PMA Monthly approvals from 11/1/2022 to 11/30/2022

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P210027	11/23/2022	PMAO - PMA Origi	QDOT MICRO¿ SYSTEM	BIOSENSE WEBSTER, INC.	Approval for the Biosense Webster QDOT MICRO Catheter and related accessory devices. The device is indicated for catheter-based cardiac electrophysiological mapping (stimulating and recording) and, when used with a compatible RF generator, for the treatment of: 1) Type I atrial flutter in patients age 18 or older; and 2) Drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used with compatible three-dimensional electroanatomic mapping systems. The QDOT MICRO Catheter provides a real-time measurement of contact force between the catheter tip and heart wall, as well as location information when used with CARTO® 3 Navigation System.
P210039	11/04/2022	PMAO - PMA Origi r	CHOCOLATE TOUCH PACLITAXEL DRUG-COATED PTA BALLOON CATHETER (CHOCOLATE TOUCH)	TRIREME MEDICAL, LLC	Approval of the Chocolate Touch® (Paclitaxel Coated PTA Balloon Catheter). The device is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo or restenotic lesions up to 180 mm in length in native femoral or popliteal arteries with reference vessel diameters of 4.0 mm to 6.0 mm.
P220006	11/14/2022	PMAO - PMA Origi	VENTANA FOLR1 (FOLR-2.1) RXDX ASSAY	VENTANA MEDICAL SYSTEMS INC.	Approval for the VENTANA FOLR1 (FOLR1-2.1) RxDx Assay. The device is a qualitative immunohistochemical assay using mouse monoclonal anti-FOLR1, clone FOLR1-2.1, intended for use in the assessment of folate receptor alpha (FOLR1) protein in formalin-fixed, paraffin-embedded epithelial ovarian, fallopian tube or primary peritoneal cancer tissue specimens by light microscopy. This assay is for use with OptiView DAB IHC Detection Kit for staining on a BenchMark ULTRA instrument. FOLR1 expression clinical cut-off is >= 75% viable tumor cells (TC) with membrane staining at moderate and/or strong intensity levels. This assay is indicated as an aid in identifying patients with epithelial ovarian, fallopian tube, or primary peritoneal cancer who may be eligible for treatment with ELAHERE (mirvetuximab soravtansine). Test results of the VENTANA FOLR1 (FOLR1-2.1) RxDx Assay should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.

