PMA Monthly approvals from 12/1/2020 to 12/31/2020

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190009	12/18/2020	PMAO - PMA Origi	OPRA IMPLANT SYSTEM	INTEGRUM AB	Approval for the OPRA Implant System. The device is indicated for patients who have transfemoral amputation due to trauma or cancer and who have or are anticipated to have rehabilitation problems with, or cannot use, a conventional socket prosthesis. The OPRA Implant System is intended for skeletally mature patients. The patient failed to receive benefit from socket prostheses or is expected to not tolerate socket use due to problems such as: 1) Recurrent skin infections and ulcerations in the socket contact area; 2) Pain; 3) A short stump preventing the use of socket prosthesis; 4) Volume fluctuation in the stump; 5) Soft tissue scarring; 6) Extensive area of skin grafting; 7) Socket retention problems due to excessive perspiration; and 8) Restricted mobility.
P190030	12/09/2020	PMAO - PMA Origi	ACTASTIM-S SPINE FUSION STIMULATOR	THERAGEN, INC.	Approval for the ActaStim-S Spine Fusion Stimulator is a noninvasive bone growth stimulator indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels. The device is Rx only, and intended for single patient use in adult patients only.
P200030	12/22/2020	PMAO - PMA Origi	GORE EXCLUDER CONFORMABLE AAA ENDOPROSTHESIS (CEXC)	W. L. GORE AND ASSOCIATES, INC.	Approval for Gore Excluder Conformable AAA Endoprosthesis (EXCC) This device is indicated to exclude the aneurysm from the blood circulation in patients diagnosed with infrarenal abdominal aortic aneurysm (AAA) disease and who have appropriate anatomy as described below: 1) Adequate iliac / femoral access; 2) Infrarenal aortic neck treatment diameter range of 16 to 32 mm; 3) A minimum aortic neck length of 15 mm when proximal aortic neck angulation is =<60 degrees; and 4) Iliac artery treatment diameter range of 8 to 25 mm and iliac distal vessel seal zone length of at least 10 mm.

Total: 3

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N18286/S036	12/10/2020	S - Special CBE	GELFOAM	PFIZER, INC.	Approval for the addition of Anaphylaxis to the Warnings and Adverse Reactions sections of the Gelfoam Instructions for Use.
P830055/S261	12/21/2020	O - Normal 180 Day	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for a manufacturing site located at Johnson & Johnson Medical (DePuy Suzhou) Ltd., No. 299, Changyang Street, Suzhou Industrial Park, Suzhou Jiangsu, China, to manufacture ATTUNE Revision Stem components of the LCS Total Knee System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830061/S189	12/22/2020	O - Normal 180 Day	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for a manufacturing site located at Medtronic Singapore Operations: 49 Changi South Avenue 2, Nasaco Tech Centre, Singapore 486056.
P850048/S056	12/16/2020	R - Real-Time Proc	TANDEM-R PSA IMMUNORADIOMETRIC ASSAY	BECKMAN COULTER, INC.	Approval for the modification to connect the UniCel DxI Immunoassay Systems to the DxA 5000 automation system.
P890023/S046	12/10/2020	R - Real-Time Proc	H55 HYDROPHILIC CONTACT LENS	THE COOPER COMPANIES	Approval for the addition of a second supplier of a raw material, including changes to the raw material specification, for the Biomedics 55 (ocufilcon D) soft (hydrophilic) contact lenses for extended wear.
P910001/S111	12/22/2020	R - Real-Time Proc	SPECTRANECTICS CVX-300 EXCIMER LASER SYSTEM	SPECTRANETICS CORP.	Approval for minor design changes to the Fiber Coupler Assembly.
P910073/S158	12/04/2020	O - Normal 180 Day	ENDOTAK LEAD SYSTEM	BOSTON SCIENTIFIC	Approval for labeling updates to the clinical study summary for the post approval study.
P930039/S220	12/22/2020	O - Normal 180 Day	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Approval for a manufacturing site located at Medtronic Singapore Operations: 49 Changi South Avenue 2, Nasaco Tech Centre, Singapore 486056.
P950037/S215	12/18/2020	R - Real-Time Proc	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Approval for the 3T MR Conditional Labeling of the Siello S 45 and Solia S 45 when combined with ProMRI IPGs.
P960013/S114	12/16/2020	N - Normal 180 Day	TENDRIL DX MODEL 1388T & 1388K ENDOCARDIAL PACING LEADS	ST JUDE MEDICAL	Approval for 3T MR Conditional labeling of certain Assurity MRI and Endurity MRI models when combined with a subset (46 cm, 52 cm and 58 cm) of Tendril STS Model 2088TC leads.
P960040/S456	12/04/2020	O - Normal 180 Day	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Approval for labeling updates to the clinical study summary for the post approval study.
