PMA Monthly approvals from 1/1/2023 to 1/31/2023

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170001	01/11/2023	PMAO - PMA Origi	VIRTIS SACRAL NEUROMODULATION SYSTEM	CIRTEC MEDICAL CORPORATIO N	Approval for the Virtis Sacral Neuromodulation System. This device is indicated for the treatment of urinary retention and the symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments.

Total: 1

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P900060/S062	01/13/2023	Y - 135 Review Tra	CARBOMEDICS PROSTHETIC HEART VALVE (CPHV)	CORCYM S.R.L.	Approval for a 3rd tier sub-supplier change for the raw PTFE felt material used in the sewing ring of the devices.
P950037/S242	01/12/2023	R - Real-Time Proc	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Approval for programmer software versions PSW 2202.U and NEO 2202.U.
P960043/S120	01/31/2023	Y - 135 Review Tra	PROSTAR 9 FR. PERCUTANEOUS VASCULAR SURGICAL (PVS) SYSTEM	ABBOTT VASCULAR INC.	Approval for a change in supplier's adhesive formulation and manufacturing.
P980023/S113	01/20/2023	N - Normal 180 Day	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Approval for design changes to the Plexa lead family, resulting in the Pamira lead family.
P980023/S118	01/16/2023	O - Normal 180 Da	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Approval for updated labeling to include a clinical summary for the Protego DF4 Post Approval Registry.
P990004/S056	01/31/2023	Y - 135 Review Tra	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Approval for implementation of a new gelatin processing line (consisting of a gelatin preparation tank, whipping equipment and plating head and table) and three (3) new drying ovens.
P990071/S055	01/24/2023	N - Normal 180 Day	STOCKERT 70 RADIOFREQUENCY ABLATION GENERATOR	BIOSENSE WEBSTER, INC.	Approval for alternate components; changes in sterilization monitoring; an alternate physical manufacturing site at Harmac Medical Products, Inc. H3 de Tijuana S. de RL de CV Calle Maquiladoras No. 320-A Col. Ciudad Industrial Nueva Tijuana CP 22500 Mexico; and an alternate sterilization site at STERIS AST, 1000 Sarah Place, Ontario, CA 91761 USA.
P000009/S100	01/12/2023	R - Real-Time Proc	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Approval for programmer software versions PSW 2202.U and NEO 2202.U.

Data as of 02/03/2023 04:01 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010030/S158	01/17/2023	R - Real-Time Proc	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Approval for design changes to the therapy electrode that include increasing the strength of the ring seals, transition from solid leads to stranded leads and removal of a redundant component.
P010030/S161	01/30/2023	R - Real-Time Proc	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Approval to increase the capacitance values from 2200nF to 4700nF in capacitors C27 and C28 of the LifeVest Wearable Defibrillator to reduce signal noise
P010032/S189	01/24/2023	P - Panel Track	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Approval for expanding the indications to include diabetic peripheral neuropathy (DPN) of the lower extremities for the tonic stimulation mode.
P010033/S048	01/24/2023	R - Real-Time Proc	QUANTTFERON-TB GOLD AND TB GOLD-IN-THE-TUBE	QIAGEN	Approval of the addition of Sodium Heparin tubes as an alternative for blood collection in the workflow of the Quantiferon TB Gold Plus Test
P030026/S037	01/24/2023	R - Real-Time Proc	VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBC IGM REAGENT PAK/ CALIBRATOR	ORTHO-CLINICAL DIAGNOSTICS, INC.	Approval for revisions to the package insert to include information on biotin interference.
P040012/S064	01/31/2023	Y - 135 Review Tra	ACCULINK CAROTID STENT SYSTEM AND RX ACCULINK CAROTID STENT SYSTEM	ABBOTT VASCULAR	Approval for a change in supplier's adhesive formulation and manufacturing.