Total: 3

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S275	11/08/2022	R - Real-Time Proc	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Approval for a software maintenance release to update the Model 3869 Brady programmer software application and Accolade pulse generator firmware.
P840001/S525	11/02/2022	R - Real-Time Proc	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Approval for an update to the Model A71200 Clinician Programming Application to correct two field performance issues and address several software anomalies that prevent the device from performing as intended.
P860057/S207	11/16/2022	Y - 135 Review Tra	EDWARDS LIFESCIENCES PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Approval for an alternate supplier of a component of the solution used for in-process bioburden reduction.
P930014/S141	11/02/2022	O - Normal 180 Da	ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES	ALCON LABORATORIES, INC.	Approval for a manufacturing site located at: PT. Ciba Vision Batam Jalan Beringin Lot #204 Batamindo Industrial Park, Mukakuning, Batam Island 29433, Indonesia.
P940015/S050	11/04/2022	S - Special CBE	SYNVISC ONE	SANOFI GENZYME CORP.	Approval for revisions of the Synvisc® and Synvisc-One® physician labeling to include a warning statement regarding skin necrosis and the Synvisc® and Synvisc-One® patient labeling to include an advisory for the patient to inform his/her doctor in the event of development of a skin disorder after treatment.
P960040/S482	11/15/2022	R - Real-Time Proc	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Approval for changes to the package label and the instructions for use of the Bi-Directional Torque Wrench Model 6628.
P990009/S071	11/22/2022	S - Special CBE	FLOSEAL MATRIX/ FLOSEAL MATRIX HEMOSTATIC SEALANT/ PROCEED HEMOSTATIC SEALANT	BAXTER HEALTHCARE CORP.	Approval to add new information to the Warnings and Adverse Events Sections of the FLOSEAL Instructions for Use.
P990018/S007	11/16/2022	N - Normal 180 Day	MENICON Z RIGID GAS PERMEABLE CONTACT LENS	MENICON CO. LTD.	Approval for incorporation of a listed color additive for tisilfocon A, an alternative wet shipping solution for Menicon Z Night, shelf-life changes for Menicon Z Night, polymer specification changes for tisilfocon A, and labeling changes for Menicon Z EW and Menicon Z Night.
P990037/S036	11/04/2022	N - Normal 180 Day	VASCULAR SOLUTIONS DUETT SEALING DEVICE	VASCULAR SOLUTIONS, INC.	Approval for minor design and manufacturing changes to the D-Stat Flowable device diluent vial and packaging sealed tray.
P990075/S054	11/16/2022	Y - 135 Review Tra	MENTOR CORPORATION SALINE-FILLED AND SPECTRUM (R) MAMMARY PROSTHESES	MENTOR WORLDWIDE LLC	Approval for the use of an alternative mold release agent during the manufacturing of the injection domes of your Spectrum Breast Implants
P010012/S558	11/15/2022	R - Real-Time Proc	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Approval for changes to the package label and the instructions for use of the Bi-Directional Torque Wrench Model 6628.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030005/S220	11/08/2022	R - Real-Time Proc	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Approval for a software maintenance release to update the Model 3869 Brady programmer software application and Accolade pulse generator firmware.
P030011/S080	11/22/2022	N - Normal 180 Day	SYNCARDIA TEMPORARY CARDIO WEST TOTAL ARTIFICIAL HEART (TAH-T)	SYNCARDIA SYSTEMS, LLC	Approval for alternate Companion 2 battery printed circuit board assembly (PCBA) sub-components and a new mold for a component of the battery assembly.
P040014/S046	11/15/2022	O - Normal 180 Da	IBI THERAPY CARDIAC ABLATION SYSTEM ERS/ 1500T RF GENERATOR	IRVINE BIOMEDICAL, INC.	Approval for a manufacturing 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 for ethylene oxide sterilization activities.
P040042/S052	11/15/2022	O - Normal 180 Da	THERAPY DUAL 8 CARDIAC ABLATION SYSTEM,THERAM 8MM THERMISTER ABLATION CATHETER SAFIRE TX ABLATION CATHETER	IRVINE BIOMEDICAL,INC.(IBI)	Approval for a manufacturing 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 for ethylene oxide sterilization activities.
P050050/S023	11/22/2022	N - Normal 180 Day	SCANDINAVIAN TOTAL ANKLE REPLACEMENT SYSTEM (S.T.A.R.ANKLE)	DJO GLOBAL	Approval for STAR PSI System, and a new manufacturing facility at Medical Modeling, a 3D Systems Company, 5381 South Alkire Circle, Littleton, CO 80127.
P100018/S037	11/02/2022	R - Real-Time Proc	PIPELINE EMBOLIZATION DEVICE	MICRO THERAPEUTICS, INC. D/B/A EV3 NEUROVASCULAR	Approval for changes to the packaging for the box/carton and pouch materials, dimensions, and sealing equipment for the Pipeline Flex Embolization Device and Pipeline Flex Embolization Device with Shield Technology.
P100044/S050	11/04/2022	S - Special CBE	PROPEL	INTERSECT ENT	Approval for an additional control to ensure the spray coaters are running optimally during the manufacturing process.
P100046/S013	11/15/2022	N - Normal 180 Day	ATRICURE SYNERGY ABLATION SYSTEM	ATRICURE INC.	Approval for the AtriCure Multifunctional Ablation Generator (MAG) as part of the Synergy Ablation System for use with the Isolator® Synergy Clamp¿ (OLL2 and OSL2).
P110002/S032	11/09/2022	Y - 135 Review Tra	MOBI-C CERVICAL DISC PROSTHESIS (ONE-LEVEL INDICATION)	ZIMMER BIOMET SPINE, INC.	Approval for two new cutting oils that are to be used in machining processes at current supplier, In¿Tech Medical, sites.
P110009/S032	11/09/2022	Y - 135 Review Tra	MOBI-C CERVICAL DISC PROSTHESIS (TWO-LEVEL INDICATION)	ZIMMER BIOMET SPINE, INC.	Approval for two new cutting oils that are to be used in machining processes at current supplier, In¿Tech Medical, sites.
P120020/S028	11/22/2022	R - Real-Time Proc	SUPERA PERIPHERAL STENT SYSTEM	ABBOTT VASCULAR (IDEF TECHNOLOGIES INC)	Approval for a change in formulation and supplier of a delivery system tubing component.
P140020/S025	11/16/2022	S - Special CBE	BRACANALYSIS CDX	MYRIAD GENETIC LABORATORIES	Approval for the removal of the companion diagnostic indication for BRACAnalysis CDx to identify patients with ovarian, fallopian tube, or primary peritoneal cancer with homologous recombination deficiency (HRD) positive status for treatment with Lynparza® (olaparib) and Rubraca® (rucaparib).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140031/S140	11/16/2022	Y - 135 Review Tra	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for an alternate supplier of a component of the solution used for in-process bioburden reduction.
P150005/S072	11/21/2022	R - Real-Time Proc	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval for supplier and design changes to the Female Luer Lock Adaptor component on Open Irrigated Cardiac Ablation Catheters.
P150012/S129	11/08/2022	R - Real-Time Proc	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Approval for a software maintenance release to update the Model 3869 Brady programmer software application and Accolade pulse generator firmware.
P150013/S025	11/03/2022	R - Real-Time Proc	PD-L1 IHC 22C3 PHARMDX	AGILENT TECHNOLOGIES, INC.	Approval of the cut section storage recommendation for cervical cancer tissue will be updated, to change the recommended maximum duration of storage at 2-8ºC from 5 months to 2 months.
P150036/S061	11/16/2022	Y - 135 Review Tra	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Approval for an alternate supplier of a component of the solution used for in-process bioburden reduction.
P150038/S023	11/02/2022	R - Real-Time Proc	EXABLATE	INSIGHTEC	Approval for the addition of another sterile disposable head ring screws (DHRS) option, manufactured by INSIGHTEC and marketed under a name PFK (Patient Fixation Kit), as an accessory to Exablate Neuro system.
P150038/S024	11/11/2022	O - Normal 180 Da	EXABLATE	INSIGHTEC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P150048/S062	11/16/2022	Y - 135 Review Tra	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Approval for an alternate supplier of a component of the solution used for in-process bioburden reduction.
P160008/S020	11/23/2022	R - Real-Time Proc	HEARTSINE TECHNOLOGIES LLC'S SAMARITAN PUBLIC ACCESS AUTOMATED EXTERNAL DEFIBRILLATORS (SAM 350P, SAM 360P AND SAM 450P) AND ACCESSORIES	HEARTSINE TECHNOLOGIES, LTD.	Approval for minor design changes to the lead-free pogo pin components used in the SAM 350P, SAM 360P and SAM 450P defibrillators.
P170022/S001	11/30/2022	R - Real-Time Proc	PYLOPLUS UBT SYSTEM	ARJ MEDICAL INC.	Approval for the PyloPlus Urea Breath Test Pro Analyzer, PyloPlus Urea Breath Test Lab Analyzer and is indicated for The PyloPlus UBT system. The device, as modified, is intended for use in the qualitative detection of urease associated with H. pylori in the human stomach and is indicated as an aid in the initial diagnosis of H. pylori infection in adults 18 years old and older. The PyloPlus UBT system consists of the PyloPlus UBT Kit and the PyloPlus UBT analyzer. The analyzer is an infrared Spectrometer used for the measurement of the ratio of 13CO2 to 12CO2 in breath samples. The PyloPlus UBT system is for use by trained health care professionals as prescribed by a physician.
P170043/S013	11/07/2022	Y - 135 Review Tra	ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM (MODEL G2-M-IS)	GLAUKOS CORPORATION	Approval for a change in the sampling plan from 100% inspection to an applicable acceptable quality level (AQL) sampling plan for the singulators manufactured by Confluent.

