PMA Monthly approvals from 8/1/2022 to 8/31/2022

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P210003	08/10/2022	PMAO - PMA Origi	ARCHITECT HBSAG NEXT QUALITATIVE REAGENT KIT, ARCHITECT HBSAG NEXT CONFIRMATORY REAGENT KIT, ARCHITECT HBSAG NEXT QUALITATIVE CALIBRATORS,	ABBOTT LABORATORIES	Approval for the ARCHITECT HBsAg NEXT Qualitative Reagent Kit. The HBsAg Next Qualitative assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of Hepatitis B surface antigen (HBsAg) in human adult and pediatric (2 years to 21 years of age) serum, serum separator tube, and plasma (dipotassium EDTA, tripotassium EDTA, lithium heparin, lithium heparin separator, sodium heparin) on the ARCHITECT i System. The assay may also be used to screen for hepatitis B virus (HBV) infection in pregnant women to identify neonates who are at risk for acquiring hepatitis B during the perinatal period. Assay results, in conjunction with other laboratory results and clinical information, may be used to provide presumptive evidence of infection with HBV (state of infection or associated disease not determined) in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis B infection. **ARCHITECT HBsAg NEXT Confirmatory Reagent Kit** The HBsAg Next Confirmatory assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative confirmation of the presence of hepatitis B surface antigen (HBsAg) in human adult and pediatric (2 years to 21 years of age) serum, serum separator, and plasma (dipotassium EDTA, tripotassium EDTA, lithium heparin, lithium heparin separator, sodium heparin) by means of specific antibody neutralization on the **ARCHITECT i System** Assay results, in conjunction with other laboratory results and clinical information, may be used to provide presumptive evidence of infection with the hepatitis B virus (HBV) (state of infection or associated disease not determined) in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis B infection. It is intended to be used for the confirmation of samples found to be repeatedly reactive by HBsAg Next Qualitative. It is intended to be used for the confirmation of samples found to be repeatedly reactive by HBsAg Next Qualitative. **ARCHITECT HBsAg NEXT Qualitative Calibrators** The HBsAg Next Qualitative Calibrators are for the calibration of the ARCHITECT i System when used for qualitative determination and confirmation of the presence of hepatitis B surface antigen (HBsAg) in human serum and plasma. **ARCHITECT HBsAg NEXT Qualitative Controls** The HBsAg Next Qualitative Controls are for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT i System when used for the qualitative detection and for the confirmation of the presence of hepatitis B surface antigen (HBsAg) in human serum and plasma. **ARCHITECT HBsAg NEXT Confirmatory Manual Diluen**t The HBsAg Next Confirmatory Manual Diluent is used for manually diluting specimens for testing on the ARCHITECT i System.

Data as of 09/16/2022 04:59 AM

Supplements

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Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P790005/S068	08/25/2022	R - Real-Time Proc	OSTEOSTIM(R)	EBI, LLC	Approval for executing an ethylene oxide terminal sterilization process validation to align with applicable requirements of ISO 11135:2014 (14-529).
P830055/S293	08/11/2022	S - Special CBE	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval to change the verification of castings for implants during the manufacturing process for the LCS® Total Knee System, by including the tail code reconciliation as an additional verification step for manufacturing process.
P850035/S057	08/25/2022	R - Real-Time Proc	EBI SPF IMPLANTABLE SPINAL FUSION STIMULATOR	EBI, LLC	Approval for executing an ethylene oxide terminal sterilization process validation to align with applicable requirements of ISO 11135:2014 (14-529).
P860004/S395	08/19/2022	S - Special CBE	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval for labeling changes to the Catheter Access Port Kit of the SynchroMed Infusion System.
P900066/S014	08/04/2022	Y - 135 Review Tra	PERFLUOROPROPANE	AIRGAS THERAPEUTICS LLC	Approval to replace the gas chromatograph used to complete in-process quality testing during the distillation of the bulk perfluoropropane gas.
P910001/S116	08/19/2022	R - Real-Time Proc	SPECTRANECTICS CVX-300 EXCIMER LASER SYSTEM	SPECTRANETICS CORP.	Approval for implementing new catheter bonding materials.
P920015/S270	08/26/2022	O - Normal 180 Da	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Approval for addition of the summary for the Post Approval Study, Pacing Capture Threshold (PCT) Change Following 3T MRI Scan of MR Conditional CIEDs, to the labeling.
