PMA Monthly approvals from 9/1/2023 to 9/30/2023

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P210017	09/26/2023	PMAO - PMA Origi	CROSS-SEAL SUTURE-MEDIATED VASCULAR CLOSURE DEVICE SYSTEM	TERUMO MEDICAL CORPORATIO N	Approval for the Cross-Seal Suture-Mediated Vascular Closure Device System. The device is indicated for the percutaneous delivery of sutures for closing the common femoral artery access site while reducing time-to-hemostasis in patients who have undergone diagnostic or interventional catheterization procedures using 8F to 18F sheaths. The Cross-Seal System is indicated for one access site per leg.
P220005	09/29/2023	PMAO - PMA Origin	CRCDX RAS MUTATION DETECTION ASSAY KIT	ENTROGEN, INC.	Approval for the CRCdx® RAS Mutation Detection Kit. The device is a qualitative real-time PCR in vitro diagnostic test intended for the detection of 35 variants of KRAS and NRAS exon 2, 3, 4 somatic mutations in genomic DNA extracted from formalin-fixed, paraffin-embedded (FFPE) colorectal cancer (CRC) tissue samples. The test is intended as a companion diagnostic (CDx) to aid in the identification of colorectal cancer (mCRC) patients who may benefit from treatment with Vectibix (panitumumab) based on a no mutation detected test result in accordance with the approved therapeutic product labeling.
P220025	09/11/2023	PMAO - PMA Origi	LIMFLOW SYSTEM	LIMFLOW, INC.	Approval for The LimFlow System. The device is indicated for patients who have chronic limb-threatening ischemia with no suitable endovascular or surgical revascularization options and are at risk of major amputation.

Total: 3

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970012/S196	09/20/2023	N - Normal 180 Day	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Approval for 1) an update to the AMS 700 product labeling to include an alternative implant location for the AMS 700 reservoir. The AMS 700 reservoir is a component of the AMS 700 system and is available with or without the drug treatment known as InhibiZone; and 2) an update to the AMS 700 product labeling and the AMS Ambicor product labeling to include new parameters for safe magnetic resonance scanning of a patient implanted with an AMS 700 system or an AMS Ambicor device.
P810031/S073	09/19/2023	Y - 135 Review Tra	HEALON, HEALON GV, HEALON5 PRODUCTS SODIUM HYALURONATE OPHTHALMIC VISCOELASTIC DEVICES	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for a change in the particle filter used during manufacturing of the subject ophthalmic viscoelastic devices.