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P180036/S012	11/14/2022	N - Normal 180 Day	OPTIMIZER SMART SYSTEM	IMPULSE DYNAMICS (USA), INC.	Approval for the OPTIhome Remote Patient Monitoring System and Patient App for use as accessories to the OPTIMIZER Smart Mini System.
P180046/S061	11/01/2022	N - Normal 180 Day	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for a manufacturing site located at Cirtec Medical Corporation, 99 Print Shop Road Enfield, CT 06082 as an alternate contract ethylene oxide sterilization facility for the Axonics Neurostimulator, Model 4101.
P190006/S061	11/01/2022	N - Normal 180 Day	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for a manufacturing site located at Cirtec Medical Corporation, 99 Print Shop Road Enfield, CT 06082 as an alternate contract ethylene oxide sterilization facility for the Axonics Neurostimulator, Model 4101.
P190014/S007	11/14/2022	S - Special CBE	MYCHOICE HRD CDX	MYRIAD GENETIC LABORATORIES, INC	Approved removal of the companion diagnostic indication for MyChoice® CDx to identify patients with ovarian, fallopian tube, or primary peritoneal cancer with homologous recombination deficiency (HRD) positive status for treatment with Zejula (niraparib).
P190023/S010	11/09/2022	R - Real-Time Proc	PORTICO TRANSCATHETER AORTIC VALVE IMPLANTATION SYSTEM	ABBOTT MEDICAL	Approval for modifications to the packaging design for the FlexNav Delivery System.
P190027/S005	11/09/2022	O - Normal 180 Day	TACK ENDOVASCULAR SYSTEM (4F, 1.5-4.5MM)	PHILIPS IMAGE GUIDED THERAPY CORPORATION (FORMERLY INTACT)	Approval for the post-approval labeling update to include the 36-month outcomes of the TOBA II BTK Post-Approval Study.
P200015/S018	11/16/2022	Y - 135 Review Tra	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Approval for an alternate supplier of a component of the solution used for in-process bioburden reduction.
P200020/S002	11/17/2022	O - Normal 180 Day	SBL-3 MULTIFOCAL INTRAOCULAR LENS	LENSTEC, INC.	Approval of the revised protocol for the post-approval study (PAS).
P200021/S013	11/04/2022	Y - 135 Review Tra	NEURO COCHLEAR IMPLANT SYSTEM	OTICON MEDICAL	Approval for increased temperature control of the brazing process of the implant assembly and adjustments to the in-process control methods for detecting hermeticity of the implant, for the Neuro Zti implant, as per the approval letter.
P200022/S009	11/02/2022	O - Normal 180 Day	SIMPLIFY® CERVICAL ARTIFICIAL DISC	NUVASIVE, INC.	Approval for the manufacturing site transfer to 805 Liberty Lane, West Carrollton (Dayton), Ohio, and 4670 East Shelby Drive, Memphis, Tennessee, for portions of the manufacturing activities for the Simplify® Cervical Artificial Disc.
P200028/S014	11/16/2022	O - Normal 180 Da	DIAMONDTEMP ABLATION SYSTEM	MEDTRONIC INC.	Approval for changes to the protocol inclusion and exclusion criteria.
P200036/S004	11/30/2022	O - Normal 180 Day	ECOIN PERIPHERAL NEUROSTIMULATOR	VALENCIA TECHNOLOGIES CORPORATION	Approval of the revised protocol for the post-approval study (PAS) - A Real World Study of eCoin for Urgency Urinary Incontinence: Post Approval Evaluation (RECIPE)

Total 46

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970012/S193	11/09/2022	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Modifying the foreign material inspection of the cylinder front tip AMS 700 components.
N970012/S194	11/14/2022	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Process change to add an automated device verification before the sterile packaging process.
P790002/S038	11/23/2022	X - 30-Day Notice	BIO OSTEOGEN SYSTEM 204	EBI, LLC	Qualify an alternate contract service provider to provide calibration services for instrumentation and lab equipment utilized to support manufacturing and quality operations.
P790005/S069	11/23/2022	X - 30-Day Notice	OSTEOSTIM(R)	EBI, LLC	Qualify an alternate contract service provider to provide calibration services for instrumentation and lab equipment utilized to support manufacturing and quality operations.
P830055/S300	11/14/2022	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Automation and electronic storage of the furnace cycles at the Load Furnace process step for Knee components of the LCS® Total Knee System.
P830055/S301	11/10/2022	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Removal of the high-pressure water cleaning sub-step from in-process cleaning for ATTUNE® Femoral PS (Posterior Stabilized) and CR (Cruciate Retaining) components
P830060/S088	11/02/2022	X - 30-Day Notice	VENTAK AND AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (AICD) SYSTEMS	BOSTON SCIENTIFIC	Replace laser printers, finished goods box and tray label stock.
P830061/S210	11/22/2022	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Relocation of the Chemical Operations area within the same manufacturing facility (Medtronic Energy and Component Center) for selected components.
P830063/S024	11/08/2022	X - 30-Day Notice	GAMBRO FIBER PLASMAFILTER	BAXTER INTERNATIONAL, INC.	Transfer of the manufacturing process of the Bubble up and the Bubble down components of the Prismaflex TPE2000 set to the Borla supplier manufacturing facility.
P840001/S531	11/16/2022	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Implement a new external function used in finished device manufacturing that will automate pass or fail decisions on global monitors.
P840001/S532	11/22/2022	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Add a larger facility to house the manufacturing operations of JunoPacific and Meier Toll and Engineering, which are both owned by Cretex Companies, within the same facility.