P960058/S149	12/02/2020	N - Normal 180 Day	CLARION MULTI-STRATEGY COCHLEAR IMPLANT	ADVANCED BIONICS	Approval for the New Sound Processors (Naida CI M30, Naida CI M90, and Sky CI M90), New Headpieces (Slim HP, Slim HP AquaMic, Slim HP Mic, and Slim HP Standard), Target CI, AB Remote, and Accessories (M Battery Small, M Battery Medium, M Battery Large, M Standard Battery, M Waterproof Battery, M Zn-Air Battery Pak, M Acoustic Earhook, M Earhook, M T-Mic, Slim HP Standard Magnet, Slim HP 3D Magnet, M Programming Cable, Slim HP Color Cap, and Slim HP Color Cap large).
P970038/S044	12/16/2020	R - Real-Time Proc	TANDEM-R FREE PSA IMMUNORADIOMETRIC ASSAY/TANDEM-MP FREE PSA IMMUNOENZYMETRIC ASSAY	BECKMAN COULTER, INC.	Approval for a modification to connect the UniCel DxI Immunoassay Systems to the DxA 5000 automation system.
P970051/S200	12/30/2020	R - Real-Time Proc	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for a new in-house terminal sterilization process to be used with a new sterilizer.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980035/S667	12/22/2020	O - Normal 180 Day	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Approval for a manufacturing site located at Medtronic Singapore Operations: 49 Changi South Avenue 2, Nasaco Tech Centre, Singapore 486056.
P980040/S117	12/29/2020	N - Normal 180 Day	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for the TECNIS EyhanceTM IOL, Model ICB00; TECNIS EyhanceTM IOL with SmartLOADTM Delivery Technology, Model GIB00; TECNIS EyhanceTM IOL with TECNIS SimplicityTM Delivery System, Model DIB00; TECNIS EyhanceTM Toric II IOLs, Models ICU150-600; and TECNIS EyhanceTM Toric II IOLs with TECNIS SimplicityTM Delivery System, Models DIU150-600, which are an extension of the TECNIS family of one-piece IOLs that incorporate an optical modification.
P980041/S049	12/16/2020	R - Real-Time Proc	ACCESS AFP IMMUNOASSAY SYSTEM	BECKMAN COULTER, INC.	Approval for a modification to connect the UniCel DxI Immunoassay Systems to the DxA 5000 automation system.
P990009/S061	12/11/2020	N - Normal 180 Day	FLOSEAL MATRIX/ FLOSEAL MATRIX HEMOSTATIC SEALANT/ PROCEED HEMOSTATIC SEALANT	BAXTER HEALTHCARE CORP.	Approval to allow Recothrom® standalone Thrombin to be used with the FLOSEAL NT.
P000006/S058	12/07/2020	R - Real-Time Proc	TITAN INFLATABLE PENILE PROSTHESIS	COLOPLAST CORP.	Approval for a minor design change to the unitary deflate pin to lower the crack force of the Titan Touch Pump.
P000015/S044	12/30/2020	R - Real-Time Proc	NUCLEUS 24 AUDITORY BRAINSTEM IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for a new in-house terminal sterilization process to be used with a new sterilizer.
P000054/S061	12/30/2020	Y - 135 Review Tra	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval for a manufacturing process change in the preparation of stopper components used in the manufacture of the product.
P000058/S080	12/30/2020	Y - 135 Review Tra	INFUSE BONE GRAFT/LT-CAGE LUMBAR TAPERED FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval for a manufacturing process change in the preparation of stopper components used in the manufacture of the product.
P010012/S525	12/04/2020	O - Normal 180 Day	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Approval for labeling updates to the clinical study summary for the post approval study.
P010014/S100	12/07/2020	O - Normal 180 Day	OXFORD(TM) MENISCAL UNICOMPARTMENTAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Approval for the modification to the labeling to reflect the findings of the Post-Approval Study (PAS) Report, for the Oxford Partial Knee System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S720	12/17/2020	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for RAMware updates to the Protecta family of devices.
P010047/S062	12/21/2020	Y - 135 Review Tra	PROGEL PLEURAL AIR LEAK SEALANT	NEOMEND, INC.	Approval for changes to the HPLC chromatography column and test method used to evaluate the protein aggregate content in the Human Serum Albumin component of the chemistry kits contained in the PROGEL PALS and TRIDYNE VS finished devices.
P030017/S338	12/01/2020	N - Normal 180 Day	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the WaveWriter Alpha Spinal Cord Stimulator (SCS) System.
P030053/S056	12/21/2020	R - Real-Time Proc	MEMORYGEL SILICONE GEL -FILLED BREAST IMPLANTS	MENTOR CORP.	Approval of the Smooth Moderate High Profile Xtra Silicone Gel-filled Breast Implants, which is an extension to the MemoryGel Xtra Breast Implants product line.
P040013/S024	12/04/2020	O - Normal 180 Day	GEM 21S (GROWTH-FACTOR ENHANCED MATRIX	LYNCH BIOLOGICS LLC	Approval for the change in supplier for the formulation, filling, and testing (with the exception of the Bioassay) of the rhPDGF-BB syringe component of GEM21S Growth Factor Enhanced Matrix to a manufacturing site located at Pyramid Laboratories, Inc., 3598 Cadillac Ave., Costa Mesa, CA 92626.
