PMA Monthly approvals from 8/1/2023 to 8/31/2023

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P220032	08/08/2023	PMAO - PMA Origi	POLARX/POLARX FIT CRYOABLATION CATHETERS, SMARTFREEZE CRYOABLATION CONSOLE, ACCESSORIES	BOSTON SCIENTIFIC CORPORATIO N	Approval for the Boston Scientific Cardiac Cryoablation System using the POLARx Cryoablation Balloon Catheters. The device is indicated for the treatment of patients with drug refractory, recurrent symptomatic paroxysmal atrial fibrillation (PAF). In addition it is intended for cryoablation and electrical mapping of the pulmonary veins for pulmonary vein isolation (PVI) in the ablation treatment of patients with drug refractory, recurrent symptomatic paroxysmal atrial fibrillation. The SMARTFREEZE Cryo-Console is intended to be used with POLARx cryoablation balloon catheters only.
1					

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840001/S529	08/08/2023	O - Normal 180 Da	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODU LATION	Approval for a manufacturing site located at Medline Industries/Centurion Medical Products Corporation (FEI: 3005846326) Tri-State de Mexico, S. de R.L. de C.V. Calzada Presidente Venustiano Carranza, No. 301 Desarrollo Industrial Colorado Mexicali, Baja California, 21397, MEXICO as an alternate facility for kitting and final packaging of the Medtronic Model 97725 Wireless External Neurostimulator (ENS). Addition of Medline Industries, LP. (FEI: 3015173212) Mexicali Directo Al Cliente S. De R.L. De C.V. Circuito Del Desierto #71-A Parque Industrial del Desierto Mexicali Baja California 21395 Mexico as an alternate facility for sterilization of the Medtronic Model 97725 Wireless External Neurostimulator (ENS). The Model 97725 ENS shall be sterile packaged in an ISO certified controlled environment area (CEA) - ISO 14644-1 [class 8] or better.
P900056/S201	08/17/2023	N - Normal 180 Day	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Approval for an alternative lubricant manufacturing facility (Fresenius Kabi - Uppsala, Sweden), packaging design and supplier changes, and product labeling revisions.
P910001/S120	08/31/2023	R - Real-Time Proc	SPECTRANECTICS CVX-300 EXCIMER LASER SYSTEM	SPECTRANETI CS CORP.	Approval for the changes to the Philips Laser System devices software to correct defects and the user interface.
P910056/S051	08/21/2023	N - Normal 180 Day	SOFLEX UV-ABSORBING SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS	BAUSCH & LOMB, INC.	Approval for the introduction of the UV + Duo material across the entire enVista® IOL portfolio along with the additions to the model number configurations, introduction of two additional IOL models (the enVista® ASPIRE monofocal [EA] and the enVista® ASPIRE toric [ETA]), and the inclusion of the option to have an electronic Instructions for Use (eIFU).
P920048/S024	08/24/2023	S - Special CBE	FETAL FIBRONECTIN ENZYME IMMUNOASSAY KIT (EIK)	HOLOGIC, INC.	Approval of a labeling update to provide additional clarity on the specimen collection by indicating that, Only results from specimens obtained during a speculum examination are valid. Results from specimens obtained in any other manner, for example, vaginal examination, are invalid.

Data as of 09/07/2023 05:15 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P930027/S027	08/30/2023	S - Special CBE	IMMULITE SYSTEMS PSA & THIRD GENERATION PSA REAGENTS	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Approval for the change in labeling to include a limitation regarding interference from the drug STRENSIQ.
P950008/S016	08/02/2023	Y - 135 Review Tra	SILIKON 1000	ALCON	Approval to implement the single re-use of the polishing filter on two bulk batches of Silikon 1000 (silicone oil) during the compounding process.
P950037/S250	08/21/2023	R - Real-Time Proc	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Approval to update the Renamic and Renamic Neo programmer software to versions PSW 2302.U and NEO 2302.U.
P980037/S090	08/08/2023	O - Normal 180 Da	ANGIOJET RHEOLYTIC THROMBECTOMY LF140 CATHETER	BOSTON SCIENTIFIC CORP.	Approval for an additional manufacturing site located in Dorado, PR for the Sprioflex and Spiroflex VG Thrombectomy Sets manufacturing, sterile packaging, and post production quality assurance.
P990004/S062	08/31/2023	S - Special CBE	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Approval for the amendments and additions to the Directions for Use, Storage and Handling, and Disposal section of the Instructions for Use sheet of the SURGIFLO® Hemostatic Matrix and the SURGIFLO® Hemostatic Matrix Kit with Thrombin.
P990075/S053	08/23/2023	Y - 135 Review Tra	MENTOR CORPORATION SALINE-FILLED AND SPECTRUM (R) MAMMARY PROSTHESES	MENTOR WORLDWIDE LLC	Approval of the implementation of the Laser Marking System 04 for the SPECTRUM® Breast Implants.
P000009/S104	08/21/2023	R - Real-Time Proc	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Approval to update the Renamic and Renamic Neo programmer software to versions PSW 2302.U and NEO 2302.U.
P000058/S088	08/25/2023	N - Normal 180 Day	INFUSE BONE GRAFT/LT-CAGE LUMBAR TAPERED FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval for expansion of the approved indications for use of INFUSE® Bone Graft to include implantation with additional interbody fusion devices, a subset of the Anteralign Spinal System with Titan NanoLOCK Surface Technology, specifically the specified sizes of the Anteralign LS and TL systems, utilizing select open surgical procedures in conjunction with supplemental spinal fixation hardware or alone.
P010007/S016	08/30/2023	S - Special CBE	IMMULITE/IMMULITE 1000 AFP AND IMMULITE 2000/ IMMULITE 2500 AFP	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Approval for the change in labeling to include a limitation regarding interference from the drug STRENSIQ.
P010030/S165	08/30/2023	R - Real-Time Proc	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Approval for a new monitor software version, V07.10M for the LifeVest® Wearable Defibrillator.
P010050/S020	08/30/2023	S - Special CBE	IMMULITE 2000 XPI HBSAG	SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS, LTD	Approval for the change in labeling to include a limitation regarding interference from the drug STRENSIQ.
P010051/S016	08/30/2023	S - Special CBE	IMMULITE 2000 XPI ANTI-HBC	SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS, LTD	Approval for the change in labeling to include a limitation regarding interference from the drug STRENSIQ.

