PMA Monthly approvals from 7/1/2022 to 7/31/2022

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P200020	07/22/2022	PMAO - PMA Origi	SBL-3 MULTIFOCAL INTRAOCULAR LENS	LENSTEC, INC.	Approval for the Lenstec SBL-3 Multifocal Intraocular Lens. This Lenstec SBL-3 Multifocal Intraocular Lens is indicated for primary implantation for the visual correction of aphakia, in adult patients with 1 diopter or less of pre-existing corneal astigmatism, in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing a bifocal correction. Compared to an aspheric monofocal IOL, the lens provides improved near visual acuity, while maintaining comparable distance and intermediate visual acuity. The lens promotes the less frequent use of vision correction choices at near distance (including glasses, contact lenses, magnifying glasses, and digital adjustments on electronic devices), compared to an aspheric monofocal IOL, as reported in patient-reported outcomes. The SBL-3 multifocal IOL is intended for capsular bag placement only.
P210005	07/22/2022	PMAO - PMA Origi r	IC-8 APTHERA INTRAOCULAR LENS (IOL)	ACUFOCUS, INC.	Approval for the IC-8 Apthera IOL. The device is indicated for unilateral implantation for the visual correction of aphakia and to create monovision in patients of age 22 or older who have been diagnosed with bilateral operable cataract, who have up to 1.5 D of astigmatism in the implanted eye, and who do not have a history of retinal disease and who are not predisposed to experiencing retinal disease in the future. The device is intended for primary implantation in the capsular bag, in the non-dominant eye, after the fellow eye has already undergone successful implantation (uncorrected distance visual acuity 20/32 or better and best-corrected distance visual acuity 20/25 or better) of a monofocal or monofocal toric IOL that is targeted for emmetropia. The refractive target for the IC-8 Apthera IOL should be -0.75 D. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal or monofocal toric IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P210019	07/27/2022	PMAO - PMA Origi	ADVIA CENTAUR ANTI-HBC TOTAL (HBCT2) AND ATELLICA IM ANTI-HBC TOTAL (HBCT2)	SIEMENS HEALTHCARE DIAGNOSTICS , INC.	Approval for the ADVIA Centaur® HBc Total 2 (HBcT2) assay. The ADVIA Centaur HBc Total 2 (HBcT2) assay is an in vitro diagnostic immunoassay for use in the qualitative determination of total antibodies to the core antigen of the hepatitis B virus (HBV) in human adult serum and plasma (EDTA, lithium heparin, and sodium heparin) using the ADVIA Centaur XP and ADVIA Centaur XPT systems. This assay can be used as an aid in the diagnosis of adults with acute or chronic hepatitis B virus (HBV) infection, and in the determination of the clinical status of HBV-infected individuals in conjunction with other HBV serological markers, for the laboratory diagnosis of HBV disease associated with HBV infection. This assay can also be used as an aid in the differential diagnosis in individuals displaying signs and symptoms of hepatitis in whom etiology is unknown. This assay is not intended for screening donors of blood or blood products or human cells, tissues, and cellular and tissue-based products (HCT/Ps). Approval for the ADVIA Centaur® HBc Total 2 Quality Control (HBcT2 QC). The ADVIA Centaur® HBc Total 2 (HBcT2) Quality Control material is for in vitro diagnostic use for monitoring the performance of the ADVIA Centaur HBc Total 2 (HBcT2) assay using the ADVIA Centaur systems. The performance of the ADVIA Centaur HBcT2 Quality Control material has not been with any other anti-HBc Total assay. Approval for the Atellica IM® HBc Total 2 (HBcT2) assay. The Atellica IM HBc Total 2 (HBcT2) assay is an in vitro diagnostic immunoassay for use in the qualitative determination of total antibodies to the core antigen of the hepatitis B virus (HBV) in human adult serum and plasma (EDTA, lithium heparin, and sodium heparin) using the Atellica IM Analyzer. This assay can be used as an aid in the diagnosis of adults with acute or chronic hepatitis B virus (HBV) infection and in the determination of the clinical status of HBV-infected individuals in conjunction with other HBV serological markers, for the laboratory diagnosis of HBV disease associated with HBV infection. This assay can also be used as an aid in the differential diagnosis in individuals displaying signs and symptoms of hepatitis in whom etiology is unknown. This assay is not intended for screening donors of blood or blood products or human cells, tissues, and cellular and tissue-based products (HCT/Ps). Approal for the Atellica IM® HBc Total 2 Quality Control (HBcT2 QC). The Atellica IM HBc Total 2 (HBcT2) Quality Control material is for in vitro diagnostic use for monitoring the performance of the Atellica IM HBc Total 2 (HBcT2) assay using the Atellica IM systems. The performance of the Atellica IM HBcT2 Quality Control material has not been with any other anti-HBc Total assay.

Total: 3

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S086	07/26/2022	R - Real-Time Proc	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Approval for labeling changes for SURGICEL Original Absorbable Hemostat, SURGICEL NU-KNIT Absorbable Hemostat, SURGICEL Fibrillar Absorbable Hemostat, SURGICEL SNoW Absorbable Hemostat, including bacteria nomenclature updates and addition of verbiage to bactericidal information, addition of U.S.P statement for oxidized regenerated cellulose, and addition of MRI safety claim.