Data as of 10/04/2023 05:16 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840001/S535	09/22/2023	N - Normal 180 Day	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Approval for adding a new requirement and new behavior to the firmware and changing the `Stim off Charge Pump Amplitude' from the maximum value to the minimum value. When stimulation is off, the Charge Pump will be set to the minimum value. Adding a new risk control measure and new behavior to the firmware. Every 5 minutes the firmware will now reset the Tel-N Phase Lock Loop (PLL). The interface and requirement will also be changed, and new behavior will be added to the firmware. When the relevant Tel-N command is received by the INS, the Tel-M module will be disabled for 5 seconds and then re-enabled. Fixing the cap balance routine configuration value to determine whether it was enabled. Updating so that a device with corrupt flash (with ECC errors) in the code space will be able to be updated over the air without causing an unexpected reset. Updating behavior so that stimulation will no longer lock up if the lead integrity test is canceled too soon. Updating a library code function that may cause a loss of data on the Serial Peripheral (SPI) bus if used. Updating behavior so group changes are always logged, even when therapy is off. INS behavior will also be changed so aDBS programs are applied correctly when the programs are enabled regardless of which aDBS program is reenabled first. Updating behavior so the Enable/disable aDBS program command works correctly and updates the settings for the sense group that was modified, but only applies the new settings to the runtime settings if the group whose settings were changed is the active group. Updating behavior so backup sensing settings are stored properly and reverting the settings works.
P860004/S406	09/26/2023	N - Normal 180 Day	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval for design and manufacturing changes associated with the Ascenda and Legacy Catheters.
P910007/S063	09/25/2023	R - Real-Time Proc	AXSYM TOTAL PSA & ARCHITECT TOTAL PSA	ABBOTT LABORATORIES	Approval for the release of Alinity i Total PSA, Alinity i Free PSA and Alinity i AFP and for use with Alinity ci-series.
P950008/S019	09/15/2023	Y - 135 Review Tra	SILIKON 1000	ALCON	Approval for an additional alternate sterilizer for the in-house dry heat sterilization of the Silikon 1000 product.
P960009/S445	09/22/2023	N - Normal 180 Day	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval for adding a new requirement and new behavior to the firmware and changing the `Stim off Charge Pump Amplitude' from the maximum value to the minimum value. When stimulation is off, the Charge Pump will be set to the minimum value. Adding a new risk control measure and new behavior to the firmware. Every 5 minutes the firmware will now reset the Tel-N Phase Lock Loop (PLL). The interface and requirement will also be changed, and new behavior will be added to the firmware. When the relevant Tel-N command is received by the INS, the Tel-M module will be disabled for 5 seconds and then re-enabled. Fixing the cap balance routine configuration value to determine whether it was enabled. Updating so that a device with corrupt flash (with ECC errors) in the code space will be able to be updated over the air without causing an unexpected reset. Updating behavior so that stimulation will no longer lock up if the lead integrity test is canceled too soon. Updating a library code function that may cause a loss of data on the Serial Peripheral (SPI) bus if used. Updating behavior so group changes are always logged, even when therapy is off. INS behavior will also be changed so aDBS programs are applied correctly when the programs are enabled regardless of which aDBS program is reenabled first. Updating behavior so the Enable/disable aDBS program command works correctly and updates the settings for the sense group that was modified, but only applies the new settings to the runtime settings if the group whose settings were changed is the active group. Updating behavior so backup sensing settings are stored properly and reverting the settings works.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970003/S241	09/15/2023	N - Normal 180 Day	VNS THERAPY SYSTEM	LIVANOVA USA, INC.	Approval for the new Model 3100 v1.0 Programmer Software, updated M2000 v1.1.2.2 Programming Wand Firmware, and the new Digital Products Platform.
P980007/S052	09/25/2023	R - Real-Time Proc	AXSYM FREE PSA	ABBOTT LABORATORIES	Approval for the release of Alinity i Total PSA, Alinity i Free PSA and Alinity i AFP and for use with Alinity ci-series.
P980016/S863	09/22/2023	R - Real-Time Proc	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for labeling changes, software changes to the CareLink SmartSync system, and firmware changes to the Blackwell family of devices to address SCP1 and L404 reset events.
P990004/S061	09/01/2023	S - Special CBE	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Approval for the amendments and additions to the Warnings, Precautions, and Adverse Events section of the instructions for Use sheet of the SURGIFLO® Hemostatic Matrix and SURGIFLO® Hemostatic Matrix Kit with Thrombin.
P990040/S031	09/29/2023	N - Normal 180 Day	TRUFILL N-BUTYL CYANOACRYLATE LIQUID EMBOLIC SYSTEM	CERENOVUS, INC.	Approval for a new packaging configuration of the TRUFILL n-BCA Liquid Embolic System that includes the device co-packaged with the procedural accessories used in the preparation of the liquid embolic in a new packaging tray, sterilized with an additional ethylene oxide (EO) sterilization cycle, and provided with electronic Instructions for Use and a Quick Start Guide.
P010031/S829	09/22/2023	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for labeling changes, software changes to the CareLink SmartSync system, and firmware changes to the Blackwell family of devices to address SCP1 and L404 reset events
P010059/S007	09/06/2023	N - Normal 180 Day	MORCHER CAPSULAR TENSION RING, TYPES 14, 14A AND 14C	MORCHER GMBH	Approval for expansion of the Capsular Tension Ring device family to include the new Type 20C Model.
P010059/S011	09/06/2023	S - Special CBE	MORCHER CAPSULAR TENSION RING, TYPES 14, 14A AND 14C	MORCHER GMBH	Approval for improved instructions for use labeling.
P050052/S144	09/25/2023	O - Normal 180 Day	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval for revisions to the post-approval study clinician labeling and patient labeling for Radiesse.
P060040/S091	09/29/2023	O - Normal 180 Da	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Approval for an alternate final sterilization site located at Centerpiece S. De R.L De C.V, Bulevar La Encantada Industrial, Parque Industrial El Florido, Seccion La Encantada #11530, Tijuana, Baja California, Mexico 22250.
P090016/S050	09/27/2023	P - Panel Track	BELOTERO BALANCE	MERZ NORTH AMERICA, INC	Approval for Belotero Balance(R) (+) for Expanding the Indications to Include Volume Augmentation for the Improvement of the Infraorbital Hollow in Adults Over the Age of 21. This device is indicated for injection into the mid-to-deep dermis for correction of moderate-to-severe facial wrinkles and folds, such as nasolabial folds. The device is also indicated for volume augmentation for the improvement of the infraorbital hollow in adults over the age of 21.
P090016/S051	09/22/2023	Y - 135 Review Tra	BELOTERO BALANCE	MERZ NORTH AMERICA, INC	Approval for changes to the preparation of samples for analytical method which measures the sodium hyaluronate (NaHA) concentration of the finished product.

