Day Notice | GORE TIGRIS VASCULAR STENT | W. L. GORE & ASSOCIATES, INC. | Transferring manufacturing of raw materials, intermediate materials and manufacturing aids to an external supplier. |
| P160007/S007 | 07/16/2018 | X - 30-Day Notice | GUARDIAN CONNECT SYSTEM | MEDTRONIC MINIMED | Relocating the molding process to a new manufacturing location and adding replacement presses and new molds for the needle hub assembly parts of the Enlite 3 Sensor and the Guardian Sensor (3). The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite 3 Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems. |
| P160014/S002 | 07/12/2018 | X - 30-Day Notice | COBRA PZF NANOCOATED CORONARY STENT SYSTEM | CELONOVA BIOSCIENCES, INC. | Change to the manufacturer of the adhesion promoter used in the coating process of the COBRA PzF stent. |
| P160017/S043 | 07/02/2018 | X - 30-Day Notice | MINIMED 670G SYSTEM PUMP | MEDTRONIC MINIMED, INC. | Addition of a laser welding equipment for the fabrication of the drive motor assembly parts used in the MiniMed 630G Pump and the MiniMed 670G Pump, part of MiniMed 630G System with SmartGuard, and MiniMed 670G System respectively. |
| P160017/S045 | 07/16/2018 | X - 30-Day Notice | MINIMED 670G SYSTEM | MEDTRONIC MINIMED, INC. | Relocating the molding process to a new manufacturing location and adding replacement presses and new molds for the needle hub assembly parts of the Enlite 3 Sensor and the Guardian Sensor (3). The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite 3 Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems. |
| P160021/S010 | 07/05/2018 | X - 30-Day Notice | GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS | W. L. GORE & ASSOCIATES, INC. | New polymer processing equipment and an alternate cleaning process. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P160021/S011 | 07/27/2018 | X - 30-Day Notice | GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS | W. L. GORE & ASSOCIATES, INC. | Transferring manufacturing of raw materials, intermediate materials and manufacturing aids to an external supplier. |
| P160030/S022 | 07/06/2018 | X - 30-Day Notice | FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM | ABBOTT DIABETES CARE INC. | Additional Wash/Vision System in order to increase production capacity for the FreeStyle Libre sensor pack. The sensor pack is a component of the FreeStyle Libre and FreeStyle Libre Pro Flash Glucose Monitoring Systems. |
| P160041/S009 | 07/03/2018 | X - 30-Day Notice | COBAS CMV TEST FOR USE ON THE COBAS 6800/8800 SYSTEM | ROCHE MOLECULAR SYSTEMS, INC. | Reduce Environmental Monitoring testing at a manufacturing facility. |
| P160041/S010 | 07/05/2018 | X - 30-Day Notice | COBAS CMV | ROCHE MOLECULAR SYSTEMS, INC. | Eliminate a duplicative in-process test for designated kit reagents. |
| P160041/S011 | 07/26/2018 | X - 30-Day Notice | COBAS CMV | ROCHE MOLECULAR SYSTEMS, INC. | Scale-up a manufacturing process. |
| P170008/S006 | 07/18/2018 | X - 30-Day Notice | ELUNIR RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM | MEDINOL, LTD. | Introduce an automated panel rotator to the stent panel coating process. |
| P170008/S007 | 07/17/2018 | X - 30-Day Notice | ELUNIR RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM | MEDINOL, LTD. | Introduce a one-stepped semi-automated inspection process. |
| P170012/S005 | 07/11/2018 | X - 30-Day Notice | HEMOBLAST¿ BELLOWS | BIOM'UP SA | Changes in the collagen powder manufacturing processes and addition of duplicate processing equipment to expand production capacity. |

**Total: 185**