P040029/S015	12/17/2020	N - Normal 180 Day	JSZ ORTHOKERATOLOGY (OPRIFOCON A) CONTACT LENSES FOR OVERNIGHT WEAR	EUCLID SYSTEMS CORPORATIO N	Approval for the addition of an alternate lens blank material color (green) for the manufacture of the Euclid Systems Orthokeratology (tisilfocon A) Contact Lenses for Overnight Wear.
P040045/S113	12/10/2020	Y - 135 Review Tra	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Approval for the addition of a purity specification for a raw material used in VISTAKON® (senofilcon A) Brand Contact Lenses.
P040045/S118	12/03/2020	N - Normal 180 Day	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Approval for use of alternate multifocal and multifocal toric lens designs and change to the ratio of components in the packaging solution.
P050006/S086	12/18/2020	O - Normal 180 Day	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,I NC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P050023/S151	12/18/2020	R - Real-Time Proc	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval for the 3T MR Conditional Labeling of the Siello S 45 and Solia S 45 when combined with ProMRI IPGs.
P050037/S099	12/21/2020	Y - 135 Review Tra	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Approval to implement campaign filling of up to six gel bowls into a single lot of sterilized units for the Radiesse and Radiesse (+) Lidocaine injectable implant products.
P050052/S116	12/21/2020	Y - 135 Review Tra	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval to implement campaign filling of up to six gel bowls into a single lot of sterilized units for the Radiesse and Radiesse (+) Lidocaine injectable implant products.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P060037/S069	12/21/2020	R - Real-Time Proc	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Approval for the change to the design and materials of the device packaging system for the ultra-high molecular weight polyethylene (UHMWPE) tibial articular surface components of the NexGen LPS-Flex Mobile / LPS-Mobile Bearing Knee System and an associated change to the product shelf life.
P070008/S118	12/18/2020	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 3T MR Conditional Labeling of the Siello S 45 and Solia S 45 when combined with ProMRI IPGs.
P080012/S056	12/30/2020	Y - 135 Review Tra	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Approval for an alternate electronics board manufacturer/supplier for the production of the Patient Therapy (PTC) Battery Charger and PTC Wand printed circuit boards.
P090013/S313	12/22/2020	O - Normal 180 Day	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Approval for a manufacturing site located at Medtronic Singapore Operations: 49 Changi South Avenue 2, Nasaco Tech Centre, Singapore 486056.
P090016/S042	12/22/2020	N - Normal 180 Day	BELOTERO BALANCE	MERZ NORTH AMERICA, INC	Approval for the addition of new release and shelf-life specifications for rheology and a change to the existing release and shelf-life specifications for ejection force for Belotero Balance Dermal Filler and Belotero Balance + Lidocaine Dermal Filler.
P090026/S030	12/16/2020	R - Real-Time Proc	ACCESS HYBRITECH P2PSA ON THE ACCESS IMMUNOASSAY SYSTEMS	BECKMAN COULTER, INC.	Approval for the modification to connect the UniCel DxI Immunoassay Systems to the DxA 5000 automation system.
P100030/S014	12/02/2020	R - Real-Time Proc	ARTERX SURGICAL SEALANT	BAXTER HEALTHCARE CORPORATION	Approval for updates to the labeling to reflect a change in ownership and other minor updates to conform with current labeling standards.
P100047/S169	12/21/2020	N - Normal 180 Day	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for a change in material (from nylon to PEEK) of the internal core in the plug used in the battery, AC adapter, DC adapter, training plugs, monitor data cable, and red alarm adapter, and associated labeling and manufacturing changes.
P110019/S114	12/16/2020	O - Normal 180 Day	XIENCE PRIME AND XIENCE PRIME LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Approval for a manufacturing site located at Abbott Vascular, 26531 Ynez Road, Temecula, CA 92591, for finished product manufacturing, catheter manufacturing, and labeling.
P130005/S031	12/10/2020	S - Special CBE	DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM	CARDIOVASCULAR SYSTEMS, INC.	Approval for clarifications made to the instructions for use.
P130008/S061	12/07/2020	R - Real-Time Proc	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval for dimensional change on a component of the pressure sensor assembly of the Model 4340 Sensing Lead.
P130013/S039	12/16/2020	R - Real-Time Proc	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Approval for an alternative packaging configuration change for WATCHMAN LAA Closure Device and Delivery System
P130016/S044	12/30/2020	R - Real-Time Proc	NUCLEUS HYBRID L24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for a new in-house terminal sterilization process to be used with a new sterilizer.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130021/S083	12/08/2020	S - Special CBE	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Approval for various labeling changes related to post implant dilatation
P130024/S037	12/22/2020	R - Real-Time Proc	LUTONIX DRUG COATED BALLOON PTA CATETER	LUTONIX	Approval for extending the shelf life for the 4-6x300 mm balloon sizes from 24 to 36 months.