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P100018/S034	09/15/2023	N - Normal 180 Day	PIPELINE EMBOLIZATION DEVICE	MICRO THERAPEUTICS, INC. D/B/A EV3 NEUROVASCULAR	Approval for a new neurovascular flow-diverting stent and delivery system in the Pipeline product family.
P100026/S087	09/28/2023	Y - 135 Review Tra	NEUROPACE RNS SYSTEM	NEUROPACE INC	Approval to add alternate cleaning equipment and solvent to degrease the Neurostimulator can and Ferrule.
P120008/S025	09/25/2023	R - Real-Time Proc	ABBOTT ARCHITECT AFP ASSAY	ABBOTT LABORATORIES	Approval for the release of Alinity i Total PSA, Alinity i Free PSA and Alinity i AFP and for use with Alinity ci-series.
P130013/S057	09/06/2023	N - Normal 180 Day	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Approval for design modifications to the WATCHMAN FLX Left Atrial Appendage Closure (LAAC) Device including the addition of a 40 mm device size, addition of radiopaque markers, and a device coating.
P140010/S074	09/22/2023	O - Normal 180 Day	IN.PACT ADMIRAL PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) BALLOON CATHETER AND IN.PACT 018 PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) BALLOON CATHETER	MEDTRONIC INC.	Approval for a labeling update to include the long-term data from the IN.PACT Admiral DCB In-stent Restenosis (ISR) Post-market Registry.
P150031/S055	09/06/2023	N - Normal 180 Day	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the Vercise Adapter S8 and the addition of the use with Abbott Lead models (6170, 6171, 6172, 6173, 6178, 6179, 6180, and 6181) to the Vercise Neural Navigator 5 (VNN5) software.
P160045/S025	09/29/2023	P - Panel Track	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Approval to expand the intended use of the Oncomine Dx Target Test to include a companion diagnostic indication for the detection of the BRAF V600E positive anaplastic thyroid cancer patients (ANA) for dabrafenib and tramatenib (Mekinist/Tafinlar).
P160054/S053	09/29/2023	O - Normal 180 Da	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Approval for an alternate final sterilization site located at Centerpiece S. De R.L De C.V, Bulevar La Encantada Industrial, Parque Industrial El Florido, Seccion La Encantada #11530, Tijuana, Baja California, Mexico 22250
P170019/S036	09/18/2023	N - Normal 180 Day	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval for a DNA/RNA CoExtraction (CoEx) method, and removal of reporting of copy number alterations (amplifications and deletions/losses) for the tumor profiling indication from the intended use/indications for use when using the DNA/RNA CoEx method.
P170024/S013	09/12/2023	R - Real-Time Proc	SURPASS STREAMLINE FLOW DIVERTER	STRYKER NEUROVASCULAR	Approval for changes to the Directions for Use (DFU) labeling, including the addition of the completed results from the post-approval study (PAS) titled, Surpass Intracranial Aneurysm Embolization System Pivotal Trial to Treat Large or Giant Wide Neck Aneurysms (SCENT).
P170038/S013	09/14/2023	R - Real-Time Proc	CENTRIMAG CIRCULATORY SUPPORT SYSTEM	ABBOTT	Approval for a design change to the packaging of blood pump box of the CentriMag Circulatory Support System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180002/S024	09/05/2023	R - Real-Time Proc	ZEPHYR ENDOBRONCHIAL VALVE SYSTEM	PULMONX CORPORATIO N	Approval for the proposed design changes to the funnel of the Endobronchial Loader System that is included with the Zephyr 4.0-LP Endobronchial valve model.
P180007/S011	09/22/2023	O - Normal 180 Day	SPIRATION® VALVE SYSTEM	GYRUS ACMI, INC.	Approval for the modification to the Informed Consent Template for the STRIVE Registry Study to permit payment to study participants for study visits.
P180011/S056	09/21/2023	O - Normal 180 Da	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval of the revised protocol to shorten follow-up for the post-approval study (PAS)
P180036/S022	09/18/2023	R - Real-Time Proc	OPTIMIZER SMART SYSTEM	IMPULSE DYNAMICS (USA), INC.	Approval for changes to the printed circuit board (PCB), including the location of the thermistor component.
P180036/S023	09/22/2023	R - Real-Time Proc	OPTIMIZER SMART SYSTEM	IMPULSE DYNAMICS (USA), INC.	Approval for changes to the battery of the Smart Mini Charger.
P190002/S014	09/22/2023	N - Normal 180 Day	SALUDA MEDICAL EVOKE SCS SYSTEM	SALUDA MEDICAL PTY LTD	Approval for a labeling change to the following implantable components of the Saluda Evoke Spinal Cord Stimulation (SCS) System as Magnetic Resonance (MR) Conditional for head and extremities (1.5 or 3.0 T) and full body (1.5 T): 1) Evoke Closed Loop Stimulator Kit; 2) Evoke CAP12 Percutaneous Leads Kit (60/90cm); 3) Evoke 12C Percutaneous Leads Kit (60/90cm); 4) Evoke Spares Kit; 5) Evoke Active Anchor Kit; and 6) Evoke CAP12X Lead Extension Kit (55cm)..
P190008/S025	09/14/2023	O - Normal 180 Da	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P190019/S024	09/22/2023	O - Normal 180 Day	RANGER¿ PACLITAXEL-COATED PTA BALLOON CATHETER	BOSTON SCIENTIFIC CORPORATIO N	Approval of the revised protocol to shorten follow-up from 5 years to 3 years for the post-approval study (PAS) protocol.
P190023/S013	09/15/2023	N - Normal 180 Day	PORTICO TRANSCATHETER AORTIC VALVE IMPLANTATION SYSTEM	ABBOTT MEDICAL	Approval for a design modification to the Navitor Transcatheter Heart Valve for the addition of three radiopaque markers (RO markers) to the valve annulus section (Vision technology), minor changes to etching on the Navitor Loading System (LS LG+), and approval of the 35mm Navitor Titan size extension which will also incorporate the three RO markers.
P200035/S009	09/06/2023	R - Real-Time Proc	ORGANOX METRA SYSTEM	ORGANOX LIMITED	Approval for a proposed change to the OrganOx metra Retained Unit. The approval is for replacement of the currently used Column Pair with a new Column Pair.
P200044/S003	09/10/2023	R - Real-Time Proc	LUNGFIT PH	BEYOND AIR, INC.	Approval for minor software changes to add support for future language translations, enhance manfucaturability and serviceability, refine alarms, limit the range for date changes, and for preparation of future compatibility and enhancements.
P200044/S004	09/29/2023	R - Real-Time Proc	LUNGFIT PH	BEYOND AIR, INC.	Approval of a minor hardware change to allow the user to increase the alarm volume by moving a mechanical slider on the backside of the LungFit PH display.