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P840001/S533	11/22/2022	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Separation of a manufacturing process, Bond Pad Array (EPA) Lid Removal, as a standalone process for better tracking at internal supplier Medtronic Tempe Campus (MTC); and the addition of a videoscope manufacturing equipment for improved process controls.
P850022/S031	11/23/2022	X - 30-Day Notice	ORTHOPAK(R) BONE GROWTH STIMULATOR	EBI, LLC	Qualify an alternate contract service provider to provide calibration services for instrumentation and lab equipment utilized to support manufacturing and quality operations.
P850035/S058	11/23/2022	X - 30-Day Notice	EBI SPF IMPLANTABLE SPINAL FUSION STIMULATOR	EBI, LLC	Qualify an alternate contract service provider to provide calibration services for instrumentation and lab equipment utilized to support manufacturing and quality operations.
P850089/S163	11/22/2022	X - 30-Day Notice	CAPSURE SP, CAPSURE, CAPSURE 2 LEADS, EXCELLENCE S, IMPULSE, IMPLUSE II EXCELLENCE SS, LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Relocation of the Chemical Operations area within the same manufacturing facility (Medtronic Energy and Component Center) for selected components.
P860004/S401	11/14/2022	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Implement a new laser welder for the SynchroMed II pumphead assembly at a first-tier supplier.
P890003/S458	11/22/2022	X - 30-Day Notice	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Relocation of the Chemical Operations area within the same manufacturing facility (Medtronic Energy and Component Center) for selected components.
P900056/S203	11/15/2022	X - 30-Day Notice	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Change to a sterilization Chamber at the Boston Scientific Corporation (BSC) Coventry Rhode Island facility.
P910073/S170	11/02/2022	X - 30-Day Notice	ENDOTAK LEAD SYSTEM	BOSTON SCIENTIFIC	Replace laser printers, finished goods box and tray label stock.
P910077/S189	11/02/2022	X - 30-Day Notice	VENTAK(R) PRX (TM) MODEL 1700,1705 PULSE GENERATOR	BOSTON SCIENTIFIC	Replace laser printers, finished goods box and tray label stock.
P920015/S273	11/22/2022	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Relocation of the Chemical Operations area within the same manufacturing facility (Medtronic Energy and Component Center) for selected components.
P920047/S129	11/15/2022	X - 30-Day Notice	EPT-1000 CARDIAC ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Change to a sterilization Chamber at the Boston Scientific Corporation (BSC) Coventry Rhode Island facility.
P930021/S029	11/16/2022	X - 30-Day Notice	BIORA EMDOGAIN(R)	THE STRAUMANN COMPANY	Improved settings for HPLC identification (ID) method for Emdogain (test method for in-process control and final release testing); 2) Removal of redundant Acetic acid content determination (release testing); 3) Removal of one redundant Calcium concentration determination (in-process control); and 4) Removal of redundant sampling step on Emdogain gel bulk(in-process control.
P930031/S070	11/22/2022	X - 30-Day Notice	WALLSTENT(R) TIPS ENDOPROSTHESIS WITH UNISTEP PLUS DELIVERY SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of an alternative heat seal coating to be used on the packaging.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P930031/S071	11/28/2022	X - 30-Day Notice	WALLSTENT(R) TIPS ENDOPROSTHESIS WITH UNISTEP PLUS DELIVERY SYSTEM	BOSTON SCIENTIFIC CORP.	New method for water bath sterilization.
P930035/S033	11/02/2022	X - 30-Day Notice	VENTAK(R) P2 SYSTEM	BOSTON SCIENTIFIC	Replace laser printers, finished goods box and tray label stock.
P930039/S247	11/22/2022	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Relocation of the Chemical Operations area within the same manufacturing facility (Medtronic Energy and Component Center) for selected components.
P940019/S061	11/22/2022	X - 30-Day Notice	WALLSTENT(R) ILIAC ENDOPROSTHESIS	BOSTON SCIENTIFIC SCIMED, INC.	Addition of an alternative heat seal coating to be used on the packaging.
P940019/S062	11/28/2022	X - 30-Day Notice	WALLSTENT(R) ILIAC ENDOPROSTHESIS	BOSTON SCIENTIFIC SCIMED, INC.	New method for water bath sterilization.
P950020/S128	11/15/2022	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Change to a sterilization Chamber at the Boston Scientific Corporation (BSC) Coventry Rhode Island facility.
P950020/S129	11/07/2022	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Add an additional blade casting cell.
P950020/S130	11/28/2022	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	New method for water bath sterilization.
P950020/S131	11/17/2022	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Relocation of bonding cell #2 to a different building.
P950024/S105	11/22/2022	X - 30-Day Notice	MEDTRONIC(R) CAPSURE (R) EPI PACING LEAD MODEL 4695	MEDTRONIC INC.	Relocation of the Chemical Operations area within the same manufacturing facility (Medtronic Energy and Component Center) for selected components.
P960004/S101	11/02/2022	X - 30-Day Notice	THINLINE ENDOCARDIAL PACING LEADS	BOSTON SCIENTIFIC	Replace laser printers, finished goods box and tray label stock.
P960006/S055	11/02/2022	X - 30-Day Notice	SWEET TIP(R) RX STEROID ELUTING LEAD	BOSTON SCIENTIFIC	Replace laser printers, finished goods box and tray label stock.
P960009/S441	11/16/2022	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Implement a new external function used in finished device manufacturing that will automate pass or fail decisions on global monitors.
P960009/S442	11/22/2022	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	to add a larger facility to house the manufacturing operations of JunoPacific and Meier Toll and Engineering, which are both owned by Cretex Companies, within the same facility
P960009/S443	11/22/2022	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Separation of a manufacturing process, Bond Pad Array (EPA) Lid Removal, as a standalone process for better tracking at internal supplier Medtronic Tempe Campus (MTC); and the addition of a videoscope manufacturing equipment for improved process controls.