P140008/S019	12/02/2020	O - Normal 180 Day	ORBERA INTRAGASTRIC BALLOON	APOLLO ENDOSURGERY INC	Approval for the ORBERATM PAS (OPAS-001.0. The OPAS-001 is a prospective, open-label, single-arm study to evaluate the safety and effectiveness of ORBERA for weight reduction in obese adults 22 years and older with a BMI of 30-40 kg/m2. This is a 52-week study in which subjects will be treated during the first 26 weeks with ORBERA in conjunction with a behavioral modification program, followed by 26 weeks of behavioral modification program alone. A total of 284 subjects will be enrolled at 10 to 20 US sites to yield 255 subjects implanted with ORBERA (assuming a 10% screen failure rate). Based on an estimated attrition rate of 10% through week 26 and 20% through week 52, the expected number of evaluable subjects is 230 subjects at 26 weeks and 204 subjects at 52 weeks. A sample size of 255 implanted subjects will provide 80% power to test the hypothesis that the rate of device- and/or procedure-related serious adverse events (SAEs) is less than 15% at 26 weeks.
P140010/S050	12/04/2020	Y - 135 Review Tra	IN PACT ADMIRAL PACLITAXEL-ELUTING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Approval for a modification in the process for preparation of packaging trays prior to use.
P140029/S029	12/21/2020	R - Real-Time Proc	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Approval for a new alternative supplier for Lidocaine Hydrochloride (Lidocaine HCl) for Restylane Kysse
P140029/S031	12/04/2020	Y - 135 Review Tra	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Approval of changes to the Line 3 cleanrooms 9:169, 9:170, 9:177 and 9:190 in Facility 2, Building 9 at Q-Med ABs site located at Seminariegatan 21, SE-752 58 Uppsala, Sweden, used for the manufacturing of Restylane Refyne, Restylane Defyne, and Restylane Kysse Injectable Gels.
P140033/S060	12/16/2020	N - Normal 180 Day	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ST. JUDE MEDICAL, INC.	Approval for 3T MR Conditional labeling of certain Assurity MRI and Endurity MRI models when combined with a subset (46 cm, 52 cm and 58 cm) of Tendril STS Model 2088TC leads.
P150005/S058	12/18/2020	N - Normal 180 Day	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval for the design and associated manufacturing changes to the Blazer OI and IntellaNav OI ablation catheters to standardize the design and manufacture of these catheters with other BSC OI catheters.
P150016/S018	12/21/2020	Y - 135 Review Tra	TRIDYNE VASCULAR SEALANT	NEOMEND, INC.	Approval for changes to the HPLC chromatography column and test method used to evaluate the protein aggregate content in the Human Serum Albumin component of the chemistry kits contained in the PROGEL PALS and TRIDYNE VS finished devices.
P150031/S028	12/29/2020	P - Panel Track	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the Vercise PC and Vercise Gevia DBS Systems for expanding the indications to include bilateral stimulation of the internal globus pallidus (GPi) as an adjunctive therapy to reduce some of the symptoms of advanced levodopa-responsive Parkinsons disease that is not adequately controlled by medications.
P160013/S007	12/03/2020	R - Real-Time Proc	ORGAN CARE SYSTEM (OCS¿) LUNG SYSTEM	TRANSMEDICS, INC	Approval for a software update (Software Version 3.1.3-C).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160054/S031	12/17/2020	N - Normal 180 Day	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATION	Approval for a labeling update regarding pediatric uses of the device.
P170023/S005	12/02/2020	R - Real-Time Proc	BULKAMID URETHRAL BULKING SYSTEM	CONTURA INTERNATIONAL A/S	Approval for minor changes to the Bulkamid Needle, including a change in the manufacturer for the Bulkamid Needle, which includes minor changes to the needle hubs outer shape, the raw materials used for the needle hub and sterile barrier system (pouch), and the dimensions of the needle pouch.
P180007/S005	12/15/2020	N - Normal 180 Day	SPIRATION® VALVE SYSTEM	GYRUS ACMI, INC.	Approval for a change to ELI grade Nitinol as raw material for Spiration valve frames.
P180007/S007	12/23/2020	O - Normal 180 Day	SPIRATION® VALVE SYSTEM	GYRUS ACMI, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P180036/S006	12/30/2020	N - Normal 180 Day	OPTIMIZER SMART SYSTEM	IMPULSE DYNAMICS (USA), INC.	Approval for MR Conditional labeling for the OPTIMIZER Smart when combined with certain market approved pacing leads.
P190015/S004	12/03/2020	R - Real-Time Proc	TREO® ABDOMINAL STENT-GRAFT SYSTEM	BOLTON MEDICAL INC.	Approval for an increase in the labeled shelf life for the bifurcate and cuff devices in the TREO Abdominal Stent-Graft System (TREO) product family from 2 years to 3 years.
