PMA Monthly approvals from 10/1/2022 to 10/31/2022

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P210015	10/31/2022	PMAO - PMA Origi	AVIVE AUTOMATED EXTERNAL DEFIBRILLATOR (AED) SYSTEM	AVIVE SOLUTIONS, INC.	Approval for the Avive Automated External Defibrillator.

Total: 1

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840024/S094	10/31/2022	N - Normal 180 Day	NUCLEUS MULTICHANNEL IMPLANTABLE HEARING PROSTHESI	COCHLEAR AMERICAS	Approval for a new sound processor (Nucleus 8 Sound Processor) and two supporting software devices (Custom Sound Pro and Nucleus Smart App).
P890003/S455	10/16/2022	R - Real-Time Proc	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Approval for new SmartSync software applications to provide support for additional families of market-released CIEDs.
P890003/S456	10/06/2022	R - Real-Time Proc	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Approval for new SmartSync software applications to provide support for additional families of market-released CIEDs.
P890027/S062	10/31/2022	N - Normal 180 Day	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT SYS / CHILDREN	COCHLEAR AMERICAS	Approval for a new sound processor (Nucleus 8 Sound Processor) and two supporting software devices (Custom Sound Pro and Nucleus Smart App).
P890055/S082	10/28/2022	S - Special CBE	MEDSTREAM PROGRAMMABLE INFUSION PUMP SYSTEM	INTERA ONCOLOGY	Approval for an added inspection of the capillary crimps and tightening of the capillary leakage acceptance criterion.
P930014/S138	10/28/2022	Y - 135 Review Tra	ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES	ALCON LABORATORIES, INC.	Approval for an updated analytical testing method for determination of Ethylene Oxide (EO) sterilant residuals and residual acetone on the subject devices by headspace gas chromatography.
P970004/S374	10/27/2022	S - Special CBE	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Approval for removal of the applicator sponge from the Interstim Evaluation Lead Kit and updated package labeling for the InterStim Evaluation Lead Kit.
P970051/S211	10/31/2022	N - Normal 180 Day	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	for a new sound processor (Nucleus 8 Sound Processor) and two supporting software devices (Custom Sound Pro and Nucleus Smart App).