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P010052/S015	08/30/2023	S - Special CBE	IMMULITE 2000 XPI ANTI-HBS	SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS, LTD	Approval for the change in labeling to include a limitation regarding interference from the drug STRENSIQ.
P010053/S015	08/30/2023	S - Special CBE	IMMULITE 2000 XPI ANTI-HBC IMG	SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS, LTD	Approval for the change in labeling to include a limitation regarding interference from the drug STRENSIQ.
P020050/S041	08/23/2023	R - Real-Time Proc	WAVELIGHT ALLEGRETTO WAVE EXCIMER LASER SYSTEM	ALCON LABORATORIES, INC.	Approval to replace the Operation Microscope Zoom (OPMI Zoom) supplied by company Carl Zeiss with an equivalent microscope (MIC-EX) supplied by ATMOS MedizinTechnik.
P030008/S037	08/23/2023	R - Real-Time Proc	WAVELIGHT ALLEGRETTO WAVE EXCIMER LASER SYSTEM	ALCON LABORATORIES, INC.	Approval to replace the Operation Microscope Zoom (OPMI Zoom) supplied by company Carl Zeiss with an equivalent microscope (MIC-EX) supplied by ATMOS MedizinTechnik.
P030031/S129	08/03/2023	N - Normal 180 Day	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Approval for changes to the Instructions for Use (IFU) for the THERMOCOOL SMARTTOUCH® and SMARTTOUCH® SF Catheters that allow for the use of direct imaging guidance, such as fluoroscopy or ultrasound, during catheter manipulation; the changes are being made based on clinical data from the REAL AF Registry Sub-Study.
P040036/S091	08/03/2023	N - Normal 180 Day	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Approval for changes to the Instructions for Use (IFU) for the THERMOCOOL SMARTTOUCH® and SMARTTOUCH® SF Catheters that allow for the use of direct imaging guidance, such as fluoroscopy or ultrasound, during catheter manipulation; the changes are being made based on clinical data from the REAL AF Registry Sub-Study.
P050023/S176	08/21/2023	R - Real-Time Proc	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval to update the Renamic and Renamic Neo programmer software to versions PSW 2302.U and NEO 2302.U.
P050038/S040	08/09/2023	Y - 135 Review Tra	ARISTA AH ABSORBABLE HEMOSTAT	DAVOL, INC.	Approval for the use of an alternate emulsifier used in the manufacturing of DSM-A (the non-sterile powder component of Arista AH).
P060005/S015	08/30/2023	S - Special CBE	IMMULITE / IMMULITE 1000 AND IMMULITE 2000 FREE PSA ASSAYS	SIEMENS MEDICAL SOLUTIONS DIAGNOSTICS LIMITED	Approval for the change in labeling to include a limitation regarding interference from the drug STRENSIQ.
P070008/S150	08/21/2023	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 to update the Renamic and Renamic Neo programmer software to versions PSW 2302.U and NEO 2302.U.
P070026/S107	08/11/2023	R - Real-Time Proc	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Approval for extending the shelf life from five (5) years to ten (10) years for the Biolox Delta TS Ceramic Femoral Heads, Biolox Delta Ceramic Femoral Heads, and CERAMAX Ceramic Inserts which are components of the CERAMAX® Ceramic Total Hip System.
P100009/S052	08/23/2023	O - Normal 180 Da	MITRACLIP DELIVERY SYSTEM	ABBOTT MEDICAL	Approval for an alternate final sterilization site located at Centerpiece S. De R.L De C.V, Bulevar La Encantada Industrial, Parque Industrial El Florido, Seccion La Encantada #11530, Tijuana, Baja California, Mexico 22250

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100010/S139	08/21/2023	R - Real-Time Proc	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Approval for a design modification to materials used in the lumen of the Arctic Front Advance Cardiac Cryoablation Catheter and the Arctic Front Advance PRO Cardiac Cryoablation Catheter.
P100026/S094	08/28/2023	R - Real-Time Proc	NEUROPACE RNS SYSTEM	NEUROPACE INC	Approval for the modification of the devices Remote Monitor to allow for the use of either a Tablet or Laptop. For the tablet interface the Remote Monitor uses Wi-Fi to communicate with the PDMS SW Application. The tablet can also receive updates remotely.
P100034/S031	08/14/2023	O - Normal 180 Day	NOVOCURE LTD'S NOVOTTF-100A TREATMENT KIT	NOVOCURE GMBH	Approval for a trade name change from Optune to Optune Gio.
P100047/S211	08/20/2023	R - Real-Time Proc	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval to update the Instructions for Use (IFU) and Patient Manual (PM) to clarify the instructions regarding the Controller Fault Alarm, the two-year expected useful life of the Primary and Back-up Controller, and the use and care instructions of the backup controller.
P110002/S035	08/01/2023	N - Normal 180 Day	MOBI-C CERVICAL DISC PROSTHESIS (ONE-LEVEL INDICATION)	ZIMMER BIOMET SPINE, INC.	Approval for the addition of H4.5mm inserts to the Mobi-C® Cervical Disc Prosthesis System.
P110009/S035	08/01/2023	N - Normal 180 Day	MOBI-C CERVICAL DISC PROSTHESIS (TWO-LEVEL INDICATION)	ZIMMER BIOMET SPINE, INC.	Approval for the addition of H4.5mm inserts to the Mobi-C® Cervical Disc Prosthesis System.
P110033/S072	08/01/2023	O - Normal 180 Day	JUVEDERM VOLUMA XC	ALLERGAN	Approval for final revised labeling.
P130008/S099	08/04/2023	O - Normal 180 Da	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval of the protocol for the post-approval study (PAS) protocol.
P130022/S049	08/01/2023	N - Normal 180 Day	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for the Patient Therapy Application, HFX, to be used on Android devices.
P150009/S009	08/10/2023	O - Normal 180 Da	GUARDIAN SYSTEM	AVERTIX MEDICAL INC	Approval for a trade name change to The Guardian System.
P150026/S015	08/11/2023	O - Normal 180 Day	HEARTLIGHT ENDOSCOPIC ABLATION SYSTEM	CARDIOFOCUS, INC.	Approval for the transition of the Console manufacturing from the current contractor, Minnetronix, 1635 Energy Park Dr, St Paul, MN 55108 USA to Gener8, 2560 Junction Ave., San Jose CA 95134 USA.
P160035/S025	08/10/2023	Y - 135 Review Tra	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Approval of the addition of alternate cooling and lubricant oil used during the machining and milling process of the titanium connectors and adapters used in Berlin Heart EXCOR blood pumps.
P160043/S066	08/08/2023	Y - 135 Review Tra	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for the transfer of component extrusion manufacturing operations for the Onyx Frontier coextrusion balloons and the Onyx Frontier Bumped Inner components used in the manufacture of the Onyx Frontier device
P160045/S042	08/17/2023	O - Normal 180 Da	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Approval to include limitation in labelling. The updated labeling to include the statement: "Interference in variant calling can be observed at higher concentrations of chenodeoxycholic acid in cholangiocarcinoma (CC) clinical FFPE samples with IDH1 variants present at an allelic frequency near the limit of detection (LoD)."