P830055/S277	07/06/2022	O - Normal 180 Da	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for a manufacturing site located at Wilsey Tool Company, 140 Penn Am Drive, Quakertown, PA 18951 to conduct the contract manufacturing for the cutting block instruments used as part of the LCS® Total Knee System.
P830055/S286	07/25/2022	Y - 135 Review Tra	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval to add coating SBP2000 as an acceptable alternative coating.
P840001/S514	07/21/2022	R - Real-Time Proc	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Approval for an update to the primary Information for Prescribers (IFP) clinician labeling, and update to the primary Patient Therapy Guide (PTG).
P890057/S025	07/22/2022	R - Real-Time Proc	MODEL 3100 FREQUENCY OSCILLATORY VENTILATOR	VYAIRE MEDICAL INC.	Approval for modifications to the material of construction of the 3100A/B bellows water trap assembly.
P940035/S017	07/12/2022	O - Normal 180 Da	NMP22 BLADDERCHECK TEST	ABBOTT DIAGNOSTICS SCARBOROUGH, INC.	Approval to manufacture Alere NMP22 BladderChek Test under Abbott Diagnostics Scarborough, Inc.s new brand name: NMP22 BladderChek Test.
P980016/S824	07/20/2022	R - Real-Time Proc	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for changes to the Cobalt/Crome devices associated with the Short Circuit Protection.
P980049/S143	07/28/2022	R - Real-Time Proc	DEFENDER II MODEL 9201 IMPLANTABLE CARDIOVERTER DEFIBRILLATOR	MICROPORT CRM USA INC.	Approval for programmer software updates.
P990081/S046	07/21/2022	S - Special CBE	PATHWAY ANTI-HCR-2/ NCU (4B5) RABBIT MONOCLONAL PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Approval for (i) a change in expiry dating from Hematoxylin and Hematoxylin II and (ii) implementation of a revised process for creating reference slides used in Surveillance and Stability testing of Hematoxylin and Hematoxylin II.
P010014/S102	07/14/2022	S - Special CBE	OXFORD(TM) MENISCAL UNICOMPARTMENTAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Approval for updating the currently approved U.S. labeling for the Oxford® Partial Knee System, including instructions for use (IFU), packaging labeling, inclusion of a new Information for Patient/IFP document, and Patient Implant Card.
P010031/S791	07/20/2022	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for changes to the Cobalt/Crome devices associated with the Short Circuit Protection.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P020004/S189	07/28/2022	O - Normal 180 Da	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Approval for an update to the labeling to include final study information provided in the final post-approval study progress report.
P020055/S026	07/21/2022	S - Special CBE	VENTANA MEDICAL SYSTEMS PATHWAY ANTI-C-KIT (9.7) PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Approval for (i) a change in expiry dating from Hematoxylin and Hematoxylin II and (ii) implementation of a revised process for creating reference slides used in Surveillance and Stability testing of Hematoxylin and Hematoxylin II.
P030009/S101	07/15/2022	Y - 135 Review Tra	DRIVER OVER-THE-WIRE, RAPID EXCHANGE, AND MULTI-EXCHANGE CORONARY STENT SYSTEMS	MEDTRONIC IRELAND	Approval for the introduction of the Optimized PCA Sterilization Cycle
P030050/S035	07/25/2022	Y - 135 Review Tra	SCULPTRA AND SCULPTRA AESTHETIC	Q-MED AB	Approval to implement new equipment for filling, lyophilization (freeze drying) and capping processes for Sculptra and Sculptra Aesthetic
P040024/S131	07/20/2022	R - Real-Time Proc	RESTYLANE INJECTABLE GEL	Q-MED AB	Approval for alternative plunger rod and finger grip to be used with the approved Beckton Dickinson syringe system.
P050006/S100	07/06/2022	O - Normal 180 Da	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P070001/S019	07/07/2022	N - Normal 180 Day	PRODISC TM-C TOTAL DISC REPLACEMENT	CENTINEL SPINE, LLC	Approval for a Line Extension to Centinel Spines prodisc® C: the prodisc® C SK, the prodisc® C Nova, and the prodisc® C Vivo.
P070004/S035	07/05/2022	R - Real-Time Proc	SIENTRA SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Approval for the Low Profile Plus projection style to the current portfolio of Sientra Silicone Gel Breast Implants.
P070026/S095	07/25/2022	Y - 135 Review Tra	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Approval to add coating SBP2000 as an acceptable alternative coating.
P080011/S146	07/25/2022	R - Real-Time Proc	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Approval for the introduction of a new primary packaging foil for Biofinity (comfilcon A) Soft (Hydrophilic) Contact Lenses for Extended Wear.
P080012/S070	07/12/2022	O - Normal 180 Da	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P100016/S011	07/14/2022	Y - 135 Review Tra	EC-3 INTRAOCULAR LENS (IOL) AND EC-3 PRECISION ASPHERIC LENS (PAL) IOL	CARL ZEISS MEDITEC PRODUCTION LLC	Approval for qualifying a new package tester.