P930039/S244	08/26/2022	O - Normal 180 Da	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Approval for addition of the summary for the Post Approval Study, Pacing Capture Threshold (PCT) Change Following 3T MRI Scan of MR Conditional CIEDs, to the labeling.
P960009/S433	08/03/2022	O - Normal 180 Da	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval to 1) Change in Exclusion Criterion #4 to state Previous diagnosis of psychogenic/non-epileptic seizures within the 12 months prior to the Enrollment Visit; and 2) Change in Implant Eligibility Criterion #4 to state, Change to: No suicide attempt or other self-harm behaviors within past year (assessed by C-SSRS at 3-month CMM Visit).
P960040/S476	08/26/2022	O - Normal 180 Da	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Approval of the MANAGE-HF Post Approval Study (PAS) to be transitioned to the HeartLogic PAS Analysis Plan.
P970003/S233	08/12/2022	R - Real-Time Proc	VNS THERAPY SYSTEM	LIVANOVA USA, INC.	Approval for MR-conditional labeling for the VNS Model 1000-D SenTiva Duo Generator.
P970004/S344	08/30/2022	S - Special CBE	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Approval for a change to the labeling to prevent migration of the percutaneous extension connector.
P970004/S367	08/19/2022	R - Real-Time Proc	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Approval for a layout change to the L408 integrated circuit used in the model 97810 InterStim Micro Implantable Neurostimulator (INS) and model 97800 InterStim X INS

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P980016/S825	08/26/2022	O - Normal 180 Da y	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for addition of the summary for the Post Approval Study, Pacing Capture Threshold (PCT) Change Following 3T MRI Scan of MR Conditional CIEDs, to the labeling.
P980035/S721	08/26/2022	O - Normal 180 Da	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Approval for addition of the summary for the Post Approval Study, Pacing Capture Threshold (PCT) Change Following 3T MRI Scan of MR Conditional CIEDs, to the labeling.
P990018/S008	08/02/2022	N - Normal 180 Day	MENICON Z RIGID GAS PERMEABLE CONTACT LENS	MENICON CO. LTD.	Approval for an expanded range of myopia treatment of up to 6.00 diopters (manifest spherical equivalent).
P990034/S042	08/19/2022	S - Special CBE	MEDTRONIC ISOMED INFUSION SYSTEM	MEDTRONIC INC.	Approval of labeling changes for the Catheter Access Port Kit used with the IsoMed Infusion System
P010012/S552	08/26/2022	O - Normal 180 Da y	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Approval for the MANAGE-HF Post Approval Study (PAS) to be transitioned to the HeartLogic PAS Analysis Plan.
P010032/S187	08/19/2022	R - Real-Time Proc	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Approval for version 3.11 of the Clinician Programmer and Patient Controller applications which merge previously approved software features into a single version and include minor enhancements and administrative updates. This Real Time Review also requests approval for four new Proclaim SCS Implantable Pulse Generator (IPG) models (models 3670, 3671, 3672, and 3673).
P060037/S080	08/15/2022	S - Special CBE y	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Approval for revising device labeling, specifically package inserts, to implement the following changes: removal of re-sterilization information; addition of caution information for metal sensitivity and product cleanliness; addition of contact information for product compatibility questions; disclosure of residual risks with products; and addition of product disposal information.
P070006/S015	08/29/2022	N - Normal 180 Day	T SPOT-TB TEST	OXFORD IMMUNOTEC,L TD.	Approval for the T-Cell Select kit. The device is intended for use with the T-SPOT.TB test for the isolation of mononuclear immune cells from whole blood stored at room temperature (18 ¿ 25 °C), using positive selection via a magnetic bead-based cell separation system.
P070026/S086	08/10/2022	O - Normal 180 Da y	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDI CS, INC.	Approval for a manufacturing site located at Johnson & Johnson Medical (DePuy Suzhou) Ltd., No. 299, Changyang Street, Suzhou Industrial Park, Suzhou Jiangsu, China, as well as a sterilization site located at Shanghai JPY Ion-Tech. Co., Ltd, No. 1168, Huihin Rd., Quigpu Industrial Zone, Shanghai, China, to manufacture and sterilize SUMMIT Standard Offset Stems (Porous) Implants components of the CERAMAX® Ceramic Total Hip System.
P080011/S142	08/15/2022	O - Normal 180 Da	BIOFINITY (COMFILCON A)	COOPERVISIO N, INC.	Approval for a trade name change for CooperVision comfilcon A soft (hydrophilic) contact lenses for extended wear to Natural Eyes HydraWear XW Extended Parameters and Natural Eyes HydraWear XW for Astigmatism Extended Parameters.