Data as of 11/17/2022 04:25 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S830	10/06/2022	R - Real-Time Proc	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for new SmartSync software applications to provide support for additional families of market-released CIEDs.
P980035/S723	10/16/2022	R - Real-Time Proc	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Approval for new SmartSync software applications to provide support for additional families of market-released CIEDs.
P990052/S026	10/11/2022	R - Real-Time Proc	VIBRANT P/ VIBRANT D SOUNDBRIDGE SYSTEM	MED-EL ELEKTROMED IZINISCHE GERATE GMBH	Approval for the SAMBA 2 VSB audio processor and the supporting SYMFIT 8.0.1 fitting software.
P990074/S049	10/05/2022	Y - 135 Review Tra	NATRELLE SALINE BREAST IMPLANTS	ALLERGAN	Approval for a change to the annual re-validation of the dry heat sterilization process to allow annual re-validation to be performed without biological indicators every other year.
P000015/S047	10/31/2022	N - Normal 180 Day	NUCLEUS 24 AUDITORY BRAINSTEM IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for a new sound processor (Nucleus 8 Sound Processor) and two supporting software devices (Custom Sound Pro and Nucleus Smart App).
P010031/S796	10/06/2022	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for new SmartSync software applications to provide support for additional families of market-released CIEDs.
P020056/S058	10/05/2022	Y - 135 Review Tra	NATRELLE SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Approval for a change to the annual re-validation of the dry heat sterilization process to allow annual re-validation to be performed without biological indicators every other year.
P030036/S139	10/03/2022	N - Normal 180 Day	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval to expand the indications for use for the Medtronic SelectSecure MRI SureScan Lead Model 3830 to include pacing at the left bundle branch area as an alternative to right ventricular pacing.
P040020/S100	10/28/2022	Y - 135 Review Tra	ACRYSOF RESTOR APODIZED DIFFRACTIVE OPTIC POSTERIOR CHAMBER IOL	ALCON RESEARCH, LTD.	Approval for an updated analytical testing method for determination of Ethylene Oxide (EO) sterilant residuals and residual acetone on the subject devices by headspace gas chromatography.
P040024/S127	10/25/2022	Y - 135 Review Tra	RESTYLANE INJECTABLE GEL	Q-MED AB	Approval for the transfer of the processing (washing and release) of plungers used in the manufacturing of Restylane-L®, Restylane Lyft® with Lidocaine, and Restylane® Silk to a new site.
P050006/S101	10/14/2022	R - Real-Time Proc	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,I NC	Approval for a modification to the formulation of coatings used in the handle of the delivery system.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P060010/S013	10/07/2022	P - Panel Track	THE SPANNER TEMPORARY PROSTATIC STENT	SRS MEDICAL	Approval for the Spanner Prostatic Stent. The device is intended for temporary use (up to 30 days) to maintain urine flow and allow voluntary urination for patients who are not candidates for pharmacologic, minimally invasive or surgical treatment of the prostate.
P070004/S036	10/06/2022	O - Normal 180 Da	SIENTRA SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Approval for a trade name change from Sientra OPUS Silicone Gel Breast Implants to Sientra Silicone Gel Breast Implants.
P080025/S269	10/27/2022	S - Special CBE	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Approval for removal of the applicator sponge from the Interstim Evaluation Lead Kit and updated package labeling for the InterStim Evaluation Lead Kit.
P090016/S049	10/26/2022	N - Normal 180 Day	BELOTERO BALANCE	MERZ NORTH AMERICA, INC	Approval to increase the tolerance range for the lidocaine hydrochloride specification from 3.00 ± 5% mg/mL (2.85-3.15 mg/mL) to 3.0 ± 10% mg/mL (2.7 - 3.3 mg/mL).
P100049/S033	10/04/2022	N - Normal 180 Day	LINX REFLUX MANAGEMENT SYSTEM	TORAX MEDICAL	Approval for the following labeling updates: 1) inclusion of final post-approval study results; 2) addition of a precaution based on RELIEF study results; 3) addition of swallow-induced syncope to the list of adverse events; and 4) revised registered/trademark status.
P110005/S012	10/07/2022	S - Special CBE	SINOVIAL (SODIUM HYALURONATE 0.8%)	IBSA INSTITUT BIOCHIMIQUE SA	Approval for revisions to the Adverse Reactions section of the Product Information and Patient Information labeling based on post-market adverse event and safety data collected up to March 2022.
P110010/S195	10/14/2022	Y - 135 Review Tra	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for reduction in the stent primer drying time for the PROMUS stent.
P130013/S050	10/17/2022	R - Real-Time Proc	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Approval for design and manufacturing changes including the addition of stabilizers to the delivery sheath material formulation, a new in-house supplier for the delivery sheath, and the addition of a liner at the end of the sheath braid to facilitate tacking.
P130013/S054	10/28/2022	O - Normal 180 Day	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Approval of the protocol for the post-approval study (PAS) protocol.
P130016/S048	10/31/2022	N - Normal 180 Day	NUCLEUS HYBRID L24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for a new sound processor (Nucleus 8 Sound Processor) and two supporting software devices (Custom Sound Pro and Nucleus Smart App).
P130021/S120	10/04/2022	O - Normal 180 Day	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Approval for modifications to the Instructions for Use to reflect the 5-year findings of the continued follow-up of premarket cohort post-approval studies.
P130022/S044	10/12/2022	N - Normal 180 Day	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for a new Implantable Pulse Generator (IPG) system called the Senza HFX iQ system. The Senza HFX iQ system includes the following devices: 1) Bluetooth enabled IPG called the HFX iQ IPG (IPG3000); 2) Updated Senza Bluetooth Trial Stimulator called the HFX Trial Stimulator (TSM3500); 3) Updated compatible Bluetooth Patient Remote called the HFX iQ Remote (PTR3000); 4) New mobile device application software called as the HFX iQ Patient Application (PTA); 5) Updated Clinician Programmer software to configure the Bluetooth Trial Stimulators and Bluetooth IPG; and 6) New software called as Gaea Cryptofunction that implements certain cybersecurity features of the Senza HFX iQ system.