P190015/S007	12/16/2020	O - Normal 180 Day	TREO® ABDOMINAL STENT-GRAFT SYSTEM	BOLTON MEDICAL INC.	Approval for a manufacturing site located at Terumo Vietnam Co., Ltd (Lot 44A-B-C, Quang Minh Industrial Zone, Me Linh District, Hanoi City, Vietnam) for kitting and sewing processes of TREO Abdominal Stent Graft.
P190016/S002	12/30/2020	R - Real-Time Proc	TULA® SYSTEM	TUSKER MEDICAL, INC.	Approval for a design modification to the Check Valve Assembly of the Earset of the Tula® System and for a 12-month expiration dating labeling claim for the modified Earset of Tula® System.
P190019/S004	12/16/2020	O - Normal 180 Day	RANGER¿ PACLITAXEL-COATED PTA BALLOON CATHETER	BOSTON SCIENTIFIC CORPORATION	Approval of the protocols for the post-approval studies (PAS) protocol.

Total: 69

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S077	12/22/2020	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Implementation of X-Ray Sterilization as an alternative to Gamma Sterilization for SURGICEL Absorbable Hemostats at the Ethicon Sarl, Neuchatel Manufacturing site.
N970003/S260	12/11/2020	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Move the Incoming Quality Assurance Acceptance Activity for testing levels of elements in Lithium Hydroxide from an external laboratory to the material supplier.
N970012/S184	12/17/2020	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE	BOSTON SCIENTIFIC CORP.	Updates to the software for sterilization aeration at the BSC Coventry, Rhode Island facility.

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P790007/S064	12/16/2020	X - 30-Day Notice	HANCOCK MODIFIED ORIFICE BIOPROSTHESIS	MEDTRONIC HEART VALVES	Change in storage temperature requirements for the tissue fixation solution.
P810031/S068	12/02/2020	X - 30-Day Notice	HEALON, HEALON GV, HEALON5 PRODUCTS SODIUM HYALURONATE OPHTHALMIC VISCOELASTIC DEVICES	JOHNSON & JOHNSON SURGICAL VISION, INC.	Expansion of the Lifecore Biomedical quality control (QC) laboratory.
P810031/S069	12/16/2020	X - 30-Day Notice	HEALON, HEALON GV, HEALON5 PRODUCTS SODIUM HYALURONATE OPHTHALMIC VISCOELASTIC DEVICES	JOHNSON & JOHNSON SURGICAL VISION, INC.	Change to the emulsion used for pretreatment of glass cylinders for Sodium Hyaluronate Ophthalmic Viscoelastic Devices (OVDs), including Healon® PRO, Healon GV® PRO, Healon5® PRO and Healon Duet® PRO Dual Pack OVDs.
P830055/S260	12/02/2020	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Use of new equipment, (Cellro) Laser Marking System (LMS), for application of a 2D barcode and human readable text to the PFC Sigma Posterior and Distal Femoral Augment components.
P830061/S187	12/15/2020	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the manufacturing execution system to FACTORYworks Release 9.8.
P830061/S188	12/08/2020	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Reduce the sampling monitoring plan for non-viable air particles in controlled environment areas.
P830061/S190	12/10/2020	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the FACTORYworks Web User Interface to version 1.1.0.
P830061/S191	12/11/2020	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of a newly qualified cleanroom at Medtronic Singapore Operations.
P840001/S476	12/10/2020	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Implementation of a new crimping process at your assembly supplier.
P840001/S477	12/18/2020	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Update of the manufacturing execution system to FACTORYWorks Release 9.8.

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P840001/S478	12/17/2020	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Update the surface finishing process of the Header Connector part for the Master Intellis Spinal Cord Stimulation Systems; Model Numbers 97715 and 97716, from a tumble finishing operation to a laser finishing operation. Consolidate two inspection test methods to one test method for the Header Connector.
P840001/S479	12/23/2020	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Implementation of a new final functional test platform.
P850089/S151	12/15/2020	X - 30-Day Notice	CAPSURE SP, CAPSURE, CAPSURE 2 LEADS, EXCELLENCE S, IMPULSE, IMPLUSE II EXCELLENCE SS, LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the manufacturing execution system to FACTORYworks Release 9.8.
P850089/S152	12/08/2020	X - 30-Day Notice	CAPSURE SP, CAPSURE, CAPSURE 2 LEADS, EXCELLENCE S, IMPULSE, IMPLUSE II EXCELLENCE SS, LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Reduce the sampling monitoring plan for non-viable air particles in controlled environment areas.
P860004/S366	12/18/2020	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Update of the manufacturing execution system to FACTORYWorks Release 9.8.
P860057/S201	12/13/2020	X - 30-Day Notice	EDWARDS LIFESCIENCES PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Implementation of an autoclave for laboratory supplies and equipment sterilization.
P870078/S049	12/16/2020	X - 30-Day Notice	HANCOCK PORCINE BIOPROSTHESIS	MEDTRONIC, INC.	Change in storage temperature requirements for the tissue fixation solution.