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P210003/S006	09/28/2023	N - Normal 180 Day	ARCHITECT HBSAG NEXT QUALITATIVE REAGENT KIT, ARCHITECT HBSAG NEXT CONFIRMATORY REAGENT KIT, ARCHITECT HBSAG NEXT QUALITATIVE CALIBRATORS,	ABBOTT LABORATORIES	Approval for the Migration of the Abbott ARCHITECT HBsAg Next Qualitative and ARCHITECT HBsAg Next Confirmatory assay (P210003) to the Alinity i system (referred to as the Alinity i analyzer), which will be known as the Alinity i HBsAg Next Qualitative and Alinity i HBsAg Next Confirmatory assay.
P210027/S004	09/19/2023	S - Special CBE	QDOT MICRO¿ SYSTEM	BIOSENSE WEBSTER, INC.	Approval for changes being made to the QDOT MICRO System Instructions for Use (IFU), part numbers M-5276-827 (QDOT MICRO Uni-Directional Navigation Catheter Instructions for Use) and M-5276-829 (QDOT MICRO Bi-Directional Navigation Catheter Instructions for Use).

Total: 44

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S105	09/13/2023	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Addition of a programmable logic controller (PLC)/human machine interface (HMI) that automatically controls the number of layers for each SURGICEL Fibrillar batt used in the manufacture of SURGICEL® Fibrillar Absorbable Hemostats.
N16837/S032	09/19/2023	X - 30-Day Notice	ARTEGRAFT{TM} AND REINFORCED ARTEGRAFT {TM}	LEMAITRE VASCULAR, INC.	Additional service supplier to perform routine sterility testing and bioburden testing on the Artegraft Collagen Vascular Graft.
N970012/S199	09/15/2023	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Changes to visual inspection requirements only for the Rear Tip Extenders (RTE) for the AMS 700 CXR cylinder models.
P830055/S312	09/15/2023	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Modification to the current in-process cleaning cycle of the femoral and tibial baseplate components of the LCS Total Knee System.
P830055/S314	09/28/2023	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Change the Penetrant Dye for the Fluorescent Penetrative Inspection of the LCS(R) Total Knee System.
P840001/S548	09/05/2023	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Utilize an addition of a new demolding tool and to update the visual inspection in the molding process for the Restore Pocket Adaptors 1x4 carrier at supplier, Trelleborg.
P840064/S081	09/05/2023	X - 30-Day Notice	VISCOAT(TM)/DVOVISC/ DISCOVISC OPHTHALMIC VISCOSURGICAL DEVICES	ALCON LABORATORIES	Installation of a new cooler within Lifecore Biomedical¿s site #3 warehouse for storage of work-in process materials and final product of the VISCOAT, DUOVISC and DISCOVISC Ophthalmic Viscosurgical Devices.
P850022/S032	09/01/2023	X - 30-Day Notice	ORTHOPAK(R) BONE GROWTH STIMULATOR	EBI, LLC	Qualify an alternate supplier to provide a replacement, non-smart, Lithium-ion battery pack solution.
P880086/S330	09/20/2023	X - 30-Day Notice	ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS	ABBOTT MEDICAL	Replace the graphite powder used during battery manufacturing with two alternatives.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P900033/S109	09/07/2023	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Qualification of two new heat sealers.
P900056/S211	09/28/2023	X - 30-Day Notice	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Replace the current Long Drive Laser with a new Long Drive Laser on the Rotalink Burr Catheter (Rotalink) Handshake Drive Assembly (Long Drive Assembly) manufacturing line.
P910023/S456	09/20/2023	X - 30-Day Notice	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ABBOTT MEDICAL	Replace the graphite powder used during battery manufacturing with two alternatives.
P960009/S459	09/05/2023	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Utilize an addition of a new demolding tool and to update the visual inspection in the molding process for the Restore Pocket Adaptors 1x4 carrier at supplier, Trelleborg.
P960009/S460	09/26/2023	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Update process monitoring controls as part of the implementation of Statistical Process Control(SPC) program at Medtronic Vascular.
P980016/S865	09/08/2023	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates to the test application software for the Mixed Signal Integrated Circuit testers at Medtronic Tempe Campus.
P980016/S867	09/29/2023	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add and update electrical test process steps for hybrid subassembly testing.
P980035/S759	09/05/2023	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implementation of a new Vision System to detect presence of desiccant in the Electronic Module Assembly.
P980040/S165	09/27/2023	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Reclassification of Clean, Inspection, and Insertion (CII) rooms of building 1 and 1A at JJSV Puerto Rico manufacturing site.
P990004/S063	09/18/2023	X - 30-Day Notice	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Alternative packaging pattern of SURGIFLO Intermediates for sterilization in the manufacturing of the SURGIFLO® Haemostatic Matrix and the SURGIFLO® Haemostatic Matrix Kit with Thrombin.
P990080/S059	09/27/2023	X - 30-Day Notice	CEEON EDGE FOLDABLE ULTRAVIOLET LIGHT-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS, MODEL 911A	JOHNSON & JOHNSON SURGICAL VISION, INC.	Reclassification of Clean, Inspection, and Insertion (CII) rooms of building 1 and 1A at JJSV Puerto Rico manufacturing site.
P000013/S022	09/27/2023	X - 30-Day Notice	TRIDENT SYSTEM	HOWMEDICA OSTEONICS CORP.	Addition of a second supplier for the raw material Alumina used for the production of the ceramic material BIOLOX®forte.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000021/S045	09/26/2023	X - 30-Day Notice	DIMENSION(R) RXL PSA FLEX(R) REAGENT CARTRIDGE	SIEMENS HEALTHCARE DIAGNOSTICS	Addition of alternate optical filters for 405nm and 452nm wavelengths used in Photometer Assembly on the Dimension Family of Instruments.
P010001/S026	09/06/2023	X - 30-Day Notice	CERAMIC TRANSCEND HIP ARTICULATION SYSTEM	CERAMTEC GMBH	Addition of a grinding machine for grinding the outer surface of ceramic inserts in the TRANSCEND® Hip Articulation System.
P010013/S090	09/22/2023	X - 30-Day Notice	NOVASURE IMPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM	HOLOGIC, INC.	Changes in sterilization parameters at the approved sterilization site Steris Costa Rica.
P010031/S831	09/08/2023	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Updates to the test application software for the Mixed Signal Integrated Circuit testers at Medtronic Tempe Campus.
P010031/S833	09/29/2023	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Add and update electrical test process steps for hybrid subassembly testing.
P010032/S203	09/22/2023	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Change of alternate catalog part numbers of graphite powder material as drop-in replacements; graphite powder is an inert material used within the lithium primary cell non-rechargeable batteries in Orion family IPG devices.
P010032/S204	09/29/2023	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Improvements to the quality control testing that is performed on finished device software applications to ensure that they continue to operate as intended on new mobile platforms or iOS versions.
P020027/S040	09/26/2023	X - 30-Day Notice	DIMENSION FPSA FLEX REAGENT CARTRIDGE AND DIMENSION T/F PSA CALIBRATOR FOR DIMENSION RXL AND XPAND SYSTEMS	SIEMENS HEALTHCARE DIAGNOSTICS	Addition of alternate optical filters for 405nm and 452nm wavelengths used in Photometer Assembly on the Dimension Family of Instruments.
P020036/S050	09/28/2023	X - 30-Day Notice	S.M.A.R.T. AND S.M.A.R.T. CONTROL NITINOL STENT SYSTEM	CORDIS US CORPORATIO N	Updating the Support Member Subassembly process parameters.
P030017/S366	09/27/2023	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Alternate packaging supplier for an Inner Tray packaging component used to package Spinal Cord Stimulator and Deep Brain Stimulator Lead Products (Extensions, Splitters, Adapters, and Connectors) at the Boston Scientific Dorado Puerto Rico manufacturing site.
P030031/S134	09/28/2023	X - 30-Day Notice	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Addition of a sub-tier supplier to an electronic component used in the PCB assembly for Thermocool Smarttouch (ST) and Thermocool Smarttouch SF (STSF) Catheters.