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P140003/S094	10/04/2022	N - Normal 180 Day	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for integrating the purge sidearm within the patient cable and changing the catheter repositioning securement type
P140003/S099	10/28/2022	N - Normal 180 Day	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for the use of an alternative programmed microcontroller.
P140008/S024	10/05/2022	R - Real-Time Proc	ORBERA INTRAGASTRIC BALLOON	APOLLO ENDOSURGERY INC	Approval for a change to the physician labeling to update Table 21: ORBERA device- and procedure- related adverse events and complaints reported through clinical product surveillance.
P150001/S099	10/17/2022	S - Special CBE	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	Approval for a labeling update to ensure that users recognize the need to save after setting all basal rate settings on new and replacement MiniMed 630G and 670G Systems.
P150011/S024	10/07/2022	N - Normal 180 Day	PERCEVAL SUTURELESS HEART VALVE	CORCYM CANADA CORP.	Approval for the Perceval RelyON PAK Accessories Kit for collapsing and releasing the Perceval PLUS valve and modification to the Instructions for Use to address the use of the new accessories.
P150031/S049	10/27/2022	N - Normal 180 Day	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval of the addition of the 2x8 Contact Lead Extensions.
P150033/S145	10/16/2022	R - Real-Time Proc	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval for new SmartSync software applications to provide support for additional families of market-released CIEDs.
P160017/S102	10/17/2022	S - Special CBE	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval for a labeling update to ensure that users recognize the need to save after setting all basal rate settings on new and replacement MiniMed 630G and 670G Systems
P170011/S039	10/28/2022	N - Normal 180 Day	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval for the Impella RP Flex with SmartAssist which incorporates a new design to the cannula to allow for device placement via the internal jugular vein.
P170011/S040	10/28/2022	N - Normal 180 Day	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval for the use of an alternative programmed microcontroller.
P170011/S044	10/06/2022	N - Normal 180 Day	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval for modifying the material used to construct the current retainer within the hybrid bearing of the motor.
P190002/S001	10/26/2022	O - Normal 180 Da	SALUDA MEDICAL EVOKE SCS SYSTEM	SALUDA MEDICAL PTY LTD	Approval to move the current cleanroom facilities located at 14 Mars Rd, Lane Cove, NSW, Australia (Lane Cove) to 5 Eden Park Drive, Macquarie Park, NSW, Australia (Macquarie Park) and approval to duplicate external device production from the current Artarmon facility (407 Pacific Highway, Artarmon, NSW, Australia) to the Macquarie Park facility.
P190002/S003	10/06/2022	O - Normal 180 Day	SALUDA MEDICAL EVOKE SCS SYSTEM	SALUDA MEDICAL PTY LTD	Approval for a manufacturing site located at Heraeus Medical Components, LLC (HMCW) 5030 Centerville Road Saint Paul, MN US 55127 for the manufacture and packaging of Evoke Percutaneous Leads and Lead Kits, Packaging and labelling of the Evoke Accessories, and Minor manufacturing process changes for the manufacture of Evoke Percutaneous Leads.
P200002/S003	10/13/2022	O - Normal 180 Da	EPI-SENSE GUIDED COAGULATION SYSTEM	ATRICURE, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P200006/S003	10/28/2022	O - Normal 180 Day	FOUNDATIONONE LIQUID CDX (F1 LIQUID CDX)	FOUNDATION MEDICINE, INC.	Approval for the termination of the post-approval study (PAS) protocol.
P200010/S009	10/26/2022	N - Normal 180 Day	GUARDANT360 CDX	GUARDANT HEALTH, INC.	Approval of the updates and revisions made to the Guardant360® CDx labeling documents.

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P200013/S009	10/24/2022	S - Special CBE	ALINITY M HBV	ABBOTT MOLECULAR, INC.	Approval is for the following addition to Limitations of the Procedure: Unexpected HBV DNA levels due to carry over may occur. If results are inconsistent with patient history and other diagnostics through patient monitoring, a retest of the sample should be considered by the physician or healthcare provider. Approval is also for the following change to the Specific Performance Characteristic Carryover section: The carryover rate for Alinity m HBV was determined in two studies. Study 1 evaluated the carryover rate in the Sample Input Rack and Sample Processing Unit by analyzing 360 valid replicates of HBV negative samples processed from alternating positions in the sample input rack with 360 valid replicates of high concentrated HBV positive samples at 100,000,000 IU/mL, across multiple runs. HBV DNA was not detected in any of the HBV negative samples, resulting in a carryover rate of 0% (95% CI: 0.0 to 1.1%). Study 2 evaluated the carryover rate in the AMP tray by evaluating 414 valid replicates of HBV negative samples processed from alternating positions at the AMP Tray with 414 valid replicates of high concentrated HBV positive samples at 100,000,000 IU/mL across multiple runs. HBV DNA was detected in 16 of the HBV negative samples resulting in a carryover rate of 3.9% (95% CI: 2.2 to 6.2%).
P200015/S024	10/28/2022	R - Real-Time Proc	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Approval for various dimensional changes to the hypotube component of the SAPIEN 3 Pulmonic Delivery System.
P200028/S012	10/12/2022	R - Real-Time Proc	DIAMONDTEMP ABLATION SYSTEM	MEDTRONIC INC.	Approval for compatibility of the DiamondTemp Ablation System with the Abbott EnSite X mapping and navigation system.
P200037/S004	10/25/2022	N - Normal 180 Day	ASSURE WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) SYSTEM	KESTRA MEDICAL TECHNOLOGIES, INC.	Approval for a revision to the software system to version 5.0 with a feature to provide additional information to the physician about the patients health.

