# PMA Monthly approvals from 7/1/2021 to 7/31/2021

## Original

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P200011 | 07/30/2021 | PMAO - PMA Origi | ONCO/REVEAL DX LUNG & COLON CANCER ASSAY (O/RDX-LCCA) | PILLAR BIOSCIENCES | Approval of the ONCO/RevealTM Dx Lung and Colon Cancer Assay (O/RDx-LCCA). The device is a qualitative next generation sequencing based in vitro diagnostic test that uses amplicon-based target enrichment technology for detection of single nucleotide variants (SNVs) and deletions in 2 genes from DNA isolated from formalin-fixed paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC) and colorectal cancer (CRC) tumor tissue specimens. The test is intended as a companion diagnostic to identify patients with NSCLC or CRC who may benefit from treatment with the targeted therapies listed in Table 1 in accordance with the approved therapeutic product labeling. The O/RDx-LCCA is intended to be used on the Illumina MiSeqDx® instrument.<br><br>Table 1. List of somatic variants for therapeutic use<br>Indication Gene Variant Targeted therapy<br>Colorectal Cancer (CRC) KRAS KRAS wild-type (absence of mutations in codons 12 and 13) ERBITUX® (cetuximab), or<br>VECTIBIX® (panitumumab)<br>Non-Small Cell Lung Cancer<br>(NSCLC) EGFR Exon 19 Deletions and Exon 21 L858R Substitution Mutations EGFR Tyrosine Kinase Inhibitors approved by FDA*<br><br>*For the most current information about the therapeutic products in this group, go to: https://www.fda.gov/medicaldevices/productsandmedicalprocedures/invitrodiagnostics/ucm301431.htm |
| P200017 | 07/14/2021 | PMAO - PMA Origi | ADVIA CENTAUR ANTI-HBE2 (AHBE2) ASSAY | SIEMENS HEALTHCARE DIAGNOSTICS , INC. | Approval of the ADIVA Centaur Anti-HBe2 (aHBe2) assay. The qualitative detection of antibodies to the e antigen of the hepatitis B virus (HBV) in human pediatric (2¿21 years old) and adult serum, EDTA plasma, or lithium heparin plasma using the ADVIA Centaur systems (XP/XPT/CP). Assay results, in conjunction with other laboratory results and clinical information may be used as an aid in the diagnosis of hepatitis B virus (HBV) infection in patients with signs or symptoms of hepatitis B infection, or with risk factors for HBV infection, or with known HBV infection. Results of the assay, in conjunction with other diagnostic information, may be used to aid in determining HBV seroconversion. |
| P200037 | 07/27/2021 | PMAO - PMA Origi | ASSURE WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) SYSTEM | KESTRA MEDICAL TECHNOLOGI ES, INC. | Approval for the ASSURE system which is indicated for adult patients who are at risk for sudden cardiac arrest and are not candidates for, or refuse, an implantable defibrillator. |

**Total: 3**

## Supplements

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| N18286/S039 | 07/08/2021 | S - Special CBE | GELFOAM | PFIZER, INC. | Approval for the addition of text to the Gelfoam Instructions for Use regarding pseudoabscess and pseudoinfection. |
| P830063/S018 | 07/16/2021 | R - Real-Time Proc | GAMBRO FIBER PLASMAFILTER | BAXTER INTERNATIONAL, INC. | Approval for a material composition change for a component of the Prismaflex TPE2000 Set, specifically the change to the PVC material used for the production of the fluid pump segments of the Prismaflex TPE 2000 Set. |
| P930014/S131 | 07/01/2021 | Y - 135 Review Tra | ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES | ALCON LABORATORIES, INC. | Approval for change to the Analytical Testing Method for the determination of Residual Monomer in AcrySof® Intraocular Lenses. |
| P960040/S467 | 07/23/2021 | 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. |
| P990046/S059 | 07/29/2021 | R - Real-Time Proc | ATS OPEN PIVOT BILEAFLET HEART VALVE | MEDTRONIC ATS MEDICAL, INC. | Approval for changes to the inner packaging design and extension of the shelf life. |
| P010012/S541 | 07/23/2021 | 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. |
| P010032/S172 | 07/26/2021 | R - Real-Time Proc | GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS | ABBOTT MEDICAL | Approval for the replacement of the supplier for the Thermal Cutoff (TCO) component used in the lithium ion (Li-Ion) Rechargeable Battery Pack used to recharge Implanted Pulse Generator (IPG), and for a design change to the TCO component of the Battery Pack. The design change includes the addition of a bottom metal strap to the TCO component, different dimensions of the Battery Pack due to the thicker new TCO component, an increased current allowance from 2 Amps to 7 Amps, lower voltage cutoff from 32 Volts to 28 Volts, and a lower temperature cutoff of from 92C to 82C. This change is implemented to the following specific Chargers: 3720 Eon Mini LE Charger, 3722 Eon Mini LE Charging System, 3727 Eon Charger, 3726 Eon Charging System, 3730 Prodigy Charging System, 6720 Brio LE Charger, 6722 Brio LE Charging System. |
| P010032/S173 | 07/02/2021 | Y - 135 Review Tra | GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS | ABBOTT MEDICAL | Approval for a cleaning process change that replaces the Trichloroethylene (TCE) cleaning agent, used in the first ultrasonic cleaning step to clean Spinal Cord Stimulation (SCS) and Dorsal Root Ganglion (DRG) needles, with CleanSafe-501ESF (CS-501ESF). |
| P010032/S177 | 07/15/2021 | S - Special CBE | GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS | ABBOTT MEDICAL | Approval for labeling updates to include additional clarification language related to magnets within consumer goods and electronic devices. |
| P020050/S038 | 07/08/2021 | R - Real-Time Proc | WAVELIGHT ALLEGRETTO WAVE EXCIMER LASER SYSTEM | ALCON LABORATORIES, INC. | Approval for a hardware design change to the measurement board. |
| P030008/S034 | 07/08/2021 | R - Real-Time Proc | WAVELIGHT ALLEGRETTO WAVE EXCIMER LASER SYSTEM | ALCON LABORATORIES, INC. | Approval for a hardware design change to the measurement board. |