P880086/S316	12/15/2020	X - 30-Day Notice	ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS	ST. JUDE MEDICAL, INC.	Implement a new Sterilizer #2R at the Sylmar, CA facility.
P880087/S030	12/17/2020	X - 30-Day Notice	KELMAN MULTIFLEX 2 MODELS: MT3-MT7 & MT2U-MT7U	ALCON LABORATORIES	Introduction of the Turbidimetric Test Method for the Detection of Endotoxin levels for PMMA, AcrySof and AcrySof ReSTOR Intraocular Lenses (IOLs), AcrySert and UltraSert Lens Delivery Systems and Purified Water at Alcon Huntington West Virginia.
P890003/S439	12/16/2020	X - 30-Day Notice	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Implement a new software check system that occurs after the wafer test steps at Medtronic Tempe Campus.
P890003/S440	12/15/2020	X - 30-Day Notice	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Update the manufacturing execution system to FACTORYworks Release 9.8.
P890003/S441	12/08/2020	X - 30-Day Notice	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Reduce the sampling monitoring plan for non-viable air particles in controlled environment areas.
P890055/S076	12/16/2020	X - 30-Day Notice	MEDSTREAM PROGRAMMABLE INFUSION PUMP SYSTEM	INTERA ONCOLOGY	Replacing one inch refill needles with previously approved 1.5 inch refill needles in OR prep kit and corresponding labeling edits.

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P900061/S162	12/15/2020	X - 30-Day Notice	MEDTRONIC PCD TACHYARRHYTHMIA CONTROL SYSTEM	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the manufacturing execution system to FACTORYworks Release 9.8.
P900061/S163	12/08/2020	X - 30-Day Notice	MEDTRONIC PCD TACHYARRHYTHMIA CONTROL SYSTEM	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Reduce the sampling monitoring plan for non-viable air particles in controlled environment areas.
P910018/S028	12/22/2020	X - 30-Day Notice	LIPOSORBER(R) LA-15 SYSTEM ADSORPTION COLUMN, SULFUX(R) FS-05 PLASMA SEPARATOR, AND TUB. SYST. FOR PLASMAPHER. (LT-MA2).	KANEKA PHARMA AMERICA CORP.	Change in the sterilization bag supplier for the SULFLUX KP-05 Plasma Separator for the LIPOSORBER LA-15 System.
P910023/S434	12/15/2020	X - 30-Day Notice	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ST. JUDE MEDICAL	Implement a new Sterilizer #2R at the Sylmar, CA facility.
P910056/S044	12/21/2020	X - 30-Day Notice	SOFLEX UV-ABSORBING SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS	BAUSCH & LOMB, INC.	Transfer of the bioburden and endotoxin testing methods from Nelson Laboratories Inc. to in-house at the B+L Clearwater, FL facility.
P920015/S248	12/03/2020	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Implement new wire take-up equipment in the supplier's manufacturing process.
P920015/S249	12/15/2020	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Update the manufacturing execution system to FACTORYworks Release 9.8.
P920015/S250	12/08/2020	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Reduce the sampling monitoring plan for non-viable air particles in controlled environment areas.
P920015/S251	12/10/2020	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Update the FACTORYworks Web User Interface to version 1.1.0.
P930014/S134	12/17/2020	X - 30-Day Notice	ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES	ALCON LABORATORIES, INC.	Introduction of the Turbidimetric Test Method for the Detection of Endotoxin levels for PMMA, AcrySof and AcrySof ReSTOR Intraocular Lenses (IOLs), AcrySert and UltraSert Lens Delivery Systems and Purified Water at Alcon Huntington West Virginia.
P930029/S068	12/15/2020	X - 30-Day Notice	ATAKR(TM) RFCA SYSTEM	MEDTRONIC INC.	Update the manufacturing execution system to FACTORYworks Release 9.8.
P930029/S069	12/23/2020	X - 30-Day Notice	ATAKR(TM) RFCA SYSTEM	MEDTRONIC INC.	Upgrade the operations data management system at the contract sterilizer.

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P930038/S098	12/09/2020	X - 30-Day Notice	ANGIO SEAL VASCULAR CLOSURE DEVICE	TERUMO MEDICAL CORPORATIO N	Addition of a new automated printing labeling system and automatic label inspection.
P930039/S218	12/15/2020	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Update the manufacturing execution system to FACTORYworks Release 9.8.
P930039/S219	12/08/2020	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Reduce the sampling monitoring plan for non-viable air particles in controlled environment areas.
P930039/S221	12/10/2020	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Update the FACTORYworks Web User Interface to version 1.1.0.
P930039/S222	12/11/2020	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Implementation of a newly qualified cleanroom at Medtronic Singapore Operations.
P950020/S111	12/16/2020	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Addition of a new ISO class 8 Cleanroom to support expansion of the Stent Delivery Catheter production unit.