P100021/S089	07/15/2022	Y - 135 Review Tra	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Approval for the introduction of the Optimized PCA Sterilization Cycle
P100026/S090	07/28/2022	R - Real-Time Proc	NEUROPACE RNS SYSTEM	NEUROPACE INC	Approval for updates and improvements to the currently approved RNS® Tablet Programmer Application Software and related change to the NeuroPace® Patient Data Management System Application Software, along with related labeling updates.
P100027/S036	07/21/2022	S - Special CBE	INFORM HER2 DUAL ISH DNA PROBE COCKTAIL	VENTANA MEDICAL SYSTEMS, INC.	Approval for (i) a change in expiry dating from Hematoxylin and Hematoxylin II and (ii) implementation of a revised process for creating reference slides used in Surveillance and Stability testing of Hematoxylin and Hematoxylin II.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110013/S109	07/15/2022	Y - 135 Review Tra	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for the introduction of the Optimized PCA Sterilization Cycle
P110033/S065	07/29/2022	P - Panel Track	JUVEDERM VOLUMA XC	ALLERGAN	Approved for the indication of subcutaneous and/or supraperiosteal injection for improvement of jawline definition in adults over the age of 21 with moderate to severe loss of jawline definition
P130008/S076	07/01/2022	N - Normal 180 Day	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval for additional MR scanning conditions using a 1.5T full body coil scanner for Model 3028 IPG, Model 4323, Model 4340 and Model 4063 leads
P130021/S088	07/15/2022	Y - 135 Review Tra	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Approval for the introduction of the Optimized PCA Sterilization Cycle
P130021/S115	07/08/2022	R - Real-Time Proc	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Approval to modify the pacing recommendation language in the Instructions for Use.
P140003/S096	07/08/2022	O - Normal 180 Da	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval to update the Instructions for Use to incorporate results from the Impella PCCS PAS.
P140003/S098	07/08/2022	O - Normal 180 Da	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for the updated labeling with the information from the Impella PROTECTED PCI Post-Approval cVAD Registry Study.
P140018/S032	07/27/2022	R - Real-Time Proc	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Approval for design changes to the dispenser gun component of the VenaSeal Closure System.
P140025/S017	07/21/2022	S - Special CBE	VENTANA ALK (D5F3) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for (i) a change in expiry dating from Hematoxylin and Hematoxylin II and (ii) implementation of a revised process for creating reference slides used in Surveillance and Stability testing of Hematoxylin and Hematoxylin II.
P140026/S020	07/20/2022	O - Normal 180 Da	ENROUTE TRANSCAROTID STENT SYSTEM	SILK ROAD MEDICAL, INC	Approval for receiving, inspection, and distribution of finished goods at a manufacturing site located at 14755 27th Ave N, Plymouth, MN 55447.
P140031/S141	07/28/2022	N - Normal 180 Day	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for the Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve.
P150033/S098	07/15/2022	Y - 135 Review Tra	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval for the introduction of the Optimized PCA Sterilization Cycle
P150038/S018	07/29/2022	O - Normal 180 Da	EXABLATE	INSIGHTEC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P160001/S047	07/18/2022	O - Normal 180 Da	OBALON BALLOON SYSTEM	RESHAPE LIFESCIENCES, INC.	Approval of the labeling reflecting the findings of the post-approval study (PAS) protocol.
P160002/S017	07/21/2022	S - Special CBE	VENTANA PD-L1(SP142) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for (i) a change in expiry dating from Hematoxylin and Hematoxylin II and (ii) implementation of a revised process for creating reference slides used in Surveillance and Stability testing of Hematoxylin and Hematoxylin II.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160012/S006	07/20/2022	R - Real-Time Proc	LIFEPAK CR® PLUS DEFIBRILLATOR, LIFEPAK EXPRESS® DEFIBRILLATOR, AND CHARGE-PAK® BATTERY CHARGER	PHYSIO-CONTROL. INC.	Approval for a temporary shelf-life extension up to 9 months beyond the expiration date for units already distributed in the field that meet the required storage conditions.
P160025/S013	07/20/2022	N - Normal 180 Day	ASTRON PULSAR STENT SYSTEM, PULSAR-18 STENT SYSTEM	BIOTRONIK, INC.	Approval for the Pulsar-18 T3 Stent System, which incorporates an updated delivery system to the Pulsar-18 Stent System.
P160026/S031	07/28/2022	R - Real-Time Proc	LIFEPAK 1000 DEFIBRILLATOR, LIFEPAK 20 DEFIBRILLATOR/ MONITOR, LIFEPAK 20E DEFIBRILLATOR/ MONITOR, LIFEPAK 15 MONITOR/DEFIBRILLATOR, LIFEPAK 12 DEFIBRILLATOR/ MONITOR	PHYSIO-CONTROL. INC.	Approval for design changes to support integration of the nanoMediCO2 capnography (EtCO2) module and software changes intended to mitigate an unexpected anomaly related to the Service LED function of the LIFEPAK 15 Monitor/Defibrillator device.
P160043/S045	07/15/2022	Y - 135 Review Tra	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for the introduction of the Optimized PCA Sterilization Cycle
P160046/S012	07/21/2022	S - Special CBE	VENTANA PD-L1 (SP263) ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for (i) a change in expiry dating from Hematoxylin and Hematoxylin II and (ii) implementation of a revised process for creating reference slides used in Surveillance and Stability testing of Hematoxylin and Hematoxylin II.