P040034/S033	01/25/2023	N - Normal 180 Day	DURASEAL DURAL SEALANT SYSTEM	INTEGRA LIFESCIENCES CORPORATION	approval for changes to the polycarbonate resin for the spray tip and Y-connector components and to extend the shelf life from 18 months to 24 months for the DuraSeal Dural Sealant System and the DuraSeal Exact Spine Sealant System
P040038/S041	01/31/2023	Y - 135 Review Tra	XACT CAROTID STENT SYSTEM	ABBOTT VASCULAR INC.	Approval for a change in supplier's adhesive formulation and manufacturing.
P040043/S132	01/12/2023	S - Special CBE	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Approval for implementation of updates to the warnings and MR compatibility information in the Instructions for Use (IFU) and patient implant card.
P040047/S064	01/24/2023	Y - 135 Review Tra	COAPTITE	MERZ NORTH AMERICA, INC	Approval for the addition of a secondary deionized water heater system.
P040047/S065	01/06/2023	Y - 135 Review Tra	COAPTITE	MERZ NORTH AMERICA, INC	Approval for a change in the order of the Quality Control Plan II testing within the calcium hydroxylapatite (CaHA) particle production process.
P050007/S043	01/31/2023	Y - 135 Review Tra	STARCLOSE VASCULAR CLOSURE SYSTEM	ABBOTT VASCULAR DEVICES	Approval for a change in suppliers adhesive formulation and manufacturing.
P050023/S169	01/12/2023	R - Real-Time Proc	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval for programmer software versions PSW 2202.U and NEO 2202.U.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P050023/S170	01/16/2023	O - Normal 180 Da	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval for updated labeling to include a clinical summary for the Protego DF4 Post Approval Registry.
P050026/S002	01/20/2023	N - Normal 180 Day	QUANTEL ACTIVIS LASER AND ZSL30 ACT, ZSL120 ACT, AND HSBMBQ ACT SLIT LAMP ADAPTERS	BAUSCH + LOMB IRELAND LIMITED	Approval for the following changes: 1) Add a new laser source, Modulight ML6710i Laser, and the related slit-lamp adapter, ML-SLA; 2) Change the device name to Quantel Activis Laser, Modulight ML6710i Laser and ML-SLA, ZSL30 ACT, ZSL120 ACT, and HSBMBQ ACT Slit Lamp Adapters; and 3) Add the following manufacturing facility where Modulight ML6710i Laser and ML-SLA are produced: Modulight, Inc. Hermiankatu 22, Tampere, 33720 FINLAND
P050037/S116	01/24/2023	Y - 135 Review Tra	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Approval for the addition of a secondary deionized water heater system.
P050037/S117	01/06/2023	Y - 135 Review Tra	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Approval for a change in the order of the Quality Control Plan II testing within the calcium hydroxylapatite (CaHA) particle production process.
P050052/S137	01/24/2023	Y - 135 Review Tra	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval for the addition of a secondary deionized water heater system.
P050052/S138	01/06/2023	Y - 135 Review Tra	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval for a change in the order of the Quality Control Plan II testing within the calcium hydroxylapatite (CaHA) particle production process.
P060040/S089	01/10/2023	R - Real-Time Proc	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Approval for a software update to the HeartMate Touch Communication (HM Touch) Application software to fix two anomalies and add eleven new language translations.
P070004/S016	01/03/2023	O - Normal 180 Da	SIENTRA SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Approval for revisions to the labeling to include the 10 year clinical study results.
P070008/S143	01/12/2023	R - Real-Time Proc	STRATOS LV CRT-P AND STRATOS LV-T CRT-P, COROX OTW BP LEAD AND COROX OTW-S BP LEAD	BIOTRONIK, INC.	Approval for programmer software versions PSW 2202.U and NEO 2202.U.
P080013/S022	01/25/2023	N - Normal 180 Day	DURASEAL EXACT SPINE SEALANT SYSTEM	INTEGRA LIFESCIENCES CORPORATION	Approval for changes to the polycarbonate resin for the spray tip and Y-connector components and to extend the shelf life from 18 months to 24 months for the DuraSeal Dural Sealant System and the DuraSeal Exact Spine Sealant System.