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P970004/S375	11/16/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Implement a new external function used in finished device manufacturing that will automate pass or fail decisions on global monitors.
P970004/S376	11/22/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Add a larger facility to house the manufacturing operations of JunoPacific and Meier Toll and Engineering, which are both owned by Cretex Companies, within the same facility.
P970004/S377	11/22/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Separation of a manufacturing process, Bond Pad Array (EPA) Lid Removal, as a standalone process for better tracking at internal supplier Medtronic Tempe Campus (MTC); and the addition of a videoscope manufacturing equipment for improved process controls.
P980003/S094	11/15/2022	X - 30-Day Notice	CHILLI COOLED RF ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Change to a sterilization Chamber at the Boston Scientific Corporation (BSC) Coventry Rhode Island facility.
P980016/S839	11/03/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update supplier site location.
P980016/S841	11/22/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Relocation of the Chemical Operations area within the same manufacturing facility (Medtronic Energy and Component Center) for selected components.
P980033/S061	11/28/2022	X - 30-Day Notice	WALLSTENT ENDOPROSTHESIS	BOSTON SCIENTIFIC CORPORATION	New method for water bath sterilization.
P980035/S733	11/18/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implement an AI Vision System in the BPA lid removal process.
P980035/S734	11/22/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Relocation of the Chemical Operations area within the same manufacturing facility (Medtronic Energy and Component Center) for selected components.
P980035/S735	11/22/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Minor modifications for the battery case cover weld laser software and associated processes.
P980040/S152	11/17/2022	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Expansion of the manufacturing facility in building 3 of the Puerto Rico facility.

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P980050/S139	11/22/2022	X - 30-Day Notice	MEDTRONIC(R) JEWEL(R) AF 7250 DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATOR, MODEL 9961 PROGRAMMER APPLICATION SOF	MEDTRONIC INC.	Relocation of the Chemical Operations area within the same manufacturing facility (Medtronic Energy and Component Center) for selected components.
P990081/S050	11/10/2022	X - 30-Day Notice	PATHWAY ANTI-HCR-2/ NCU (4B5) RABBIT MONOCLONAL PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Changes to a manufacturing process.
P000053/S128	11/14/2022	X - 30-Day Notice	AMS SPHINCTER 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Process change to add an automated device verification before the sterile packaging process.
P010012/S564	11/02/2022	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Replace laser printers, finished goods box and tray label stock.
P010013/S088	11/02/2022	X - 30-Day Notice	NOVASURE IMPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM	HOLOGIC, INC.	Change in supplier of a wire component of Novasure Gen3.
P010015/S510	11/22/2022	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Relocation of the Chemical Operations area within the same manufacturing facility (Medtronic Energy and Component Center) for selected components.
P010015/S511	11/22/2022	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Minor modifications for the battery case cover weld laser software and associated processes.
P010031/S805	11/03/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update supplier site location.
P010031/S808	11/22/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Relocation of the Chemical Operations area within the same manufacturing facility (Medtronic Energy and Component Center) for selected components.

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P020004/S193	11/18/2022	X - 30-Day Notice	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Implementation of an external supplier for the extruded catheter components of the GORE EXCLUDER AAA Endoprosthesis and GORE EXCLUDER Iliac Branch Endoprosthesis.
P020025/S137	11/15/2022	X - 30-Day Notice	EP TECHNOLOGIES EPT-1000 XP RF ABLATION SYSTEM	BOSTON SCIENTIFIC	Change to a sterilization Chamber at the Boston Scientific Corporation (BSC) Coventry Rhode Island facility.
P020055/S028	11/10/2022	X - 30-Day Notice	VENTANA MEDICAL SYSTEMS PATHWAY ANTI-C-KIT (9.7) PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Changes to a manufacturing process.
P030017/S352	11/22/2022	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Add a 6-feet device storage requirement at the Final Pack Automated Test Equipment (ATE) functional test step for Implantable Pulse Generators at the Clonmel Ireland manufacturing site.
P030019/S027	11/08/2022	X - 30-Day Notice	ORTHOVISC HIGH MOLECULAR WEIGHT HYALURONAN	ANIKA THERAPEUTICS, INC.	Addition of an alternate supplier of fermented hyaluronic acid (HA) raw material for Orthovisc and Monovisc.
P030036/S140	11/22/2022	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Relocation of the Chemical Operations area within the same manufacturing facility (Medtronic Energy and Component Center) for selected components.
P030036/S141	11/28/2022	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement a mechanical de-gating fixture and to update in-process inspections at a direct supplier.
P040047/S066	11/29/2022	X - 30-Day Notice	COAPTITE	MERZ NORTH AMERICA, INC	Reduce the frequency of air particle sampling from the current three (3) times per month to one (1) time per month in the Merz Site 125 Cleanroom (Sturtevant, WI).
P040047/S067	11/30/2022	X - 30-Day Notice	COAPTITE	MERZ NORTH AMERICA, INC	Addition of a modular ancillary cleanroom for device manufacturing.
P050019/S036	11/28/2022	X - 30-Day Notice	CAROTID WALLSTENT MONORAIL ENDOPROSTHESIS	BOSTON SCIENTIFIC CORP.	New method for water bath sterilization.
P050028/S086	11/14/2022	X - 30-Day Notice	COBAS TAQMAN HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Removal of an in-process testing (IPT) from the manufacturing process.
P050037/S118	11/29/2022	X - 30-Day Notice	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Reduce the frequency of air particle sampling from the current three (3) times per month to one (1) time per month in the Merz Site 125 Cleanroom.
P050037/S119	11/30/2022	X - 30-Day Notice	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Addition of a modular ancillary cleanroom for device manufacturing.
P050052/S139	11/29/2022	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Reduce the frequency of air particle sampling from the current three (3) times per month to one (1) time per month in the Merz Site 125 Cleanroom.