P170013/S004	07/28/2022	N - Normal 180 Day	LOW-PROFILE VISUALIZED INTRALUMINAL SUPPORT (LVIS) AND LVIS JR.	MICROVENTION, INC.	Approval for the new Low-Profile Visualized Intraluminal Support (LVIS) EVO. The LVIS EVO has a modified design compared to the approved LVIS and LVIS Jr. with a change in the radiopacity profile and shorter flared ends of the stent.
P170019/S035	07/08/2022	O - Normal 180 Da	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval to update the mock patient report.
P180014/S007	07/14/2022	O - Normal 180 Da	XPS¿ WITH STEEN SOLUTION¿ PERFUSATE	XVIVO PERFUSION, INC.	Approval for a manufacturing site located at IPAX Inc. as the new contract manufacturer for manufacturing the XVIVO Perfusion System.
P180047/S017	07/08/2022	R - Real-Time Proc	LIAISON QUANTIFERON - TB GOLD PLUS, LIAISON CONTROL QUANTIFERON - TB GOLD PLUS AND LIAISON QUANTIFERON SOFTWARE	DIASORIN, INC.	Approval for a software version change to the LIAISON XS Software.
P190002/S005	07/06/2022	R - Real-Time Proc	SALUDA MEDICAL EVOKE SCS SYSTEM	SALUDA MEDICAL PTY LTD	Approval for design changes to the lead and stylet used with the Evoke Spinal Cord Stimulation (SCS) System, including decreasing the stylet length by 14mm and removing the epoxy material surrounding the non-active band at the proximal end of the lead.
P190002/S007	07/14/2022	R - Real-Time Proc	SALUDA MEDICAL EVOKE SCS SYSTEM	SALUDA MEDICAL PTY LTD	Approval for design changes to the Evoke® SCS System, lead (including the trial lead) and stylet components.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190002/S009	07/26/2022	R - Real-Time Proc	SALUDA MEDICAL EVOKE SCS SYSTEM	SALUDA MEDICAL PTY LTD	Approval for updated kit configurations for the Percutaneous Lead Kit, Trial Lead Kit, and Spares Kit, addition of the new Active Anchor Kit, updated shelf-life from one to two years, and minor labeling changes.
P190024/S006	07/21/2022	S - Special CBE	CINTEC PLUS CYTOLOGY	VENTANA MEDICAL SYSTEMS, INC.	Approval for (i) a change in expiry dating from Hematoxylin and Hematoxylin II and (ii) implementation of a revised process for creating reference slides used in Surveillance and Stability testing of Hematoxylin and Hematoxylin II.
P190031/S004	07/21/2022	S - Special CBE	HER2 DUAL ISH DNA PROBE COCKTAIL	VENTANA MEDICAL SYSTEMS, INC.	Approval for (i) a change in expiry dating from Hematoxylin and Hematoxylin II and (ii) implementation of a revised process for creating reference slides used in Surveillance and Stability testing of Hematoxylin and Hematoxylin II.
P200019/S004	07/21/2022	S - Special CBE	VENTANA MMR RXDX PANEL	VENTANA MEDICAL SYSTEMS	Approval for (i) a change in expiry dating from Hematoxylin and Hematoxylin II and (ii) implementation of a revised process for creating reference slides used in Surveillance and Stability testing of Hematoxylin and Hematoxylin II.
P200026/S005	07/22/2022	O - Normal 180 Da	ABRE VENOUS SELF-EXPANDING STENT SYSTEM	MEDTRONIC VASCULAR, INC.	Approval for updates to the labeling to include long-term results from the ABRE Continued Follow-Up Study.
P200035/S003	07/07/2022	O - Normal 180 Da	ORGANOX METRA SYSTEM	ORGANOX LIMITED	Approval of the revised protocol for the post-approval studies (PAS) protocol.
P200036/S003	07/15/2022	O - Normal 180 Da	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.
P210001/S004	07/21/2022	S - Special CBE	VENTANA MMR RXDX PANEL	VENTANA MEDICAL SYSTEMS INC (ROCHE TISSUE DIAGNOSTICS)	Approval for (i) a change in expiry dating from Hematoxylin and Hematoxylin II and (ii) implementation of a revised process for creating reference slides used in Surveillance and Stability testing of Hematoxylin and Hematoxylin II.
P210032/S001	07/08/2022	O - Normal 180 Da	GORE TAG THORACIC BRANCH ENDOPROSTHESIS (TBE DEVICE)	W. L. GORE & ASSOCIATES, INC.	Approval of the protocol for the post-approval study (PAS) protocol.

Total: 81

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S094	07/08/2022	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Establish a new slit and cutting room in the Ethicon LLC San Lorenzo, Puerto Rico manufacturing facility.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S273	07/13/2022	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Addition of Ansell nitrile gloves as an alternative glove for use during cardiac rhythm management (CRM) pulse generator manufacturing at the St. Paul site.
N970003/S274	07/27/2022	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Addition of an alternate surge suppressor due to a new second-tier supplier.