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|---|---|---|---|---|---|
| P030017/S344 | 07/12/2021 | N - Normal 180 Day | PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM | BOSTON SCIENTIFIC CORP. | Approval for an update to the existing Software Bionic Navigator 3D version 4.0 to version 4.1. The updated software will be installed on the Clinician Programmer using the Bionic Navigator (BN) 3D 4.1 Installer (Model # SC-7101-410). This would allow one single software version (BN3D 4.1) to support all the Precision Spectra, Precision Novi, Precision Montage MRI, and Spectra WaveWriter and WaveWriter Alpha BCS Stimulators. The user interface of BN 3D 4.1 remain the same except for translations into various languages to support the international markets. In addition, BN 3D 4.1 introduces a new Sequence feature for additional flexibility when programming WaveWriter Alpha stimulators, in which a Sequence composed of various blocks of pulses can be created using a Composer tool and applied to the stimulators in a Programming Mode called Sequence Mode.<br><br>The BN 3D software will be updated to Version 4.1 so that one single software version (BN3D 4.1) can support all the Precision Spectra, Precision Novi, Precision Montage MRI, and Spectra WaveWriter and WaveWriter Alpha BCS Stimulators. The user interface of BN 3D 4.1 will remain the same except for translations into various languages to support the international markets. In addition, BN 3D 4.1 introduces a new Sequence feature for additional flexibility when programming WaveWriter Alpha stimulators, in which a Sequence composed of various blocks of pulses can be created using a Composer tool and applied to the stimulators in a Programming Mode called Sequence Mode. Note that the new Sequence feature is only applicable to WaveWriter Alpha stimulators. The existing programming features for all stimulators remain the same. |
| P030019/S026 | 07/02/2021 | Y - 135 Review Tra | ORTHOVISC HIGH MOLECULAR WEIGHT HYALURONAN | ANIKA THERAPEUTICS, INC. | Approval for a new rubber stopper formulation for the 3 mL stoppers formulation. |
| P030039/S026 | 07/15/2021 | N - Normal 180 Day | COSEAL SURGICAL SEALANT | BAXTER BIO SCIENCE | Approval for implementation of the BD Sterifill Advanced Syringe as a replacement for the previously used BD Sterifill. |
| P040020/S093 | 07/01/2021 | Y - 135 Review Tra | ACRYSOF RESTOR APODIZED DIFFRACTIVE OPTIC POSTERIOR CHAMBER IOL | ALCON RESEARCH, LTD. | Approval for change to the Analytical Testing Method for the determination of Residual Monomer in AcrySof® Intraocular Lenses. |
| P040046/S031 | 07/26/2021 | O - Normal 180 Day | NATRELLE HIGHLY COHESIVE SILICONE-FILLED BREAST IMPLANTS | ALLERGAN | Approval of the revised protocol for the post-approval study (PAS) protocol. |
| P050038/S037 | 07/06/2021 | O - Normal 180 Day | ARISTA AH ABSORBABLE HEMOSTAT | DAVOL, INC. | Approval for an additional filling and packaging site for the Arista AH Absorbable Hemostatic device at the Davol, Inc. Woburn, Massachusetts manufacturing site. |
| P050047/S080 | 07/21/2021 | Y - 135 Review Tra | JUVEDERM 24HV, JUVEDERM 30 AND JUVEDERM 30HV GEL IMPLANTS | ALLERGAN | Approval of the implementation of additional cleanrooms for the manufacturing of Juvéderm® Gel Implants and Juvéderm® Injectable Gel. |
| P070006/S017 | 07/26/2021 | O - Normal 180 Day | T SPOT-TB TEST | OXFORD IMMUNOTEC,LTD. | Approval to include an additional manufacturing site establishment to perform manufacturing of the device. |
| P070026/S082 | 07/07/2021 | S - Special CBE | CERAMAX CERAMIC HIP SYSTEM | DEPUY ORTHOPAEDICS, INC. | Approval for an additional inspection step for the CERAMAX® Total Hip Systems Pinnacle shell Apex hole feature by using a plug gauge to confirm hole minor diameter conformance. |

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| P100016/S008 | 07/08/2021 | N - Normal 180 Day | EC-3 INTRAOCULAR LENS (IOL) AND EC-3 PRECISION ASPHERIC LENS (PAL) IOL | CARL ZEISS MEDITEC PRODUCTION LLC | Approval for a new product model, CT LUCIA 611P, which is a design change to product CT LUCIA 602. |
| P100018/S032 | 07/19/2021 | O - Normal 180 Day | PIPELINE EMBOLIZATION DEVICE | MICRO THERAPEUTICS, INC. D/B/A EV3 NEUROVASCULAR | Approval of the revised protocol for the post-approval study (PAS) protocol.. |
| P100034/S026 | 07/07/2021 | O - Normal 180 Day | NOVOCURE LTD'S NOVOTTF-100A TREATMENT KIT | NOVOCURE GMBH | Approval for an update of the Optune System labeling with the final post-approval study (Registry Study for Optune System) results. |
| P110033/S058 | 07/21/2021 | Y - 135 Review Tra | JUVEDERM VOLUMA XC | ALLERGAN | Approval of the implementation of additional cleanrooms for the manufacturing of Juvéderm® Gel Implants and Juvéderm® Injectable Gel. |
| P120022/S022 | 07/07/2021 | R - Real-Time Proc | THERASCREEN EGFR RGQ PCR KIT | QIAGEN GMBH | Approval for incorporation of a lower boundary for the therascreen EGFR RGQ PCR assay Ct cutoff range and an update to the software and handbook to address this change. |
| P130022/S039 | 07/16/2021 | P - Panel Track | NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM | NEVRO CORPORATION | Approval for the Senza Spinal Cord Stimulation (SCS) System for expanding the indications to add the following: The Senza®, Senza II and Senza Omnia neuromodulation systems, when programmed to include a frequency of 10 kHz, are indicated as aids in the management of chronic intractable pain of the lower limbs, including unilateral or bilateral pain, associated with diabetic neuropathy. |
| P140003/S078 | 07/09/2021 | N - Normal 180 Day | IMPELLA 2.5 SYSTEM | ABIOMED, INC. | Approval for material and assembly design changes to the interior cylinder, rack and piston components of the Purge Cassette. |
| P140003/S081 | 07/13/2021 | O - Normal 180 Day | IMPELLA 2.5 SYSTEM | ABIOMED, INC. | Approval of the revised protocol for the post-approval study (PAS) protocol. |
| P140003/S082 | 07/13/2021 | O - Normal 180 Day | IMPELLA 2.5 SYSTEM | ABIOMED, INC. | Approval of the revised protocol for the post-approval study (PAS) protocol. |
| P140003/S083 | 07/13/2021 | O - Normal 180 Day | IMPELLA 2.5 SYSTEM | ABIOMED, INC. | Approval of the revised protocol for the post-approval study (PAS) protocol. |
| P140009/S067 | 07/26/2021 | R - Real-Time Proc | BRIO NEUROSTIMULATION SYSTEM | ABBOTT MEDICAL | Approval for the replacement of the supplier for the Thermal Cutoff (TCO) component used in the lithium ion (Li-Ion) Rechargeable Battery Pack used to recharge Implanted Pulse Generator (IPG), and for a design change to the TCO component of the Battery Pack. The design change includes the addition of a bottom metal strap to the TCO component, different dimensions of the Battery Pack due to the thicker new TCO component, an increased current allowance from 2 Amps to 7 Amps, lower voltage cutoff from 32 Volts to 28 Volts, and a lower temperature cutoff of from 92C to 82C. This change is implemented to the following specific Chargers: 3720 Eon Mini LE Charger, 3722 Eon Mini LE Charging System, 3727 Eon Charger, 3726 Eon Charging System, 3730 Prodigy Charging System, 6720 Brio LE Charger, 6722 Brio LE Charging System. |
| P140009/S070 | 07/15/2021 | S - Special CBE | BRIO NEUROSTIMULATION SYSTEM | ABBOTT MEDICAL | Approval for labeling updates to include additional clarification language related to magnets within consumer goods and electronic devices. |
| P150004/S045 | 07/02/2021 | Y - 135 Review Tra | AXIUM NEUROSTIMULATOR SYSTEM | ABBOTT MEDICAL | Approval for a cleaning process change that replaces the Trichloroethylene (TCE) cleaning agent, used in the first ultrasonic cleaning step to clean Spinal Cord Stimulation (SCS) and Dorsal Root Ganglion (DRG) needles, with CleanSafe-501ESF (CS-501ESF). |