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P170019/S042	08/11/2023	N - Normal 180 Day	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval order to expand the intended use of FoundationOne®CDx (F1CDx) to include a companion diagnostic (CDx) indication for identifying prostate cancer patients with BRCA1, BRCA2 alterations who may benefit from treatment with AKEEGA (niraparib + abiraterone acetate).
P170019/S046	08/10/2023	O - Normal 180 Da	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval for updates to labeling including updates to the Technical Information document for FICDx.
P180014/S010	08/09/2023	O - Normal 180 Day	XPS¿ WITH STEEN SOLUTION¿ PERFUSATE	XVIVO PERFUSION, INC.	Approval of the revised protocol (version 4.0) for the post-approval study (PAS) protocol.
P180036/S021	08/03/2023	R - Real-Time Proc	OPTIMIZER SMART SYSTEM	IMPULSE DYNAMICS (USA), INC.	Approval to add the OPTIMIZER Lite system version.
P190021/S005	08/24/2023	O - Normal 180 Day	REACTIV8 IMPLANTABLE NEUROSTIMULATION SYSTEM	MAINSTAY MEDICAL LIMITED	Approval for a manufacturing site located at 2159 India Street, San Diego, California 92101, for the manufacturing of the ReActiv8 Implantable Neurostimulation System.
P200035/S006	08/08/2023	O - Normal 180 Da	ORGANOX METRA SYSTEM	ORGANOX LIMITED	Approval for a manufacturing site located at Integrated Technologies Ltd, Viking House, Ellingham Way, Ashford, Kent, TN23 6NF, UK.
P200035/S010	08/09/2023	R - Real-Time Proc	ORGANOX METRA SYSTEM	ORGANOX LIMITED	Approval for replacing OrganOx metra Liver Perfusion Circuit (Part Number D0146) IVC cannula component model RV40028 with model V122-28.
P200039/S005	08/17/2023	Y - 135 Review Tra	SHOCKWAVE INTRAVASCULAR LITHOTRIPSY (IVL) SYSTEM WITH SHOCKWAVE C2 CORONARY INTRAVASCULAR LITHOTRIPSY (IVL) CATHETER	SHOCKWAVE MEDICAL, INC.	Approval for the addition of an alternate supplier for the Shockwave C2 Coronary IVL Catheter hypotube.
P200045/S006	08/04/2023	O - Normal 180 Day	RELAYPRO THORACIC STENT-GRAFT SYSTEM	BOLTON MEDICAL, INC.	Approval of the protocol for the post-approval study (PAS) protocol.
P210039/S001	08/16/2023	O - Normal 180 Da	CHOCOLATE TOUCH PACLITAXEL DRUG-COATED PTA BALLOON CATHETER (CHOCOLATE TOUCH)	TRIREME MEDICAL, LLC	Approval for updated labeling, including the 24-month clinical study results, removed paclitaxel warning, and other minor modifications.
P220002/S001	08/11/2023	O - Normal 180 Day	TOPS¿ SYSTEM	PREMIA SPINE LTD.	Approval of the protocol for the post-approval study (PAS) protocol.
P220006/S001	08/23/2023	N - Normal 180 Day	VENTANA FOLR1 (FOLR-2.1) RXDX ASSAY	VENTANA MEDICAL SYSTEMS INC.	Approval to modify the VENTANA FOLR1 (FOLR1-2.1) RxDx Assay to remove the Stain Intensity Reference (SIR) slide from the assay configuration.
P220021/S001	08/09/2023	O - Normal 180 Day	DETOUR SYSTEM	ENDOLOGIX, LLC	Approval of the protocol for the post-approval study (PAS) protocol.
P220029/S001	08/25/2023	O - Normal 180 Da	OPTILUME¿ BPH CATHETER SYSTEM	UROTRONIC, INC	Approval of the protocol for the post-approval study (PAS) protocol.

Total: 57

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N18033/S111	08/21/2023	X - 30-Day Notice	ACUVUE CONTACT LENS	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Qualification of an existing re-cartoning line to be used to re-carton primary packages of VISTAKON® (etafilcon A) Brand Contact Lenses.
P830055/S308	08/22/2023	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Using new machining equipment in the manufacturing of the LCS poly patella parts of the LCS Total Knee System and increasing inspection frequency after machining.
P830061/S218	08/01/2023	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modifications to the cutting and straining process for raw silicone material at a supplier.
P840001/S545	08/03/2023	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Relocation of the distribution center sorter tool from Medtronics Memphis Distribution Center Swinnea Road site to Airways Road site.
P840001/S546	08/10/2023	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Install new equipment and implement updated process for differential pressure monitoring in a controlled environment area.
P840001/S547	08/10/2023	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Processing change at the supplier of medical grade silicone.
P840064/S080	08/15/2023	X - 30-Day Notice	VISCOAT(TM)/DVOVISC/ DISCOVISC OPHTHALMIC VISCOSURGICAL DEVICES	ALCON LABORATORIES	Addition of a redundant Ethylene Oxide (EO) sterilization chamber for routine sterilization of the subject ophthalmic viscosurgical devices.
P840064/S082	08/31/2023	X - 30-Day Notice	VISCOAT(TM)/DVOVISC/ DISCOVISC OPHTHALMIC VISCOSURGICAL DEVICES	ALCON LABORATORIES	Addition of a sterility isolator in Lifecore Biomedical for performance of in-process and finished device testing of sterility for the subject devices.
P850089/S166	08/01/2023	X - 30-Day Notice	CAPSURE SP, CAPSURE, CAPSURE 2 LEADS, EXCELLENCE S, IMPULSE, IMPLUSE II EXCELLENCE SS, LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modifications to the cutting and straining process for raw silicone material at a supplier.