P810006/S100	07/06/2022	X - 30-Day Notice	COLLASTAT	INTEGRA LIFESCIENCES CORPORATION	Replacement of the Honeywell temperature recorders with the Viewpoint Temperature Monitoring system at the Collagen Manufacturing Center (CMC) located at 105 Morgan Lane, Plainsboro, NJ 08536.
P830055/S292	07/06/2022	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Change to add a new laser machine for poly products and the movement of process steps from building #1 (B1) to building #2 (B2).
P840001/S522	07/28/2022	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Change to the Ionograph Out-of-Control Action Plan (OCAP) and the test sampling plan within the Final Clean process for hybrids manufactured at Medtronic Tempe Campus (MTC).
P840062/S086	07/06/2022	X - 30-Day Notice	COLLACOTE(TM)	INTEGRA LIFESCIENCES CORP.	Replacement of the Honeywell temperature recorders with the Viewpoint Temperature Monitoring system at the Collagen Manufacturing Center (CMC) located at 105 Morgan Lane, Plainsboro, NJ 08536.
P850010/S103	07/06/2022	X - 30-Day Notice	HELISTAT(TM) ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	INTEGRA LIFESCIENCES CORPORATION	Replacement of the Honeywell temperature recorders with the Viewpoint Temperature Monitoring system at the Collagen Manufacturing Center (CMC) located at 105 Morgan Lane, Plainsboro, NJ 08536.
P860004/S394	07/28/2022	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Change to the Ionograph Out-of-Control Action Plan (OCAP) and the test sampling plan within the Final Clean process for hybrids manufactured at Medtronic Tempe Campus (MTC).
P880047/S050	07/08/2022	X - 30-Day Notice	INTERCEED TC7 ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Establish a new slit and cutting room in the Ethicon LLC San Lorenzo, Puerto Rico manufacturing facility.
P880086/S324	07/14/2022	X - 30-Day Notice	ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS	ABBOTT MEDICAL	Second-tier supplier's manufacturing site transfer.
P900033/S101	07/06/2022	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Replacement of the Honeywell temperature recorders with the Viewpoint Temperature Monitoring system at the Collagen Manufacturing Center (CMC) located at 105 Morgan Lane, Plainsboro, NJ 08536.
P900033/S102	07/01/2022	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Change is to the lyophilization software to ensure it returns data values in daylight savings time, to ensure that data points are properly reported with the actual time the value occurred.
P910023/S446	07/14/2022	X - 30-Day Notice	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ABBOTT MEDICAL	Second-tier supplier's manufacturing site transfer.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P950009/S026	07/11/2022	X - 30-Day Notice	AUTOPAP(R) 300 QC AUTOMATIC PAP SCREENER/QC SYSTEM	BD DIAGNOSTICS	Change of supplier for an instrument component.
P950020/S123	07/13/2022	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Add an additional Plasma and Blade Bonding cell.
P950020/S124	07/18/2022	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Relocate blade casting manufacturing equipment from one cleanroom to another at the same manufacturing facility.
P960004/S100	07/28/2022	X - 30-Day Notice	THINLINE ENDOCARDIAL PACING LEADS	BOSTON SCIENTIFIC	Add a specification and inspection for a component of the packaging.
P960009/S435	07/28/2022	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Change to the Ionograph Out-of-Control Action Plan (OCAP) and the test sampling plan within the Final Clean process for hybrids manufactured at Medtronic Tempe Campus (MTC).
P960040/S479	07/13/2022	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Addition of Ansell nitrile gloves as an alternative glove for use during cardiac rhythm management (CRM) pulse generator manufacturing at the St. Paul site.
P960040/S480	07/22/2022	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Change the second-tier supplier of the Analog integrated circuits (ICs) used in ICD and CRT-D pulse generators.
P960043/S116	07/14/2022	X - 30-Day Notice	PROSTAR 9 FR. PERCUTANEOUS VASCULAR SURGICAL (PVS) SYSTEM	ABBOTT VASCULAR INC.	Addition of a replicate manufacturing line within the existing approved facility for the Perclose ProGlide and Perclose ProStyle Suture-Mediated Closure and Repair Systems.
P970004/S369	07/08/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Modification to the battery laser marking process.
P970004/S371	07/28/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Change to the Ionograph Out-of-Control Action Plan (OCAP) and the test sampling plan within the Final Clean process for hybrids manufactured at Medtronic Tempe Campus (MTC).
P980016/S827	07/19/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Reduce the frequency of the seamweld monitoring currently used to control the weld penetration at the welded interface between the left-hand and right-hand shields.

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P980016/S829	07/25/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Modifications to the hybrid Final Clean process at the Medtronic Tempe Campus.
P980035/S722	07/19/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Reduce the frequency of the seamweld monitoring currently used to control the weld penetration at the welded interface between the left-hand and right-hand shields.
P980035/S724	07/25/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Modifications to the hybrid Final Clean process at the Medtronic Tempe Campus.
P980040/S148	07/20/2022	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Adoption of additional intraocular lens models and packaging configurations into the existing approved sterilization process, SPS100, using sterilization vessel #8 and hot cell #5, at AMO Puerto Rico site.