Total: 51

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N16837/S028	10/14/2022	X - 30-Day Notice	ARTEGRAFT{TM} AND REINFORCED ARTEGRAFT {TM}	LEMAITRE VASCULAR, INC.	Implementation of Bacterial Endotoxin Testing (BET) as a product release requirement for the Artegraft Collagen Vascular Graft.
N970003/S279	10/28/2022	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Update the Automated Optical Inspection on the battery feedthrough equipment.
P830055/S296	10/04/2022	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Change to the pressure & temperature parameter settings to accommodate the use of six (6) cavities that are used to the packaging process step for some components of the LCS Total Knee systems.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830055/S297	10/04/2022	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Change in inspection frequency that will reduce size inspection of casting trays from 100% of all parts to one part per batch for ATTUNE FB and RP castings.
P830055/S298	10/27/2022	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Implement a Robotic Process Automation (RPA) for the Sterilization Certificate approval process, which applies to LCS Total Knee System manufactured at Johnson and Johnson Medical (Suzhou) LTD in China.
P830055/S299	10/07/2022	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Change to inspection frequency of Attune CR and PS products during the HAAS grinding process at the Johnson & Johnson Medical (DePuy Suzhou) Ltd manufacturing site.
P830061/S209	10/25/2022	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add two ethylene oxide sterilization systems at Medtronics Singapore Operations.
P840001/S530	10/21/2022	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Update the Olympus PC and Pain PC burn-in solution to use newly redesigned Burn In Boards and new burn-in software application at the Tempe Campus.
P860004/S400	10/26/2022	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Implementation of a duplicate cleaning line and an update from manual operation to automatic operation.
P860057/S210	10/19/2022	X - 30-Day Notice	EDWARDS LIFESCIENCES PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Change in yarn extruder and an additional bias cloth manufacturing step.
P900056/S202	10/17/2022	X - 30-Day Notice	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Transfer incoming inspection activities of the core wire to the supplier and a change in the measurement tool.
P910001/S117	10/21/2022	X - 30-Day Notice	SPECTRANECTICS CVX-300 EXCIMER LASER SYSTEM	SPECTRANETICS CORP.	Elimination of a quality control test.
P910007/S058	10/12/2022	X - 30-Day Notice	AXSYM TOTAL PSA & ARCHITECT TOTAL PSA	ABBOTT LABORATORIES	Add an additional supplier for a kit component.
P910073/S169	10/14/2022	X - 30-Day Notice	ENDOTAK LEAD SYSTEM	BOSTON SCIENTIFIC	Add a new raw material supplier to extrude heat shrink tubing.
P920015/S272	10/25/2022	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Add two ethylene oxide sterilization systems at Medtronics Singapore Operations.
P930027/S028	10/14/2022	X - 30-Day Notice	IMMULITE SYSTEMS PSA & THIRD GENERATION PSA REAGENTS	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Change in material composition of the glass bulb used in PMT (Photo Multiplier Tube) Assembly on the IMMULITE Family of Instruments.
P930039/S246	10/25/2022	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Add two ethylene oxide sterilization systems at Medtronics Singapore Operations.

