# PMA Monthly approvals from 3/1/2022 to 3/31/2022

## Original

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P150035 | 03/31/2022 | PMAO - PMA Origi | AVEIR VR LEADLESS SYSTEM | ABBOTT MEDICAL | Approval for the Aveir Leadless Pacemaker, Aveir Delivery System Catheter, and Aveir Link Module. |
| P200036 | 03/01/2022 | PMAO - PMA Origi | ECOIN PERIPHERAL NEUROSTIMULATOR | VALENCIA TECHNOLOGIES CORPORATION | Approval of the eCoin® Peripheral Neurostimulator. The device is intended to be used to treat urgency urinary incontinence in patients intolerant to or having an inadequate response to other more conservative treatments or who have undergone a successful trial of percutaneous tibial nerve stimulation. |
| P210018 | 03/17/2022 | PMAO - PMA Origi | ET CONTROL | DATEX-OHMEDA, INC., A GENERAL ELECTRIC COMPANY | Approval for Et Control indicated for use with the Datex-Ohmeda Aisys CS2 anesthesia system to support clinicians in maintaining the targeted end tidal oxygen and end tidal anesthetic agent concentrations that the clinician sets during an anesthetic procedure, by making multiple, limited adjustments to the fresh gas composition and total flow. The Et Control feature is indicated for patients, 18 years of age and older.<br>The Aisys CS2 anesthesia system and the Et Control feature are intended for prescription use only. |
| P210034 | 03/29/2022 | PMAO - PMA Origi | AGILI-C | CARTIHEAL LTD. | Approval for Agili-C. The Agili-C scaffold is indicated for the treatment of an International Cartilage Repair Society (ICRS) grade III or above knee-joint surface lesion(s), with a total treatable area of 1-7cm2, without severe osteoarthritis (Kellgren-Lawrence grade 0-3). |

**Total: 4**

## Supplements

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
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| N12159/S088 | 03/15/2022 | Y - 135 Review Tra | SURGICEL BRAND ABSORBABLE HEMOSTAT | ETHICON, INC. | Approval for qualification of a new carding suite and addition of duplicate equipment in the Ethicon, LLC, San Lorenzo, Puerto Rico facility. |
| P830055/S284 | 03/24/2022 | S - Special CBE | LCS(R) TOTAL KNEE SYSTEM | DEPUY, INC. | Approval for including instructions on taping method for final shipper boxes and addition of inspection of the package before shipping process. |
| P840001/S501 | 03/16/2022 | Y - 135 Review Tra | ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS | MEDTRONIC NEUROMODULATION | Approval for the replacement of degreasing equipment and use of a new degreasing solvent. |
| P840001/S506 | 03/14/2022 | R - Real-Time Proc | ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS | MEDTRONIC NEUROMODULATION | Approval for changes to the user manual for the Intellis Recharge Therapy Manager (RTM) to provide guidelines to help guide patients on how to prevent damage to the RTM cable. |
| P850068/S014 | 03/18/2022 | N - Normal 180 Day | SILSOFT (ELASTOFILCON A) CONTACT LENSES | BAUSCH & LOMB, INC. | Approval for implementing an alternate packaging configuration and revisions to the cosmetic inspection criteria for the silsoft (elastofilcon A) contact lenses. |



Data as of 04/12/2022 06:44 AM

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
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| P860004/S379 | 03/16/2022 | Y - 135 Review Tra | MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM | MEDTRONIC INC. | Approval for the replacement of degreasing equipment and use of a new degreasing solvent. |
| P860004/S384 | 03/18/2022 | R - Real-Time Proc | MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM | MEDTRONIC INC. | Approval for outer packaging changes. |
| P880047/S047 | 03/07/2022 | R - Real-Time Proc | INTERCEED TC7 ABSORBABLE ADHESION BARRIER | ETHICON, INC. | Approval for the addition of three additional size varieties (3 inches x 2 inches, 3 inches x 5 inches, and 3 inches x 6 inches) to the GYNECARE INTERCEED Absorbable Adhesion Barrier device line. |
| P890017/S022 | 03/08/2022 | R - Real-Time Proc | PALMAZ BALLOON EXPANDABLE STENT | CORDIS US CORPORATIO N | Approval for updates to the MRI section in the Palmaz labeling and other minor labeling updates. |
| P950005/S082 | 03/08/2022 | N - Normal 180 Day | WEBSTER DIAG./ABLATION DEFLECTABLE TIP CATHETER | BIOSENSE WEBSTER, INC | Approval for the nGEN Generator (compatible with the THERMOCOOL, NAVISTAR and CELSIUS catheters), the addition of a manufacturing site in Israel to manufacture the nGEN Generator and nGEN Pump, and the addition of a manufacturing site in Mexico to manufacture the Interface Cable between the CELSIUS catheters to the nGEN Generator. |
| P950037/S232 | 03/08/2022 | R - Real-Time Proc | DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS | BIOTRONIK, INC. | Approval for a change to the battery cathode separator material. |
| P950037/S233 | 03/04/2022 | O - Normal 180 Day | DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS | BIOTRONIK, INC. | Approval for updated labeling for Siello Pacing Leads based on final post approval study results. |
| P960009/S409 | 03/16/2022 | Y - 135 Review Tra | MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM | MEDTRONIC INC. | Approval for the replacement of degreasing equipment and use of a new degreasing solvent. |
| P960009/S417 | 03/18/2022 | R - Real-Time Proc | MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM | MEDTRONIC INC. | Approval for outer packaging changes. |
| P960009/S422 | 03/25/2022 | O - Normal 180 Day | MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM | MEDTRONIC INC. | Approval of the following revisions to the protocol for the post-approval study (PAS), DBS for Epilepsy New Enrollment PAS: a) evaluate seizure worsening and changes in seizure frequency over time without formal hypothesis testing for safety; b) change the sample size for the primary effectiveness objective to approximately 72 evaluable subjects at 3 years (140 enrolled subjects to have 90 implanted subjects) from 112 evaluable subjects at 3 years (216 enrolled subjects to have 140 implanted subjects); c) change in baseline diary length from 84 days to 28 days; d) update to estimated study milestones; e) migration to a new Medtronic Clinical Investigation Plan (CIP) template; and f) general clerical edits (e.g., addition of lead Principal Investigator name and contact information, formatting, grammar/ wording for consistency, improved readability, etc.). |
| P960040/S475 | 03/04/2022 | O - Normal 180 Day | VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM | BOSTON SCIENTIFIC | Approval to suspend enrollment for six (6) months for MANAGE-HF. |