P980040/S149	07/25/2022	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Reduction in frequency of flat-time testing for 1-piece acrylic intraocular lenses.
P990081/S048	07/29/2022	X - 30-Day Notice	PATHWAY ANTI-HCR-2/ NCU (4B5) RABBIT MONOCLONAL PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Addition of alternative suppliers for component parts.
P000053/S126	07/06/2022	X - 30-Day Notice	AMS SPHINCTER 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Use of a new, automated control pump functional tester.
P010001/S025	07/20/2022	X - 30-Day Notice	CERAMIC TRANSCEND HIP ARTICULATION SYSTEM	CERAMTEC GMBH	Addition of a second supplier for the raw material Alumina used for the production of the ceramic material BIOLOX®forte.
P010012/S555	07/13/2022	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Addition of Ansell nitrile gloves as an alternative glove for use during cardiac rhythm management (CRM) pulse generator manufacturing at the St. Paul site.
P010012/S556	07/22/2022	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Change the second-tier supplier of the Analog integrated circuits (ICs) used in ICD and CRT-D pulse generators.

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P010015/S502	07/19/2022	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Reduce the frequency of the seamweld monitoring currently used to control the weld penetration at the welded interface between the left-hand and right-hand shields.
P010015/S503	07/25/2022	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Modifications to the hybrid Final Clean process at the Medtronic Tempe Campus.
P010019/S083	07/06/2022	X - 30-Day Notice	FOCUS NIGHT AND DAY (LOTRAFILCON A) SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Adding an alternate supplier for the primary packaging material of Alcon lotrafilcon A and B soft contact lens products.
P010031/S793	07/19/2022	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 seamweld monitoring currently used to control the weld penetration at the welded interface between the left-hand and right-hand shields.
P010031/S795	07/25/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modifications to the hybrid Final Clean process at the Medtronic Tempe Campus.
P020055/S027	07/29/2022	X - 30-Day Notice	VENTANA MEDICAL SYSTEMS PATHWAY ANTI-C-KIT (9.7) PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Addition of alternative suppliers for component parts.
P030004/S029	07/28/2022	X - 30-Day Notice	ONYX LIQUID EMBOLIC SYSTEM	EV3 NEUROVASCULAR	Addition of two new sub-tier suppliers of the raw material used in the coating of the Apollo Onyx Delivery Micro Catheter.
P030005/S218	07/13/2022	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Addition of Ansell nitrile gloves as an alternative glove for use during cardiac rhythm management (CRM) pulse generator manufacturing at the St. Paul site.
P030005/S219	07/27/2022	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Addition of an alternate surge suppressor due to a new second-tier supplier.
P030022/S048	07/05/2022	X - 30-Day Notice	REFLECTION CERAMIC ACETABULAR SYSTEM	SMITH & NEPHEW, INC.	Manufacturing process change by revising the hydroxyapatite (HA) powder flow limits for the Anthology stems which are approved for use in combination with the Reflection Ceramic Acetabular System.

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P030023/S008	07/21/2022	X - 30-Day Notice	OPHTEC CAPSULAR TENSION RING MODELS 276 AND 275 AND STABILEYES MODELS STBL2US AND STBL13US	OPHTEC USA, INC.	Change to the processing agent used in the milling process for the Capsular Tension Ring (CTR) and RingJect.
P030028/S009	07/22/2022	X - 30-Day Notice	ARTISAN (MODEL 206 AND 204) PHAKIC INTRAOCULAR LENS (PIOL) VERISYSE (VRSM5US AND VRSM6US) PHAKIC INTRAOCULAR LENS (PIOL)	OPHTEC BV	Change to the processing agent used in the milling process for the ARTISAN Myopia.
P030035/S190	07/14/2022	X - 30-Day Notice	ANTHEM AND FRONTIER II CRT-P'S	ABBOTT MEDICAL	Second-tier supplier's manufacturing site transfer.
P030054/S399	07/14/2022	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ABBOTT MEDICAL	Second-tier supplier's manufacturing site transfer.
P040027/S091	07/07/2022	X - 30-Day Notice	GORE VIATORR TIPS	W. L. GORE & ASSOCIATES, INC.	Implementation of new hardware and software in the training and loading processes.
P040038/S040	07/13/2022	X - 30-Day Notice	XACT CAROTID STENT SYSTEM	ABBOTT VASCULAR INC.	Update to the on-line sampling plan and the implementation of process monitoring alerts.
P070004/S037	07/20/2022	X - 30-Day Notice	SIENTRA SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Changes to the environmental monitoring plan for both viable and non-viable particulates in Sientras manufacturing cleanroom, located in Franklin, Wisconsin.
P070026/S100	07/12/2022	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Change to a new inspection equipment and new hard gauges for inspection of the Summit Hip Stem components.
P080020/S048	07/22/2022	X - 30-Day Notice	GEL-ONE	SEIKAGAKU CORP.	Implementation of a new viscometer.
P080025/S264	07/08/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Modification to the battery laser marking process.
P080025/S266	07/28/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Change to the Ionograph Out-of-Control Action Plan (OCAP) and the test sampling plan within the Final Clean process for hybrids manufactured at Medtronic Tempe Campus (MTC).