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P950020/S127	10/17/2022	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
P950027/S017	10/04/2022	X - 30-Day Notice	HYALGAN(R)	FIDIA FARMACEUTICI SPA	Change to the storage condition for the sodium hyaluronate bulk powder.
P950037/S239	10/20/2022	X - 30-Day Notice	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Update process monitoring sampling and remove redundant testing and inspection processes.
P960009/S439	10/04/2022	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Change to re-define the production batch size used for the bacterial endotoxin test of DBS leads.
P960009/S440	10/21/2022	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Update the Olympus PC and Pain PC burn-in solution to use newly redesigned Burn In Boards and new burn-in software application at the Tempe Campus.
P960011/S034	10/03/2022	X - 30-Day Notice	BIOLON 1% SODIUM HYALURONATE VISCOELASTIC SURGICAL AID FLUID	ALTACOR LTD.	Change to the concentration step in the manufacturing process.
P960040/S486	10/28/2022	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Update the Automated Optical Inspection on the battery feedthrough equipment.
P960040/S487	10/14/2022	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Implement an Automated Optical Inspection System for inspection of capacitor components at a supplier.
P980007/S047	10/12/2022	X - 30-Day Notice	AXSYM FREE PSA	ABBOTT LABORATORIES	Add an additional supplier for a kit component.
P980016/S837	10/14/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add a sub-tier supplier of an ingredient for manufacturing polyurethane resin.
P980016/S838	10/20/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add a second supplier for a component used in connector subassemblies at MECC.

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P980016/S840	10/25/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Implement manufacturing software External Function.
P980023/S115	10/20/2022	X - 30-Day Notice	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Update process monitoring sampling and remove redundant testing and inspection processes.
P980033/S060	10/14/2022	X - 30-Day Notice	WALLSTENT ENDOPROSTHESIS	BOSTON SCIENTIFIC CORPORATIO N	Addition of an alternative heat seal coating to be used on the packaging.
P980035/S731	10/25/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Add two ethylene oxide sterilization systems at Medtronics Singapore Operations.
P980035/S732	10/25/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implement manufacturing software External Function.
P980040/S150	10/07/2022	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Alternate method for surface phenomenon testing.
P980040/S151	10/27/2022	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Change to the location to perform the repackaging activity of Trimethoxysilane Polyethylene Glycol (mPEG) and its receiving testing in Puerto Rico facility.
P980053/S019	10/27/2022	X - 30-Day Notice	DURASPHERE INJECTABLE BULKING AGENT	CARBON MEDICAL TECHNOLOGI ES, INC.	Change in the sterilization process parameters within the existing sterilization facility.
P990046/S065	10/21/2022	X - 30-Day Notice	ATS OPEN PIVOT BILEAFLET HEART VALVE	MEDTRONIC ATS MEDICAL, INC.	Implementation of updated equipment used in the orifice core (graphite mold) removal process.
P010007/S017	10/14/2022	X - 30-Day Notice	IMMULITE/IMMULITE 1000 AFP AND IMMULITE 2000/ IMMULITE 2500 AFP	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Change in material composition of the glass bulb used in PMT (Photo Multiplier Tube) Assembly on the IMMULITE Family of Instruments.
P010012/S562	10/28/2022	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Update the Automated Optical Inspection on the battery feedthrough equipment.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010012/S563	10/14/2022	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Implement an Automated Optical Inspection System for inspection of capacitor components at a supplier.
P010014/S103	10/25/2022	X - 30-Day Notice	OXFORD(TM) MENISCAL UNICOMPARTMENTAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Introduction of a FOBA laser for the etching process of the Oxford Partial Knee System at Biomet Orthopedics, Warsaw, IN.
P010015/S507	10/14/2022	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Add a sub-tier supplier of an ingredient for manufacturing polyurethane resin.
P010015/S508	10/20/2022	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Add a second supplier for a component used in connector subassemblies at MECC.
P010015/S509	10/25/2022	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implement manufacturing software External Function.
P010031/S803	10/14/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add a sub-tier supplier of an ingredient for manufacturing polyurethane resin.
P010031/S804	10/20/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add a second supplier for a component used in connector subassemblies at MECC.
P010031/S806	10/25/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement manufacturing software External Function.
P010032/S194	10/28/2022	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Implement two manufacturing changes used in the production of contact assemblies in supplier Bal Seal Engineering, Inc.¿s production of contact assemblies, i.e., 1) to qualify alternate welding equipment used to process the spring component of contact assemblies; and 2) to implement visual automated optical inspection for performing the 100% inspection of the spring component's inner diameter.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010050/S021	10/14/2022	X - 30-Day Notice	IMMULITE 2000 XPI HBSAG	SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS, LTD	Change in material composition of the glass bulb used in PMT (Photo Multiplier Tube) Assembly on the IMMULITE Family of Instruments.
P010051/S017	10/14/2022	X - 30-Day Notice	IMMULITE 2000 XPI ANTI-HBC	SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS, LTD	Change in material composition of the glass bulb used in PMT (Photo Multiplier Tube) Assembly on the IMMULITE Family of Instruments.
P010052/S016	10/14/2022	X - 30-Day Notice	IMMULITE 2000 XPI ANTI-HBS	SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS, LTD	Change in material composition of the glass bulb used in PMT (Photo Multiplier Tube) Assembly on the IMMULITE Family of Instruments.
P010053/S016	10/14/2022	X - 30-Day Notice	IMMULITE 2000 XPI ANTI-HBC IMG	SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS, LTD	Change in material composition of the glass bulb used in PMT (Photo Multiplier Tube) Assembly on the IMMULITE Family of Instruments.
P020004/S192	10/05/2022	X - 30-Day Notice	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Implementation of changes to the lot acceptance sampling plan requirements for components that support the sealing cuff of the endoprosthesis.
P030005/S224	10/28/2022	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Update the Automated Optical Inspection on the battery feedthrough equipment.
P040024/S133	10/04/2022	X - 30-Day Notice	RESTYLANE INJECTABLE GEL	Q-MED AB	Changes to the WFI3 distribution system.
P040034/S035	10/07/2022	X - 30-Day Notice	DURASEAL DURAL SEALANT SYSTEM	INTEGRA LIFESCIENCES CORPORATION	Change in the raw material supplier of the laminated film component of the Tyvek Pouch used in packaging the DuraSeal products.
P040043/S131	10/05/2022	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implementation of changes to the lot acceptance sampling plan requirements for components that support the sealing cuff of the endoprosthesis.
P040044/S093	10/27/2022	X - 30-Day Notice	MATRIX VASCULAR CLOSURE SYSTEM (VSG)	CORDIS US CORPORATION	Source components from a supplier's new facility.
P050051/S047	10/12/2022	X - 30-Day Notice	ABBOTT ARCHITECT AUSAB	ABBOTT LABORATORIES INC	Add an additional supplier for a kit component.