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| P970004/S343 | 03/16/2022 | Y - 135 Review Tra | MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL | MEDTRONIC NEUROMODULATION | Approval for the replacement of degreasing equipment and use of a new degreasing solvent. |
| P970004/S352 | 03/18/2022 | R - Real-Time Proc | MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL | MEDTRONIC NEUROMODULATION | Approval for outer packaging changes. |
| P970051/S210 | 03/11/2022 | O - Normal 180 Day | NUCLEUS 24 COCHLEAR IMPLANT SYSTEM | COCHLEAR AMERICAS | Approval for the PAS protocol which has been submitted to comply with the conditions of approval. |
| P990009/S067 | 03/09/2022 | R - Real-Time Proc | FLOSEAL MATRIX/ FLOSEAL MATRIX HEMOSTATIC SEALANT/ PROCEED HEMOSTATIC SEALANT | BAXTER HEALTHCARE CORP. | Approval for kitting an alternate 5 mL FLOSEAL kit configuration, where the human Thrombin vial will be replaced with a vial of recombinant human Thrombin (RECOTHROM). |
| P990021/S005 | 03/02/2022 | N - Normal 180 Day | DIOMED 630 PDT LASER | PINNACLE BIOLOGICS, INC. | Approval for PHOTOFRIN® 630 PDT Laser, Model BWF5-630-2-PI (an updated design of the currently marketed laser, the DIOMED 630 PDT Laser, Model T2USA), and B&W TEK Inc., located at 18 Shea Way, Suite 103, Newark, DE, 19713 as the new manufacturing site of the PHOTOFRIN® 630 PDT Laser, Model BWF5-630-2-PIN. |
| P990025/S067 | 03/08/2022 | N - Normal 180 Day | NAVI-STAR DIAGNOSTIC/ ABLATION DEFLECTABLE TIP CATHETER | BIOSENSE WEBSTER, INC. | Approval for the nGEN Generator (compatible with the THERMOCOOL, NAVISTAR and CELSIUS catheters), the addition of a manufacturing site in Israel to manufacture the nGEN Generator and nGEN Pump, and the addition of a manufacturing site in Mexico to manufacture the Interface Cable between the CELSIUS catheters to the nGEN Generator. |
| P990071/S051 | 03/08/2022 | N - Normal 180 Day | STOCKERT 70 RADIOFREQUENCY ABLATION GENERATOR | BIOSENSE WEBSTER, INC. | Approval for the nGEN Generator (compatible with the THERMOCOOL, NAVISTAR and CELSIUS catheters), the addition of a manufacturing site in Israel to manufacture the nGEN Generator and nGEN Pump, and the addition of a manufacturing site in Mexico to manufacture the Interface Cable between the CELSIUS catheters to the nGEN Generator. |
| P000029/S094 | 03/22/2022 | Y - 135 Review Tra | DEFLUX INJECTABLE GEL | PALETTE LIFE SCIENCES | Approval for a new alternate contract sterility testing laboratory for the DEFLUX Injectable Gel and the Solestra Injectable Gel. |
| P010012/S550 | 03/04/2022 | O - Normal 180 Day | CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL | BOSTON SCIENTIFIC CORP. | Approval to suspend enrollment for six (6) months for MANAGE-HF. |
| P010068/S067 | 03/08/2022 | N - Normal 180 Day | NAVISTAR/CELSIUS DS DIAGNOSTIC/ABLATION DEFLECTABLE 8MM TIP CATHETER | BIOSENSE WEBSTER, INC. | Approval for the nGEN Generator (compatible with the THERMOCOOL, NAVISTAR and CELSIUS catheters), the addition of a manufacturing site in Israel to manufacture the nGEN Generator and nGEN Pump, and the addition of a manufacturing site in Mexico to manufacture the Interface Cable between the CELSIUS catheters to the nGEN Generator. |

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| P030016/S035 | 03/25/2022 | P - Panel Track | VISIAN ICL (IMPLANTABLE COLLAMER LENS) | STAAR SURGICAL COMPANY | Approval for the EVO/EVO+ Visian Implantable Collamer Lens.<br><br>The ICL is indicated for use in patients 21-45 years of age:<br>1. for the correction of myopia with spherical equivalent ranging from -3.0D to less than or equal to-15.0D with less than or equal to 2.5D of astigmatism at the spectacle plane;<br>2. for the reduction of myopia with spherical equivalent ranging from greater than -15.0D to -20.0D with less than or equal to 2.5D of astigmatism at the spectacle plane;<br>3. with an anterior chamber depth (ACD) of 3.00 mm or greater, when measured from the corneal endothelium to the anterior surface of the crystalline lens and a stable refractive history (within 0.5D for 1 year prior to implantation); and<br>4.The ICL is intended for placement in the posterior chamber (ciliary sulcus) of the phakic eye.<br><br>The EVO TICL is indicated for use in patients 21-45 years of age:<br>1. for the correction of myopic astigmatism with spherical equivalent ranging from -3.0D to less than or equal to -15.0D (in the spectacle plane) with cylinder (spectacle plane) of 1.0D to 4.0D;<br>2. for the reduction of myopic astigmatism with spherical equivalent ranging from greater than -15.0D to -20.0D (in the spectacle plane) with cylinder (spectacle plane)1.0D to 4.0D;<br>3. with an anterior chamber depth (ACD) of 3.00 mm or greater, when measured from the corneal endothelium to the anterior surface of the crystalline lens and a stable refractive history (within 0.5 D for both spherical equivalent and cylinder for 1 year prior to implantation); and<br>4. The TICL is intended for placement in the posterior chamber (ciliary sulcus) of the phakic eye. |
| P030031/S122 | 03/08/2022 | N - Normal 180 Day | BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS | BIOSENSE WEBSTER, INC. | Approval for the nGEN Generator (compatible with the THERMOCOOL, NAVISTAR and CELSIUS catheters), the addition of a manufacturing site in Israel to manufacture the nGEN Generator and nGEN Pump, and the addition of a manufacturing site in Mexico to manufacture the Interface Cable between the CELSIUS catheters to the nGEN Generator. |
| P040036/S084 | 03/08/2022 | N - Normal 180 Day | NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER | BIOSENSE WEBSTER, INC. | Approval for the nGEN Generator (compatible with the THERMOCOOL, NAVISTAR and CELSIUS catheters), the addition of a manufacturing site in Israel to manufacture the nGEN Generator and nGEN Pump, and the addition of a manufacturing site in Mexico to manufacture the Interface Cable between the CELSIUS catheters to the nGEN Generator. |
| P050023/S165 | 03/08/2022 | R - Real-Time Proc | TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD | BIOTRONIK, INC. | Approval for a change to the battery cathode separator material. |
| P060028/S044 | 03/08/2022 | O - Normal 180 Day | MENTOR MEMORYSHAPE BREAST IMPLANTS | MENTOR WORLDWIDE LLC | Approval of the revised statistical analysis plan (SAP) for the post-approval study (PAS) protocol. The SAP has been submitted to align with protocol changes. |
| P070008/S134 | 03/08/2022 | 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 a change to the battery cathode separator material. |
| P070026/S079 | 03/05/2022 | O - Normal 180 Day | CERAMAX CERAMIC HIP SYSTEM | DEPUY ORTHOPAEDICS, INC. | Approval for revisions to device labeling that was updated to include information on the Post-Approval Study (PAS) of the CERAMAX Ceramic Total Hip System. |

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| P070026/S094 | 03/22/2022 | S - Special CBE | CERAMAX CERAMIC HIP SYSTEM | DEPUY ORTHOPAEDICS, INC. | Approval for improving instructions of the taping method for final shipper boxes and inspection. |
| P080025/S238 | 03/16/2022 | Y - 135 Review Tra | MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM | MEDTRONIC NEUROMODULATION | Approval for the replacement of degreasing equipment and use of a new degreasing solvent. |
| P080025/S247 | 03/18/2022 | R - Real-Time Proc | MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM | MEDTRONIC NEUROMODULATION | Approval for outer packaging changes. |
| P100010/S123 | 03/07/2022 | R - Real-Time Proc | ARCTIC FRONT CRYOCATHETER SYSTEM | MEDTRONIC CRYOCATH LP | Approval for changes to the instructions for use and labels to align with product specifications and changes to the adverse events section in the instructions for use to align with products in the same family. |
| P100014/S032 | 03/22/2022 | Y - 135 Review Tra | SOLESTA INJECTABLE GEL | PALETTE LIFE SCIENCES | Approval for a new alternate contract sterility testing laboratory for the DEFLUX Injectable Gel and the Solestra Injectable Gel. |
| P100047/S193 | 03/11/2022 | S - Special CBE | HEARTWARE VENTRICULAR ASSIST SYSTEM | MEDTRONIC | Approval for updates to the controller visual inspection assembly procedure. |
| P100047/S195 | 03/16/2022 | S - Special CBE | HEARTWARE VENTRICULAR ASSIST SYSTEM | MEDTRONIC | Approval for updates to the clinician Instructions for Use (IFU) and the Patient Manual (PM) to add clarity with regard to cleaning certain components of the HVAD System |
| P110019/S118 | 03/11/2022 | N - Normal 180 Day | XIENCE PRIME AND XIENCE PRIME LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM | ABBOTT VASCULAR | Approval for approval for two changes to the existing design: 1) additional XIENCE Skypoint sizes, specifically diameters 4.50 mm and 5.0 mm; and 2) a dual neck catheter chassis with dimensional changes to the outer membrane diameters. |
| P130021/S111 | 03/24/2022 | S - Special CBE | MEDTRONIC COREVALVE SYSTEM | MEDTRONIC, INC. | Approval for an additional visual inspection to be temporarily implemented at the packaging work step. |
| P130026/S072 | 03/04/2022 | N - Normal 180 Day | TACTICATH QUARTZ SET | ST. JUDE MEDICAL | Approval for a change to a patient-contacting adhesive material and the curing mechanism. |
| P140003/S091 | 03/16/2022 | R - Real-Time Proc | IMPELLA 2.5 SYSTEM | ABIOMED, INC. | Approval for an alternative luer to be used in the manufacture of the purge sidearm assembly. |
| P140004/S028 | 03/02/2022 | R - Real-Time Proc | SUPERION INTERSPINOUS SPACER | BOSTON SCIENTIFIC NEUROMODULATION | Approval for a manufacturing change for an instrument component. |
| P140020/S022 | 03/11/2022 | N - Normal 180 Day | BRACANALYSIS CDX | MYRIAD GENETIC LABORATORIES | Approval for inclusion of an additional clinical study (OlympiA) data in the clinical section of the labeling. |
| P150030/S016 | 03/04/2022 | Y - 135 Review Tra | R3 DELTA CERAMIC HIP SYSTEM | SMITH & NEPHEW, INC. | Approval for a change of coolant lubricant emulsion formulation during manufacturing. |