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P080011/S144	08/15/2022	O - Normal 180 Day	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Approval for a trade name change for CooperVision comfilcon A soft (hydrophilic) contact lenses for extended wear: Sofmed breathables XW Extended Parameters and Sofmed breathables XW toric Extended Parameters.
P080025/S239	08/30/2022	S - Special CBE	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Approval for a change to the labeling to prevent migration of the percutaneous extension connector.
P080025/S262	08/19/2022	R - Real-Time Proc	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Approval for a layout change to the L408 integrated circuit used in the model 97810 InterStim Micro Implantable Neurostimulator (INS) and model 97800 InterStim X INS
P080030/S024	08/29/2022	N - Normal 180 Day	GLAUKOS ISTENT TRABECULAR BYPASS STENT MODEL GTS100R/L	GLAUKOS, CORPORATION	Approval for an alternate supplier and modifications to the specifications and incoming receiving testing for the stearalkonium heparin coating raw material.
P090013/S323	08/26/2022	O - Normal 180 Day	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Approval for addition of the summary for the Post Approval Study, Pacing Capture Threshold (PCT) Change Following 3T MRI Scan of MR Conditional CIEDs, to the labeling.
P090018/S041	08/24/2022	O - Normal 180 Da	ESTEEM TOTALLY IMPLANTABLE HEARING SYSTEM	ENVOY MEDICAL CORPORATION	Approval of final labeling changes for the post-approval study (PAS) referenced above. The updates to the final PAS labeling have been submitted to comply with the conditions of approval outlined in our approval order for P090018.
P100009/S045	08/08/2022	O - Normal 180 Day	MITRACLIP DELIVERY SYSTEM	ABBOTT MEDICAL	Approval for the addition of a manufacturing site located at 1820 Bastian Court, Westfield, Indiana, 46074.
P100049/S029	08/26/2022	Y - 135 Review Tra	LINX REFLUX MANAGEMENT SYSTEM	TORAX MEDICAL	Approval for the qualification of a new supplier to manufacture the washer, bead case-female, bead case-male and clasp case.
P110010/S201	08/18/2022	Y - 135 Review Tra	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the optimization of the Promus BHT analytical chemistry method's sample preparation and gas chromatography instrument conditions.
P130026/S077	08/17/2022	O - Normal 180 Da	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Approval for protocol (ABT-CIP-10436 Version A) for the post-approval study (PAS) protocol.
P140003/S102	08/18/2022	O - Normal 180 Day	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval of the protocol for the post-approval study (PAS) protocol.
P140009/S077	08/19/2022	R - Real-Time Proc	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Approval for version 3.11 of the Clinician Programmer and Patient Controller applications which merge previously approved software features into a single version and include minor enhancements and administrative updates. In addition, approval for four new Proclaim SCS Implantable Pulse Generator (IPG) models (models 3670, 3671, 3672, and 3673).
P140026/S023	08/19/2022	O - Normal 180 Day	ENROUTE TRANSCAROTID STENT SYSTEM	SILK ROAD MEDICAL, INC	Approval of the revised protocol for the ROADSTER 3 post-approval study (PAS) protocol.
P150004/S057	08/19/2022	R - Real-Time Proc	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Approval for version 3.11 of the Clinician Programmer and Patient Controller applications which merge previously approved software features into a single version and include minor enhancements and administrative updates. In addition, approval for four new Proclaim SCS Implantable Pulse Generator (IPG) models (models 3670, 3671, 3672, and 3673).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150012/S125	08/29/2022	O - Normal 180 Day	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Approval for updated clinical summary labeling for the INGEVITY+ leads.
P160024/S012	08/23/2022	O - Normal 180 Da	LIFESTREAM BALLOON EXPANDABLE VASCULAR COVERED STENT	BARD PERIPHERAL VASCULAR, INC.	Approval for a manufacturing site located at Angiomed GmbH & Co. Medizintechnik KG, Wachhausstrasse 6, Karlsruhe Baden-Wurttemberg 76227, Germany for supplying the bare metal stent component.