P950022/S137	12/15/2020	X - 30-Day Notice	TVL(TM) LEAD SYSTEM	ST. JUDE MEDICAL, INC.	Implement a new Sterilizer #2R at the Sylmar, CA facility.
P950024/S096	12/15/2020	X - 30-Day Notice	MEDTRONIC(R) CAPSURE (R) EPI PACING LEAD MODEL 4695	MEDTRONIC INC.	Update the manufacturing execution system to FACTORYworks Release 9.8.
P950024/S097	12/08/2020	X - 30-Day Notice	MEDTRONIC(R) CAPSURE (R) EPI PACING LEAD MODEL 4695	MEDTRONIC INC.	Reduce the sampling monitoring plan for non-viable air particles in controlled environment areas.
P950037/S217	12/01/2020	X - 30-Day Notice	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Replace 100% Bake and Out Gas testing of electronic module components with lot sampling.
P950037/S218	12/18/2020	X - 30-Day Notice	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Implement automated cleaning equipment during an intermediate cleaning step.
P960009/S390	12/18/2020	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Update of the manufacturing execution system to FACTORYWorks Release 9.8.
P960013/S116	12/15/2020	X - 30-Day Notice	TENDRIL DX MODEL 1388T & 1388K ENDOCARDIAL PACING LEADS	ST JUDE MEDICAL	Implement a new Sterilizer #2R at the Sylmar, CA facility.
P960030/S072	12/15/2020	X - 30-Day Notice	PASSIVE PLUS DX ENDOCARDIAL STEROID ELUTING, PASSIVE-FIXATION PACING LEADS	ST. JUDE MEDICAL	Implement a new Sterilizer #2R at the Sylmar, CA facility.

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P960040/S461	12/11/2020	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Add a new X-ray System to the battery manufacturing process.
P960043/S110	12/04/2020	X - 30-Day Notice	PROSTAR 9 FR. PERCUTANEOUS VASCULAR SURGICAL (PVS) SYSTEM	ABBOTT VASCULAR INC.	Addition of a third sterilization chamber at the Synergy Health Ireland Facility.
P960058/S151	12/22/2020	X - 30-Day Notice	CLARION MULTI-STRATEGY COCHLEAR IMPLANT	ADVANCED BIONICS	Manufacturing process change for the external cases of the Naida Q Series Li-Ion Batteries.
P970004/S323	12/16/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Reduction in the sample size of an acceptance activity.
P970004/S324	12/16/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Additional manufacturing equipment.
P970004/S325	12/18/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Update of the manufacturing execution system to FACTORYWorks Release 9.8.
P970004/S326	12/16/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Transfer of manufacturing activities of the lead assembly to the Heraeus Costa Rica manufacturing facility and minor manufacturing equipment changes at the facility to support the proposed transfer. Also,changes to a processing aid used during the manufacturing process of the material that is used at Heraeus Medical Components to coat the lead assembly.
P970031/S069	12/16/2020	X - 30-Day Notice	MEDTRONIC FREESTYLE AORTIC ROOT BIOPROSTHESIS	MEDTRONIC, INC.	Change in storage temperature requirements for the tissue fixation solution.
P970051/S201	12/08/2020	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	New lower limit for the wireless power test system used for testing the bidirectional wireless link for the CP1000 (Nucleus 7) sound processor.
P970051/S202	12/16/2020	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Process modifications for the laser welding of the magnet cassette assembly for the CI600 Series of implants.
P980016/S762	12/15/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add a dark field inspection step of Resistor Array Network wafers at supplier AVX.
P980016/S763	12/16/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement a new software check system that occurs after the wafer test steps at Medtronic Tempe Campus.

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P980016/S765	12/15/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update the manufacturing execution system to FACTORYworks Release 9.8.
P980016/S766	12/18/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update wire bond manufacturing and test process documentation with Wire Bond Destructive Test Coupon requirements.
P980023/S103	12/01/2020	X - 30-Day Notice	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Replace 100% Bake and Out Gas testing of electronic module components with lot sampling.
P980023/S104	12/18/2020	X - 30-Day Notice	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Implement automated cleaning equipment during an intermediate cleaning step.
P980024/S021	12/11/2020	X - 30-Day Notice	PATHVYSION HER-2 DNA PROBE KIT	ABBOTT MOLECULAR, INC.	Use of alternative parts for in-process testing.
P980035/S664	12/16/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implement a new software check system that occurs after the wafer test steps at Medtronic Tempe Campus.
P980035/S665	12/18/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Increase the battery impedance acceptance limit at room temperature for the final functional real time telemetry finished device test.
P980035/S666	12/15/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Update the manufacturing execution system to FACTORYworks Release 9.8.
P980035/S668	12/10/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Update the FACTORYworks Web User Interface to version 1.1.0.
P980035/S669	12/11/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implementation of a newly qualified cleanroom at Medtronic Singapore Operations.
P980037/S084	12/17/2020	X - 30-Day Notice	ANGIOJET RHEOLYTIC THROMBECTOMY LF140 CATHETER	BOSTON SCIENTIFIC CORP.	Updates to the software for sterilization aeration at the BSC Coventry, Rhode Island facility.