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| P150031/S045 | 03/24/2022 | N - Normal 180 Day | VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM | BOSTON SCIENTIFIC CORP. | Approval to labeling change to add the Medtronic Leads, Extensions, Lead Accessories and the BSN M8 Adaptor to the list of devices that are Magnetic resonance imaging (MRI) scan eligible for the Vercise Genus DBS System. There is no change to the MRI radiology conditions of use or any other implant conditions of use compared to those approved for the Vercise Genus DBS System. |
| P150036/S057 | 03/11/2022 | Y - 135 Review Tra | EDWARDS INTUITY ELITE VALVE SYSTEM | EDWARDS LIFESCIENCES, LLC. | Approval for the use of a new dimension measuring system for INTUITY valve delivery systems manufactured at the Edwards Draper facility. |
| P150048/S047 | 03/16/2022 | N - Normal 180 Day | EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500) | EDWARDS LIFESCIENCES, LLC. | Approval for material and design modifications related to the wireform, sewing ring, valve holder and valve handle |
| P160035/S024 | 03/04/2022 | Y - 135 Review Tra | EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE | BERLIN HEART INC. | Approval to change to the post-conditioning aeration process following Ethylene Oxide sterilization and the addition of another aeration chamber. |
| P160049/S015 | 03/25/2022 | P - Panel Track | STELLAREX 0.035 OTW DRUG-COATED ANGIOPLASTY BALLOON | THE SPECTRANETICS CORP. | Approval for The Stellarex 0.035 inch OTW Drug-coated Angioplasty Balloon. The Stellarex 0.035 inch OTW Drug-coated Angioplasty Balloon is indicated for percutaneous transluminal angioplasty (PTA), after appropriate vessel preparation, of de novo, restenotic, or in-stent restenotic lesions up to 180 mm in length in superficial femoral or popliteal arteries with reference vessel diameters of 4-6 mm. |
| P160054/S039 | 03/24/2022 | O - Normal 180 Day | HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM | ABBOTT MEDICAL | Approval for various updates to the Instructions for Use to add the final clinical results of the Long-Term Durability Cohort of the pivotal trial and of the post-approval study entitled "Continued Follow-up of the Continued Access Cohort." |
| P170011/S036 | 03/16/2022 | R - Real-Time Proc | IMPELLA RP SYSTEM | ABIOMED, INC. | Approval for an alternative luer to be used in the manufacture of the purge sidearm assembly. |
| P170019/S033 | 03/16/2022 | R - Real-Time Proc | FOUNDATIONONE CDX | FOUNDATION MEDICINE, INC. | Approval for FoundationOne CDx (FICDx) label expansion to obtain companion diagnostic group labeling claim for non-small cell lung cancer patients harboring EGFR exon 19 deletions or EGFR exon 21 L858R mutations for treatment with any one of the FDA-approved EGFR Tyrosine Kinase Inhibitors (TKI). |
| P170027/S009 | 03/10/2022 | N - Normal 180 Day | THEROX DOWNSTREAM SYSTEM | THEROX, INC. | Approval for a new material plasticizer for the tubing associated with the TherOx SSO2 DownStream Cartridge, part of the TherOx Downstream System. |
| P170042/S011 | 03/24/2022 | O - Normal 180 Day | COVERA¿ VASCULAR COVERED STENT | C.R. BARD, INC | Approval for an update to the labeling to include the 36-month data on patients enrolled in the AVeNEW IDE extended follow-up study. |
| P180002/S020 | 03/09/2022 | O - Normal 180 Day | ZEPHYR ENDOBRONCHIAL VALVE SYSTEM | PULMONX CORPORATION | Approval for revising the study timeline due to COVID-19 pandemic delays |
| P180003/S005 | 03/01/2022 | N - Normal 180 Day | BIOMIMICS 3D VASCULAR STENT SYSTEM | VERYAN MEDICAL LTD. | Approval for the addition of an alternative sterilization site located at Synergy Health Sterilization UK Ltd, STERIS AST Unit 1, Alpha Court, Capitol Park, Thorne, DN8 5TZ, United Kingdom, addition of a new sterilization cycle, an alternative load configuration and ability to perform endotoxin testing on non-sterile samples in the current laboratory. |
| P180036/S009 | 03/16/2022 | N - Normal 180 Day | OPTIMIZER SMART SYSTEM | IMPULSE DYNAMICS (USA), INC. | Approval for MR Conditional labeling for the OPTIMIZER Smart Mini when combined with certain market approved pacing leads |

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| P180046/S038 | 03/07/2022 | N - Normal 180 Day | AXONICS SACRAL NEUROMODULATION SYSTEM | AXONICS MODULATION TECHNOLOGIES, INC. | Approval for a non-rechargeable Axonics Implantable Pulse Generator (IPG). |
| P180046/S046 | 03/03/2022 | R - Real-Time Proc | AXONICS SACRAL NEUROMODULATION SYSTEM | AXONICS MODULATION TECHNOLOGIES, INC. | Approval to extend the shelf life of the PNE Lead to 36 months. |
| P190006/S038 | 03/07/2022 | N - Normal 180 Day | AXONICS SACRAL NEUROMODULATION SYSTEM | AXONICS MODULATION TECHNOLOGIES, INC. | Approval for a non-rechargeable Axonics Implantable Pulse Generator (IPG). |
| P190006/S046 | 03/03/2022 | R - Real-Time Proc | AXONICS SACRAL NEUROMODULATION SYSTEM | AXONICS MODULATION TECHNOLOGIES, INC. | Approval to extend the shelf life of the PNE Lead to 36 months. |
| P190008/S018 | 03/04/2022 | O - Normal 180 Day | IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER | MEDTRONIC VASCULAR INC. | Approval of the revised protocol for the post-approval study (PAS) protocol. |
| P200010/S005 | 03/16/2022 | R - Real-Time Proc | GUARDANT360 CDX | GUARDANT HEALTH, INC. | Approval to use reagent lots interchangeably for Guardant360 CDx Sample Preparation Kit Boxes and a minor software update to accommodate the reagent interchangeability update. |
| P200028/S008 | 03/17/2022 | R - Real-Time Proc | DIAMONDTEMP ABLATION SYSTEM | MEDTRONIC INC. | Approval for software changes to the DiamondTemp Radiofrequency (RF) Generator. |
| P200039/S006 | 03/23/2022 | R - Real-Time Proc | SHOCKWAVE INTRAVASCULAR LITHOTRIPSY (IVL) SYSTEM WITH SHOCKWAVE C2 CORONARY INTRAVASCULAR LITHOTRIPSY (IVL) CATHETER | SHOCKWAVE MEDICAL, INC. | Approval for minor design, software, and labeling modifications to the device. |
| P210001/S001 | 03/21/2022 | N - Normal 180 Day | VENTANA MMR RXDX PANEL | VENTANA MEDICAL SYSTEMS INC (ROCHE TISSUE DIAGNOSTICS) | Approval for the Ventana MMR RxDx Panel as a CDx for identifying patients with solid tumors with dMMR status who may benefit from treatment with KEYTRUDA. |