P090028/S018	01/24/2023	R - Real-Time Proc	VITROS IMMUNODIAGNOSTIC PRODUCTS HBEAG REAGENT PACK/ PRODUCTS HBEAG CALIBRATOR/PRODUCTS HBE CONTROLS	ORTHO-CLINICAL DIAGNOSTICS, INC.	Approval for revisions to the package insert to include information on biotin interference.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100001/S017	01/24/2023	R - Real-Time Proc	VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBE REAGENT PACK/ANTI-HBE CALIBRATOR/ANTI HBE CONTROLS	ORTHO-CLINICAL DIAGNOSTICS	Approval for revisions to the package insert to include information on biotin interference.
P110002/S033	01/12/2023	Y - 135 Review Tra	MOBI-C CERVICAL DISC PROSTHESIS (ONE-LEVEL INDICATION)	ZIMMER BIOMET SPINE, INC.	Approval for qualifying alternative detergents Deconex MT12 & MT13 used for cleaning of the Mobi-C implant and a sub-supplier change to KEYBIO.
P110009/S033	01/12/2023	Y - 135 Review Tra	MOBI-C CERVICAL DISC PROSTHESIS (TWO-LEVEL INDICATION)	ZIMMER BIOMET SPINE, INC.	Approval for qualifying alternative detergents Deconex MT12 & MT13 used for cleaning of the Mobi-C implant and a sub-supplier change to KEYBIO.
P110028/S023	01/31/2023	Y - 135 Review Tra	ABSOLUTE PRO VASCULAR SELF-EXPANDING STENT SYSTEM	ABBOTT VASCULAR INC.	Approval for a change in supplier's adhesive formulation and manufacturing.
P110038/S027	01/20/2023	S - Special CBE	RELAY THORACIC STENT-GRAFT WITH PLUS DELIVERY SYSTEM	BOLTON MEDICAL, INC.	Approval for implementation of updates to the procedural guidance in the Instructions for Use (IFU) and MR compatibility information in the IFU and patient implant card.
P120005/S090	01/12/2023	O - Normal 180 Da	DEXCOM G4 PLATINUM CONTIUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Approval to modify the prior inclusion criterion to the following: Clinical diagnosis of Type 1 or Type 2 diabetes with at least one (1) week of insulin initiation at time of study entry.
P120020/S030	01/31/2023	Y - 135 Review Tra	SUPERA PERIPHERAL STENT SYSTEM	ABBOTT VASCULAR (IDEF TECHNOLOGIES INC)	Approval for a change in supplier's adhesive formulation and manufacturing.
P130013/S053	01/20/2023	R - Real-Time Proc	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Approval for changing the location of the wall thickness measurement on the WATCHMAN FLX implant and modifying the 20mm implant size wall thickness specification
P130013/S056	01/20/2023	R - Real-Time Proc	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Approval for an increase in the filter fabric length for each device size along with several other associated minor changes related to the increase in fabric length.
P130022/S045	01/27/2023	R - Real-Time Proc	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for use of an alternate Contego 440 proposed battery component for the IPG2500 device of the Senza System.
P140003/S106	01/06/2023	R - Real-Time Proc	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for various labeling updates regarding arterial access and timing of Impella use in the setting of acute myocardial infarction complicated by cardiogenic shock.
P140031/S151	01/20/2023	O - Normal 180 Da	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for a manufacturing site located at 35 Changi North Crescent, Changi South East, SG 499641 (Edwards Lifesciences Singapore Pte Ltd.) for RESILIA tissue processing.
P150033/S162	01/18/2023	R - Real-Time Proc	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval for software updates to the CareLink SmartSync software application.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160030/S052	01/17/2023	O - Normal 180 Da	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval of the revised protocol for the post-approval study.
P160054/S050	01/10/2023	R - Real-Time Proc	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Approval for a software update to the HeartMate Touch Communication (HM Touch) Application software to fix two anomalies and add eleven new language translations.