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| P150004/S048 | 07/15/2021 | S - Special CBE | AXIUM NEUROSTIMULATOR SYSTEM | ABBOTT MEDICAL | Approval for labeling updates to include additional clarification language related to magnets within consumer goods and electronic devices. |
| P150028/S005 | 07/28/2021 | R - Real-Time Proc | CHEATHAM PLATINUM (CP) STENT SYSTEM (COVERED CP STENT, COVERED MOUNTED CP STENT, CP STENT, MOUNTED CP STENT) | NUMED, INC. | Approval to extend the packaging shelf life of the NuDEL Delivery System. |
| P150038/S013 | 07/22/2021 | N - Normal 180 Day | EXABLATE | INSIGHTEC | Approval for design changes to the Exablate Model 4000 Type 1.0 & 1.1 System (Exablate Neuro) to address the end-of-life of some of the system components; to support Exablate Neuro Type 1.1 imaging quality improvements to align with the imaging quality improvements approved for the Exablate Neuro Type 1.0 and to address minor software version 7.33 defects and usability aspects. |
| P160012/S003 | 07/08/2021 | N - Normal 180 Day | LIFEPAK CR® PLUS DEFIBRILLATOR, LIFEPAK EXPRESS® DEFIBRILLATOR, AND CHARGE-PAK® BATTERY CHARGER | PHYSIO-CONTROL. INC. | Approval for the Infant/Child Reduced Energy Defibrillation electrode for use with the LIFEPAK 1000, LIFEPAK CRO Plus, and LIFEPAK EXPRESS defibrillators. |
| P160026/S015 | 07/08/2021 | N - Normal 180 Day | LIFEPAK 1000 DEFIBRILLATOR, LIFEPAK 20 DEFIBRILLATOR/ MONITOR, LIFEPAK 20E DEFIBRILLATOR/ MONITOR, LIFEPAK 15 MONITOR/DEFIBRILLATOR, LIFEPAK 12 DEFIBRILLATOR/ MONITOR | PHYSIO-CONTROL. INC. | Approval for the Infant/Child Reduced Energy Defibrillation Electrodes for use with the LIFEPAK 1000, LIFEPAK CR Plus, and LIFEPAK EXPRESS defibrillators. |
| P160038/S019 | 07/29/2021 | O - Normal 180 Day | PRAXIS EXTENDED RAS PANEL | ILLUMINA, INC. | Approval for a manufacturing site located at Illumina Singapore, 29 Woodlands Industrial Park E1, Singapore, South East 757716, for manufacturing of MiSeqDx Cartridge and MiSeqDx Flow Cell. |
| P160039/S006 | 07/28/2021 | N - Normal 180 Day | REMEDE® SYSTEM | RESPICARDIA | Approval for reducing the IPG size, increasing the IPG battery longevity, reducing the number of set screw connections between the lead terminal and IPG header, and improving features within the Remede Programer software application and the remede Reports application. |
| P170011/S031 | 07/09/2021 | N - Normal 180 Day | IMPELLA RP SYSTEM | ABIOMED, INC. | Approval for material and assembly design changes to the interior cylinder, rack and piston components of the Purge Cassette. |
| P170011/S033 | 07/12/2021 | O - Normal 180 Day | IMPELLA RP SYSTEM | ABIOMED, INC. | Approval of the revised protocol for the post-approval study (PAS) protocol. |
| P170013/S006 | 07/16/2021 | R - Real-Time Proc | LOW-PROFILE VISUALIZED INTRALUMINAL SUPPORT (LVIS) AND LVIS JR. | MICROVENTION, INC. | Approval for the change in antioxidants used in the dispenser hoop of packaging of the Flow Re-Direction Endoluminal Device (FRED) System, Woven EndoBridge (WEB) Aneurysm Embolization System and Low-Profile Visualized Intraluminal Support (LVIS) and LVIS Jr. devices. |
| P170019/S022 | 07/21/2021 | R - Real-Time Proc | FOUNDATIONONE CDX | FOUNDATION MEDICINE, INC. | Approval for the variant classification procedure to add additional variants to existing BRCA1, BRCA2 and ATM companion diagnostic claims for PARP inhibitors (e.g., rucaparib and olaparib) on FoundationOne CDx and FoundationOne Liquid CDx |