P160026/S030	08/05/2022	R - Real-Time Proc	LIFEPAK 1000 DEFIBRILLATOR, LIFEPAK 20 DEFIBRILLATOR/ MONITOR, LIFEPAK 20E DEFIBRILLATOR/ MONITOR, LIFEPAK 15 MONITOR/DEFIBRILLATOR, LIFEPAK 12 DEFIBRILLATOR/ MONITOR	PHYSIO-CONTROL. INC.	Approval for a design change associated with the existing NIBP module component of the LIFEPAK 15 monitor/defibrillator.
P160045/S035	08/11/2022	P - Panel Track	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Approval to expand the indications for use to include a companion diagnostic indication for the detection of ERBB2 activating mutations (SNVs and exon 20 insertions) in non-small cell lung cancer patients who may benefit from treatment with ENHERTU® (fam-trastuzumab deruxtecan-nxki).
P160045/S036	08/11/2022	Y - 135 Review Tra	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Approval to reduce the number of replicates assessed for quality control (QC) release testing.
P170011/S043	08/19/2022	O - Normal 180 Da	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval of the protocol for the post-approval study (PAS) protocol.
P170024/S010	08/05/2022	O - Normal 180 Day	SURPASS STREAMLINE FLOW DIVERTER	STRYKER NEUROVASCULAR	Approval for labeling changes to incorporate completed results from the post-approval study (PAS) titled Surpass Intracranial Aneurysm Embolization System Pivotal Trial to Treat Large or Giant Wide Neck Aneurysms (SCENT).
P170030/S022	08/31/2022	O - Normal 180 Da	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Approval for the PMA Post-Approval Study Labeling Update for the Orsiro and Orsiro Mission Siolimus Eluting Coronary Stent Systems.
P170043/S014	08/29/2022	N - Normal 180 Day	ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM (MODEL G2-M-IS)	GLAUKOS CORPORATION	Approval for an alternate supplier and modifications to the specifications and incoming receiving testing for the stearalkonium heparin coating raw material.
P180036/S015	08/18/2022	O - Normal 180 Da	OPTIMIZER SMART SYSTEM	IMPULSE DYNAMICS (USA), INC.	Approval of the revised Conditions of Approval for nonclinical MR testing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190002/S010	08/03/2022	R - Real-Time Proc	SALUDA MEDICAL EVOKE SCS SYSTEM	SALUDA MEDICAL PTY LTD	Approval for modifications to software and firmware intended to reduce programming time in patients with significant evoked compound action potential (ECAP) artifact or negative ECAP values by adding the ClearCAP feature as well as minor labeling changes which include providing appropriate instructions for the new ClearCAP feature, updating the Evoke Pocket Console (EPC) product name to Evoke Patient Controller, and labelling updates required for commercialization.
P190002/S011	08/09/2022	R - Real-Time Proc	SALUDA MEDICAL EVOKE SCS SYSTEM	SALUDA MEDICAL PTY LTD	Approval for alternate Surface Pro tablet models, SP6 and SP7+, to be used for the Clinical Interface due to obsolescence of previous models.
P200002/S002	08/16/2022	N - Normal 180 Day	EPI-SENSE GUIDED COAGULATION SYSTEM	ATRICURE, INC.	Approval for a modified version of the coagulation probe called EPi-Sense ST, a new radiofrequency (RF) cable for use with EPi-Sense ST, and a modified cannula for use with both EPi-Sense and EPi-Sense ST.
P200010/S008	08/11/2022	P - Panel Track	GUARDANT360 CDX	GUARDANT HEALTH, INC.	Approval for expanding the indications for use to include the companion diagnostic claim to identify non-small cell lung cancer patients with ERBB2 activating mutations (SNVs and exon 20 insertions) for treatment with ENHERTU (fam-trastuzumab deruxtecan-nxki).
P200015/S020	08/08/2022	O - Normal 180 Day	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Approval for a new e-beam sterilizer for the Alterra Adaptive Prestent System.
P200036/S001	08/17/2022	O - Normal 180 Da	ECOIN PERIPHERAL NEUROSTIMULATOR	VALENCIA TECHNOLOGIES CORPORATION	Approval for the Post-Approval Study of eCoin® for treatment of urgency urinary incontinence (UUI) which is designed to collect effectiveness and safety data in a post-approval setting.
P210006/S001	08/08/2022	O - Normal 180 Day	THORAFLEX¿ HYBRID	VASCUTEK LTD.	Approval of the protocol for the post-approval study (PAS) protocol.

Total: 54

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830055/S294	08/15/2022	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Manufacturing change to the inspection frequency from 100% to AQL 1.0 for CTQ inspection dimensions #2, #3, #4, #5, and #7 for the Attune Revision CRS RP insert reinforcing pins, which are components of the LCS® Total Knee System.