P160055/S022	01/31/2023	N - Normal 180 Day	LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Approval for the following modifications: 1) reducing the LDD footprint (i.e., making the LDD system more compact in a different physical configuration); 2) converting the operating system to Linux; 3) modifying the graphic user interface for better patient data entry; 4) updating the LDD work instructions based on the modified LDD; and 5) and modifications to the labeling.
P160055/S025	01/12/2023	R - Real-Time Proc	LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Approval updates to LDD graphical user interface for better usage, treatment protocol table format, and minor bug fixes.
P170018/S015	01/10/2023	R - Real-Time Proc	LIFEPAK® CR2 DEFIBRILLATOR	PHYSIO-CONTROL, INC	Approval for adding a clip over the magnetic component in the LIFEPAK CR2 defibrillator lid.
P170030/S025	01/26/2023	Y - 135 Review Tra	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Approval for the addition of an alternate supplier for the inner shaft component clS7
P180032/S011	01/17/2023	S - Special CBE	CERENE® CRYOTHERAPY DEVICE	CHANNEL MEDSYSTEMS , INC.	Approval for a modification to the manufacturing process to improve the PCB-to-battery tray solder joint for the Cerene Controller Board.
P180035/S015	01/13/2023	O - Normal 180 Da	MISIGHT 1 DAY (OMAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES FOR DAILY WEAR	COOPERVISIO N, INC.	Approval for the revision of PAS002 protocol v4.0.
P180046/S056	01/30/2023	N - Normal 180 Day	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGI ES, INC.	Approval of a rechargeable Neurostimulator, model 5101 and updated software for the Clinician Programmer, model 2501.
P180050/S008	01/20/2023	O - Normal 180 Da	BAROSTIM NEO® SYSTEM	CVRX, INC.	Approval of the revised protocol for the post-approval study protocol.
P190006/S056	01/30/2023	N - Normal 180 Day	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGI ES, INC.	Approval of a rechargeable Neurostimulator, model 5101 and updated software for the Clinician Programmer, model 2501.
P190012/S003	01/23/2023	S - Special CBE	SPATZ3 ADJUSTABLE BALLOON SYSTEM	SPATZ FGIA INC.	Approval for the Spatz3 Adjustable Balloon System is indicated for temporary use for weight loss in adults with obesity Body Mass Index (BMI) of 35.0-40.0 kg/m2 or a BMI of 30.0 to 34.9 kg/m2 with one or more major obesity-related comorbid conditions who have failed to achieve and maintain weight-loss with a supervised weight control program. The Spatz3 Adjustable Balloon System is to be used in conjunction with a long-term supervised diet and behavior modification program designed to increase the possibility of long-term weight-loss maintenance. The maximum placement period for Spatz3 Adjustable Balloon System is 8 months.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190015/S010	01/20/2023	S - Special CBE	TREO® ABDOMINAL STENT-GRAFT SYSTEM	BOLTON MEDICAL INC.	Approval for implementation of updates to the procedural guidance in the Instructions for Use (IFU) and MR compatibility information in the IFU and patient implant card.
P190023/S002	01/13/2023	N - Normal 180 Day	PORTICO TRANSCATHETER AORTIC VALVE IMPLANTATION SYSTEM	ABBOTT MEDICAL	Approval for design changes including modification of the valve inner skirt material, addition of an outer skirt, and minor changes to the valve stent frame and loading system
P200010/S010	01/27/2023	P - Panel Track	GUARDANT360 CDX	GUARDANT HEALTH, INC.	Approval for expanding the indications for use to include the companion diagnostic claim to identify breast cancer patients with ESR1 missense mutations between codons 310-547 for treatment with ORSERDU (elacestrant).
P200015/S028	01/19/2023	Y - 135 Review Tra	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Approval for adding an alternate supplier for the balloon shaft component of the Edwards Pulmonic Delivery System.

Total: 61

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N16837/S029	01/25/2023	X - 30-Day Notice	ARTEGRAFT{TM} AND REINFORCED ARTEGRAFT {TM}	LEMAITRE VASCULAR, INC.	Add alternative facilities for routine sterility testing and bioburden testing of the Artegraft Collagen Vascular Graft product line.