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| P170019/S026 | 07/30/2021 | N - Normal 180 Day | FOUNDATIONONE CDX | FOUNDATION MEDICINE, INC. | Approval for a new fractional-based (FB) microsatellite instability (MSI) classification algorithm to replace the principal component analysis (PCA)- based MSI algorithm within F1CDxs tumor profiling indication. |
| P170032/S007 | 07/16/2021 | R - Real-Time Proc | WOVEN ENDOBRIDGE (WEB) ANEURYSM EMBOLIZATION SYSTEM | MICROVENTION, INC. | Approval for the change in antioxidants used in the dispenser hoop of packaging of the Flow Re-Direction Endoluminal Device (FRED) System, Woven EndoBridge (WEB) Aneurysm Embolization System and Low-Profile Visualized Intraluminal Support (LVIS) and LVIS Jr. devices. |
| P180027/S003 | 07/16/2021 | R - Real-Time Proc | FLOW RE-DIRECTION ENDOLUMINAL DEVICE (FRED®) SYSTEM | MICROVENTION, INC. | Approval for a change in antioxidants used in the dispenser hoop of packaging of the FRED System, WEB Aneurysm Embolization System and LVIS and LVIS Jr. |
| P180035/S003 | 07/26/2021 | O - Normal 180 Day | MISIGHT 1 DAY (OMAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES FOR DAILY WEAR | COOPERVISION, INC. | Approval of the protocol for the MiSight® 1 Day post-approval study (PAS) protocol. |
| P180035/S004 | 07/12/2021 | O - Normal 180 Day | MISIGHT 1 DAY (OMAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES FOR DAILY WEAR | COOPERVISION, INC. | Approval of the protocol for the MiSight®1 Day Safety Post Approval Study (PAS) protocol. |
| P180036/S007 | 07/30/2021 | N - Normal 180 Day | OPTIMIZER SMART SYSTEM | IMPULSE DYNAMICS (USA), INC. | Approval for commercial distribution of the OPTIMIZER SMART Mini System. |
| P190032/S001 | 07/15/2021 | P - Panel Track | FOUNDATIONONE LIQUID CDX (F1 LIQUID CDX) | FOUNDATION MEDICINE INC. | Approval to include a companion diagnostic indication for detection of MET single nucleotide variants (SNVs) and indels that lead to MET exon 14 skipping in non-small cell lung cancer patients who may benefit from treatment with TABRECTA (capmatinib) |

**Total: 51**

## 30-Day Notice

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| N12159/S080 | 07/30/2021 | X - 30-Day Notice | SURGICEL BRAND ABSORBABLE HEMOSTAT | ETHICON, INC. | Change to the cutter machine used in the manufacturing of SURGICEL Nu-Knit Absorbable Hemostats at the Ethicon LLC Puerto Rico site. |
| N970012/S188 | 07/08/2021 | X - 30-Day Notice | AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES | BOSTON SCIENTIFIC CORP. | Addition of two sterilization chambers to conduct ethylene oxide gas sterilization Cycle 101. |
| P810025/S042 | 07/08/2021 | X - 30-Day Notice | AMVISC(R) | BAUSCH & LOMB, INC. | Change in the site of Ethylene Oxide/Ethylene Chlorohydrin (EO/ECH) Residual Testing for the Amvisc and Amvisc Plus Ophthalmic Viscosurgical Devices. |
| P810031/S072 | 07/13/2021 | X - 30-Day Notice | HEALON, HEALON GV, HEALON5 PRODUCTS SODIUM HYALURONATE OPHTHALMIC VISCOELASTIC DEVICES | JOHNSON & JOHNSON SURGICAL VISION, INC. | Change from sterility testing to parametric release for product release of the Healon® PRO (packaged individually and in the Healon® Duet PRO Dual Pack), Healon5® PRO and Healon® GV PRO ophthalmic viscoelastic devices (OVDs), in their primary glass syringe packaging, following moist heat steam sterilization. |

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| P830055/S268 | 07/07/2021 | X - 30-Day Notice | LCS(R) TOTAL KNEE SYSTEM | DEPUY, INC. | Addition of an automated clean and passivation system (Miraclean) at the Lincotek Medical manufacturing facility. |
| P830061/S196 | 07/16/2021 | X - 30-Day Notice | STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T | Addition of alternate annealed polyurethane tubing part numbers. |
| P840001/S491 | 07/08/2021 | X - 30-Day Notice | ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS | MEDTRONIC NEUROMODU LATION | Incorporate the Post Wafer Probe Check system to monitor the steps for all wafer lots that have completed wafer probe testing. |
| P840001/S492 | 07/21/2021 | X - 30-Day Notice | ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS | MEDTRONIC NEUROMODU LATION | Updates to battery processing and other related minor manufacturing updates at Medtronic ¿s internal supplier, Medtronic Energy Component Center. |
| P840001/S495 | 07/15/2021 | X - 30-Day Notice | ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS | MEDTRONIC NEUROMODU LATION | Use additional existing sealer tray machines and to update applicable procedures to include validated sealing and peel strength testing parameters on the Sterile Pack Manufacturing Line. |
| P860004/S376 | 07/21/2021 | X - 30-Day Notice | MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM | MEDTRONIC INC. | Updates to battery processing and other related minor manufacturing updates at Medtronics internal supplier, Medtronic Energy Component Center. |
| P880086/S320 | 07/07/2021 | X - 30-Day Notice | ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS | ABBOTT MEDICAL | Adjust Bioburden action limit and alert levels at the Sylmar manufacturing site. |
| P900033/S096 | 07/09/2021 | X - 30-Day Notice | INTEGRA DERMAL REGENERATION TEMPLATE | INTEGRA LIFESCIENCE S CORP. | Qualification of upgrades to the lyophilizer system software and hardware. |
| P900056/S193 | 07/06/2021 | X - 30-Day Notice | ROTABLATOR(R) | BOSTON SCIENTIFIC CORP. | Tightening of device component specifications. |
| P910018/S031 | 07/28/2021 | X - 30-Day Notice | LIPOSORBER(R) LA-15 SYSTEM ADSORPTION COLUMN, SULFUX(R) FS-05 PLASMA SEPARATOR, AND TUB. SYST. FOR PLASMAPHER. (LT-MA2). | KANEKA PHARMA AMERICA CORP. | Introduction of parametric release into the manufacturing process for the LIPOSORBER LA-15 LDL Adsorption Column which is a component device of the LIPOSORBER LA-15 System. |
| P910023/S438 | 07/07/2021 | X - 30-Day Notice | CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM | ABBOTT MEDICAL | Adjust Bioburden action limit and alert levels at the Sylmar manufacturing site. |
| P910056/S046 | 07/21/2021 | X - 30-Day Notice | SOFLEX UV-ABSORBING SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS | BAUSCH & LOMB, INC. | Use of alternative milling equipment, including vacuum plate and protective, to manufacture process for enVista Hydrophobic Acrylic Intraocular Lens. |
| P930014/S137 | 07/14/2021 | X - 30-Day Notice | ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES | ALCON LABORATORI ES, INC. | Remove constant T microvacuole testing as release criteria for Alcon AcrySof® and AcrySof® IQ ReSTOR® intraocular lenses. |