P840001/S524	08/26/2022	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Change to the surface finish inspection method.
P840039/S064	08/09/2022	X - 30-Day Notice	ULTRA VIOLET (UV) AND NON-UV ABSORBING PMMA INTRAOCULAR LENSES	BAUSCH & LOMB, INC.	Change in the tumble polishing formulation for the Polymethylmethacrylate (PMMA) Anterior Intraocular lenses (IOLs), Models L122UV and S122UV.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P930038/S100	08/26/2022	X - 30-Day Notice	ANGIO SEAL VASCULAR CLOSURE DEVICE	TERUMO MEDICAL CORPORATION	Replace a facility with an alternative facility that will conduct bioburden testing and sterility testing associated with routine dose audits.
P950018/S021	08/12/2022	X - 30-Day Notice	PERFLUORON (PURIFIED PERFLUORO-N-OCTANE LIQUID)	ALCON LABORATORIES	Adding an alternate supplier of potassium hydroxide.
P950022/S143	08/01/2022	X - 30-Day Notice	TVL(TM) LEAD SYSTEM	ABBOTT MEDICAL	Implementation of the automated system Vaisala EMS system for environmental and process equipment monitoring at the Rogers, Minnesota manufacturing site.
P950027/S016	08/08/2022	X - 30-Day Notice	HYALGAN(R)	FIDIA FARMACEUTICI SPA	Change from manual to automated syringe quality inspection.
P950037/S237	08/22/2022	X - 30-Day Notice	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Optimization of the automated Header Milling process.
P960009/S434	08/10/2022	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Add TSE/Ametek as an alternate supplier for the SenSight Lead Test Cable Kit and SenSight Extension Test Cable Kit.
P960009/S436	08/26/2022	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Change to the surface finish inspection method.
P960013/S121	08/01/2022	X - 30-Day Notice	TENDRIL DX MODEL 1388T & 1388K ENDOCARDIAL PACING LEADS	ABBOTT MEDICAL	Implementation of the automated system Vaisala EMS system for environmental and process equipment monitoring at the Rogers, Minnesota manufacturing site.
P960030/S076	08/01/2022	X - 30-Day Notice	PASSIVE PLUS DX ENDOCARDIAL STEROID ELUTING, PASSIVE-FIXATION PACING LEADS	ABBOTT MEDICAL	Implementation of the automated system Vaisala EMS system for environmental and process equipment monitoring at the Rogers, Minnesota manufacturing site.
P960043/S117	08/23/2022	X - 30-Day Notice	PROSTAR 9 FR. PERCUTANEOUS VASCULAR SURGICAL (PVS) SYSTEM	ABBOTT VASCULAR INC.	Qualification of manufacturing room (Suite 5) at a higher occupancy of equipment and personnel than the initial qualification.
P960058/S155	08/11/2022	X - 30-Day Notice	CLARION MULTI-STRATEGY COCHLEAR IMPLANT	ADVANCED BIONICS	Approval of a new facility at the supplier for the manufacturing of implant and headpiece magnets.
P970004/S370	08/04/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Alternate Adhesive Coating Material used in the packaging of leads and cable assemblies of the InterStim therapies of Medtronic Neuromodulation and Pelvic health business unit.
P970004/S372	08/26/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Change to the surface finish inspection method.
P970051/S213	08/09/2022	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Additional laser welding system for the top shell to shield welding process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S831	08/08/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Change to the energy window settings on laser equipment.
P980016/S832	08/16/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	New wafer bump service supplier for accelerometers.
P980016/S833	08/29/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Implementation of an AI vision system in the Direct Chip Attach (DCA) process.
P980016/S834	08/25/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Transfer manufacturing processes for the Multi Beam Contact assemblies to Brunk.
P980035/S725	08/09/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implementation of an automated optical inspection procedure of tantalum capacitors at the external supplier, Kyocera AVX Tantalum Corporation (AVX).
P980035/S726	08/23/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Change to the Laser Ribbon Bonding (LRB) welding energy operating range.
P980035/S727	08/26/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Change in the incoming inspection test method for two components at MECC.
P980052/S011	08/31/2022	X - 30-Day Notice	TMJ CONCEPTS PATIENT-FITTED TMJ RECONSTRUCTION PROSTHESIS	TMJ CONCEPTS	Addition of a back-up Ethylene Oxide Sterilizer.