P090031/S013	07/13/2022	X - 30-Day Notice	MONOVISC	ANIKA THERAPEUTICS, INC.	Change in raw material acceptance testing.
P100027/S037	07/29/2022	X - 30-Day Notice	INFORM HER2 DUAL ISH DNA PROBE COCKTAIL	VENTANA MEDICAL SYSTEMS, INC.	Addition of alternative suppliers for component parts.
P110027/S015	07/11/2022	X - 30-Day Notice	THERASCREEN KRAS RGQ PCR KIT	QIAGEN GMBH	Addition of a calibration step for manufacturing Internal Control.

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P110042/S171	07/13/2022	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Addition of Ansell nitrile gloves as an alternative glove for use during cardiac rhythm management (CRM) pulse generator manufacturing at the St. Paul site.
P130011/S011	07/28/2022	X - 30-Day Notice	FREEDOM SOLO STENTLESS HEART VALVE	CORCYM CANADA CORP.	Decrease in the number of samples used in the Limulus Amoebocyte Lysate testing performed per sterilization batch.
P130013/S049	07/01/2022	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Addition of an optional Scanning Electron Microscope inspection for the anchor.
P130013/S051	07/29/2022	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Update to the visual standard used during the frame inspection process in manufacturing of the WATCHMAN FLX Implant.
P130017/S052	07/07/2022	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Qualification of an alternate supplier for reagent components.
P130017/S053	07/19/2022	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Qualification of an alternate supplier for reagent components.
P130021/S118	07/07/2022	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Additional inspections in the delivery system assembly process.
P140003/S101	07/01/2022	X - 30-Day Notice	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Additional supplier to clean and measure the insertion pins.
P140010/S066	07/08/2022	X - 30-Day Notice	IN PACT ADMIRAL PACLITAXEL-ELUTING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Additional controls be added to the luer inspection and gluing processes.
P140025/S018	07/29/2022	X - 30-Day Notice	VENTANA ALK (D5F3) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Addition of alternative suppliers for component parts.
P140030/S015	07/27/2022	X - 30-Day Notice	ASTRON PERIPHERAL SELF-EXPANDING NITINOL STENT SYSTEM	BIOTRONIK, INC.	Addition of alternative packaging verification testing.
P140033/S073	07/14/2022	X - 30-Day Notice	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ABBOTT MEDICAL	Second-tier supplier's manufacturing site transfer.

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P150011/S025	07/28/2022	X - 30-Day Notice	PERCEVAL SUTURELESS HEART VALVE	CORCYM CANADA CORP.	Decrease in the number of samples used in the Limulus Amoebocyte Lysate testing performed per sterilization batch.
P150012/S126	07/13/2022	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Addition of Ansell nitrile gloves as an alternative glove for use during cardiac rhythm management (CRM) pulse generator manufacturing at the St. Paul site.
P150012/S127	07/27/2022	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Addition of an alternate surge suppressor due to a new second-tier supplier.
P150012/S128	07/25/2022	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Addition of a filter for use during manufacturing of the INGEVITY family of lead devices.
P150025/S015	07/22/2022	X - 30-Day Notice	PD-L1 IHC 28-8 PHARMDX	AGILENT TECHNOLOGIES, INC.	Update of manufacturing documents relating to Post-QC testing.
P150033/S144	07/15/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Minor changes to the Micra TPS manufacturing and inspection process.
P150033/S146	07/25/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Modifications to the hybrid Final Clean process at the Medtronic Tempe Campus.
P150033/S147	07/26/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Minor updates to the manufacturing and inspection process at Medtronic¿s high-volume manufacturing facility in Galway, Ireland.
P150033/S148	07/27/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Implementation of a rework backfill process at Medtronic¿s high volume manufacturing facility - Medtronic Swiss Operations (SMO) in Tolochenaz, Switzerland.
P160002/S018	07/29/2022	X - 30-Day Notice	VENTANA PD-L1(SP142) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Addition of alternative suppliers for component parts.
P160003/S015	07/27/2022	X - 30-Day Notice	PRO-KINETIC ENERGY COBALT CHROMIUM (COCR) CORONARY STENT SYSTEM	BIOTRONIK, INC.	Addition of alternative packaging verification testing.
P160021/S035	07/05/2022	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Expansion of a manufacturing space for the balloon cover assembly process.
P160025/S015	07/27/2022	X - 30-Day Notice	ASTRON PULSAR STENT SYSTEM, PULSAR-18 STENT SYSTEM	BIOTRONIK, INC.	Addition of alternative packaging verification testing.

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P160026/S032	07/28/2022	X - 30-Day Notice	LIFEPAK 1000 DEFIBRILLATOR, LIFEPAK 20 DEFIBRILLATOR/ MONITOR, LIFEPAK 20E DEFIBRILLATOR/ MONITOR, LIFEPAK 15 MONITOR/DEFIBRILLATOR, LIFEPAK 12 DEFIBRILLATOR/ MONITOR	PHYSIO-CONTROL. INC.	Change in manufacturing location for several critical components.