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| P950005/S081 | 07/09/2021 | X - 30-Day Notice | WEBSTER DIAG./ABLATION DEFLECTABLE TIP CATHETER | BIOSENSE WEBSTER, INC | Addition of an electronic vision sensor to the device packaging process. |
| P950022/S139 | 07/07/2021 | X - 30-Day Notice | TVL(TM) LEAD SYSTEM | ABBOTT MEDICAL | Adjust Bioburden action limit and alert levels at the Sylmar manufacturing site. |
| P950022/S140 | 07/29/2021 | X - 30-Day Notice | TVL(TM) LEAD SYSTEM | ABBOTT MEDICAL | Changes related to the high voltage passive (Durata and Optisure) cardiac leads MCRD component manufacturing and analytical testing. |
| P950037/S226 | 07/21/2021 | X - 30-Day Notice | DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS | BIOTRONIK, INC. | Reduce incoming inspections on specified batteries, wiring bands, and resistors. |
| P960009/S402 | 07/21/2021 | X - 30-Day Notice | MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM | MEDTRONIC INC. | Updates to battery processing and other related minor manufacturing updates at Medtronic ¿s internal supplier Medtronic Energy Component Center. |
| P960009/S403 | 07/29/2021 | X - 30-Day Notice | MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM | MEDTRONIC INC. | Update the manufacturing process of subcomponents for the SenSight Directional Lead at the Medtronic Danvers facility. |
| P960013/S119 | 07/07/2021 | X - 30-Day Notice | TENDRIL DX MODEL 1388T & 1388K ENDOCARDIAL PACING LEADS | ABBOTT MEDICAL | Adjust Bioburden action limit and alert levels at the Sylmar manufacturing site. |
| P960030/S075 | 07/07/2021 | X - 30-Day Notice | PASSIVE PLUS DX ENDOCARDIAL STEROID ELUTING, PASSIVE-FIXATION PACING LEADS | ABBOTT MEDICAL | Adjust Bioburden action limit and alert levels at the Sylmar manufacturing site. |
| P970004/S335 | 07/21/2021 | X - 30-Day Notice | MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL | MEDTRONIC NEUROMODULATION | Updates to battery processing and other related minor manufacturing updates at Medtronics internal supplier, Medtronic Energy Component Center. |
| P970004/S336 | 07/15/2021 | X - 30-Day Notice | MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL | MEDTRONIC NEUROMODULATION | Use additional existing sealer tray machines and to update applicable procedures to include validated sealing and peel strength testing parameters on the Sterile Pack Manufacturing Line. |
| P970013/S088 | 07/07/2021 | X - 30-Day Notice | MICRONY PACEMAKERS | ABBOTT MEDICAL | Adjust Bioburden action limit and alert levels at the Sylmar manufacturing site. |
| P980016/S786 | 07/02/2021 | X - 30-Day Notice | VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Implementation of modifications of the seal inspection process and requirements. |
| P980016/S787 | 07/14/2021 | X - 30-Day Notice | VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT | Implementation of modifications of the laser solder plated through hole inspection process. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P980023/S106 | 07/21/2021 | X - 30-Day Notice | PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM | BIOTRONIK, INC. | Reduce incoming inspections on specified batteries, wiring bands, and resistors. |
| P980035/S686 | 07/07/2021 | X - 30-Day Notice | MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE | MEDTRONIC INC. | Inclusion of a process aid and additional inspections for the preform solder process used in hybrid board manufacturing. |
| P980035/S687 | 07/14/2021 | X - 30-Day Notice | MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE | MEDTRONIC INC. | Implementation of modifications of the laser solder plated through hole inspection process. |
| P980040/S141 | 07/28/2021 | X - 30-Day Notice | SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS | JOHNSON & JOHNSON SURGICAL VISION, INC. | Slight increase to the lower tolerance for the ring height for the lens insert of the daisy-wheel package configuration for one-piece acrylic IOLs. |
| P990013/S041 | 07/19/2021 | X - 30-Day Notice | COLLAMER ULTRAVIOLET ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS | STARR SURGICAL CO. | Adding an alternative facility for water and pre-sterile product bioburden testing. |
| P990025/S066 | 07/09/2021 | X - 30-Day Notice | NAVI-STAR DIAGNOSTIC/ ABLATION DEFLECTABLE TIP CATHETER | BIOSENSE WEBSTER, INC. | Addition of an electronic vision sensor to the device packaging process. |
| P990037/S035 | 07/13/2021 | X - 30-Day Notice | VASCULAR SOLUTIONS DUETT SEALING DEVICE | VASCULAR SOLUTIONS, INC. | Alternate sealer for the sterile barrier of the D-Stat Flowable Hemostat of the Duett Sealing Device. |
| P990071/S050 | 07/09/2021 | X - 30-Day Notice | STOCKERT 70 RADIOFREQUENCY ABLATION GENERATOR | BIOSENSE WEBSTER, INC. | Addition of an electronic vision sensor to the device packaging process. |
| P990074/S047 | 07/20/2021 | X - 30-Day Notice | NATRELLE SALINE BREAST IMPLANTS | ALLERGAN | Change to implement new temperature controllers used in the alcohol shell drying ovens in the manufacturing process of the Allergan Natrelle® Saline-Filled Breast Implants and the Allergan Natrelle® Silicone-Filled Breast Implants |
| P990074/S048 | 07/30/2021 | X - 30-Day Notice | NATRELLE SALINE BREAST IMPLANTS | ALLERGAN | Installation of a new patch curing oven and electronic data acquisition system for the manufacture of silicone-filled and saline-filled breast implants at Allergans Costa Rica facility. |
| P990075/S052 | 07/21/2021 | X - 30-Day Notice | MENTOR CORPORATION SALINE-FILLED AND SPECTRUM (R) MAMMARY PROSTHESES | MENTOR WORLDWIDE LLC | Change to implement the use of an automated seal vision system for inspection of seal defects in the primary packaging process for the MemoryGel® Breast Implants, the Saline-Filled Breast Implants and MemoryShape® Breast Implants |
| P000009/S093 | 07/21/2021 | X - 30-Day Notice | PHYLAX AV ICD SYSTEM | BIOTRONIK, INC. | Reduce incoming inspections on specified batteries, wiring bands, and resistors. |
| P000039/S074 | 07/27/2021 | X - 30-Day Notice | THE AMPLATZER(R) SEPTAL OCCLUDER (ASO) AND THE AMPLATZER EXCHANGE SYSTEM | ABBOTT MEDICAL | Update to the dome weld and end screw weld visual acceptance criteria. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P000053/S121 | 07/08/2021 | X - 30-Day Notice | AMS SPHINCTER 800 URINARY CONTROL SYSTEM | BOSTON SCIENTIFIC CORP. | Addition of two sterilization chambers to conduct ethylene oxide gas sterilization Cycle 101. |
| P010003/S038 | 07/23/2021 | X - 30-Day Notice | BIOGLUE SURGICAL ADHESIVE | CRYOLIFE, INC. | Change LAL extraction methods for the syringe, extender tips, and delivery tip extensions, and implementation of electronic IFU. |
| P010015/S478 | 07/14/2021 | X - 30-Day Notice | MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM | MEDTRONIC INC. | Implementation of modifications of the laser solder plated through hole inspection process. |
| P010031/S749 | 07/02/2021 | X - 30-Day Notice | CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T | Implementation of modifications of the seal inspection process and requirements. |
| P010031/S751 | 07/14/2021 | X - 30-Day Notice | CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T | Implementation of modifications of the laser solder plated through hole inspection process. |
| P010031/S752 | 07/22/2021 | X - 30-Day Notice | CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION | MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T | Implementation of modifications of the seal inspection process and requirements. |
| P010032/S179 | 07/28/2021 | X - 30-Day Notice | GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS | ABBOTT MEDICAL | Implementation of a reduced sample size for bacterial endotoxin and bioburden testing for finished devices manufactured at Plano, TX and Arecibo, PR facility. |
| P010068/S066 | 07/09/2021 | X - 30-Day Notice | NAVISTAR/CELSIUS DS DIAGNOSTIC/ABLATION DEFLECTABLE 8MM TIP CATHETER | BIOSENSE WEBSTER, INC. | Addition of an electronic vision sensor to the device packaging process. |
| P020024/S065 | 07/27/2021 | X - 30-Day Notice | AMPLATZER DUCT OCCLUDER AND 180 DEGREE DELIVERY SYSTEM | ABBOTT MEDICAL | Update to the dome weld and end screw weld visual acceptance criteria. |
| P020056/S056 | 07/20/2021 | X - 30-Day Notice | NATRELLE SILICONE-FILLED BREAST IMPLANTS | ALLERGAN | Change to implement new temperature controllers used in the alcohol shell drying ovens in the manufacturing process of the Allergan Natrelle® Saline-Filled Breast Implants and the Allergan Natrelle® Silicone-Filled Breast Implants |
| P020056/S057 | 07/30/2021 | X - 30-Day Notice | NATRELLE SILICONE-FILLED BREAST IMPLANTS | ALLERGAN | Installation of a new patch curing oven and electronic data acquisition system for the manufacture of silicone-filled and saline-filled breast implants at Allergan's Costa Rica facility. |