P810002/S116	01/27/2023	X - 30-Day Notice	BILEAFLET-CENTER OPENING CARDIAC VALVE	ABBOTT MEDICAL	Change to the supplier of resin material used in manufacturing mechanical heart valve fabric and conduit components.
P820033/S016	01/05/2023	X - 30-Day Notice	PLASMAFLO OP-05 W(A) ASAHI PLASMA SEPARATOR	ASAHI KASEI MEDICAL CO., LTD.	Change in quality control testing for the Plasmaflo OP-05W (A), regarding a change of gas chromatograph (GC) equipment for measurement of residual propanol.
P830055/S302	01/30/2023	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Addition of a laser marked 2D barcode, and post-marking 2D barcode verification as additional mechanisms for part identification and traceability throughout the manufacturing process for products from the LCS® Total Knee System, as well as approval for the removal of the second operator visual inspection of the human readable text (HRT) marking.
P830061/S211	01/16/2023	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates to the Final Packaging Process to allow manual loading.
P910007/S059	01/30/2023	X - 30-Day Notice	AXSYM TOTAL PSA & ARCHITECT TOTAL PSA	ABBOTT LABORATORIES	Switch to a new supplier of a noncritical manufacturing ingredient.
P910073/S171	01/16/2023	X - 30-Day Notice	ENDOTAK LEAD SYSTEM	BOSTON SCIENTIFIC	Addition of a 100% Human Visual Inspection for the RELIANCE 4-FRONT lead.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P920015/S274	01/16/2023	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Updates to the Final Packaging Process to allow manual loading.
P930039/S248	01/16/2023	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Updates to the Final Packaging Process to allow manual loading.
P940015/S051	01/13/2023	X - 30-Day Notice	SYNVISC ONE	SANOFI GENZYME CORP.	Replacement of the water distribution system (piping) used to supply water in the manufacture of Synvisc and Synvisc-One.
P950020/S134	01/18/2023	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Relocate manufacturing equipment from one cleanroom to another at the same manufacturing facility.
P950027/S018	01/19/2023	X - 30-Day Notice	HYALGAN(R)	FIDIA FARMACEUTICI SPA	Change to the manufacturing procedure, including methods for filtration and washes for the sodium hyaluronate bulk powder.
P970003/S237	01/18/2023	X - 30-Day Notice	VNS THERAPY SYSTEM	LIVANOVA USA, INC.	Introduce a new parallel-gap welding system and its associated parameter changes used in the production of the M303 and M304 Leads.
P980007/S048	01/30/2023	X - 30-Day Notice	AXSYM FREE PSA	ABBOTT LABORATORIES	Switch to a new supplier of a noncritical manufacturing ingredient.
P980016/S845	01/13/2023	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Aligning the limits used to process the Triple Capacitors incorporated in ICD and CRT-D devices.
P980016/S846	01/26/2023	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Addition of a second welder, alignment of FACTORYworks PODs, and equipment layout changes to increase manufacturing capacity of AVM capacitors at Medtronic Energy and Component Center.
P980035/S736	01/04/2023	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Updates to the Laser Solder Inspection and Lid Attach Procedure for continuous improvement.
P980035/S737	01/16/2023	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Updates to the Final Packaging Process to allow manual loading.
P980035/S738	01/17/2023	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Add a new visual inspection step for set screw blocks on device connector modules.
P000006/S065	01/12/2023	X - 30-Day Notice	TITAN INFLATABLE PENILE PROSTHESIS	COLOPLAST CORP.	Manufacturing changes to the adhesive curing process and pump wash procedure

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S512	01/17/2023	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Add a new visual inspection step for set screw blocks on device connector modules.
P010030/S163	01/19/2023	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Update to the manufacturing test software and a fixture used with USB Service Interface.
P010031/S811	01/13/2023	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Aligning the limits used to process the Triple Capacitors incorporated in ICD and CRT-D devices.
P010031/S812	01/26/2023	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Addition of a second welder, alignment of FACTORYworks PODs, and equipment layout changes to increase manufacturing capacity of AVM capacitors at Medtronic Energy and Component Center.