P000006/S062	08/24/2022	X - 30-Day Notice	TITAN INFLATABLE PENILE PROSTHESIS	COLOPLAST CORP.	Addition of the Kinetic Turbidimetric method to perform Bacterial Endotoxin testing for the Titan Inflatable Penile Prosthesis (IPP).
P000037/S060	08/01/2022	X - 30-Day Notice	ON-X (R) PROSTHETIC HEART VALVE, MODEL ONXA	ON-X LIFE TECHNOLOGI ES, INC.	Alternate defoaming agent used in the manufacturing process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000054/S068	08/09/2022	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Replacement of the water purification system used in manufacture of the collagen sponge component.
P000058/S087	08/09/2022	X - 30-Day Notice	INFUSE BONE GRAFT/LT-CAGE LUMBAR TAPERED FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Replacement of the water purification system used in manufacture of the collagen sponge component.
P010013/S087	08/04/2022	X - 30-Day Notice	NOVASURE IMPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM	HOLOGIC, INC.	New supplier of WIR-00312 and WIR-00313 insulated wires for the Novasure Gen4.1 and V5 disposable devices.
P010015/S504	08/09/2022	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implementation of an automated optical inspection procedure of tantalum capacitors at the external supplier, Kyocera AVX Tantalum Corporation (AVX).
P010015/S505	08/26/2022	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Change in the incoming inspection test method for two components at MECC.
P010030/S160	08/18/2022	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Relocation of the automated electrical functional testing of Printed Circuit Assemblies performed during incoming inspection.
P010031/S797	08/08/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Change to the energy window settings on laser equipment.
P010031/S798	08/16/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	New wafer bump service supplier for accelerometers.
P010031/S799	08/29/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of an AI vision system in the Direct Chip Attach (DCA) process.

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P010031/S800	08/25/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Transfer manufacturing processes for the Multi Beam Contact assemblies to Brunk.
P020003/S010	08/24/2022	X - 30-Day Notice	COLOPLAST SALINE-FILLED TESTICULAR PROSTHESIS	COLOPLAST CORP.	Addition of the Kinetic Turbidimetric method to perform Bacterial Endotoxin testing for the Coloplast Saline-Filled Testicular Prosthesis (Torosa).
P020004/S190	08/31/2022	X - 30-Day Notice	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,I NC	Implementation of updates to the Radio Frequency bonding equipment used in the manufacturing of the GORE Excluder AAA and Iliac Branch Endoprostheses.
P020012/S041	08/05/2022	X - 30-Day Notice	ARTEFILL, BELLAFILL PMMA COLLAGEN PERMANENT DERMAL FILLER	SUNEVA MEDICAL, INC.	Implementing an alternate particle testing method as the primary test method for PMMA microsphere count and size distribution testing.
P020045/S101	08/24/2022	X - 30-Day Notice	7F FREEZOR CARDIAC CRYOABLATION CATHETER AND CCT.2 CRYOCONSOLE SYSTEM	MEDTRONIC CRYOCATH LP	Manufacturing and supplier changes to the female coaxial connector and female coaxial fitting of the Arctic Front Advance (AFA), Arctic Front Advance Pro (AFA Pro), Freezor, Freezor Xtra, and Freezor MAX cryoablation catheters.
P030022/S049	08/08/2022	X - 30-Day Notice	REFLECTION CERAMIC ACETABULAR SYSTEM	SMITH & NEPHEW, INC.	Change to replace the existing grinding and buffing wheels utilized in the polishing process with size-specific custom wheels for the R3 acetabular shells.
P030054/S400	08/01/2022	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ABBOTT MEDICAL	Implementation of the automated system Vaisala EMS system for environmental and process equipment monitoring at the Rogers, Minnesota manufacturing site.
P040027/S092	08/24/2022	X - 30-Day Notice	GORE VIATORR TIPS	W. L. GORE & ASSOCIATES, INC.	Alternate manufacturing location of extruded components of the catheter sub-assembly for the GORE VIATORR TIPS Endoprosthesis and GORE VIATORR TIPS Endoprosthesis with Controlled Expansion.
P050047/S086	08/05/2022	X - 30-Day Notice	JUVEDERM 24HV, JUVEDERM 30 AND JUVEDERM 30HV GEL IMPLANTS	ALLERGAN	Implementing an additional duplicate syringe assembly and packaging line for manufacturing Juvéderm injectable gel products.