| Submission Number | Date Final Decision | Review Track | Trade Name | Appl/Spr Name | Approval Order Statement |
|---|---|---|---|---|---|
| P030016/S041 | 07/19/2021 | X - 30-Day Notice | VISIAN ICL (IMPLANTABLE COLLAMER LENS) | STAAR SURGICAL COMPANY | Adding an alternative facility for water and pre-sterile product bioburden testing. |
| P030031/S121 | 07/09/2021 | X - 30-Day Notice | BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS | BIOSENSE WEBSTER, INC. | Addition of an electronic vision sensor to the device packaging process. |
| P030035/S187 | 07/07/2021 | X - 30-Day Notice | ANTHEM AND FRONTIER II CRT-P'S | ABBOTT MEDICAL | Adjust Bioburden action limit and alert levels at the Sylmar manufacturing site. |
| P030053/S064 | 07/22/2021 | X - 30-Day Notice | MEMORYGEL SILICONE GEL -FILLED BREAST IMPLANTS | MENTOR CORP. | Change to implement the use of an automated seal vision system for inspection of seal defects in the primary packaging process for the MemoryGel® Breast Implants, the Saline-Filled Breast Implants and MemoryShape® Breast Implants |
| P030054/S393 | 07/07/2021 | X - 30-Day Notice | ST JUDE MEDICAL EPIC HF SYSTEM | ABBOTT MEDICAL | Adjust Bioburden action limit and alert levels at the Sylmar manufacturing site. |
| P040020/S099 | 07/14/2021 | X - 30-Day Notice | ACRYSOF RESTOR APODIZED DIFFRACTIVE OPTIC POSTERIOR CHAMBER IOL | ALCON RESEARCH, LTD. | Remove constant T microvacuole testing as release criteria for Alcon AcrySof® and AcrySof® IQ ReSTOR® intraocular lenses. |
| P040029/S020 | 07/26/2021 | X - 30-Day Notice | JSZ ORTHOKERATOLOGY (OPRIFOCON A) CONTACT LENSES FOR OVERNIGHT WEAR | EUCLID SYSTEMS CORPORATIO N | Changes in the software that generates the code for lathing Euclid Systems Orthokeratology Contact Lenses for Overnight Wear. |
| P040036/S083 | 07/09/2021 | X - 30-Day Notice | NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER | BIOSENSE WEBSTER, INC. | Addition of an electronic vision sensor to the device packaging process. |
| P040040/S044 | 07/27/2021 | X - 30-Day Notice | AMPLATZER MUSCULAR VSD OCCLUDER | ABBOTT MEDICAL | Update to the dome weld and end screw weld visual acceptance criteria. |
| P050018/S031 | 07/27/2021 | X - 30-Day Notice | ANGIOSCULPT SCORING BALLOON CATHETER | SPECTRANETI CS CORP. | Supplier site change. |
| P050023/S158 | 07/21/2021 | X - 30-Day Notice | TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD | BIOTRONIK, INC. | Reduce incoming inspections on specified batteries, wiring bands, and resistors. |
| P050047/S082 | 07/21/2021 | X - 30-Day Notice | JUVEDERM 24HV, JUVEDERM 30 AND JUVEDERM 30HV GEL IMPLANTS | ALLERGAN | Implementation of two additional automatic visual inspection equipment in the manufacture of the Juvederm products. |
| P060028/S043 | 07/22/2021 | X - 30-Day Notice | MENTOR MEMORYSHAPE BREAST IMPLANTS | MENTOR WORLDWIDE LLC | Change to implement the use of an automated seal vision system for inspection of seal defects in the primary packaging process for the MemoryGel® Breast Implants, the Saline-Filled Breast Implants and MemoryShape® Breast Implants |
| P060037/S072 | 07/19/2021 | X - 30-Day Notice | NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM | ZIMMER, INC. | Expanding the packaging cleanroom to increase capacity within the existing Zimmer facility in Warsaw Indiana. |