P020045/S102	01/19/2023	X - 30-Day Notice	7F FREEZOR CARDIAC CRYOABLATION CATHETER AND CCT.2 CRYOCONSOLE SYSTEM	MEDTRONIC CRYOCATH LP	Supplier, mold, and drawing changes for the Freezor 7Fr and 9Fr Y-Blocks.
P030017/S356	01/06/2023	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Introduce an additional cleanroom facility at your Clonmel Ireland manufacturing facility.
P030017/S359	01/04/2023	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Use existing equipment at the BSC Dorado facility to perform the laser ablation on the multi-lumen tubes used in the assembly of the D4 and W4 2x4 Splitters, 2x8 Splitters, and M1 Connectors used in the SCS Systems.
P040047/S069	01/12/2023	X - 30-Day Notice	COAPTITE	MERZ NORTH AMERICA, INC	Change to the manufacturing equipment cleaning procedure.
P050037/S121	01/12/2023	X - 30-Day Notice	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Change to the manufacturing equipment cleaning procedure.
P050051/S049	01/30/2023	X - 30-Day Notice	ABBOTT ARCHITECT AUSAB	ABBOTT LABORATORIES INC	Switch to a new supplier of a noncritical manufacturing ingredient.
P050052/S142	01/12/2023	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Change to the manufacturing equipment cleaning procedure.
P060035/S037	01/30/2023	X - 30-Day Notice	ARCHITECT CORE-M REAGENT KIT/ CALIBRATORS/CONTROLS	ABBOTT LABORATORIES	Switch to a new supplier of a noncritical manufacturing ingredient.
P080011/S153	01/19/2023	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Change in carrier gas of two gas chromatography (GC) methods for analyzing raw materials at the CooperVision Manufacturing Puerto Rico LLC facility.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P080020/S051	01/05/2023	X - 30-Day Notice	GEL-ONE	SEIKAGAKU CORP.	Sharing of the existing Gel-One manufacturing equipment in Preparation Building-3 in the SKK-Takahagi Plant to manufacture Gel-One samples using h-HAD manufactured at SKK-Kurihama Plant.
P080023/S039	01/30/2023	X - 30-Day Notice	ARCHITECT CORE REAGENT KIT, ARCHITECT CORE CALIBRATOR AND ARCHITECT CORE CONTROLS	ABBOTT LABORATORIES	Switch to a new supplier of a noncritical manufacturing ingredient.
P100009/S051	01/31/2023	X - 30-Day Notice	MITRACLIP DELIVERY SYSTEM	ABBOTT MEDICAL	Change in the raw material sub-supplier for the Lock Line component of the MitraClip delivery system.
P100010/S134	01/19/2023	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Implementation of an alternative to the batch endotoxin monitoring program at the Montreal Medtronic Operations (MMO) manufacturing site in Canada.
P100010/S135	01/19/2023	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Supplier, mold, and drawing changes for the Freezor 7Fr and 9Fr Y-Blocks.
P100016/S015	01/05/2023	X - 30-Day Notice	EC-3 INTRAOCULAR LENS (IOL) AND EC-3 PRECISION ASPHERIC LENS (PAL) IOL	CARL ZEISS MEDITEC PRODUCTION LLC	Changing to an automated extraction system used in hydrophobic button production of CT Lucia 602, CT Lucia 202, and CT Lucia 611P intraocular lens.
P100045/S064	01/06/2023	X - 30-Day Notice	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ABBOTT MEDICAL	Updates to the Temperature Test System Analysis Software.
P110029/S041	01/30/2023	X - 30-Day Notice	ARCHITECT HBSAG QUALITATIVE, QUALITATIVE CONFIRMATORY, CONFIRMATORY MANUAL DILUENT, CALIBRATORS, AND CONTROLS	ABBOTT LABORATORIES	Switch to a new supplier of a noncritical manufacturing ingredient.