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P030035/S196	09/20/2023	X - 30-Day Notice	ANTHEM AND FRONTIER II CRT-P'S	ABBOTT MEDICAL	Replace the graphite powder used during battery manufacturing with two alternatives.
P030054/S411	09/20/2023	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ABBOTT MEDICAL	Replace the graphite powder used during battery manufacturing with two alternatives.
P040034/S038	09/05/2023	X - 30-Day Notice	DURASEAL DURAL SEALANT SYSTEM	INTEGRA LIFESCIENCES CORPORATION	Change in the test method for elemental impurity specifications of the sodium borate component to comply with USP <232> and USP <233>.
P040036/S096	09/28/2023	X - 30-Day Notice	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Addition of a sub-tier supplier to an electronic component used in the PCB assembly for Thermocool Smarttouch (ST) and Thermocool Smarttouch SF (STSF) Catheters.
P040037/S162	09/07/2023	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Relocating the destructive quality control lot release testing activities from the Medical West facility to the Kendrick Peak facility.
P040047/S071	09/13/2023	X - 30-Day Notice	COAPTITE	MERZ NORTH AMERICA, INC	Implementation of a new filtration system of Merz CaHA particles used for manufacture in COAPTITE, RADIESSE, and RADIESSE (+).
P040047/S072	09/20/2023	X - 30-Day Notice	COAPTITE	MERZ NORTH AMERICA, INC	Implementation of new sieve system of CaHA particles used for manufacture in COAPTITE, RADIESSE, and RADIESSE (+).
P050006/S106	09/11/2023	X - 30-Day Notice	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Addition of a new oven for delivery catheter curve shaping.
P050017/S022	09/22/2023	X - 30-Day Notice	ZILVER VASCULAR STENT	COOK IRELAND, LTD.	Changes to adhesives used in stent delivery systems.
P050037/S130	09/13/2023	X - 30-Day Notice	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Implementation of a new filtration system of Merz CaHA particles used for manufacture in COAPTITE, RADIESSE, and RADIESSE (+).
P050037/S131	09/20/2023	X - 30-Day Notice	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Implementation of new sieve system of CaHA particles used for manufacture in COAPTITE, RADIESSE, and RADIESSE (+).
P050052/S152	09/13/2023	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Implementation of a new filtration system of Merz CaHA particles used for manufacture in COAPTITE, RADIESSE, and RADIESSE (+).
P050052/S153	09/20/2023	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Implementation of new sieve system of CaHA particles used for manufacture in COAPTITE, RADIESSE, and RADIESSE (+).
P060001/S036	09/18/2023	X - 30-Day Notice	PROTEGE GPS AND PROTEGE RX CAROTID STENT SYSTEMS	MEDTRONIC VASCULAR INC	Alternative to batch testing for bacterial endotoxin testing.
P060001/S037	09/12/2023	X - 30-Day Notice	PROTEGE GPS AND PROTEGE RX CAROTID STENT SYSTEMS	MEDTRONIC VASCULAR INC	Change the electropolishing upper specification limit calculation for the stent component.
P060011/S034	09/05/2023	X - 30-Day Notice	C-FLEX MODEL 570C INTRAOCULAR LENS (IOL)	RAYNER INTRAOCULAR LENSES LTD.	Add an alternate supplier of molded parts.