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|---|---|---|---|---|---|
| P070008/S127 | 07/21/2021 | X - 30-Day Notice | STRATOS LV CRT-P AND STRATOS LV-T CRT-P, COROX OTW BP LEAD AND COROX OTW-S BP LEAD | BIOTRONIK, INC. | Reduce incoming inspections on specified batteries, wiring bands, and resistors. |
| P070026/S083 | 07/20/2021 | X - 30-Day Notice | CERAMAX CERAMIC HIP SYSTEM | DEPUY ORTHOPAEDICS, INC. | Addition of an alternate supplier for one of the raw materials used for manufacturing the ceramic components of the CERAMAX® Ceramic Total Hip System. |
| P080025/S230 | 07/21/2021 | X - 30-Day Notice | MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM | MEDTRONIC NEUROMODULATION | Updates to battery processing and other related minor manufacturing updates at Medtronics internal supplier, Medtronic Energy Component Center. |
| P080025/S231 | 07/15/2021 | X - 30-Day Notice | MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM | MEDTRONIC NEUROMODULATION | Use additional existing sealer tray machines and to update applicable procedures to include validated sealing and peel strength testing parameters on the Sterile Pack Manufacturing Line. |
| P100018/S033 | 07/27/2021 | X - 30-Day Notice | PIPELINE EMBOLIZATION DEVICE | MICRO THERAPEUTICS, INC. D/B/A EV3 NEUROVASCULAR | Modifications to hypotube tensile strength test of Pipeline Flex Embolization Device and Pipeline Flex Embolization Device with Shield Technology, using an in-process manufacturing acceptance criteria of >= 3.0 N for the test, and shifting the hypotube tensile strength test from the final inspection step to an earlier subassembly step. |
| P100030/S015 | 07/27/2021 | X - 30-Day Notice | ARTERX SURGICAL SEALANT | BAXTER HEALTHCARE CORPORATION | Change in location for the quality control testing performed on the PreveLeak, from the Baxter Mountain View to Baxter Hayward facilities. |
| P100045/S055 | 07/01/2021 | X - 30-Day Notice | CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM | ST. JUDE MEDICAL | Addition of an in-house pairing process for 4G Patient Electronic Systems. |
| P100047/S185 | 07/22/2021 | X - 30-Day Notice | HEARTWARE VENTRICULAR ASSIST SYSTEM | MEDTRONIC | Clarify/add inspection steps and to align procedures with the supplier for the motor header assembly used on the HVAD System pump. |
| P110010/S196 | 07/02/2021 | X - 30-Day Notice | PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM | BOSTON SCIENTIFIC CORP. | Introduction of an automated loading process of corewire and hypotube components and an automated vision system. |
| P110019/S117 | 07/30/2021 | X - 30-Day Notice | XIENCE PRIME AND XIENCE PRIME LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM | ABBOTT VASCULAR | Moving the stent ring inspection process to the first inspection step. |
| P110033/S061 | 07/21/2021 | X - 30-Day Notice | JUVEDERM VOLUMA XC | ALLERGAN | Implementation of two additional automatic visual inspection equipment in the manufacture of the Juvederm products. |
| P120021/S021 | 07/27/2021 | X - 30-Day Notice | AMPLATZER PFO OCCLUDER | ABBOTT MEDICAL | Update to the dome weld and end screw weld visual acceptance criteria. |

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|---|---|---|---|---|---|
| P130021/S100 | 07/12/2021 | X - 30-Day Notice | MEDTRONIC COREVALVE SYSTEM | MEDTRONIC COREVALVE LLC | Dimensional modifications to a measurement tool used for in-process inspection of the delivery catheter. |
| P130021/S101 | 07/19/2021 | X - 30-Day Notice | MEDTRONIC COREVALVE SYSTEM | MEDTRONIC COREVALVE LLC | Addition of a new tissue supplier. |
| P140009/S072 | 07/28/2021 | X - 30-Day Notice | BRIO NEUROSTIMULATION SYSTEM | ABBOTT MEDICAL | Implementation of a reduced sample size for bacterial endotoxin and bioburden testing for finished devices manufactured at Plano, TX and Arecibo, PR facility. |
| P140016/S003 | 07/09/2021 | X - 30-Day Notice | ZENITH ALPHA THORACIC ENDOVASCULAR GRAFT | COOK MEDICAL INCORPORATED | Change to the delivery system trigger-wire coating facility and updates to the acceptance criteria used in testing of the trigger wires. |
| P140020/S021 | 07/02/2021 | X - 30-Day Notice | BRACANALYSIS CDX | MYRIAD GENETIC LABORATORIES | Replacement of a confirmatory test reagent. |
| P140031/S129 | 07/22/2021 | X - 30-Day Notice | SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES | EDWARDS LIFESCIENCES, LLC. | Implementation of sterilization parametric release for the SAPIEN 3 Ultra Transcatheter Heart Valves (THVs) manufactured at the Edwards Irvine, CA and Changi, Singapore facilities. |
| P140032/S073 | 07/21/2021 | X - 30-Day Notice | IMPLANTABLE SYSTEM FOR REMODULIN | MEDTRONIC, INC. | proposed updates to battery processing and other related minor manufacturing updates at Medtronic¿s internal supplier, Medtronic Energy Component Center. |
| P140033/S069 | 07/07/2021 | X - 30-Day Notice | ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE | ABBOTT MEDICAL | Adjust Bioburden action limit and alert levels at the Sylmar manufacturing site. |
| P150001/S091 | 07/07/2021 | X - 30-Day Notice | MINIMED 630G SYSTEM WITH SMARTGUARD(TM) | MEDTRONIC MINIMED | Addition of a second production line for Next Generation Pump (NGP) motors at Medtronics current supplier. The NGP motors are components of the MiniMed 630G and MiniMed 670G Insulin Pumps. |
| P150003/S077 | 07/02/2021 | X - 30-Day Notice | SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM | BOSTON SCIENTIFIC CORPORATION | Introduction of an automated loading process of corewire and hypotube components and an automated vision system. |
| P150004/S050 | 07/28/2021 | X - 30-Day Notice | AXIUM NEUROSTIMULATOR SYSTEM | ABBOTT MEDICAL | Implementation of a reduced sample size for bacterial endotoxin and bioburden testing for finished devices manufactured at Plano, TX and Arecibo, PR facility. |
| P150005/S063 | 07/14/2021 | X - 30-Day Notice | BLAZER OPEN-IRRIGATED ABLATION CATHETER | BOSTON SCIENTIFIC CORP. | Addition of a new vendor for the tip and ring electrode. |
| P150005/S064 | 07/20/2021 | X - 30-Day Notice | BLAZER OPEN-IRRIGATED ABLATION CATHETER | BOSTON SCIENTIFIC CORP. | Tightened acceptance criterion and a duplicated test method to address reports of electrical malfunctions. |
| P150005/S065 | 07/21/2021 | X - 30-Day Notice | BLAZER OPEN-IRRIGATED ABLATION CATHETER | BOSTON SCIENTIFIC CORP. | Change to the lubricant used in the polycarbonate base resign and to add an alternative dye technology for the 4-way stopcock component used in the MetriQ Irrigation Tubing Set. |