**Total: 69**

## 30-Day Notice

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
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| N16895/S105 | 03/15/2022 | X - 30-Day Notice | SOFLENS CONTACT LENSES (POLYMACON) | BAUSCH & LOMB, INC. | Replacement of UV lamps with the same light wavelength. |
| P830055/S282 | 03/08/2022 | X - 30-Day Notice | LCS(R) TOTAL KNEE SYSTEM | DEPUY, INC. | Equipment changes for the LCS Total Knee System from current Neiodymium Yttrium Aluminum Garnet (YAG) Laser equipment to Ultraviolet (UV) Laser equipment for direct marking of UHMWPE components at an approved supplier. |
| P830055/S285 | 03/29/2022 | X - 30-Day Notice | LCS(R) TOTAL KNEE SYSTEM | DEPUY, INC. | Move GSR testing from a sub-tier supplier (Cambridge Polymer Group) of Mitsubishi Chemicals Advanced Materials (also known as MediTECH Medical Polymers) to Depuy Orthopaedics (i.e., in-house testing) for UHMWPE components used in the LCS® Total Knee System. |
| P830061/S203 | 03/14/2022 | X - 30-Day Notice | STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Modification to the electrode coating inspection process at Medtronic's supplier-Heraeus located in Hanau, Germany. |
| P830061/S205 | 03/29/2022 | X - 30-Day Notice | STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Modify test setups used for process monitoring of packaging. |
| P830063/S022 | 03/31/2022 | X - 30-Day Notice | GAMBRO FIBER PLASMAFILTER | BAXTER INTERNATIONAL, INC. | Sponsor proposed removal of visual inspection of two components at their Tunisia plant. The risk assessment and the quality report support this request. |
| P840001/S513 | 03/30/2022 | X - 30-Day Notice | ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS | MEDTRONIC NEUROMODULATION | Change to a new transport bin used in manufacturing at Medtronic Tempe Campus (MTC). |
| P850048/S058 | 03/03/2022 | X - 30-Day Notice | TANDEM-R PSA IMMUNORADIOMETRIC ASSAY | BECKMAN COULTER, INC. | Manufacturing change to scale up the antibody purification processed used in the Access Hybritech PSA assay. |
| P850064/S047 | 03/31/2022 | X - 30-Day Notice | MODEL 203 LIFE PULSE HIGH FREQUENCY VENTILATOR | BUNNELL, INC. | Change to the current Pneumatics Test Fixture that is used to perform in-process performance tests on the Pneumatics Subassembly (HFV 204) to ensure basic functionality and to make rough adjustments prior to installation of this subassembly into the Life PulseHigh Frequency Ventilator. |
| P860003/S106 | 03/11/2022 | X - 30-Day Notice | UVAR PHOTOPHERESIS SYSTEM | MALLINCKRODT PHARMACEUTICALS IRELAND LIMITED | Moving the moulding production of the Y-Fitting Adapter component from Harmac Buffalo, NY, USA site to Harmac Castlerea, Republic of Ireland site to improve moulding capacity and component supply. |
| P860004/S388 | 03/30/2022 | X - 30-Day Notice | MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM | MEDTRONIC INC. | Change to a new transport bin used in manufacturing at Medtronic Tempe Campus (MTC). |
| P860057/S206 | 03/31/2022 | X - 30-Day Notice | EDWARDS LIFESCIENCES PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES | EDWARDS LIFESCIENCES, LLC. | Increased number in manning in the Dry Plant Main Cleanroom at the Edwards Costa Rica Facility. |

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| P900056/S198 | 03/30/2022 | X - 30-Day Notice | ROTABLATOR(R) | BOSTON SCIENTIFIC CORP. | Add an alternate component supplier for the activation button switch on the device handle. |
| P900060/S064 | 03/07/2022 | X - 30-Day Notice | CARBOMEDICS PROSTHETIC HEART VALVE (CPHV) | CORCYM S.R.L. | Change to the formulation of a detergent used to clean valve orifices and leaflets. |
| P910073/S168 | 03/08/2022 | X - 30-Day Notice | ENDOTAK LEAD SYSTEM | BOSTON SCIENTIFIC | Add sterilization chamber equipment to the Dorado, Puerto Rico manufacturing facility. |
| P920015/S265 | 03/02/2022 | X - 30-Day Notice | MEDTRONIC(R) TRANSVENE LEAD SYSTEM | MEDTRONIC INC. | Inspect the surface finish on received components using a profilometer rather than a visual inspection. |
| P930014/S142 | 03/25/2022 | X - 30-Day Notice | ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES | ALCON LABORATORIES, INC. | Modification to the testing frequency of the acrylate monomer inhibitor removal in-process test. |
| P930027/S026 | 03/29/2022 | X - 30-Day Notice | IMMULITE SYSTEMS PSA & THIRD GENERATION PSA REAGENTS | SIEMENS HEALTHCARE DIAGNOSTICS INC. | Implementation of a change to the physical state of a raw material. |
| P930036/S019 | 03/29/2022 | X - 30-Day Notice | ADVIA CENTAUR AFP REAGENTS AND CALIBRATORS | SIEMENS HEALTHCARE DIAGNOSTICS INC. | Manufacture an instrument component at another location. |
| P930039/S238 | 03/14/2022 | X - 30-Day Notice | MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568 | MEDTRONIC, INC. | Modification to the electrode coating inspection process at Medtronic's supplier-Heraeus located in Hanau, Germany. |
| P930039/S240 | 03/29/2022 | X - 30-Day Notice | MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568 | MEDTRONIC, INC. | Modify test setups used for process monitoring of packaging. |
| P950020/S117 | 03/09/2022 | X - 30-Day Notice | FLEXATOME CUTTING BALLOON | BOSTON SCIENTIFIC CORP. | Additional Blade Casting Cell for the Wolverine Coronary Cutting Balloon production. |
| P950020/S118 | 03/31/2022 | X - 30-Day Notice | FLEXATOME CUTTING BALLOON | BOSTON SCIENTIFIC CORP. | Add Galway, Ireland as an additional manufacturing site for the WOLVERINE Monorail (MR) and Over the Wire (OTW) distal outer (monorail only), distal inner, proximal inner and bumper tip components. |
| P950020/S120 | 03/30/2022 | X - 30-Day Notice | FLEXATOME CUTTING BALLOON | BOSTON SCIENTIFIC CORP. | Automation of laser marker, leak test, and balloon inspect stations. |
| P950021/S025 | 03/29/2022 | X - 30-Day Notice | ADVIA CENTAUR & ADVIA CENTAUR CP PSA IMMUNOASSAY | SIEMENS HEALTHCARE DIAGNOSTICS | Manufacture an instrument component at another location. |
| P950037/S235 | 03/15/2022 | X - 30-Day Notice | DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS | BIOTRONIK, INC. | Tensile test optimization and lead tip welding inspection changes. |