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P860003/S110	08/10/2023	X - 30-Day Notice	UVAR PHOTOPHERESIS SYSTEM	MALLINCKRODT PHARMACEUTICALS IRELAND LIMITED	Change to qualify a new core for the drive tube injection mold tool used to manufacture the O-ring sealing gland of the THERAKOS® CELLEX® Procedural Kit, which will also alter the cavity insert for the molding process from P20 Tool Steel to S7 Tool Steel, and improve production readiness.
P860004/S413	08/03/2023	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Relocation of the distribution center sorter tool from Medtronics Memphis Distribution Center Swinnea Road site to Airways Road site.
P860004/S414	08/10/2023	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Processing change at the supplier of medical grade silicone.
P860057/S213	08/22/2023	X - 30-Day Notice	EDWARDS LIFESCIENCES PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Additional process water system for use in manufacturing of surgical and transcatheter heart valves.
P890047/S061	08/15/2023	X - 30-Day Notice	PROVISC(TM) VISCOELASTIC PREPARATION	ALCON RESEARCH, LTD.	Addition of a redundant Ethylene Oxide (EO) sterilization chamber for routine sterilization of the subject ophthalmic viscosurgical devices.
P900033/S108	08/21/2023	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Qualification of modifications to the Cleans team (CS) System at the Collagen Manufacturing Center at 109 Morgan Lane in Plainsboro, NJ.
P900056/S210	08/29/2023	X - 30-Day Notice	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Implementation of new software to automate electrical in-process inspections of the ROTAPRO Console at the current contract manufacturer.
P900061/S171	08/01/2023	X - 30-Day Notice	MEDTRONIC PCD TACHYARRHYTHMIA CONTROL SYSTEM	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modifications to the cutting and straining process for raw silicone material at a supplier.
P920015/S280	08/01/2023	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Modifications to the cutting and straining process for raw silicone material at a supplier.
P930031/S073	08/04/2023	X - 30-Day Notice	WALLSTENT(R) TIPS ENDOPROSTHESIS WITH UNISTEP PLUS DELIVERY SYSTEM	BOSTON SCIENTIFIC CORP.	Supplier addition for the interior tubing for the devices in the submission.
P930039/S254	08/01/2023	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Modifications to the cutting and straining process for raw silicone material at a supplier.
P950018/S024	08/29/2023	X - 30-Day Notice	PERFLUORON (PURIFIED PERFLUORO-N-OCTANE LIQUID)	ALCON LABORATORIES	Change to add an alternate sterilization cycle for items used in the filling operation of the Perfluoron product.
P950020/S140	08/03/2023	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Adjust the settings of the pre-blade bonding plasma process and to remove the O2 plasma accessory tray cleaning cycle.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P950024/S108	08/01/2023	X - 30-Day Notice	MEDTRONIC(R) CAPSURE (R) EPI PACING LEAD MODEL 4695	MEDTRONIC INC.	Modifications to the cutting and straining process for raw silicone material at a supplier.
P950037/S251	08/16/2023	X - 30-Day Notice	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	New limits for cathode mass and pressing force used in the manufacturing of LiS 2650 MK batteries.
P960004/S104	08/03/2023	X - 30-Day Notice	THINLINE ENDOCARDIAL PACING LEADS	BOSTON SCIENTIFIC	Addition of an alternate supplier for the product labels on the FINELINE® II EZ Sterox families of leads.
P960009/S456	08/03/2023	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Relocation of the distribution center sorter tool from Medtronics Memphis Distribution Center Swinnea Road site to Airways Road site.
P960009/S457	08/10/2023	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Install new equipment and implement updated process for differential pressure monitoring in a controlled environment area.
P960009/S458	08/10/2023	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Processing change at the supplier of medical grade silicone.
P970004/S386	08/03/2023	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Relocation of the distribution center sorter tool from Medtronics Memphis Distribution Center Swinnea Road site to Airways Road site.
P970004/S388	08/10/2023	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Install new equipment and implement updated process for differential pressure monitoring in a controlled environment area.
P970004/S389	08/10/2023	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Processing change at the supplier of medical grade silicone.
P970031/S070	08/10/2023	X - 30-Day Notice	MEDTRONIC FREESTYLE AORTIC ROOT BIOPROSTHESIS	MEDTRONIC, INC.	Manufacturing site addition for the supplier of the primary packaging component for the Mosaic, Freestyle, Hancock II, and Avalus bioprostheses.
P980016/S864	08/01/2023	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modifications to the cutting and straining process for raw silicone material at a supplier.
P980016/S866	08/28/2023	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement software changes on battery laser welding equipment at MECC.
P980033/S063	08/04/2023	X - 30-Day Notice	WALLSTENT ENDOPROSTHESIS	BOSTON SCIENTIFIC CORPORATION	Supplier addition for the interior tubing for the devices in the submission.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980035/S755	08/09/2023	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Changes to the Foreign Material reject criteria and associated cleaning instructions at Medtronic Singapore Operations.
P980035/S756	08/03/2023	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Expand the seam weld energy range for IPG seam welding at Medtronic Singapore Operations.
P980035/S757	08/01/2023	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Modifications to the cutting and straining process for raw silicone material at a supplier.
P980035/S758	08/30/2023	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implement Automated Telemetry Head Positioning System (ATHPS) at Post Sterilization Testers (PST).
P980040/S162	08/21/2023	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Qualification of an alternate supplier of one-piece edge blocker.
P980043/S076	08/10/2023	X - 30-Day Notice	HANCOCK II PORCINE BIOPROSTHESIS	MEDTRONIC, INC.	Manufacturing site addition for the supplier of the primary packaging component for the Mosaic, Freestyle, Hancock II, and Avalus bioprostheses.
P980050/S141	08/01/2023	X - 30-Day Notice	MEDTRONIC(R) JEWEL(R) AF 7250 DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATOR, MODEL 9961 PROGRAMMER APPLICATION SOF	MEDTRONIC INC.	Modifications to the cutting and straining process for raw silicone material at a supplier.
P980052/S012	08/22/2023	X - 30-Day Notice	TMJ CONCEPTS PATIENT-FITTED TMJ RECONSTRUCTION PROSTHESIS	TMJ CONCEPTS	Implementation of SAP ERP System to replace Factory Edge
P990064/S085	08/10/2023	X - 30-Day Notice	MEDTRONIC MOSAIC PORCINE BIOPROSTHETIC HEART VALVE	MEDTRONIC, INC.	Manufacturing site addition for the supplier of the primary packaging component for the Mosaic, Freestyle, Hancock II, and Avalus bioprostheses.
P990065/S013	08/09/2023	X - 30-Day Notice	SIR-SPHERES	SIRTEX MEDICAL PTY LTD	Manufacturing change to add the Y-90 chloride solution manufacturing facility in Wilmington, Massachusetts USA for the current supplier Eckert & Ziegler Radiopharma (EZR or E&Z).
P990081/S051	08/29/2023	X - 30-Day Notice	PATHWAY ANTI-HCR-2/ NCU (4B5) RABBIT MONOCLONAL PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Addition of two contract manufacturers as approved suppliers of parts/components.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000054/S069	08/21/2023	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Manufacturing changes including modifications to two ISO 7 Collagen Packaging Cleanrooms and the associated Gowning Room and the replacement of the Honeywell temperature recorders with the Viewpoint Temperature Monitoring system at the Collagen Manufacturing Center (CMC) located at 105 Morgan Lane, Plainsboro, NJ 08536
P000054/S070	08/21/2023	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Manufacturing changes including modifications to two ISO 7 Collagen Packaging Cleanrooms and the associated Gowning Room and the replacement of the Honeywell temperature recorders with the Viewpoint Temperature Monitoring system at the Collagen Manufacturing Center (CMC) located at 105 Morgan Lane, Plainsboro, NJ 08536
P000058/S089	08/21/2023	X - 30-Day Notice	INFUSE BONE GRAFT/LT-CAGE LUMBAR TAPERED FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Manufacturing changes including modifications to two ISO 7 Collagen Packaging Cleanrooms and the associated Gowning Room and the replacement of the Honeywell temperature recorders with the Viewpoint Temperature Monitoring system at the Collagen Manufacturing Center (CMC) located at 105 Morgan Lane, Plainsboro, NJ 08536
P000058/S090	08/21/2023	X - 30-Day Notice	INFUSE BONE GRAFT/LT-CAGE LUMBAR TAPERED FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Manufacturing changes including modifications to two ISO 7 Collagen Packaging Cleanrooms and the associated Gowning Room and the replacement of the Honeywell temperature recorders with the Viewpoint Temperature Monitoring system at the Collagen Manufacturing Center (CMC) located at 105 Morgan Lane, Plainsboro, NJ 08536
P010015/S524	08/01/2023	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Modifications to the cutting and straining process for raw silicone material at a supplier.
P010031/S830	08/01/2023	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modifications to the cutting and straining process for raw silicone material at a supplier.
P010031/S832	08/28/2023	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement software changes on battery laser welding equipment at MECC.
P010032/S201	08/09/2023	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Implement the utilization of an alternate second tier supplier to supply a sub-component of the Epo-Tek 301 epoxy and to utilize alternate packaging pouches for the Epo-Tek 301.
P010059/S010	08/17/2023	X - 30-Day Notice	MORCHER CAPSULAR TENSION RING, TYPES 14, 14A AND 14C	MORCHER GMBH	Configuration change to the gamma radiation sterilization.
P020004/S195	08/15/2023	X - 30-Day Notice	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Changes to the in-process inspection sampling plan for ultra-thin wall components of the GORE EXCLUDER AAA Endoprosthesis and Iliac Branch Endoprosthesis.
P020055/S029	08/29/2023	X - 30-Day Notice	VENTANA MEDICAL SYSTEMS PATHWAY ANTI-C-KIT (9.7) PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Addition of two contract manufacturers as approved suppliers of parts/components.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030011/S085	08/01/2023	X - 30-Day Notice	SYNCARDIA TEMPORARY CARDIO WEST TOTAL ARTIFICIAL HEART (TAH-T)	SYNCARDIA SYSTEMS, LLC	Change the internal tubing for the Freedom Driver System.
P030011/S086	08/09/2023	X - 30-Day Notice	SYNCARDIA TEMPORARY CARDIO WEST TOTAL ARTIFICIAL HEART (TAH-T)	SYNCARDIA SYSTEMS, LLC	Change the Loctite used internally in the Freedom Driver of the SynCardia temporary Total Artificial Heart System.
P030036/S144	08/01/2023	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Modifications to the cutting and straining process for raw silicone material at a supplier.
P030053/S070	08/08/2023	X - 30-Day Notice	MEMORYGEL SILICONE GEL -FILLED BREAST IMPLANTS	MENTOR CORP.	Implementation of a new vulcanizer, which is equipment used to adhere the patch against the back of the implant shell by applying pressure during the patching and vulcanizing process.
P030054/S410	08/08/2023	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ABBOTT MEDICAL	Manufacturing process changes related to the Cardiac Resynchronization Therapy (CRT) Leads tip electrode and weld schedule.
P050019/S039	08/10/2023	X - 30-Day Notice	CAROTID WALLSTENT MONORAIL ENDOPROSTHESIS	BOSTON SCIENTIFIC CORP.	Supplier change of an injection molded delivery system component.
P050028/S087	08/17/2023	X - 30-Day Notice	COBAS TAQMAN HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Elimination of redundant in-process testing.
P050028/S088	08/23/2023	X - 30-Day Notice	COBAS TAQMAN HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Change manufacturing tolerances for a component.
P050047/S090	08/30/2023	X - 30-Day Notice	JUVEDERM 24HV, JUVEDERM 30 AND JUVEDERM 30HV GEL IMPLANTS	ALLERGAN	Change in the way that the plunger stopper component is supplied.
P050047/S091	08/31/2023	X - 30-Day Notice	JUVEDERM 24HV, JUVEDERM 30 AND JUVEDERM 30HV GEL IMPLANTS	ALLERGAN	Changing an acceptance criterion for an in-process quality control measure during the manufacturing of Juvéderm injectable gel products
P050053/S060	08/21/2023	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC INC.	Manufacturing changes including modifications to two ISO 7 Collagen Packaging Cleanrooms and the associated Gowning Room and the replacement of the Honeywell temperature recorders with the Viewpoint Temperature Monitoring system at the Collagen Manufacturing Center (CMC) located at 105 Morgan Lane, Plainsboro, NJ 08536
P050053/S061	08/21/2023	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC INC.	Manufacturing changes including modifications to two ISO 7 Collagen Packaging Cleanrooms and the associated Gowning Room and the replacement of the Honeywell temperature recorders with the Viewpoint Temperature Monitoring system at the Collagen Manufacturing Center (CMC) located at 105 Morgan Lane, Plainsboro, NJ 08536