P050053/S059	08/09/2022	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC INC.	Replacement of the water purification system used in manufacture of the collagen sponge component.
P060011/S030	08/15/2022	X - 30-Day Notice	C-FLEX MODEL 570C INTRAOCULAR LENS (IOL)	RAYNER INTRAOCULA R LENSES LTD.	Changes to the endotoxin test sample preparation, test method, and sampling plan for routine release testing.
P070008/S138	08/22/2022	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.	Optimization of the automated Header Milling process.
P070026/S101	08/26/2022	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDI CS, INC.	Process change by introducing new sealing parameters and the use of six (6) cavities as opposed to the current four (4) cavitie.

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P080011/S147	08/08/2022	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Installation and qualification of three Gas Chromatography (GC) replacement equipment at the CooperVision Manufacturing Puerto Rico, LLC facility.
P080011/S148	08/18/2022	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Addition of Biofinity XR Toric and Biofinity Toric Multifocal N-Type lenses on the Biofinity Made-to-Order (MTO) manufacturing Line 3 at the CooperVision, Inc. facility in Scottsville, NY. Biofinity.
P080025/S265	08/04/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Alternate Adhesive Coating Material used in the packaging of leads and cable assemblies of the InterStim therapies of Medtronic Neuromodulation and Pelvic health business unit.
P080025/S267	08/26/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Change to the surface finish inspection method.
P090003/S052	08/25/2022	X - 30-Day Notice	EXPRESS LD ILIAC PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Relocation of the Express LD manufacturing line.
P100009/S046	08/16/2022	X - 30-Day Notice	MITRACLIP DELIVERY SYSTEM	ABBOTT MEDICAL	Implement a revised sampling plan for torque strength testing of the Press-Fit Assembly of the MitraClip G4 Clip Delivery System 01410.
P100010/S129	08/24/2022	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Manufacturing and supplier changes to the female coaxial connector and female coaxial fitting of the Arctic Front Advance (AFA), Arctic Front Advance Pro (AFA Pro), Freezor, Freezor Xtra, and Freezor MAX cryoablation catheters.
P100021/S105	08/16/2022	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Changes to inspection methods for the delivery system manufacturing process.
P110029/S037	08/10/2022	X - 30-Day Notice	ARCHITECT HBSAG QUALITATIVE, QUALITATIVE CONFIRMATORY, CONFIRMATORY MANUAL DILUENT, CALIBRATORS, AND CONTROLS	ABBOTT LABORATORIES	Increasing batch size for a critical bulk material.
P110033/S067	08/05/2022	X - 30-Day Notice	JUVEDERM VOLUMA XC	ALLERGAN	Implementing an additional duplicate syringe assembly and packaging line for manufacturing Juvéderm injectable gel products.
P110038/S026	08/11/2022	X - 30-Day Notice	RELAY THORACIC STENT-GRAFT WITH PLUS DELIVERY SYSTEM	BOLTON MEDICAL, INC.	Replacement of manufacturing equipment for a delivery system component of RelayPro and RelayPlus Thoracic Stent-Graft Systems.
P130008/S088	08/19/2022	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Additional qualified supplier for barium titanate.
P130017/S054	08/03/2022	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Manufacturing process change for a component of Cologuard.
P130021/S119	08/03/2022	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Re-validation of an existing cleanroom.

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P130026/S079	08/31/2022	X - 30-Day Notice	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	New visual inspection to identify twists in the catheter fluid lumen in both the TactiCath SE Uni-Directional and Bi-Directional Handle Assembly manufacturing procedures.
P140003/S103	08/31/2022	X - 30-Day Notice	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Change to the bonding process between the pressure reservoir and check valve components in the pressure storage set assembly.
P140017/S022	08/03/2022	X - 30-Day Notice	MELODY TRANSCATHETER PULMONARY VALVE (TPV), ENSEMBLE TRANSCATHETER VALVE DELIVERY SYSTEM (DS)	MEDTRONIC INC.	Re-validation of an existing cleanroom.
P140028/S074	08/29/2022	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Move the secondary assembly, inspection and packaging of proximal inner parts to a new facility.
P140033/S074	08/01/2022	X - 30-Day Notice	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ABBOTT MEDICAL	Implementation of the automated system Vaisala EMS system for environmental and process equipment monitoring at the Rogers, Minnesota manufacturing site.
P150010/S002	08/08/2022	X - 30-Day Notice	HYMOVIS	FIDIA FARMACEUTICI	Change from manual to automated syringe quality inspection.