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P060005/S016	10/14/2022	X - 30-Day Notice	IMMULITE / IMMULITE 1000 AND IMMULITE 2000 FREE PSA ASSAYS	SIEMENS MEDICAL SOLUTIONS DIAGNOSTICS LIMITED	Change in material composition of the glass bulb used in PMT (Photo Multiplier Tube) Assembly on the IMMULITE Family of Instruments.
P060035/S035	10/12/2022	X - 30-Day Notice	ARCHITECT CORE-M REAGENT KIT/ CALIBRATORS/CONTROLS	ABBOTT LABORATORIES	Add an additional supplier for a kit component.
P060035/S036	10/25/2022	X - 30-Day Notice	ARCHITECT CORE-M REAGENT KIT/ CALIBRATORS/CONTROLS	ABBOTT LABORATORIES	Addition of a new fill line in existing manufacturing space.
P060037/S081	10/14/2022	X - 30-Day Notice	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Change in the sterilant supplier for the hydrogen peroxide gas plasma sterilization process used for the NexGen LPS Flex/LPS Mobile Bearing Knee System, Cross-Linked Polyethylene Prolong Articular Surface components.
P060037/S082	10/06/2022	X - 30-Day Notice	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Change in fluorescent penetrant inspection (FPI) materials used during an in-process quality control validation on NexGen LPS/LPS-Flex femoral components and tibia baseplate components.
P060040/S087	10/14/2022	X - 30-Day Notice	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Add an alternate 2nd tier supplier of cable bands.
P070008/S140	10/20/2022	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.	Update process monitoring sampling and remove redundant testing and inspection processes.
P070026/S102	10/04/2022	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Process change by introducing new sealing parameters and the use of six (6) cavities as opposed to the current four (4) cavities that are used to package some components of the CERAMAX Ceramic Total Hip system.
P080011/S149	10/26/2022	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Modification to optimize the lens transfer module of the manufacturing process for the Biofinity Toric at the CooperVision manufacturing Puerto Rico LLC Juana Diaz facility.
P080013/S024	10/07/2022	X - 30-Day Notice	DURASEAL EXACT SPINE SEALANT SYSTEM	INTEGRA LIFESCIENCES CORPORATION	Change in the raw material supplier of the laminated film component of the Tyvek Pouch used in packaging the DuraSeal products.
P080020/S049	10/19/2022	X - 30-Day Notice	GEL-ONE	SEIKAGAKU CORP.	Elimination of existing distiller for water for injection (WFI).
P080023/S037	10/12/2022	X - 30-Day Notice	ARCHITECT CORE REAGENT KIT, ARCHITECT CORE CALIBRATOR AND ARCHITECT CORE CONTROLS	ABBOTT LABORATORIES	Add an additional supplier for a kit component.
P080023/S038	10/25/2022	X - 30-Day Notice	ARCHITECT CORE REAGENT KIT, ARCHITECT CORE CALIBRATOR AND ARCHITECT CORE CONTROLS	ABBOTT LABORATORIES	Addition of a new fill line in existing manufacturing space.