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P080010/S024	09/27/2023	X - 30-Day Notice	TECNIS MULTIFOCAL FOLDABLE POSTERIOR CHAMBER INTRAOCULAR LENS (IOL)	JOHNSON & JOHNSON SURGICAL VISION, INC.	Reclassification of Clean, Inspection, and Insertion (CII) rooms of building 1 and 1A at JJSV Puerto Rico manufacturing site.
P080011/S157	09/28/2023	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Relocation of Syncro Langenpac Label Only Machine and Label Only Tray Loader (LP7 Syncro) from ground floor to the 1st Floor at the Cooper Vision Manufacturing, Ltd, Mountpark, UK Facility to produce Biofinity family lenses.
P080013/S027	09/05/2023	X - 30-Day Notice	DURASEAL EXACT SPINE SEALANT SYSTEM	INTEGRA LIFESCIENCES CORPORATION	Change in the test method for elemental impurity specifications of the sodium borate component to comply with USP <232> and USP <233>.
P100010/S140	09/19/2023	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Change in manufacturing site for a 2nd tier supplier with associated manufacturing changes at the supplier.
P100018/S040	09/06/2023	X - 30-Day Notice	PIPELINE EMBOLIZATION DEVICE	MICRO THERAPEUTICS, INC. D/B/A EV3 NEUROVASCULAR	Manufacturing facility location change and a new degreasing solvent for the solder preform ring component of the Pipeline Flex Embolization Device and Pipeline Flex Embolization Device with Shield Technology.
P100021/S117	09/13/2023	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Implementation of an alternative supplier for the tapered tip components of the Endurant Aortic Delivery System.
P100022/S042	09/22/2023	X - 30-Day Notice	ZILVER PTX DRUG-ELUTING PERIPHERAL STENT	COOK IRELAND, LTD.	Changes to adhesives used in stent delivery systems.
P100045/S069	09/06/2023	X - 30-Day Notice	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ABBOTT MEDICAL	Implementing upgraded testing equipment for use during manufacturing of the CardioMEMS PASensor.
P110023/S038	09/05/2023	X - 30-Day Notice	EVERFLEX SELF-EXPANDING PERIPHERAL STENT SYSTEM (EVERFLEX)	MEDTRONIC VASCULAR INC	Changes in the composition, suppliers and location for a cyanoacrylate adhesive used in the delivery catheter.
P110023/S039	09/18/2023	X - 30-Day Notice	EVERFLEX SELF-EXPANDING PERIPHERAL STENT SYSTEM (EVERFLEX)	MEDTRONIC VASCULAR INC	Alternative to batch testing for bacterial endotoxin testing.
P110023/S040	09/12/2023	X - 30-Day Notice	EVERFLEX SELF-EXPANDING PERIPHERAL STENT SYSTEM (EVERFLEX)	MEDTRONIC VASCULAR INC	Change the electropolishing upper specification limit calculation for the stent component.
P110035/S070	09/18/2023	X - 30-Day Notice	EPIC SELF-EXPANDING NITINOL STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Implement an alternative stent laser cutting system.

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P120002/S025	09/28/2023	X - 30-Day Notice	SMA RT CONTROL AND SMART VASCULAR STENT SYSTEMS	CORDIS US CORPORATION	Updating the Support Member Subassembly process parameters.
P120003/S002	09/12/2023	X - 30-Day Notice	ICAST COVERED STENT SYSTEM	ATRIUM MEDICAL CORP.	Second site for a raw stainless steel tubing supplier.
P130005/S038	09/07/2023	X - 30-Day Notice	DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM	CARDIOVASCULAR SYSTEMS, INC.	Change to use an alternate coating on the Tyvek pouch.
P130006/S101	09/07/2023	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Relocating the destructive quality control lot release testing activities from the Medical West facility to the Kendrick Peak facility.
P130021/S145	09/19/2023	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Relocation of the alpha-amino oleic acid (AOA) solution formulation process from ISO Class 7 Controlled Environment Area (CEA) 31 to ISO Class 8 CEA 33.
P130021/S146	09/25/2023	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	New sterilization cycle for moist heat sterilization of the primary packaging for the Evolut R, PRO, PRO+, FX Transcatheter Aortic Valves (TAV), the Harmony and Melody Transcatheter Pulmonary Valves (TPV), and the Avalus Bioprosthesis manufactured in Tijuana, Mexico. Additionally, a new sterilization configuration for the primary packaging sterilization is also being introduced for the Evolut TAV jars and Harmony TPV jars.
P130024/S043	09/07/2023	X - 30-Day Notice	LUTONIX DRUG COATED BALLOON PTA CATETER	LUTONIX	Addition of oxygen sachets to the packaging of the Lutonix Drug Coated PTA Balloon Catheter.
P140002/S026	09/21/2023	X - 30-Day Notice	MISAGO PERIPHERAL SELF-EXPANDING STENT SYSTEM	TERUMO MEDICAL CORPORATION	Alternate residual analytical instrument and method change.
P140009/S088	09/22/2023	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Change of alternate catalog part numbers of graphite powder material as drop-in replacements; graphite powder is an inert material used within the lithium primary cell non-rechargeable batteries in Orion family IPG devices.
P140009/S089	09/29/2023	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Improvements to the quality control testing that is performed on finished device software applications to ensure that they continue to operate as intended on new mobile platforms or iOS versions.
P140017/S025	09/25/2023	X - 30-Day Notice	MELODY TRANSCATHETER PULMONARY VALVE (TPV), ENSEMBLE TRANSCATHETER VALVE DELIVERY SYSTEM (DS)	MEDTRONIC INC.	New sterilization cycle for moist heat sterilization of the primary packaging for the Evolut R, PRO, PRO+, FX Transcatheter Aortic Valves (TAV), the Harmony and Melody Transcatheter Pulmonary Valves (TPV), and the Avalus Bioprosthesis manufactured in Tijuana, Mexico. Additionally, a new sterilization configuration for the primary packaging sterilization is also being introduced for the Evolut TAV jars and Harmony TPV jars.
P140018/S038	09/06/2023	X - 30-Day Notice	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Implement the VenaSeal Vision System for inspecting VenaSeal kit components.
P140018/S039	09/15/2023	X - 30-Day Notice	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	New dry heat sterilization oven used in terminal sterilization of the VenaSeal Adhesive.