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| P960004/S099 | 03/08/2022 | X - 30-Day Notice | THINLINE ENDOCARDIAL PACING LEADS | BOSTON SCIENTIFIC | Add sterilization chamber equipment to the Dorado, Puerto Rico manufacturing facility. |
| P960009/S423 | 03/30/2022 | X - 30-Day Notice | MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM | MEDTRONIC INC. | Change to a new transport bin used in manufacturing at Medtronic Tempe Campus (MTC). |
| P970003/S235 | 03/09/2022 | X - 30-Day Notice | VNS THERAPY SYSTEM | LIVANOVA USA, INC. | Add a new inspection of the bifurcated tubing wall thickness associated with the M303 Lead. |
| P970004/S357 | 03/30/2022 | X - 30-Day Notice | MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL | MEDTRONIC NEUROMODULATION | Change to a new transport bin used in manufacturing at Medtronic Tempe Campus (MTC). |
| P970004/S358 | 03/17/2022 | X - 30-Day Notice | MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL | MEDTRONIC NEUROMODULATION | Change to the visual inspection process at Medtronic Vascular for the lead model 978B1 subassembly. |
| P970051/S209 | 03/03/2022 | X - 30-Day Notice | NUCLEUS 24 COCHLEAR IMPLANT SYSTEM | COCHLEAR AMERICAS | Introduction of an alternate laser welding system to the current system, to perform hermitization hole welding in the implant assembly. |
| P980006/S034 | 03/21/2022 | X - 30-Day Notice | PURE VISION VISIBILITY TINTED CONTACT LENS FOR EXTENDED WEAR | BAUSCH & LOMB, INC. | Change to the distillation and storage bottle stabilizer used in the manufacture of the Ultra® (samfilcon A) and Pure Vision (balafilcon A)® product families. |
| P980016/S808 | 03/23/2022 | X - 30-Day Notice | VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Replacement Vapor Solvent Degreaser. |
| P980016/S809 | 03/24/2022 | X - 30-Day Notice | VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Reduce the frequency of the monitoring currently used to control the residual moisture level inside hermetically sealed electronic module assemblies (EMAs). |
| P980023/S112 | 03/15/2022 | X - 30-Day Notice | PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM | BIOTRONIK, INC. | Tensile test optimization and lead tip welding inspection changes. |
| P980024/S022 | 03/18/2022 | X - 30-Day Notice | PATHVYSION HER-2 DNA PROBE KIT | ABBOTT MOLECULAR, INC. | Extension of expiration dating of certain assay pretreatment reagent kit components. |
| P980035/S703 | 03/02/2022 | X - 30-Day Notice | MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE | MEDTRONIC INC. | Inspect the surface finish on received components using a profilometer rather than a visual inspection. |
| P980035/S706 | 03/15/2022 | X - 30-Day Notice | MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE | MEDTRONIC INC. | Add alternate equipment used in the Laser Ribbon Bonding (LRB) manufacturing process. |

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| P980035/S707 | 03/08/2022 | X - 30-Day Notice | MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE | MEDTRONIC INC. | Update the BPA lid removal process to improve process validation procedures. |
| P980035/S708 | 03/23/2022 | X - 30-Day Notice | MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE | MEDTRONIC INC. | Replacement Vapor Solvent Degreaser. |
| P980035/S709 | 03/23/2022 | X - 30-Day Notice | MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE | MEDTRONIC INC. | Implement the New Vision System for component detection in the Electronic Module Assembly. |
| P980035/S710 | 03/24/2022 | X - 30-Day Notice | MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE | MEDTRONIC INC. | Reduce the frequency of the monitoring currently used to control the residual moisture level inside hermetically sealed electronic module assemblies (EMAs). |
| P980035/S711 | 03/29/2022 | X - 30-Day Notice | MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE | MEDTRONIC INC. | Modify test setups used for process monitoring of packaging. |
| P980040/S146 | 03/30/2022 | X - 30-Day Notice | SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS | JOHNSON & JOHNSON SURGICAL VISION, INC. | Expansion of feed rate, tumbling, high-resolution technology and 100-percent in-line image quality measurement system to 3 existing production lines at AMO Puerto Rico facility for manufacturing TECNIS Symfony and TECNIS Symfony Toric II Optiblue Extended Range of Vision Intraocular Lenses (IOL) as well as TECNIS Synergy and TECNIS Synergy Toric II IOLs with TECNIS Simplicity Delivery System. |
| P980044/S059 | 03/31/2022 | X - 30-Day Notice | SUPARTZ FX | SEIKAGAKU CORP. | Change to the Near Infrared (NIR) testing conditions. |
| P990046/S062 | 03/10/2022 | X - 30-Day Notice | ATS OPEN PIVOT BILEAFLET HEART VALVE | MEDTRONIC ATS MEDICAL, INC. | New yarn extrusion and compounding suppliers and automation of the scouring process for the polyester yarn components. |
| P990046/S063 | 03/11/2022 | X - 30-Day Notice | ATS OPEN PIVOT BILEAFLET HEART VALVE | MEDTRONIC ATS MEDICAL, INC. | Update to optical inspection equipment to reduce the number of conforming samples that were rejected. |
| P990046/S064 | 03/10/2022 | X - 30-Day Notice | ATS OPEN PIVOT BILEAFLET HEART VALVE | MEDTRONIC ATS MEDICAL, INC. | Implement in-house verification of mass flow controllers used in the pyrolytic coating process. |
| P990055/S024 | 03/29/2022 | X - 30-Day Notice | BAYER IMMUNO 1 COMPLEXED PSA ASSAY | SIEMENS HEALTHCARE DIAGNOSTICS | Manufacture an instrument component at another location. |
| P990071/S053 | 03/15/2022 | X - 30-Day Notice | STOCKERT 70 RADIOFREQUENCY ABLATION GENERATOR | BIOSENSE WEBSTER, INC. | Transfer of quality inspection for the SmartAblate Irrigation Tubing Set from BWI Irwindale to Venusa De Mexico S. De R.L De C.V, DBA Lake Region Medical (LRM), a previously approved supplier. |
| P000013/S019 | 03/01/2022 | X - 30-Day Notice | TRIDENT SYSTEM | HOWMEDICA OSTEONICS CORP. | Introduction of a process optimization for the sintering process with a new Hot Isostatic Pressure (HIP) equipment for the Trident Acetabular System. |

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| P000029/S095 | 03/17/2022 | X - 30-Day Notice | DEFLUX INJECTABLE GEL | PALETTE LIFE SCIENCES | Additional supplier for sodium hydroxide solution, hydrochloric acid solution and phosphate buffer concentrate. |
| P000037/S059 | 03/24/2022 | X - 30-Day Notice | ON-X (R) PROSTHETIC HEART VALVE, MODEL ONXA | ON-X LIFE TECHNOLOGIES, INC. | Implementation of a new Controlled Environment Area (CEA) to perform On-X Heart Valve (HV) and Ascending Aortic Prosthesis (AAP) manufacturing steps from subassembly through sterilization and final packaging. |
| P000053/S123 | 03/07/2022 | X - 30-Day Notice | AMS SPHINCTER 800 URINARY CONTROL SYSTEM | BOSTON SCIENTIFIC CORP. | Adding alternate tubing for the Manual Control Pump test fixture. |
| P010007/S015 | 03/29/2022 | X - 30-Day Notice | IMMULITE/IMMULITE 1000 AFP AND IMMULITE 2000/ IMMULITE 2500 AFP | SIEMENS HEALTHCARE DIAGNOSTICS INC. | Implementation of a change to the physical state of a raw material. |
| P010012/S551 | 03/08/2022 | X - 30-Day Notice | CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL | BOSTON SCIENTIFIC CORP. | Add sterilization chamber equipment to the Dorado, Puerto Rico manufacturing facility. |
| P010015/S493 | 03/23/2022 | X - 30-Day Notice | MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM | MEDTRONIC INC. | Replacement Vapor Solvent Degreaser. |
| P010015/S494 | 03/24/2022 | X - 30-Day Notice | MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM | MEDTRONIC INC. | Reduce the frequency of the monitoring currently used to control the residual moisture level inside hermetically sealed electronic module assemblies (EMAs). |
| P010031/S774 | 03/23/2022 | X - 30-Day Notice | CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Replacement Vapor Solvent Degreaser. |
| P010031/S776 | 03/24/2022 | X - 30-Day Notice | CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Reduce the frequency of the monitoring currently used to control the residual moisture level inside hermetically sealed electronic module assemblies (EMAs). |
| P010032/S185 | 03/24/2022 | X - 30-Day Notice | GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS | ABBOTT MEDICAL | Update to the Post-Header Test System Non-Product Software used during assembly of Orion family (Proclaim SCS, Infinity DBS, Proclaim DRG) Implantable Pulse Generators (IPGs). |
| P010051/S015 | 03/29/2022 | X - 30-Day Notice | IMMULITE 2000 XPI ANTI-HBC | SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS, LTD | Manufacturing process change for a critical raw material. |