P150030/S023	08/08/2022	X - 30-Day Notice	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Change to replace the existing grinding and buffing wheels utilized in the polishing process with size-specific custom wheels for the R3 acetabular shells.
P150033/S149	08/16/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	New wafer bump service supplier for accelerometers.
P150048/S066	08/01/2022	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Additional inspection following valve assembly.
P160026/S033	08/16/2022	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.	Updates to the suppliers jumper wire insertion process for the QUIK-COMBO therapy cable accessory.
P160035/S027	08/04/2022	X - 30-Day Notice	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Removing the additional output test in the EXCOR blood pumps production line.

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P160035/S028	08/12/2022	X - 30-Day Notice	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Manufacturing change to the printed circuit board used in the Berlin Heart EXCOR IKUS Driver.
P160035/S030	08/30/2022	X - 30-Day Notice	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Change in the heparin coating supplier manufacturing site for the Berlin Heart EXCOR Pediatric Ventricular Assist Device.
P160035/S031	08/24/2022	X - 30-Day Notice	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Changes in the production steps of the inflow and outflow valves of the Berlin Heart EXCOR Pediatric VAD blood pump.
P160038/S023	08/30/2022	X - 30-Day Notice	PRAXIS EXTENDED RAS PANEL	ILLUMINA, INC.	Change the supplier material for manufacturing.
P170006/S021	08/03/2022	X - 30-Day Notice	AVALUS(TM) BIOPROSTHESIS	MEDTRONIC INC.	Re-validation of an existing cleanroom.
P170011/S045	08/31/2022	X - 30-Day Notice	IMPELLA RP SYSTEM	ABIOMED, INC.	Change to the bonding process between the pressure reservoir and check valve components in the pressure storage set assembly.
P170023/S009	08/05/2022	X - 30-Day Notice	BULKAMID URETHRAL BULKING SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Alternate sub-suppliers of a manufacturing raw material.
P170023/S010	08/05/2022	X - 30-Day Notice	BULKAMID URETHRAL BULKING SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Alternate sub-supplier of a raw material.
P170023/S011	08/05/2022	X - 30-Day Notice	BULKAMID URETHRAL BULKING SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Alternate sub-supplier of a manufacturing raw material.
P170030/S026	08/05/2022	X - 30-Day Notice	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Modification to polymer batch characterization methods.
P180011/S050	08/29/2022	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Move the secondary assembly, inspection and packaging of proximal inner parts to a new facility.
P180040/S002	08/08/2022	X - 30-Day Notice	TRILURON	FIDIA FARMACEUTICI S.P.A.	Change from manual to automated syringe quality inspection.
P180047/S018	08/11/2022	X - 30-Day Notice	LIAISON QUANTIFERON - TB GOLD PLUS, LIAISON CONTROL QUANTIFERON - TB GOLD PLUS AND LIAISON QUANTIFERON SOFTWARE	DIASORIN, INC.	Transfer of manufacturing activities for an instrument component.
P190023/S009	08/01/2022	X - 30-Day Notice	PORTICO TRANSCATHETER AORTIC VALVE IMPLANTATION SYSTEM	ABBOTT MEDICAL	Process changes to ensure retainer alignment to the delivery system handle.

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P200030/S009	08/16/2022	X - 30-Day Notice	GORE EXCLUDER CONFORMABLE AAA ENDOPROSTHESIS (CEXC)	W. L. GORE AND ASSOCIATES, INC.	Modifications to the thermal treatment process for sealing cuffs of the Gore Excluder Conformable AAA Endoprosthesis.
P200045/S003	08/11/2022	X - 30-Day Notice	RELAYPRO THORACIC STENT-GRAFT SYSTEM	BOLTON MEDICAL, INC.	Replacement of manufacturing equipment for a delivery system component of RelayPro and RelayPlus Thoracic Stent-Graft Systems.
P200046/S010	08/03/2022	X - 30-Day Notice	HARMONY¿ TPV SYSTEM	MEDTRONIC, INC.	Re-validation of an existing cleanroom.
P210032/S003	08/05/2022	X - 30-Day Notice	GORE TAG THORACIC BRANCH ENDOPROSTHESIS (TBE DEVICE)	W. L. GORE & ASSOCIATES, INC.	Removal of cytotoxicity and infrared spectroscopy inspections for incoming components and to modify the ovens used to manufacture sidebranch catheter assembly.

Total: 92