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P060006/S108	08/31/2023	X - 30-Day Notice	BOSTON SCIENTIFIC EXPRESS SD RENAL MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Alternate supplier for a Tyvek header bag.
P060028/S049	08/08/2023	X - 30-Day Notice	MENTOR MEMORYSHAPE BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Implementation of a new vulcanizer, which is equipment used to adhere the patch against the back of the implant shell by applying pressure during the patching and vulcanizing process.
P060039/S114	08/01/2023	X - 30-Day Notice	ATTAIN STARFIX MODEL 4195 LEAD	MEDTRONIC INC.	Modifications to the cutting and straining process for raw silicone material at a supplier.
P080006/S178	08/01/2023	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Modifications to the cutting and straining process for raw silicone material at a supplier.
P080011/S155	08/09/2023	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Introduction of a High Volume (HV) Biofinity dry line and wet line installed at the CooperVision Manufacturing, Ltd. facility in Hamble, UK to produce Biofinity Sphere lenses.
P080011/S156	08/21/2023	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Introduction of a new Programmable Logic Controller (PLC) code version on the labeling and packaging MPac Syncro line 3 (LP3) at the CooperVision Manufacturing, Ltd., Mountpark to produce Biofinity family of lenses.
P080025/S281	08/03/2023	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Relocation of the distribution center sorter tool from Medtronics Memphis Distribution Center Swinnea Road site to Airways Road site.
P080025/S283	08/10/2023	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Install new equipment and implement updated process for differential pressure monitoring in a controlled environment area.
P080025/S284	08/10/2023	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Processing change at the supplier of medical grade silicone.
P090013/S329	08/01/2023	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Modifications to the cutting and straining process for raw silicone material at a supplier.
P090031/S016	08/08/2023	X - 30-Day Notice	MONOVISC	ANIKA THERAPEUTICS, INC.	Process improvement changes for p-Phenylene-bis-ethylcarbodiimide (BCDI) component of the Monvisc product
P100009/S057	08/30/2023	X - 30-Day Notice	MITRACLIP DELIVERY SYSTEM	ABBOTT MEDICAL	Manufacturing process change from the manual handling to an automated handling of the Clip Introducer components during the UV curing process.
P100020/S056	08/17/2023	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Elimination of redundant in-process testing.
P100020/S057	08/23/2023	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Change manufacturing tolerances for a component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100021/S116	08/23/2023	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Process modifications for manufacturing of thumbwheel components used in the delivery system of the Endurant Stent Graft family of products.
P100027/S039	08/29/2023	X - 30-Day Notice	INFORM HER2 DUAL ISH DNA PROBE COCKTAIL	VENTANA MEDICAL SYSTEMS, INC.	Addition of two contract manufacturers as approved suppliers of parts/components.
P110016/S085	08/17/2023	X - 30-Day Notice	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ABBOTT MEDICAL	Additional equipment inspection in the Bi-Directional handle assembly manufacturing procedure.
P110020/S038	08/17/2023	X - 30-Day Notice	COBAS 4800 BRAF V600 MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Elimination of redundant in-process testing.
P110020/S039	08/23/2023	X - 30-Day Notice	COBAS 4800 BRAF V600 MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Change manufacturing tolerances for a component.
P110024/S004	08/23/2023	X - 30-Day Notice	RESQCPR SYSTEM	ZOLL MEDICAL CORPORATIO N	Addition of a new automated flow tester for ResQPOD ITD16.
P110033/S077	08/30/2023	X - 30-Day Notice	JUVEDERM VOLUMA XC	ALLERGAN	Change in the way that the plunger stopper component is supplied.
P110033/S078	08/31/2023	X - 30-Day Notice	JUVEDERM VOLUMA XC	ALLERGAN	Changing an acceptance criterion for an in-process quality control measure during the manufacturing of Juvéderm injectable gel products
P110037/S058	08/17/2023	X - 30-Day Notice	COBAS® AMPLIPREP/ COBAS® TAQMAN® CMV TEST (CAP/CTM CMV TEST)	ROCHE MOLECULAR SYSTEMS, INC.	Elimination of redundant in-process testing.
P110037/S059	08/23/2023	X - 30-Day Notice	COBAS® AMPLIPREP/ COBAS® TAQMAN® CMV TEST (CAP/CTM CMV TEST)	ROCHE MOLECULAR SYSTEMS, INC.	Change manufacturing tolerances for a component.
P120017/S033	08/01/2023	X - 30-Day Notice	MODEL 5071 LEAD	MEDTRONIC INC.	Modifications to the cutting and straining process for raw silicone material at a supplier.
P120019/S035	08/17/2023	X - 30-Day Notice	COBAS EGFR MUTATION TEST	ROCHE	Elimination of redundant in-process testing.
P120019/S036	08/23/2023	X - 30-Day Notice	COBAS EGFR MUTATION TEST	ROCHE	Change manufacturing tolerances for a component.
P130008/S100	08/15/2023	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Changes to the manufacturing of the IS-1 connector end, which is part of both the Model 4063 Stimulation Lead and Model 4340 Sensing Lead.