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| P010053/S014 | 03/29/2022 | X - 30-Day Notice | IMMULITE 2000 XPI ANTI-HBC IMG | SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS, LTD | Manufacturing process change for a critical raw material. |
| P020045/S100 | 03/15/2022 | X - 30-Day Notice | 7F FREEZOR CARDIAC CRYOABLATION CATHETER AND CCT.2 CRYOCONSOLE SYSTEM | MEDTRONIC CRYOCATH LP | Implementation of a parametric release method at the Sterigenics sterilization site (Sterigenics US LLC) in Queensbury, New York. |
| P030036/S136 | 03/14/2022 | X - 30-Day Notice | MEDTRONIC SELECTSECURE LEAD MODEL 3830 | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Modification to the electrode coating inspection process at Medtronic's supplier-Heraeus located in Hanau, Germany. |
| P030040/S021 | 03/29/2022 | X - 30-Day Notice | ADVIA CENTAUR HBC IGM READYPACK REAGENTS, ADVIA CENTAUR HBC IGM QUALITY CONTROL MATERIALS | SIEMENS HEALTHCARE DIAGNOSTICS | Manufacture an instrument component at another location. |
| P030052/S028 | 03/18/2022 | X - 30-Day Notice | UROVYSION BLADDER CANCER KIT | ABBOTT MOLECULAR | Extension of expiration dating of certain assay pretreatment reagent kit components. |
| P040004/S021 | 03/29/2022 | X - 30-Day Notice | ADVIA CENTAUR HBC TOTAL READYPACK REAGENTS/ADVIA CENTAUR HBC TOTAL QUALITY CONTROL MATERIALS | SIEMENS HEALTHCARE DIAGNOSTICS | Manufacture an instrument component at another location. |
| P040020/S102 | 03/25/2022 | X - 30-Day Notice | ACRYSOF RESTOR APODIZED DIFFRACTIVE OPTIC POSTERIOR CHAMBER IOL | ALCON RESEARCH, LTD. | Modification to the testing frequency of the acrylate monomer inhibitor removal in-process test. |
| P040037/S151 | 03/18/2022 | X - 30-Day Notice | VIABAHN ENDOPROSTHESIS | W.L. GORE & ASSOCIATES,INC | New test article preparation equipment for heparin activity and heparin concentration testing. |
| P040037/S153 | 03/03/2022 | X - 30-Day Notice | VIABAHN ENDOPROSTHESIS | W.L. GORE & ASSOCIATES,INC | Automation of the traction line hole manufacturing process. |
| P050019/S034 | 03/24/2022 | X - 30-Day Notice | CAROTID WALLSTENT MONORAIL ENDOPROSTHESIS | BOSTON SCIENTIFIC CORP. | Vendor manufacturing site and die cutting process changes for a packaging component. |
| P050027/S030 | 03/17/2022 | X - 30-Day Notice | KARL STORZ PHOTODYNAMIC DIAGNOSTIC D-LIGHT C (PDD) SYSTEM | KARL STORZ ENDOSCOPY-AMERICA, INC. | Manufacturing change to transfer the PDD Cystoscope Monocoil to a vertebrae weld and the PDD Cystoscope Screw Tube sub-assembly weld to be welded by the welder in the Pilot production room. |

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| P050050/S022 | 03/11/2022 | X - 30-Day Notice | SCANDINAVIAN TOTAL ANKLE REPLACEMENT SYSTEM (S.T.A.R.ANKLE) | DJO GLOBAL | Replacing a sub-supplier of folded boxes for STAR Ankle implant components. |
| P060005/S014 | 03/29/2022 | X - 30-Day Notice | IMMULITE / IMMULITE 1000 AND IMMULITE 2000 FREE PSA ASSAYS | SIEMENS MEDICAL SOLUTIONS DIAGNOSTICS LIMITED | Implementation of a change to the physical state of a raw material. |
| P060037/S078 | 03/23/2022 | X - 30-Day Notice | NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM | ZIMMER, INC. | 1) New 2nd tier supplier for the layer lamination process; 2) alternate adhesive material used in lamination process; 3) relocation of PET/AlOx production; and 4) alternate supplier of LLDPE sealant layer material. |
| P070004/S034 | 03/02/2022 | X - 30-Day Notice | SIENTRA SILICONE GEL BREAST IMPLANTS | SIENTRA, INC | Addition of a gel dispersion viscosity assessment method, ¿Percent Solids Method¿ to provide supplementary dispersion viscosity information during the manufacture of Sientra Silicone Gel Breast Implants. |
| P070026/S093 | 03/10/2022 | X - 30-Day Notice | CERAMAX CERAMIC HIP SYSTEM | DEPUY ORTHOPAEDICS, INC. | Introduction of two alternative polishing belts sourced from a new supplier. |
| P080006/S169 | 03/14/2022 | X - 30-Day Notice | MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD | MEDTRONIC INC. | Modification to the electrode coating inspection process at Medtronic's supplier-Heraeus located in Hanau, Germany. |
| P080020/S047 | 03/31/2022 | X - 30-Day Notice | GEL-ONE | SEIKAGAKU CORP. | Change to the Near Infrared (NIR) testing conditions. |
| P080025/S252 | 03/30/2022 | X - 30-Day Notice | MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM | MEDTRONIC NEUROMODULATION | Change to a new transport bin used in manufacturing at Medtronic Tempe Campus (MTC). |
| P080025/S253 | 03/17/2022 | X - 30-Day Notice | MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM | MEDTRONIC NEUROMODULATION | Change to the visual inspection process at Medtronic Vascular for the lead model 978B1 subassembly. |
| P090024/S011 | 03/29/2022 | X - 30-Day Notice | ADVIA CENTAUR HBEAG ASSAY AND QUALITY CONTROL MATERIAL | SIEMENS HEALTHCARE DIAGNOSTICS | Manufacture an instrument component at another location. |
| P100010/S125 | 03/16/2022 | X - 30-Day Notice | ARCTIC FRONT CRYOCATHETER SYSTEM | MEDTRONIC CRYOCATH LP | Supplier change, a cavity mold change, and clarified specifications for the Y-Block fitting. |
| P100010/S126 | 03/15/2022 | X - 30-Day Notice | ARCTIC FRONT CRYOCATHETER SYSTEM | MEDTRONIC CRYOCATH LP | Implementation of a parametric release method at the Sterigenics sterilization site (Sterigenics US LLC) in Queensbury, New York. |
| P100013/S024 | 03/01/2022 | X - 30-Day Notice | CORDIS EXOSEAL VASCULAR CLOSURE DEVICE | CORDIS US CORPORATION | Relocation of the supplier of the Plunger Shaft and Indicator Wire Lumen Tube components. |
| P100014/S033 | 03/17/2022 | X - 30-Day Notice | SOLESTA INJECTABLE GEL | PALETTE LIFE SCIENCES | Additional supplier for sodium hydroxide solution, hydrochloric acid solution and phosphate buffer concentrate. |