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P140031/S164	09/12/2023	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCE S, LLC.	Implement the cleaning process for the PVL (paravalvular leak) skirt cloth component using the 70% Isopropyl Alcohol at the Edwards Singapore facility.
P140033/S081	09/20/2023	X - 30-Day Notice	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ABBOTT MEDICAL	Replace the graphite powder used during battery manufacturing with two alternatives.
P150004/S066	09/22/2023	X - 30-Day Notice	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Change of alternate catalog part numbers of graphite powder material as drop-in replacements; graphite powder is an inert material used within the lithium primary cell non-rechargeable batteries in Orion family IPG devices.
P150004/S067	09/29/2023	X - 30-Day Notice	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Improvements to the quality control testing that is performed on finished device software applications to ensure that they continue to operate as intended on new mobile platforms or iOS versions.
P150012/S149	09/08/2023	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIE NTIFIC	Implement an alternate supplier of a component in the Ingevity leads.
P150031/S061	09/27/2023	X - 30-Day Notice	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Alternate packaging supplier for an Inner Tray packaging component used to package Spinal Cord Stimulator and Deep Brain Stimulator Lead Products (Extensions, Splitters, Adapters, and Connectors) at the Boston Scientific Dorado Puerto Rico manufacturing site.
P160043/S071	09/28/2023	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Extension to the manufacturing cleanroom space for Resolute Onyx and Onyx Frontier.
P160054/S057	09/07/2023	X - 30-Day Notice	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	New supplier, manufacturing process change, and new supplier of titanium for the HeartMate 3 Cuff Lock.
P160054/S058	09/12/2023	X - 30-Day Notice	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	New machining supplier, new anodization process supplier, and new titanium supplier for the HeartMate 3 Motor Cap.
P160054/S059	09/27/2023	X - 30-Day Notice	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Addition of an alternate supplier for screws used in the manufacturing of the HeartMate 3 Left Ventricular Assist Device (LVAD).
P160055/S031	09/21/2023	X - 30-Day Notice	LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Addition of an alternate haptic tip activation method used during manufacturing of the RxSight Intraocular Lenses (IOL) (the LAL model 60005 and the LAL+ model 60007).
P170002/S033	09/29/2023	X - 30-Day Notice	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Increased quantity of the preparation of the lidocaine solution.
P170003/S027	09/07/2023	X - 30-Day Notice	LUTONIX® 035 DRUG COATED BALLOON PTA CATHETER, MODEL 9010	LUTONIX	Addition of oxygen sachets to the packaging of the Lutonix Drug Coated PTA Balloon Catheter.
P170006/S026	09/19/2023	X - 30-Day Notice	AVALUS(TM) BIOPROSTHESIS	MEDTRONIC INC.	Relocation of the alpha-amino oleic acid (AOA) solution formulation process from ISO Class 7 Controlled Environment Area (CEA) 31 to ISO Class 8 CEA 33.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170006/S027	09/25/2023	X - 30-Day Notice	AVALUS(TM) BIOPROSTHESIS	MEDTRONIC INC.	New sterilization cycle for moist heat sterilization of the primary packaging for the Evolut R, PRO, PRO+, FX Transcatheter Aortic Valves (TAV), the Harmony and Melody Transcatheter Pulmonary Valves (TPV), and the Avalus Bioprosthesis manufactured in Tijuana, Mexico. Additionally, a new sterilization configuration for the primary packaging sterilization is also being introduced for the Evolut TAV jars and Harmony TPV jars.
P180038/S015	09/28/2023	X - 30-Day Notice	LIAISON XL MUREX ANTI-HBC, LIAISON MUREX CONTROL ANTI-HBC	DIASORIN INC.	Transfer of logistics activities for the storage warehouse.
P180039/S014	09/28/2023	X - 30-Day Notice	LIAISON® XL MUREX ANTI-HBS, LIAISON® XL MUREX CONTROL ANTI-HBS AND LIAISON® XL MUREX ANTI-HBS VERIFIERS	DIASORIN INC.	Transfer of logistics activities for the storage warehouse.
P180043/S005	09/15/2023	X - 30-Day Notice	THERASCREEN FGFR RGQ RT-PCR KIT	QIAGEN GMBH	Manufacturing process and QC specification improvements for device components.
P180045/S012	09/28/2023	X - 30-Day Notice	LIAISON® XL MUREX HBC IGM, LIAISON® XL MUREX CONTROL HBC IGM	DIASORIN INC.	Transfer of logistics activities for the storage warehouse.
P180046/S073	09/26/2023	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Addition of a sterilization chamber.
P180047/S023	09/28/2023	X - 30-Day Notice	LIAISON QUANTIFERON - TB GOLD PLUS, LIAISON CONTROL QUANTIFERON - TB GOLD PLUS AND LIAISON QUANTIFERON SOFTWARE	DIASORIN, INC.	Transfer of logistics activities for the storage warehouse.
P180048/S012	09/28/2023	X - 30-Day Notice	LIAISON® XL MUREX HBEAG, LIAISON® XL MUREX CONTROL HBEAG	DIASORIN INC.	Transfer of logistics activities for the storage warehouse.
P180049/S013	09/28/2023	X - 30-Day Notice	LIAISON® XL MUREX ANTI-HBE, LIAISON® XL MUREX CONTROL ANTI-HBE	DIASORIN INC.	Transfer of logistics activities for the storage warehouse.
P190006/S073	09/26/2023	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Addition of a sterilization chamber.
P190017/S015	09/28/2023	X - 30-Day Notice	LIAISON® XL MUREX HBSAG QUAL, LIAISON® MUREX CONTROL HBSAG, AND LIAISON® XL MUREX HBSAG CONFIRMATORY TEST	DIASORIN INC	Transfer of logistics activities for the storage warehouse.