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P130014/S018	08/25/2023	X - 30-Day Notice	ADHERUS AUTOSPRAY DURAL SEALANT	HYPERBRANCH MEDICAL TECHNOLOGY, INC.	Replacement of the server system and related equipment which processes raw data from analytical instrumentation.
P130021/S142	08/01/2023	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Alternative supplier for the 18Fr and 22Fr capsule components.
P130021/S143	08/30/2023	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Use of additional media for pre-sterilization bioburden enumeration.
P130021/S144	08/25/2023	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	New equipment used in the manufacturing process of the Evolut FX Delivery Catheter System (DCS) stability member bond.
P130026/S087	08/17/2023	X - 30-Day Notice	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Additional equipment inspection in the Bi-Directional handle assembly manufacturing procedure.
P140009/S086	08/25/2023	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Qualify an alternate manufacturing equipment used in the manufacturing of the DBS Extensions.
P140010/S075	08/30/2023	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.	Move manufacturing lines from one building to another building.
P140019/S009	08/15/2023	X - 30-Day Notice	I-FACTOR PEPTIDE ENHANCED BONE GRAFT	CERAPEDICS, LLC	Removal of redundant in-process percent solid testing.
P140023/S026	08/17/2023	X - 30-Day Notice	COBAS KRAS MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Elimination of redundant in-process testing.
P140025/S021	08/29/2023	X - 30-Day Notice	VENTANA ALK (D5F3) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Addition of two contract manufacturers as approved suppliers of parts/components.
P140031/S160	08/05/2023	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Addition of an alternative supplier of the main liner and pull wire lumen components used in the Commander Delivery System Flex Shaft subassemblies.
P140031/S161	08/22/2023	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Additional process water system for use in manufacturing of surgical and transcatheter heart valves.
P140031/S163	08/25/2023	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Add a receiving inspection at the Edwards Añasco, Puerto Rico facility to support the manufacturing line for the Crimper.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150003/S097	08/17/2023	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Increasing the temperature range on the equipment that extrudes the SYNERGY balloon material.
P150004/S064	08/09/2023	X - 30-Day Notice	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Implement the utilization of an alternate second tier supplier to supply a sub-component of the Epo-Tek 301 epoxy and to utilize alternate packaging pouches for the Epo-Tek 301.
P150014/S044	08/17/2023	X - 30-Day Notice	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Elimination of redundant in-process testing.
P150014/S045	08/16/2023	X - 30-Day Notice	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Addition of new manufacturing equipment.
P150014/S046	08/23/2023	X - 30-Day Notice	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Change manufacturing tolerances for a component.
P150030/S035	08/11/2023	X - 30-Day Notice	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Addition of an additional furnace (VF-14) for the heat-treating process of ANTHOLOGY and SYNERGY stems approved for use in combination with the R3TM Delta Ceramic Acetabular System.
P150035/S005	08/24/2023	X - 30-Day Notice	AVEIR VR LEADLESS SYSTEM	ABBOTT MEDICAL	Implement a new battery voltage measurement tool for the Aveir Leadless Pacemakers.
P150036/S070	08/22/2023	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Additional process water system for use in manufacturing of surgical and transcatheter heart valves.
P150040/S014	08/15/2023	X - 30-Day Notice	VISUMAX FEMTOSECOND LASER	CARL ZEISS MEDITEC, INC.	Second clean room for the manufacture of the Treatment Pack Accessory at the Jena, Germany manufacturing site.
P150048/S074	08/22/2023	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Additional process water system for use in manufacturing of surgical and transcatheter heart valves.
P160002/S021	08/29/2023	X - 30-Day Notice	VENTANA PD-L1(SP142) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Addition of two contract manufacturers as approved suppliers of parts/components.
P160003/S017	08/07/2023	X - 30-Day Notice	PRO-KINETIC ENERGY COBALT CHROMIUM (COCR) CORONARY STENT SYSTEM	BIOTRONIK, INC.	Implementing an additional bioindicator to prepare the external process challenge devices for routine release.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160003/S018	08/16/2023	X - 30-Day Notice	PRO-KINETIC ENERGY COBALT CHROMIUM (COCR) CORONARY STENT SYSTEM	BIOTRONIK, INC.	Introduction of new shrink tubes for the welding process of delivery system components and laser welding equipment.
P160026/S041	08/16/2023	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.	Implementation of a new automatic welder to replace the current manual manufacturing process.
P160035/S034	08/10/2023	X - 30-Day Notice	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Change the valve test stand used for testing EXCOR blood pump valves.
P160035/S035	08/22/2023	X - 30-Day Notice	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Add a new blood pump test stand.
P160041/S036	08/17/2023	X - 30-Day Notice	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Elimination of redundant in-process testing.
P160041/S037	08/16/2023	X - 30-Day Notice	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Addition of new manufacturing equipment.
P160041/S038	08/23/2023	X - 30-Day Notice	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Change manufacturing tolerances for a component.
P160045/S043	08/10/2023	X - 30-Day Notice	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Change the supplier and associated manufacturing process of chips.
P160046/S016	08/29/2023	X - 30-Day Notice	VENTANA PD-L1 (SP263) ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Addition of two contract manufacturers as approved suppliers of parts/components.
P160050/S007	08/25/2023	X - 30-Day Notice	BARRICAID ANULAR CLOSURE DEVICE (ACD)	INTRINSIC THERAPEUTICS	Modification of grip material for the grit blasting step of the Ti64 bone anchor.
P170002/S032	08/31/2023	X - 30-Day Notice	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Extension of in-process gel holding times at two points during the manufacturing of RHA Redensity