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P100009/S048	10/17/2022	X - 30-Day Notice	MITRACLIP DELIVERY SYSTEM	ABBOTT MEDICAL	Addition of the Micro-Vu Vertex 341 System and a change in the torque strength sampling plan.
P100013/S026	10/28/2022	X - 30-Day Notice	CORDIS EXOSEAL VASCULAR CLOSURE DEVICE	CORDIS US CORPORATION	Change to paper weight used with for the EXOSEAL® IFU from 50 lb to 40 lb at Steri-Tek.
P100021/S106	10/17/2022	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Use of a wire manufactured and inspected on the supplier's relocated equipment in the manufacturing of the Endurant Stents.
P100021/S107	10/13/2022	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Implementation of an additional laser cutter to manufacture a component of the delivery system of the Endurant Stent Graft System, Endurant II Stent Graft System, Endurant IIs Stent Graft System.
P100040/S052	10/27/2022	X - 30-Day Notice	VALIANT THORACIC STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Implementation of visual inspection for a component of the Valiant Thoracic Stent Graft with Captivia Delivery System.
P100047/S202	10/31/2022	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Relocate an assembly step of a battery component to a different location.
P110029/S039	10/12/2022	X - 30-Day Notice	ARCHITECT HBSAG QUALITATIVE, QUALITATIVE CONFIRMATORY, CONFIRMATORY MANUAL DILUENT, CALIBRATORS, AND CONTROLS	ABBOTT LABORATORIES	Add an additional supplier for a kit component.
P110042/S175	10/28/2022	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Update the Automated Optical Inspection on the battery feedthrough equipment.
P120008/S020	10/12/2022	X - 30-Day Notice	ABBOTT ARCHITECT AFP ASSAY	ABBOTT LABORATORIES	Add an additional supplier for a kit component.
P130012/S009	10/05/2022	X - 30-Day Notice	MYOPORE SUTURELESS MYOCARDIAL PACING LEAD	GREATBATCH MEDICAL	Implement a revised sterilization parameter for Myopore products in an effort to reduce the EO emission.
P130026/S080	10/28/2022	X - 30-Day Notice	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Modifications to the Deflection Tester and a re-arrangement of the manufacturing workflow.
P140002/S022	10/21/2022	X - 30-Day Notice	MISAGO PERIPHERAL SELF-EXPANDING STENT SYSTEM	TERUMO MEDICAL CORPORATION	Modification of the sterilization cycle and validation method.
P140009/S079	10/17/2022	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Qualify an additional manufacturing site in Bethel, Connecticut to manufacture nitinol tubes, which will be used in the manufacture of the DBS Extensions.
P140009/S080	10/28/2022	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Implement two manufacturing changes used in the production of contact assemblies in supplier Bal Seal Engineering, Inc.s production of contact assemblies, i.e., 1) to qualify alternate welding equipment used to process the spring component of contact assemblies; and 2) to implement visual automated optical inspection for performing the 100% inspection of the spring component's inner diameter.