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P050052/S140	11/30/2022	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Addition of a modular ancillary cleanroom for device manufacturing.
P060006/S104	11/15/2022	X - 30-Day Notice	BOSTON SCIENTIFIC EXPRESS SD RENAL MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Change to a sterilization Chamber at the Boston Scientific Corporation (BSC) Coventry Rhode Island facility.
P060039/S112	11/22/2022	X - 30-Day Notice	ATTAIN STARFIX MODEL 4195 LEAD	MEDTRONIC INC.	Relocation of the Chemical Operations area within the same manufacturing facility (Medtronic Energy and Component Center) for selected components.
P060040/S088	11/10/2022	X - 30-Day Notice	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Add an alternate supplier for the polyester mesh used in the manufacture of the HeartMate II Inflow Conduit subassembly.
P070008/S141	11/16/2022	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.	Alternate suppliers for several injection molded silicone parts used in Sentus QP left ventricular pacing leads.
P080006/S173	11/22/2022	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Relocation of the Chemical Operations area within the same manufacturing facility (Medtronic Energy and Component Center) for selected components.
P080011/S150	11/21/2022	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Update of post-autoclave sampling and packaging inspection regime of Biofinity MTS (Made To Stock) products manufactured at the CooperVision Manufacturing, Ltd. facility in Hamble, United Kingdom.
P080025/S270	11/16/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Implement a new external function used in finished device manufacturing that will automate pass or fail decisions on global monitors.
P080025/S271	11/22/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Add a larger facility to house the manufacturing operations of JunoPacific and Meier Toll and Engineering, which are both owned by Cretex Companies, within the same facility.
P080025/S272	11/22/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Separation of a manufacturing process, Bond Pad Array (EPA) Lid Removal, as a standalone process for better tracking at internal supplier Medtronic Tempe Campus (MTC); and the addition of a videoscope manufacturing equipment for improved process controls.
P090003/S053	11/28/2022	X - 30-Day Notice	EXPRESS LD ILIAC PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	New method for water bath sterilization.
P090013/S325	11/22/2022	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Relocation of the Chemical Operations area within the same manufacturing facility (Medtronic Energy and Component Center) for selected components.
P090031/S014	11/04/2022	X - 30-Day Notice	MONOVISC	ANIKA THERAPEUTICS, INC.	Changes to in-process testing and final formulation steps in the product manufacturing process.
P090031/S015	11/08/2022	X - 30-Day Notice	MONOVISC	ANIKA THERAPEUTICS, INC.	Addition of an alternate supplier of fermented hyaluronic acid (HA) raw material for Orthovisc and Monovisc.

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P100009/S049	11/20/2022	X - 30-Day Notice	MITRACLIP DELIVERY SYSTEM	ABBOTT MEDICAL	Modify the flexural rigidity acceptance criteria for the MitraClip delivery catheter shaft component.
P100010/S132	11/09/2022	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Addition of new process monitoring statistical process control software.
P100020/S054	11/14/2022	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Removal of an in-process testing (IPT) from the manufacturing process.
P100021/S108	11/01/2022	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Automation of a verification step undertaken by Sterile Release Personnel (SRP) for Limulus amebocyte lysate (LAL) Bacterial Endotoxin Testing (BET) prior to final release of product.
P100021/S109	11/30/2022	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Implementation of a graft coupon permeability specification for the Endurant Stent Graft System, Endurant II Stent Graft System, Eudurant IIs Stent Graft System and Endurant II Aorto-Uni-Iliac (AUI) Stent Graft System.
P100021/S110	11/28/2022	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Internal facility transfer of component extrusion and secondary cutting manufacturing operations.
P100027/S038	11/10/2022	X - 30-Day Notice	INFORM HER2 DUAL ISH DNA PROBE COCKTAIL	VENTANA MEDICAL SYSTEMS, INC.	Changes to a manufacturing process.
P100029/S047	11/29/2022	X - 30-Day Notice	ST JUDE MEDICAL TRIFECTA VALVE	ABBOTT MEDICAL	Modifications to a controlled access environment (CAE) and relocation of manufacturing processes within the CAE.
P100040/S053	11/01/2022	X - 30-Day Notice	VALIANT THORACIC STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Automation of a verification step undertaken by Sterile Release Personnel (SRP) for Limulus amebocyte lysate (LAL) Bacterial Endotoxin Testing (BET) prior to final release of product.
P100040/S054	11/28/2022	X - 30-Day Notice	VALIANT THORACIC STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Internal facility transfer of component extrusion and secondary cutting manufacturing operations.
P110002/S034	11/28/2022	X - 30-Day Notice	MOBI-C CERVICAL DISC PROSTHESIS (ONE-LEVEL INDICATION)	ZIMMER BIOMET SPINE, INC.	Additional raw material supplier.
P110009/S034	11/28/2022	X - 30-Day Notice	MOBI-C CERVICAL DISC PROSTHESIS (TWO-LEVEL INDICATION)	ZIMMER BIOMET SPINE, INC.	Additional raw material supplier.
P110010/S205	11/15/2022	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Change to a sterilization Chamber at the Boston Scientific Corporation (BSC) Coventry Rhode Island facility.
P110010/S206	11/28/2022	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	New method for water bath sterilization.