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170006/S022	08/10/2023	X - 30-Day Notice	AVALUS(TM) BIOPROSTHESIS	MEDTRONIC INC.	Manufacturing site addition for the supplier of the primary packaging component for the Mosaic, Freestyle, Hancock II, and Avalus bioprostheses.
P170006/S023	08/22/2023	X - 30-Day Notice	AVALUS(TM) BIOPROSTHESIS	MEDTRONIC INC.	Addition of one new bovine tissue supplier for the Avalus Bioprosthesis.
P170018/S016	08/31/2023	X - 30-Day Notice	LIFEPAK® CR2 DEFIBRILLATOR	PHYSIO-CONTROL, INC	Additional test system workstations on the LIFEPAK CR2 defibrillator manufacturing line.
P170030/S030	08/07/2023	X - 30-Day Notice	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Implementing an additional bioindicator to prepare the external process challenge devices for routine release.
P170030/S031	08/24/2023	X - 30-Day Notice	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Introducing an alternative tool for stent coating.
P170030/S032	08/25/2023	X - 30-Day Notice	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Introducing new acceptance criteria, inspection equipment, and welding equipment for the guidewire exit port.
P170034/S010	08/24/2023	X - 30-Day Notice	HYDRUS MICROSTENT	IVANTIS, INC. WHOLLY-OWNED SUBSIDIARY OF ALCON RESEARCH, LLC	Additional supplier, Alcon Precision Devices (APD), of the Delivery System subassembly of the Hydrus Microstent.
P180046/S072	08/25/2023	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Addition of Amcor as an alternate supplier for sourcing sterile product pouches.
P190006/S072	08/25/2023	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Addition of Amcor as an alternate supplier for sourcing sterile product pouches.
P190008/S026	08/30/2023	X - 30-Day Notice	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Move manufacturing lines from one building to another building.
P190017/S014	08/22/2023	X - 30-Day Notice	LIAISON® XL MUREX HBSAG QUAL, LIAISON® MUREX CONTROL HBSAG, AND LIAISON® XL MUREX HBSAG CONFIRMATORY TEST	DIASORIN INC	Introduction of an automated process for washing laboratory equipment