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P140010/S068	10/11/2022	X - 30-Day Notice	IN PACT ADMIRAL PACLITAXEL-ELUTING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Replicate a manufacturing line.
P140029/S046	10/04/2022	X - 30-Day Notice	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Changes to the WFI3 distribution system.
P140031/S147	10/26/2022	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Change to the hub material for the overmold introducer.
P140031/S148	10/24/2022	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Implementation of Commander Delivery System Flex Shaft subassembly manufacturing at the Edwards Draper, UT facility.
P150012/S133	10/28/2022	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Update the Automated Optical Inspection on the battery feedthrough equipment.
P150033/S154	10/12/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Update the cleaning process for the Micra tines.
P150035/S002	10/06/2022	X - 30-Day Notice	AVEIR VR LEADLESS SYSTEM	ABBOTT MEDICAL	Add an alternate supplier for the sub-processing of the Wafer Level Chip Scale Package.
P150036/S065	10/19/2022	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Change in yarn extruder and an additional bias cloth manufacturing step.
P150048/S069	10/19/2022	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Change in yarn extruder and an additional bias cloth manufacturing step.
P160017/S103	10/27/2022	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Implementation of a reclamation process to allow printed circuit board assemblies to be reused for construction of MiniMed 770G pumps. The 770G insulin pump is a component of the MiniMed 770G system.
P160026/S034	10/27/2022	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.	Supplier manufacturing process change to implement a new automatic spot welder and new automated electrical inspection testers.

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P160054/S049	10/14/2022	X - 30-Day Notice	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Add an alternate 2nd tier supplier of cable bands.
P170007/S014	10/14/2022	X - 30-Day Notice	DUROLANE	BIOVENTUS LLC	Installation of a new point of use and a higher capacity centrifugal water pump for a Water for Injection (WFI) system used in the manufacturing of DUROLANE.
P170011/S046	10/11/2022	X - 30-Day Notice	IMPELLA RP SYSTEM	ABIOMED, INC.	Modification to the process used to construct the retainer within the hybrid bearing of the motor.
P170023/S012	10/26/2022	X - 30-Day Notice	BULKAMID URETHRAL BULKING SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Alternate sub-supplier of a manufacturing raw material.
P170023/S013	10/26/2022	X - 30-Day Notice	BULKAMID URETHRAL BULKING SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Alternate sub-supplier of a manufacturing raw material.
P170027/S010	10/27/2022	X - 30-Day Notice	THEROX DOWNSTREAM SYSTEM	THEROX, INC.	Supplier change of the TherOx® DownStream® Console Model DS-2 sub-assemblies due to impacts from COVID-19 pandemic.
P180040/S003	10/04/2022	X - 30-Day Notice	TRILURON	FIDIA FARMACEUTICI S.P.A.	Change to the storage condition for the sodium hyaluronate bulk powder.
P190008/S020	10/11/2022	X - 30-Day Notice	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Replicate a manufacturing line.
P190019/S014	10/12/2022	X - 30-Day Notice	RANGER¿ PACLITAXEL-COATED PTA BALLOON CATHETER	BOSTON SCIENTIFIC CORPORATION	Modified sampling plan for batch release tests.
P200015/S030	10/24/2022	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Implementation of Commander Delivery System Flex Shaft subassembly manufacturing at the Edwards Draper, UT facility.
P200030/S010	10/05/2022	X - 30-Day Notice	GORE EXCLUDER CONFORMABLE AAA ENDOPROSTHESIS (CEXC)	W. L. GORE AND ASSOCIATES, INC.	Implementation of changes to the lot acceptance sampling plan requirements for components that support the sealing cuff of the endoprosthesis.
P200037/S005	10/27/2022	X - 30-Day Notice	ASSURE WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) SYSTEM	KESTRA MEDICAL TECHNOLOGIES, INC.	Alternate diode and N-Channel MOSFET component to be used on the Therapy and H-Bridge PCBA.

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P210003/S002	10/12/2022	X - 30-Day Notice	ARCHITECT HBSAG NEXT QUALITATIVE REAGENT KIT, ARCHITECT HBSAG NEXT CONFIRMATORY REAGENT KIT, ARCHITECT HBSAG NEXT QUALITATIVE CALIBRATORS,	ABBOTT LABORATORIES	Add an additional supplier for a kit component.
P210032/S004	10/05/2022	X - 30-Day Notice	GORE TAG THORACIC BRANCH ENDOPROSTHESIS (TBE DEVICE)	W. L. GORE & ASSOCIATES, INC.	Implementation of changes to the lot acceptance sampling plan requirements for components that support the sealing cuff of the endoprosthesis.
P220003/S001	10/19/2022	X - 30-Day Notice	PASCAL PRECISION TRANSCATHETER VALVE REPAIR SYSTEM	EDWARDS LIFESCIENCES LLC	Change in yarn extruder and an additional bias cloth manufacturing step.

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