P120008/S021	01/30/2023	X - 30-Day Notice	ABBOTT ARCHITECT AFP ASSAY	ABBOTT LABORATORIES	Switch to a new supplier of a noncritical manufacturing ingredient.
P130014/S016	01/05/2023	X - 30-Day Notice	ADHERUS AUTOSPRAY DURAL SEALANT	HYPERBRANCH MEDICAL TECHNOLOGY, INC.	Implementing a procedure to perform testing of a sample from each lot of NHS (N-hydroxylsuccinimide) raw material prior to purchasing it from the supplier.
P130021/S131	01/29/2023	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	New sub-tier supplier for a component of the Evolut FX delivery catheter system.
P140004/S029	01/06/2023	X - 30-Day Notice	SUPERION INTERSPINOUS SPACER	BOSTON SCIENTIFIC NEUROMODULATION	Introduce an additional cleanroom facility at your Clonmel Ireland manufacturing facility.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140020/S026	01/27/2023	X - 30-Day Notice	BRACANALYSIS CDX	MYRIAD GENETIC LABORATORIES	Extension of lab space.
P150031/S054	01/06/2023	X - 30-Day Notice	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Introduce an additional cleanroom facility at your Clonmel Ireland manufacturing facility.
P160026/S037	01/04/2023	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.	Manufacturing site location change for the inductive resistor component.
P160038/S024	01/13/2023	X - 30-Day Notice	PRAXIS EXTENDED RAS PANEL	ILLUMINA, INC.	Modification of a QC process in the Praxis Extended RAS Panel.
P160044/S005	01/13/2023	X - 30-Day Notice	ABBOTT REALTIME CMV	ABBOTT MOLECULAR	Supplier site relocation with process changes for a critical component.
P160047/S028	01/19/2023	X - 30-Day Notice	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	COOPERSURGICAL, INC.	Change to the manufacturer and manufacturing of the Sleeve Cartridge Sub-Assembly, Outflow Tube Sub-Assembly, and Syringe Sub-Assembly to reduce manufacturing yield loss.
P170002/S025	01/26/2023	X - 30-Day Notice	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Manufacturing change to increase the mixing batch size from 12L to 24L.
P180035/S013	01/12/2023	X - 30-Day Notice	MISIGHT 1 DAY (OMAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES FOR DAILY WEAR	COOPERVISION, INC.	Manufacture of MiSight 1 Day (omafilcon A) product on Dry Line HD and Wet Line HVD at the Warrior Close manufacturing facility in Chandler's Ford, Eastleigh, UK.
P180035/S014	01/10/2023	X - 30-Day Notice	MISIGHT 1 DAY (OMAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES FOR DAILY WEAR	COOPERVISION, INC.	Change of loading and unloading locking mechanism for the autoclave at CooperVision Manufacturing Ltd. in Chandler's Ford, Eastleigh, UK.
P180040/S004	01/19/2023	X - 30-Day Notice	TRILURON	FIDIA FARMACEUTICI S.P.A.	Change to the manufacturing procedure, including methods for filtration and washes for the sodium hyaluronate bulk powder.
P190024/S009	01/30/2023	X - 30-Day Notice	CINTEC PLUS CYTOLOGY	VENTANA MEDICAL SYSTEMS, INC.	Changes to a manufacturing process.
P200013/S012	01/13/2023	X - 30-Day Notice	ALINITY M HBV	ABBOTT MOLECULAR, INC.	Supplier site relocation with process changes for a critical component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P200037/S006	01/10/2023	X - 30-Day Notice	ASSURE WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) SYSTEM	KESTRA MEDICAL TECHNOLOGIES, INC.	Utilizing a new washer for the printed circuit board assembly of critical components.
P210003/S005	01/30/2023	X - 30-Day Notice	ARCHITECT HBSAG NEXT QUALITATIVE REAGENT KIT, ARCHITECT HBSAG NEXT CONFIRMATORY REAGENT KIT, ARCHITECT HBSAG NEXT QUALITATIVE CALIBRATORS,	ABBOTT LABORATORIES	Switch to a new supplier of a noncritical manufacturing ingredient.

Total: 59