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P200013/S017	09/14/2023	X - 30-Day Notice	ALINITY M HBV	ABBOTT MOLECULAR, INC.	Add a new component supplier.
P200015/S046	09/25/2023	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCE S, LLC	Use of an alternate crimping accessory to be used with the Edwards Pulmonic Delivery System.
P200023/S006	09/22/2023	X - 30-Day Notice	ZILVER VENA VENOUS SELF-EXPANDING STENT	COOK IRELAND LTD.	Changes to adhesives used in stent delivery systems.
P200026/S006	09/18/2023	X - 30-Day Notice	ABRE VENOUS SELF-EXPANDING STENT SYSTEM	MEDTRONIC VASCULAR, INC.	Alternative to batch testing for bacterial endotoxin testing.
P200046/S019	09/11/2023	X - 30-Day Notice	HARMONY¿ TPV SYSTEM	MEDTRONIC, INC.	Move the entire drawing process of the Nitinol wire used in manufacture of the Harmony Transcatheter Pulmonary Valve (TPV) to Fort Wayne Metals (FWM).
P200046/S020	09/19/2023	X - 30-Day Notice	HARMONY¿ TPV SYSTEM	MEDTRONIC, INC.	Relocation of the alpha-amino oleic acid (AOA) solution formulation process from ISO Class 7 Controlled Environment Area (CEA) 31 to ISO Class 8 CEA 33.
P200046/S021	09/25/2023	X - 30-Day Notice	HARMONY¿ TPV SYSTEM	MEDTRONIC, INC.	New sterilization cycle for moist heat sterilization of the primary packaging for the Evolut R, PRO, PRO+, FX Transcatheter Aortic Valves (TAV), the Harmony and Melody Transcatheter Pulmonary Valves (TPV), and the Avalus Bioprosthesis manufactured in Tijuana, Mexico. Additionally, a new sterilization configuration for the primary packaging sterilization is also being introduced for the Evolut TAV jars and Harmony TPV jars.
P210006/S006	09/21/2023	X - 30-Day Notice	THORAFLEX¿ HYBRID	VASCUTEK LTD.	Recommission a cleanroom for manufacturing of the Thoraflex Hybrid device.
P210022/S007	09/14/2023	X - 30-Day Notice	ALINITY M CMV	ABBOTT MOLECULAR, INC.	Add a new component supplier.
P220002/S002	09/07/2023	X - 30-Day Notice	TOPS¿ SYSTEM	PREMIA SPINE LTD.	Information provided by the firm to support the following changes: 1. The addition of two (2) semi-automated assembly machines (Boot to TOP Plate machine-EGEQ88244 and Core Assembly to TOP Plate-EGEQ88242), as alternative to the current manual process, for certain assembly steps of the TOPS; and 2) Flip the insertion orientation of the Polycarbonate Urethane (PcU) Plug prior to its insertion into the TOPS Top Plate.
P220013/S006	09/07/2023	X - 30-Day Notice	TACTIFLEX¿ ABLATION CATHETER, SENSOR ENABLED¿, TACTISYS ¿ QUARTZ EQUIPMENT, TACTISYS¿ QUARTZ, TACTIFLEX ¿ RADIOFREQUENCY CABLE, AMPERE ¿ RADIOFREQUENCY GENERATOR, COOL POINT PUMP	ABBOTT MEDICAL	Change to the manufacturing process and adhesive used to bond the tip thermocouple to the tip cap.

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P220013/S007	09/07/2023	X - 30-Day Notice	TACTIFLEX¿ ABLATION CATHETER, SENSOR ENABLED¿, TACTISYS ¿ QUARTZ EQUIPMENT, TACTISYS¿ QUARTZ, TACTIFLEX ¿ RADIOFREQUENCY CABLE, AMPERE ¿ RADIOFREQUENCY GENERATOR, COOL POINT PUMP	ABBOTT MEDICAL	Manufacturing equipment updates and associated inspection automation.

Total: 110