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P110020/S036	11/29/2022	X - 30-Day Notice	COBAS 4800 BRAF V600 MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Discontinuation of redundant pH testing for vialed Paraffin Binding Buffer.
P110020/S037	11/14/2022	X - 30-Day Notice	COBAS 4800 BRAF V600 MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Removal of an in-process testing (IPT) from the manufacturing process.
P110035/S068	11/07/2022	X - 30-Day Notice	EPIC SELF-EXPANDING NITINOL STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Move portions of the component level manufacturing into a new building at the Maple Grove, Minnesota BSC site.
P110037/S057	11/14/2022	X - 30-Day Notice	COBAS® AMPLIPREP/ COBAS® TAQMAN® CMV TEST (CAP/CTM CMV TEST)	ROCHE MOLECULAR SYSTEMS, INC.	Removal of an in-process testing (IPT) from the manufacturing process.
P120016/S030	11/08/2022	X - 30-Day Notice	VASCADE VASCULAR CLOSURE SYSTEM	CARDIVA MEDICAL, INC.	Alternative to batch testing for bacterial endotoxins.
P120019/S033	11/29/2022	X - 30-Day Notice	COBAS EGFR MUTATION TEST	ROCHE	Discontinuation of redundant pH testing for vialed Paraffin Binding Buffer.
P120019/S034	11/14/2022	X - 30-Day Notice	COBAS EGFR MUTATION TEST	ROCHE	Removal of an in-process testing (IPT) from the manufacturing process.
P130013/S055	11/07/2022	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Move portions of the component level manufacturing into a new building at the Maple Grove, Minnesota BSC site.
P130021/S123	11/03/2022	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Implement new manufacturing equipment for a component of the delivery catheter system.
P130021/S125	11/01/2022	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Implementation of process monitoring software in the manufacturing of the EnVeo PRO, Evolut PRO+, and Evolut FX delivery catheter subassemblies.
P130021/S126	11/01/2022	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Automation of a verification step undertaken by Sterile Release Personnel (SRP) for Limulus amebocyte lysate (LAL) Bacterial Endotoxin Testing (BET) prior to final release of product.
P130021/S127	11/28/2022	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Internal facility transfer of component extrusion and secondary cutting manufacturing operations.
P130030/S074	11/15/2022	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE	BOSTON SCIENTIFIC CORP.	Change to a sterilization Chamber at the Boston Scientific Corporation (BSC) Coventry Rhode Island facility.
P140002/S023	11/18/2022	X - 30-Day Notice	MISAGO PERIPHERAL SELF-EXPANDING STENT SYSTEM	TERUMO MEDICAL CORPORATIO N	Changes to the endotoxin testing reagent, detection equipment and water.

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P140010/S070	11/01/2022	X - 30-Day Notice	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.	Automation of a verification step undertaken by Sterile Release Personnel (SRP) for Limulus amebocyte lysate (LAL) Bacterial Endotoxin Testing (BET) prior to final release of product.
P140017/S023	11/28/2022	X - 30-Day Notice	MELODY TRANSCATHETER PULMONARY VALVE (TPV), ENSEMBLE TRANSCATHETER VALVE DELIVERY SYSTEM (DS)	MEDTRONIC INC.	Modifications to the tissue inspection process at tissue processing and valve assembly manufacturing steps.
P140018/S035	11/08/2022	X - 30-Day Notice	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Updates to the visual inspection criteria for the VenaSeal Adhesive vials.
P140019/S007	11/15/2022	X - 30-Day Notice	I-FACTOR PEPTIDE ENHANCED BONE GRAFT	CERAPEDICS, LLC	Change to the manufacturing process for i-FACTOR® Bone Graft to allow blending of up to four batches of P-15 coated anorganic bone mineral (ABM).
P140020/S024	11/10/2022	X - 30-Day Notice	BRACANALYSIS CDX	MYRIAD GENETIC LABORATORIES	Modification of a buffer.
P140023/S024	11/29/2022	X - 30-Day Notice	COBAS KRAS MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Discontinuation of redundant pH testing for vialed Paraffin Binding Buffer.
P140023/S025	11/14/2022	X - 30-Day Notice	COBAS KRAS MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Removal of an in-process testing (IPT) from the manufacturing process.
P140025/S020	11/10/2022	X - 30-Day Notice	VENTANA ALK (D5F3) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Changes to a manufacturing process.
P140028/S075	11/07/2022	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Move portions of the component level manufacturing into a new building at the Maple Grove, Minnesota BSC site.
P140031/S149	11/16/2022	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Modification to the in-process acceptance criteria and inspection method for tissue separations on the leaflet free edge of the SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA transcatheter heart valves.

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P150003/S089	11/28/2022	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	New method for water bath sterilization.
P150005/S073	11/15/2022	X - 30-Day Notice	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Change to a sterilization Chamber at the Boston Scientific Corporation (BSC) Coventry Rhode Island facility.
P150011/S026	11/21/2022	X - 30-Day Notice	PERCEVAL SUTURELESS HEART VALVE	CORCYM CANADA CORP.	Implement modifications to the sterilization cycle for Perceval accessories.
P150012/S135	11/02/2022	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Replace laser printers, finished goods box and tray label stock.
P150030/S028	11/18/2022	X - 30-Day Notice	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Introduction of a new cell line module into the R3 Shell production process.
P150031/S051	11/22/2022	X - 30-Day Notice	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Add a 6-feet device storage requirement at the Final Pack Automated Test Equipment (ATE) functional test step for Implantable Pulse Generators at the Clonmel Ireland manufacturing site.
P150033/S155	11/04/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Add traceability for the preform placement rework activities and to clarify the associated work instructions.
P150033/S156	11/03/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Update supplier site location.
P150033/S157	11/01/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Automation of a verification step undertaken by Sterile Release Personnel (SRP) for Limulus amebocyte lysate (LAL) Bacterial Endotoxin Testing (BET) prior to final release of product.
P150033/S158	11/14/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Several manufacturing process changes to the Micra Transcatheter Pacing System Accelerometer Activity Test System and Post Sterilization Test applications.
P150033/S159	11/15/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Minor manufacturing process changes to the Micra Transcatheter Pacing System.
P150033/S160	11/11/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Implement an alternative bacterial water testing method.
P150033/S163	11/28/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Update the end cap welder monitoring equipment at Medtronic Swiss Operations.
P160002/S019	11/10/2022	X - 30-Day Notice	VENTANA PD-L1(SP142) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Changes to a manufacturing process.