P160029/S017	07/27/2022	X - 30-Day Notice	HEARTSTART ONSITE DEFIBRILLATOR (MODEL M5066A) AND HEARTSTART HOME DEFIBRILLATOR (MODEL M5068A)	PHILIPS MEDICAL SYSTEMS, INC.	Replace the current Water Spray System on the Hydrogel Heat Cure Line with a new Water Spray System in order to reduce the variation in the final gel water content.
P160038/S022	07/05/2022	X - 30-Day Notice	PRAXIS EXTENDED RAS PANEL	ILLUMINA, INC.	Device shipping/storage changes and increased lot sizes for a buffer component of the Praxis Extended RAS Panel.
P160046/S014	07/29/2022	X - 30-Day Notice	VENTANA PD-L1 (SP263) ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Addition of alternative suppliers for component parts.
P160049/S019	07/15/2022	X - 30-Day Notice	STELLAREX 0.035 OTW DRUG-COATED ANGIOPLASTY BALLOON	THE SPECTRANETICS CORP.	Change in supplier of a packaging material.
P160055/S023	07/05/2022	X - 30-Day Notice	LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Use of alternate equipment for the manufacture of Light Adjustable Lens haptics.
P170011/S042	07/01/2022	X - 30-Day Notice	IMPELLA RP SYSTEM	ABIOMED, INC.	Additional supplier to clean and measure the insertion pins.
P170025/S018	07/20/2022	X - 30-Day Notice	APTIMA HBV QUANT ASSAY	HOLOGIC, INC	Add additional monitoring and final release criteria.
P170030/S024	07/27/2022	X - 30-Day Notice	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Addition of alternative packaging verification testing.
P170036/S011	07/01/2022	X - 30-Day Notice	M6-C ARTIFICIAL CERVICAL DISC	SPINAL KINETICS LLC	Additional weld system EQ 0169 Amada Miyachi Laser System to increase manufacturing capacity.
P180046/S057	07/20/2022	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Use of an alternate supplier for printed circuit board assemblies (PCBAs).
P190006/S057	07/20/2022	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Use of an alternate supplier for printed circuit board assemblies (PCBAs).

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P190008/S019	07/08/2022	X - 30-Day Notice	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Additional controls be added to the luer inspection and gluing processes.
P190023/S008	07/07/2022	X - 30-Day Notice	PORTICO TRANSCATHETER AORTIC VALVE IMPLANTATION SYSTEM	ABBOTT MEDICAL	Addition of a new abattoir to source bovine pericardium and a change to the in-process tissue shelf life.
P190024/S007	07/29/2022	X - 30-Day Notice	CINTEC PLUS CYTOLOGY	VENTANA MEDICAL SYSTEMS, INC.	Addition of alternative suppliers for component parts.
P190031/S005	07/29/2022	X - 30-Day Notice	HER2 DUAL ISH DNA PROBE COCKTAIL	VENTANA MEDICAL SYSTEMS, INC.	Addition of alternative suppliers for component parts.
P200010/S011	07/29/2022	X - 30-Day Notice	GUARDANT360 CDX	GUARDANT HEALTH, INC.	Relocation of the manufacturing room for reagent components.
P200015/S022	07/06/2022	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Changes to the Alterra prestent visual receiving inspection acceptance criteria and the austenite start temperature specification of the nitinol ingots used to manufacture the frame.
P200015/S023	07/25/2022	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Addition of an optional manufacturing aid for the SAPIEN 3 Pulmonic Delivery System balloon component.
P200019/S005	07/29/2022	X - 30-Day Notice	VENTANA MMR RXDX PANEL	VENTANA MEDICAL SYSTEMS	Addition of alternative suppliers for component parts.
P200030/S008	07/27/2022	X - 30-Day Notice	GORE EXCLUDER CONFORMABLE AAA ENDOPROSTHESIS (CEXC)	W. L. GORE AND ASSOCIATES, INC.	Implementation of an update to the burst strength destructive testing sampling plan for the GORE EXCLUDER Conformable AAA Endoprosthesis.
P200046/S011	07/27/2022	X - 30-Day Notice	HARMONY¿ TPV SYSTEM	MEDTRONIC, INC.	Increase in the timeframe for receipt of porcine pericardial tissue from abattoirs and initiation of tissue fixation.
P200049/S004	07/28/2022	X - 30-Day Notice	AMPLATZER¿ AMULET ¿ LEFT ATRIAL APPENDAGE OCCLUDER	ABBOTT MEDICAL	Addition of alternate laser cutting and welding systems used in the manufacturing of the Amplatzer Amulet Left Atrial Appendage Occluder.

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P210001/S006	07/29/2022	X - 30-Day Notice	VENTANA MMR RXDX PANEL	VENTANA MEDICAL SYSTEMS INC (ROCHE TISSUE DIAGNOSTICS)	Addition of alternative suppliers for component parts.
P210029/S001	07/20/2022	X - 30-Day Notice	APTIMA CMV QUANT ASSAY	HOLOGIC, INC.	Add additional monitoring and final release criteria.
P210032/S002	07/21/2022	X - 30-Day Notice	GORE TAG THORACIC BRANCH ENDOPROSTHESIS (TBE DEVICE)	W. L. GORE & ASSOCIATES, INC.	Implementation of a pneumatic sample cutter and revised release and warning limits for heparin surface activity testing.

Total: 110