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| P100016/S012 | 03/25/2022 | X - 30-Day Notice | EC-3 INTRAOCULAR LENS (IOL) AND EC-3 PRECISION ASPHERIC LENS (PAL) IOL | CARL ZEISS MEDITEC PRODUCTION LLC | Addition of validated ethylene oxide sterilization Chamber #9 with its validated Cycle #834 to the routine sterilization process. |
| P100039/S015 | 03/29/2022 | X - 30-Day Notice | ADVIA CENTAUR ANTI-HBS2 (AHBS2) ASSAY AND QAULITY CONTROL MATERIAL | SIEMENS HEALTHCARE DIAGNOSTICS INC. | Manufacture an instrument component at another location. |
| P100045/S060 | 03/04/2022 | X - 30-Day Notice | CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM | ST. JUDE MEDICAL | Retroactive approval for alternate, drop-in replacement printed circuit board assembly (PCBA) components for use with the CardioMEMS CM1100 Patient Electronics System. |
| P100045/S061 | 03/31/2022 | X - 30-Day Notice | CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM | ST. JUDE MEDICAL | alternate, drop-in replacement printed circuit board assembly components for use with the CardioMEMS CM3100 Hospital System |
| P100047/S192 | 03/01/2022 | X - 30-Day Notice | HEARTWARE VENTRICULAR ASSIST SYSTEM | MEDTRONIC | Addition of a visual inspection step in splice kit assembly procedure. |
| P100047/S194 | 03/15/2022 | X - 30-Day Notice | HEARTWARE VENTRICULAR ASSIST SYSTEM | MEDTRONIC | Implementation of additional process controls for the connector of the Splice Assembly |
| P110001/S018 | 03/24/2022 | X - 30-Day Notice | RX HERCULINK ELITE RENAL STENT SYSTEM | ABBOTT VASCULAR | Updated sampling plan for an in-process device testing. |
| P110005/S011 | 03/18/2022 | X - 30-Day Notice | SINOVIAL (SODIUM HYALURONATE 0.8%) | IBSA INSTITUT BIOCHIMIQUE SA | Addition of an alternative filter for bulk solution filtration. |
| P110010/S203 | 03/30/2022 | X - 30-Day Notice | PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM | BOSTON SCIENTIFIC CORP. | Automation of laser marker, leak test, and balloon inspect stations. |
| P110041/S013 | 03/29/2022 | X - 30-Day Notice | ADVIA CENTAUR HBSAGII | SIEMENS CORP. | Manufacture an instrument component at another location. |
| P130005/S035 | 03/11/2022 | X - 30-Day Notice | DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM | CARDIOVASCULAR SYSTEMS, INC. | Introducing alternate suppliers for different non-patient-contacting device components. |
| P130006/S090 | 03/18/2022 | X - 30-Day Notice | GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE | W.L. GORE & ASSOCIATES,INC | New test article preparation equipment for heparin activity and heparin concentration testing. |

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| P130006/S092 | 03/03/2022 | X - 30-Day Notice | GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE | W.L. GORE & ASSOCIATES,INC | Automation of the traction line hole manufacturing process. |
| P130008/S079 | 03/10/2022 | X - 30-Day Notice | INSPIRE II UPPER AIRWAY STIMULATOR | INSPIRE MEDICAL SYSTEMS | Notification of replacing obsolete components of the Inspire Model 2740 Programmer tablet and updates to the tablet Basic Input/Output System (BIOS). |
| P130008/S080 | 03/16/2022 | X - 30-Day Notice | INSPIRE II UPPER AIRWAY STIMULATOR | INSPIRE MEDICAL SYSTEMS | Addition of a manufacturing site for the inductor coil used in the Model 2580 remote. |
| P130008/S081 | 03/14/2022 | X - 30-Day Notice | INSPIRE II UPPER AIRWAY STIMULATOR | INSPIRE MEDICAL SYSTEMS | Notification of replacing obsolete Metal- Oxide- Semiconductor Field-Effect Transistor (MOSFET) for the Sensor Assembly in the Inspire Model 4340 Respiratory Sensing Lead. |
| P130011/S010 | 03/07/2022 | X - 30-Day Notice | FREEDOM SOLO STENTLESS HEART VALVE | CORCYM CANADA CORP. | Use of a new temperature indicator. |
| P130014/S015 | 03/16/2022 | X - 30-Day Notice | ADHERUS AUTOSPRAY DURAL SEALANT | HYPERBRANCH MEDICAL TECHNOLOGY, INC. | Steris Applied Technologies dba Synergy Health AST, LLC facility located in Saxonburg, Pennsylvania (Steris AST Saxonburg) to use a functionally equivalent electron accelerator to sterilize Adherus AutoSpray ET Dural Sealants |
| P130016/S047 | 03/03/2022 | X - 30-Day Notice | NUCLEUS HYBRID L24 COCHLEAR IMPLANT SYSTEM | COCHLEAR AMERICAS | Introduction of an alternate laser welding system to the current system, to perform hermitization hole welding in the implant assembly. |
| P130021/S110 | 03/01/2022 | X - 30-Day Notice | MEDTRONIC COREVALVE SYSTEM | MEDTRONIC, INC. | Use of a new data management system for microbiology laboratory test data and data reporting at the Medtronic Tijuana facility for the Evolut R, Evolut PRO, Evolut PRO+, and Evolut FX Transcatheter Aortic Valves (TAVs), Harmony and Melody Transcatheter Pulmonic Valves (TPV), and Avalus bioprosthesis products. |
| P130021/S112 | 03/21/2022 | X - 30-Day Notice | MEDTRONIC COREVALVE SYSTEM | MEDTRONIC, INC. | Implementation of a new semi-automatic cutting machine. |
| P130021/S114 | 03/31/2022 | X - 30-Day Notice | MEDTRONIC COREVALVE SYSTEM | MEDTRONIC, INC. | Add an alternative supplier for the packaging tray used in the EnVeo R, EnVeo PRO, Evolut PRO+, and Evolut FX delivery systems. |
| P140003/S095 | 03/08/2022 | X - 30-Day Notice | IMPELLA 2.5 SYSTEM | ABIOMED, INC. | Replace a discontinued model of the electrical safety analyzer with a newer model for the final functional testing of the Automated Impella Controller. |
| P140009/S076 | 03/24/2022 | X - 30-Day Notice | BRIO NEUROSTIMULATION SYSTEM | ABBOTT MEDICAL | Update to the Post-Header Test System Non-Product Software used during assembly of Orion family (Proclaim SCS, Infinity DBS, Proclaim DRG) Implantable Pulse Generators (IPGs). |
| P140017/S021 | 03/01/2022 | X - 30-Day Notice | MELODY TRANSCATHETER PULMONARY VALVE (TPV), ENSEMBLE TRANSCATHETER VALVE DELIVERY SYSTEM (DS) | MEDTRONIC INC. | Use of a new data management system for microbiology laboratory test data and data reporting at the Medtronic Tijuana facility for the Evolut R, Evolut PRO, Evolut PRO+, and Evolut FX Transcatheter Aortic Valves (TAVs), Harmony and Melody Transcatheter Pulmonic Valves (TPV), and Avalus bioprosthesis products. |
| P150003/S084 | 03/30/2022 | X - 30-Day Notice | SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM | BOSTON SCIENTIFIC CORPORATION | Automation of laser marker, leak test, and balloon inspect stations. |