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190018/S026	08/10/2023	X - 30-Day Notice	CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM, CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM	ALCON LABORATORIES, LLC	Addition of an alternative manufacturer of Clareon intraocular lens (IOL) lens cases; and 2) using an alternative polypropylene raw material.
P190021/S006	08/15/2023	X - 30-Day Notice	REACTIV8 IMPLANTABLE NEUROSTIMULATION SYSTEM	MAINSTAY MEDICAL LIMITED	Removal of the spot weld process for Reactiv8 Implantable Neurostimulation System¿s Implantable Pulse Generator (IPG) internal battery sleeve at Centro De Construccion De Cardioestimuladores Del Uruguay S.A.
P190024/S010	08/29/2023	X - 30-Day Notice	CINTEC PLUS CYTOLOGY	VENTANA MEDICAL SYSTEMS, INC.	Addition of two contract manufacturers as approved suppliers of parts/components.
P190028/S010	08/17/2023	X - 30-Day Notice	COBAS HPV FOR USE ON THE COBAS 6800/8800 SYSTEMS	ROCHE MOLECULAR SYSTEMS, INC.	Elimination of redundant in-process testing.
P190028/S011	08/16/2023	X - 30-Day Notice	COBAS HPV FOR USE ON THE COBAS 6800/8800 SYSTEMS	ROCHE MOLECULAR SYSTEMS, INC.	Addition of new manufacturing equipment.
P190028/S012	08/23/2023	X - 30-Day Notice	COBAS HPV FOR USE ON THE COBAS 6800/8800 SYSTEMS	ROCHE MOLECULAR SYSTEMS, INC.	Change manufacturing tolerances for a component.
P190031/S008	08/29/2023	X - 30-Day Notice	HER2 DUAL ISH DNA PROBE COCKTAIL	VENTANA MEDICAL SYSTEMS, INC.	Addition of two contract manufacturers as approved suppliers of parts/components.
P200014/S005	08/17/2023	X - 30-Day Notice	COBAS® EZH2 MUTATION TEST	ROCHE MOLECULAR SYSTEM, INC.	Elimination of redundant in-process testing.
P200014/S006	08/23/2023	X - 30-Day Notice	COBAS® EZH2 MUTATION TEST	ROCHE MOLECULAR SYSTEM, INC.	Change manufacturing tolerances for a component.

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P200015/S043	08/05/2023	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Addition of an alternative supplier of the main liner and pull wire lumen components used in the Commander Delivery System Flex Shaft subassemblies.
P200015/S044	08/22/2023	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Additional process water system for use in manufacturing of surgical and transcatheter heart valves.
P200015/S045	08/25/2023	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Add a receiving inspection at the Edwards Añasco, Puerto Rico facility to support the manufacturing line for the Crimper.
P200019/S007	08/29/2023	X - 30-Day Notice	VENTANA MMR RXDX PANEL	VENTANA MEDICAL SYSTEMS	Addition of two contract manufacturers as approved suppliers of parts/components.
P200037/S009	08/17/2023	X - 30-Day Notice	ASSURE WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) SYSTEM	KESTRA MEDICAL TECHNOLOGIES, INC.	New process to replace the electrodes in the therapy cables.
P200046/S018	08/10/2023	X - 30-Day Notice	HARMONY¿ TPV SYSTEM	MEDTRONIC, INC.	Alternate sub-tier supplier for adhesives used in the middle shaft component of the Harmony Delivery Catheter System (DCS).
P210001/S009	08/29/2023	X - 30-Day Notice	VENTANA MMR RXDX PANEL	VENTANA MEDICAL SYSTEMS INC (ROCHE TISSUE DIAGNOSTICS)	Addition of two contract manufacturers as approved suppliers of parts/components.
P210032/S011	08/30/2023	X - 30-Day Notice	GORE TAG THORACIC BRANCH ENDOPROSTHESIS (TBE DEVICE)	W. L. GORE & ASSOCIATES, INC.	Qualification of new heparin coating machine.
P220006/S002	08/29/2023	X - 30-Day Notice	VENTANA FOLR1 (FOLR-2.1) RXDX ASSAY	VENTANA MEDICAL SYSTEMS INC.	Addition of two contract manufacturers as approved suppliers of parts/components.
P220007/S002	08/11/2023	X - 30-Day Notice	PRECISION7¿; PRECISION7 ¿ FOR ASTIGMATISM; PRECISION7 ¿ MULTIFOCAL; PRECISION7¿ MULTIFOCAL TORIC (SERAFILCON A) SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Modification of tool inserts for production of serafiicon A contact lenses.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P220013/S003	08/16/2023	X - 30-Day Notice	TACTIFLEX¿ ABLATION CATHETER, SENSOR ENABLED¿, TACTISYS ¿ QUARTZ EQUIPMENT, TACTISYS¿ QUARTZ, TACTIFLEX ¿ RADIOFREQUENCY CABLE, AMPERE ¿ RADIOFREQUENCY GENERATOR, COOL POINT PUMP	ABBOTT MEDICAL	Addition of a second ethylene oxide (EO) sterilization cycle for previously sterilized TactiFlex Ablation Catheters.
P220013/S004	08/17/2023	X - 30-Day Notice	TACTIFLEX¿ ABLATION CATHETER, SENSOR ENABLED¿, TACTISYS ¿ QUARTZ EQUIPMENT, TACTISYS¿ QUARTZ, TACTIFLEX ¿ RADIOFREQUENCY CABLE, AMPERE ¿ RADIOFREQUENCY GENERATOR, COOL POINT PUMP	ABBOTT MEDICAL	Additional equipment inspection in the Bi-Directional handle assembly manufacturing procedure.
P220013/S005	08/11/2023	X - 30-Day Notice	TACTIFLEX¿ ABLATION CATHETER, SENSOR ENABLED¿, TACTISYS ¿ QUARTZ EQUIPMENT, TACTISYS¿ QUARTZ, TACTIFLEX ¿ RADIOFREQUENCY CABLE, AMPERE ¿ RADIOFREQUENCY GENERATOR, COOL POINT PUMP	ABBOTT MEDICAL	Alternative supplier for the Flex Tip subassembly (Flex Tip).

Total: 166