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P160008/S021	11/23/2022	X - 30-Day Notice	HEARTSINE TECHNOLOGIES LLC'S SAMARITAN PUBLIC ACCESS AUTOMATED EXTERNAL DEFIBRILLATORS (SAM 350P, SAM 360P AND SAM 450P) AND ACCESSORIES	HEARTSINE TECHNOLOGIES, LTD.	Implementation of a manufacturing process change to detect faulty membrane LED components in the testing of a printed circuit board assembly.
P160026/S035	11/10/2022	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.	Transfer of the supplier's manufacturing of the NIBP module component to another facility.
P160037/S011	11/19/2022	X - 30-Day Notice	BD ONCLARITY HPV ASSAY	BECTON, DICKINSON AND COMPANY	Modification to the circuit board layout on the instrumentation module.
P160043/S062	11/01/2022	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Automation of a verification step undertaken by Sterile Release Personnel (SRP) for Limulus amebocyte lysate (LAL) Bacterial Endotoxin Testing (BET) prior to final release of product.
P160043/S063	11/28/2022	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Internal facility transfer of component extrusion and secondary cutting manufacturing operations.
P160046/S015	11/10/2022	X - 30-Day Notice	VENTANA PD-L1 (SP263) ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Changes to a manufacturing process.
P160055/S026	11/30/2022	X - 30-Day Notice	LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Addition of an alternative foil pouch sealer.
P170036/S012	11/01/2022	X - 30-Day Notice	M6-C ARTIFICIAL CERVICAL DISC	SPINAL KINETICS LLC	Additional Cervical Instron Tester EQ 0180 and associated Bluehill software to increase manufacturing capacity.
P180011/S051	11/07/2022	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Move portions of the component level manufacturing into a new building at the Maple Grove, Minnesota BSC site.
P180031/S005	11/15/2022	X - 30-Day Notice	NEUROFORM ATLAS® STENT SYSTEM	STRYKER NEUROVASCULAR	Change to the in-process specification of the inner diameter of the nitinol stent component of the Neuroform Atlas Stent System,

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190008/S021	11/01/2022	X - 30-Day Notice	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Automation of a verification step undertaken by Sterile Release Personnel (SRP) for Limulus amebocyte lysate (LAL) Bacterial Endotoxin Testing (BET) prior to final release of product.
P190019/S015	11/10/2022	X - 30-Day Notice	RANGER¿ PACLITAXEL-COATED PTA BALLOON CATHETER	BOSTON SCIENTIFIC CORPORATION	Change to the cut to length manufacturing process.
P190019/S016	11/15/2022	X - 30-Day Notice	RANGER¿ PACLITAXEL-COATED PTA BALLOON CATHETER	BOSTON SCIENTIFIC CORPORATION	Change to a sterilization Chamber at the Boston Scientific Corporation (BSC) Coventry Rhode Island facility.
P190019/S017	11/23/2022	X - 30-Day Notice	RANGER¿ PACLITAXEL-COATED PTA BALLOON CATHETER	BOSTON SCIENTIFIC CORPORATION	Additional inspection equipment for markerbands.
P190024/S008	11/10/2022	X - 30-Day Notice	CINTEC PLUS CYTOLOGY	VENTANA MEDICAL SYSTEMS, INC.	Changes to a manufacturing process.
P190031/S007	11/10/2022	X - 30-Day Notice	HER2 DUAL ISH DNA PROBE COCKTAIL	VENTANA MEDICAL SYSTEMS, INC.	Changes to a manufacturing process.
P200014/S004	11/29/2022	X - 30-Day Notice	COBAS® EZH2 MUTATION TEST	ROCHE MOLECULAR SYSTEM, INC.	Discontinuation of redundant pH testing for vialed Paraffin Binding Buffer.
P200015/S031	11/16/2022	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Modification to the in-process acceptance criteria and inspection method for tissue separations on the leaflet free edge of the SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA transcatheter heart valves.
P200019/S006	11/10/2022	X - 30-Day Notice	VENTANA MMR RXDX PANEL	VENTANA MEDICAL SYSTEMS	Changes to a manufacturing process.
P200046/S012	11/01/2022	X - 30-Day Notice	HARMONY¿ TPV SYSTEM	MEDTRONIC, INC.	Automation of a verification step undertaken by Sterile Release Personnel (SRP) for Limulus amebocyte lysate (LAL) Bacterial Endotoxin Testing (BET) prior to final release of product.
P210001/S007	11/10/2022	X - 30-Day Notice	VENTANA MMR RXDX PANEL	VENTANA MEDICAL SYSTEMS INC (ROCHE TISSUE DIAGNOSTICS)	Changes to a manufacturing process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P210022/S002	11/28/2022	X - 30-Day Notice	ALINITY M CMV	ABBOTT MOLECULAR, INC.	Implement a large-scale manufacturing process for the Alinity m CMV AMP Tray 1.
P220003/S002	11/20/2022	X - 30-Day Notice	PASCAL PRECISION TRANSCATHETER VALVE REPAIR SYSTEM	EDWARDS LIFESCIENCES LLC	Implement a custom automated vision system for part detection on the packaging card during the pouch packaging and inspection process for the PASCAL Precision implant systems.

Total: 162