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| P150004/S056 | 03/24/2022 | X - 30-Day Notice | AXIUM NEUROSTIMULATOR SYSTEM | ABBOTT MEDICAL | Update to the Post-Header Test System Non-Product Software used during assembly of Orion family (Proclaim SCS, Infinity DBS, Proclaim DRG) Implantable Pulse Generators (IPGs). |
| P150011/S023 | 03/07/2022 | X - 30-Day Notice | PERCEVAL SUTURELESS HEART VALVE | CORCYM CANADA CORP. | Use of a new temperature indicator. |
| P150012/S123 | 03/08/2022 | X - 30-Day Notice | IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD | BOSTONSCIENTIFIC | Add sterilization chamber equipment to the Dorado, Puerto Rico manufacturing facility. |
| P150012/S124 | 03/29/2022 | X - 30-Day Notice | IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD | BOSTONSCIENTIFIC | Implement an additional inspection verification to the polyurethane tubing manufacturing process performed at the Dorado, Puerto Rico facility. |
| P150021/S055 | 03/02/2022 | X - 30-Day Notice | FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM | ABBOTT DIABETES CARE INC. | Addition of an alternate manufacturing site for the manufacture of a sensor membrane polymer component. The sensor is a component of the FreeStyle Libre Pro Flash Glucose Monitoring System and Freestyle Libre Flash Glucose Monitoring System. |
| P150021/S056 | 03/16/2022 | X - 30-Day Notice | FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM | ABBOTT DIABETES CARE INC. | Addition of a manufacturing site for the manufacture of a sensor electrode material. The sensor is a component of the FreeStyle Libre Pro Flash Glucose Monitoring System and Freestyle Libre 14-Day Flash Glucose Monitoring System. |
| P150036/S060 | 03/31/2022 | X - 30-Day Notice | EDWARDS INTUITY ELITE VALVE SYSTEM | EDWARDS LIFESCIENCES, LLC. | Increased number in manning in the Dry Plant Main Cleanroom at the Edwards Costa Rica Facility. |
| P150038/S020 | 03/31/2022 | X - 30-Day Notice | EXABLATE | INSIGHTEC | Sandblasting machine and a dicing machine added to the production line at the Tirat Carmel, Israel facility. |
| P150048/S061 | 03/31/2022 | X - 30-Day Notice | EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500) | EDWARDS LIFESCIENCES, LLC. | Increased number in manning in the Dry Plant Main Cleanroom at the Edwards Costa Rica Facility. |
| P160015/S013 | 03/01/2022 | X - 30-Day Notice | AED PLUS AND FULLY AUTOMATIC AED PLUS | ZOLL MEDICAL CORPORATION | Update the sequence and fully automate a shock test. |
| P160021/S034 | 03/18/2022 | X - 30-Day Notice | GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS | W. L. GORE & ASSOCIATES, INC. | New test article preparation equipment for heparin activity and heparin concentration testing. |
| P160029/S015 | 03/20/2022 | X - 30-Day Notice | HEARTSTART ONSITE DEFIBRILLATOR (MODEL M5066A) AND HEARTSTART HOME DEFIBRILLATOR (MODEL M5068A) | PHILIPS MEDICAL SYSTEMS, INC. | Alternate supplier for the high voltage capacitor used for the HS1 and FRx devices |

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| P160030/S049 | 03/02/2022 | X - 30-Day Notice | FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM | ABBOTT DIABETES CARE INC. | Addition of an alternate manufacturing site for the manufacture of a sensor membrane polymer component. The sensor is a component of the FreeStyle Libre Pro Flash Glucose Monitoring System and Freestyle Libre Flash Glucose Monitoring System. |
| P160030/S050 | 03/16/2022 | X - 30-Day Notice | FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM | ABBOTT DIABETES CARE INC. | Addition of a manufacturing site for the manufacture of a sensor electrode material. The sensor is a component of the FreeStyle Libre Pro Flash Glucose Monitoring System and Freestyle Libre 14-Day Flash Glucose Monitoring System. |
| P160038/S021 | 03/28/2022 | X - 30-Day Notice | PRAXIS EXTENDED RAS PANEL | ILLUMINA, INC. | Improvement to an in-process analytical HPLC method. |
| P170006/S020 | 03/01/2022 | X - 30-Day Notice | AVALUS(TM) BIOPROSTHESIS | MEDTRONIC INC. | Use of a new data management system for microbiology laboratory test data and data reporting at the Medtronic Tijuana facility for the Evolut R, Evolut PRO, Evolut PRO+, and Evolut FX Transcatheter Aortic Valves (TAVs), Harmony and Melody Transcatheter Pulmonic Valves (TPV), and Avalus bioprosthesis products. |
| P170007/S012 | 03/02/2022 | X - 30-Day Notice | DUROLANE | BIOVENTUS LLC | Addition of an alternative supplier for the supply of phosphate buffer concentrate for the manufacturing of DUROLANE®. |
| P170007/S013 | 03/03/2022 | X - 30-Day Notice | DUROLANE | BIOVENTUS LLC | Addition of an alternative supplier for sodium hydroxide and hydrochloric acid solutions used in the manufacturing of DUROLANE. |
| P170011/S037 | 03/08/2022 | X - 30-Day Notice | IMPELLA RP SYSTEM | ABIOMED, INC. | Replace a discontinued model of the electrical safety analyzer with a newer model for the final functional testing of the Automated Impella Controller. |
| P170035/S016 | 03/21/2022 | X - 30-Day Notice | BAUSCH + LOMB ULTRA (SAMFILCON A) CONTACT LENSES | BAUSCH AND LOMB, INC. | Change to the distillation and storage bottle stabilizer used in the manufacture of the Ultra® (samfilcon A) and Pure Vision (balafilcon A)® product families. |
| P180027/S007 | 03/01/2022 | X - 30-Day Notice | FLOW RE-DIRECTION ENDOLUMINAL DEVICE (FRED®) SYSTEM | MICROVENTION, INC. | Relocation of the supplier of several Flow Re-Direction Endoluminal Device (FRED) System and FRED X System components, Creganna Medical, from the manufacturing location in Tualatin, Oregon, to Wilsonville, Oregon, and Heredia, Costa Rica. |
| P180027/S008 | 03/25/2022 | X - 30-Day Notice | FLOW RE-DIRECTION ENDOLUMINAL DEVICE (FRED®) SYSTEM | MICROVENTION, INC. | Relocation of existing equipment used for inner stent braiding and heat setting for Flow Re-Direction Endoluminal Device (FRED) System and FRED X System to a new building at the existing Costa Rica manufacturing facility. |
| P180028/S012 | 03/20/2022 | X - 30-Day Notice | HEARTSTART FRX DEFIBRILLATOR | PHILIPS MEDICAL SYSTEMS | Alternate supplier for the high voltage capacitor used for the HS1 and FRx devices. |
| P180046/S051 | 03/03/2022 | X - 30-Day Notice | AXONICS SACRAL NEUROMODULATION SYSTEM | AXONICS MODULATION TECHNOLOGIES, INC. | Reduction in the frequency of bacterial endotoxin testing. |
| P190006/S051 | 03/03/2022 | X - 30-Day Notice | AXONICS SACRAL NEUROMODULATION SYSTEM | AXONICS MODULATION TECHNOLOGIES, INC. | Reduction in the frequency of bacterial endotoxin testing. |
| P190023/S005 | 03/07/2022 | X - 30-Day Notice | PORTICO TRANSCATHETER AORTIC VALVE IMPLANTATION SYSTEM | ABBOTT MEDICAL | One new abattoir as a tissue supplier for the Portico valve. |

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| P190023/S006 | 03/04/2022 | X - 30-Day Notice | PORTICO TRANSCATHETER AORTIC VALVE IMPLANTATION SYSTEM | ABBOTT MEDICAL | Change to the final device label stock and implementation of a new printer to aid in the production of the final packaging labels for the Portico Valve. |
| P200013/S006 | 03/14/2022 | X - 30-Day Notice | ALINITY M HBV | ABBOTT MOLECULAR, INC. | Extend the expiration date of a critical raw material. |
| P200017/S002 | 03/29/2022 | X - 30-Day Notice | ADVIA CENTAUR ANTI-HBE2 (AHBE2) ASSAY | SIEMENS HEALTHCARE DIAGNOSTICS , INC. | Manufacture an instrument component at another location. |
| P200021/S011 | 03/15/2022 | X - 30-Day Notice | NEURO COCHLEAR IMPLANT SYSTEM | OTICON MEDICAL | Replacing several electronic components for the sub-assembled PCB of the Neuro2 sound processor. |
| P200028/S010 | 03/04/2022 | X - 30-Day Notice | DIAMONDTEMP ABLATION SYSTEM | MEDTRONIC INC. | Conversion of ISO Class 8 cleanroom space to ISO Class 7 and the addition of a passthrough window. |
| P200046/S007 | 03/01/2022 | X - 30-Day Notice | HARMONY¿ TPV SYSTEM | MEDTRONIC, INC. | Use of a new data management system for microbiology laboratory test data and data reporting at the Medtronic Tijuana facility for the Evolut R, Evolut PRO, Evolut PRO+, and Evolut FX Transcatheter Aortic Valves (TAVs), Harmony and Melody Transcatheter Pulmonic Valves (TPV), and Avalus bioprosthesis products. |
| **Total: 146** | | | | | |