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| P150012/S113 | 07/14/2021 | X - 30-Day Notice | IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD | BOSTONSCIENTIFIC | Simplify the test article used for finished drug product testing such as lot release, stability, and retention for INGEVITY passive fixation leads. |
| P150033/S112 | 07/01/2021 | X - 30-Day Notice | MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM | MEDTRONIC INC. | Implementation of modifications of the feedthrough glass crack inspection process. |
| P150033/S113 | 07/08/2021 | X - 30-Day Notice | MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM | MEDTRONIC INC. | Update the monitoring on protrusion of the feedthrough and ground pin weld. |
| P150033/S114 | 07/09/2021 | X - 30-Day Notice | MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM | MEDTRONIC INC. | Implement testing and process monitoring changes for the endcap trim and bend. |
| P150033/S115 | 07/14/2021 | X - 30-Day Notice | MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM | MEDTRONIC INC. | Implementation of modifications of the laser solder plated through hole inspection process. |
| P150033/S116 | 07/16/2021 | X - 30-Day Notice | MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM | MEDTRONIC INC. | Update tooling and work instructions for the assembly of the Micra leadless pacing system. |
| P150048/S055 | 07/23/2021 | X - 30-Day Notice | EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500) | EDWARDS LIFESCIENCES, LLC. | Changes to the sewing procedures used to manufacture the Inspiris Model 11500A valve. |
| P160003/S014 | 07/13/2021 | X - 30-Day Notice | PRO-KINETIC ENERGY COBALT CHROMIUM (COCR) CORONARY STENT SYSTEM | BIOTRONIK, INC. | Source change for an acid solution used during the stent manufacturing. |
| P160017/S092 | 07/07/2021 | X - 30-Day Notice | MINIMED 670G SYSTEM | MEDTRONIC MINIMED, INC. | Addition of a second production line for Next Generation Pump (NGP) motors at Medtronics current supplier. The NGP motors are components of the MiniMed 630G and MiniMed 670G Insulin Pumps. |
| P160043/S050 | 07/27/2021 | X - 30-Day Notice | RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM | MEDTRONIC VASCULAR | Revisions to the stent coating appearance testing acceptance criteria. |
| P170024/S009 | 07/12/2021 | X - 30-Day Notice | SURPASS STREAMLINE FLOW DIVERTER | STRYKER NEUROVASCULAR | Equipment relocation of the primary coil winders, used in the manufacturing and assembly of the Surpass Evolve Flow Diverter System, from their existing location in a Class 8 cleanroom to a Non-Controlled Environment Area (Non-CE) in the warehouse of Stryker¿s manufacturing facility in Cork, Ireland. |
| P170030/S017 | 07/13/2021 | X - 30-Day Notice | ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM | BIOTRONIK, INC | Source change for an acid solution used during the stent manufacturing. |
| P170030/S018 | 07/28/2021 | X - 30-Day Notice | ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM | BIOTRONIK, INC | Changes to the stability study parameters and the introduction of a leak test method for packaging integrity testing. |

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| P180032/S007 | 07/22/2021 | X - 30-Day Notice | CERENE® CRYOTHERAPY DEVICE | CHANNEL MEDSYSTEMS, INC. | Change to the manufacturing procedure involving a tool design change and qualification of a new part supplier. |
| P180032/S008 | 07/26/2021 | X - 30-Day Notice | CERENE® CRYOTHERAPY DEVICE | CHANNEL MEDSYSTEMS, INC. | Modification to the manufacturing procedure for the subject device. This change is the implementation of a Desco Ionizing Fan into the tray sealing process to replace the ionizing air gun that is currently used. |
| P190008/S016 | 07/21/2021 | X - 30-Day Notice | IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER | MEDTRONIC VASCULAR INC. | Implementation of change in component suppliers and other minor process control changes. |
| P200022/S007 | 07/21/2021 | X - 30-Day Notice | SIMPLIFY® CERVICAL ARTIFICIAL DISC | NUVASIVE, INC. | Add a second raw material supplier for the raw material used to manufacture the core of the device. |
| P200026/S002 | 07/09/2021 | X - 30-Day Notice | ABRE VENOUS SELF-EXPANDING STENT SYSTEM | MEDTRONIC VASCULAR, INC. | Addition of a new electropolishing station to the manufacturing process. |
| P200039/S003 | 07/22/2021 | X - 30-Day Notice | SHOCKWAVE INTRAVASCULAR LITHOTRIPSY (IVL) SYSTEM WITH SHOCKWAVE C2 CORONARY INTRAVASCULAR LITHOTRIPSY (IVL) CATHETER | SHOCKWAVE MEDICAL, INC. | New class 8 cleanroom. |
| P200046/S004 | 07/07/2021 | X - 30-Day Notice | HARMONY¿ TPV SYSTEM | MEDTRONIC, INC. | Automation of the bioburden reduction process. |
| P200046/S005 | 07/19/2021 | X - 30-Day Notice | HARMONY¿ TPV SYSTEM | MEDTRONIC, INC. | Addition of a new tissue supplier. |

**Total: 115**