P980043/S075	12/16/2020	X - 30-Day Notice	HANCOCK II PORCINE BIOPROSTHESIS	MEDTRONIC, INC.	Change in storage temperature requirements for the tissue fixation solution.

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P980050/S130	12/15/2020	X - 30-Day Notice	MEDTRONIC(R) JEWEL(R) AF 7250 DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATOR, MODEL 9961 PROGRAMMER APPLICATION SOF	MEDTRONIC INC.	Update the manufacturing execution system to FACTORYworks Release 9.8.
P980050/S131	12/08/2020	X - 30-Day Notice	MEDTRONIC(R) JEWEL(R) AF 7250 DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATOR, MODEL 9961 PROGRAMMER APPLICATION SOF	MEDTRONIC INC.	Reduce the sampling monitoring plan for non-viable air particles in controlled environment areas.
P990009/S064	12/08/2020	X - 30-Day Notice	FLOSEAL MATRIX/ FLOSEAL MATRIX HEMOSTATIC SEALANT/ PROCEED HEMOSTATIC SEALANT	BAXTER HEALTHCARE CORP.	Add an alternate supplier for sodium chloride used in FLOSEAL Hemostatic Matrix manufacturing.
P990009/S065	12/23/2020	X - 30-Day Notice	FLOSEAL MATRIX/ FLOSEAL MATRIX HEMOSTATIC SEALANT/ PROCEED HEMOSTATIC SEALANT	BAXTER HEALTHCARE CORP.	Allowing Thrombin pouches built with the original FLOSEAL Fast Prep packaging system to be combined with syringe pouches built with packaging system.
P990064/S084	12/16/2020	X - 30-Day Notice	MEDTRONIC MOSAIC PORCINE BIOPROSTHETIC HEART VALVE	MEDTRONIC, INC.	Change in storage temperature requirements for the tissue fixation solution.
P990075/S049	12/01/2020	X - 30-Day Notice	MENTOR CORPORATION SALINE-FILLED AND SPECTRUM (R) MAMMARY PROSTHESES	MENTOR WORLDWIDE LLC	Changes to manufacturing equipment for production of Mentor Saline-filled and Spectrum Breast Implants.
P000009/S088	12/01/2020	X - 30-Day Notice	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Replace 100% Bake and Out Gas testing of electronic module components with lot sampling.
P000009/S089	12/18/2020	X - 30-Day Notice	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Implement automated cleaning equipment during an intermediate cleaning step.
P000015/S045	12/08/2020	X - 30-Day Notice	NUCLEUS 24 AUDITORY BRAINSTEM IMPLANT SYSTEM	COCHLEAR AMERICAS	New lower limit for the wireless power test system used for testing the bidirectional wireless link for the CP1000 (Nucleus 7) sound processor.
P000029/S092	12/11/2020	X - 30-Day Notice	DEFLUX INJECTABLE GEL	PALETTE LIFE SCIENCES	Change in water source during the washing process.
P000029/S093	12/18/2020	X - 30-Day Notice	DEFLUX INJECTABLE GEL	PALETTE LIFE SCIENCES	Modify the microbiological control set sampling plan in accordance with ISO 146981:2003 by replacing batch-related air sample testing to air sampling testing twice a month is acceptable.
P000040/S040	12/17/2020	X - 30-Day Notice	HYDRO THERMABLATOR ENDOMETRIAL ABLATION SYSTEM	MINERVA SURGICAL, INC.	Updates to the software for sterilization aeration at the BSC Coventry, Rhode Island facility

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P000053/S118	12/11/2020	X - 30-Day Notice	AMS SPHINCTER 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Process change to upgrade the molding process of the silicone valve block and curved cuff components and move to a controlled, non-classified molding room.
P000053/S119	12/17/2020	X - 30-Day Notice	AMS SPHINCTER 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Updates to the software for sterilization aeration at the BSC Coventry, Rhode Island facility
P010012/S530	12/11/2020	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Add a new X-ray System to the battery manufacturing process.
P010015/S459	12/16/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implement a new software check system that occurs after the wafer test steps at Medtronic Tempe Campus.
P010015/S460	12/17/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implementation of modifications of the seal inspection process and requirements at Medtronics Swiss Manufacturing Operations
P010015/S461	12/15/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Update the manufacturing execution system to FACTORYworks Release 9.8.
P010015/S462	12/08/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Reduce the sampling monitoring plan for non-viable air particles in controlled environment areas.
P010019/S077	12/14/2020	X - 30-Day Notice	FOCUS NIGHT AND DAY (LOTRAFILCON A) SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Expansion of production site manufacturing operations for addition of AIR OPTIX plus HydraGlyde for ASTIGMATISM (lotrafilcon B) soft contact lenses.
P010031/S723	12/15/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add a dark field inspection step of Resistor Array Network wafers at supplier AVX.
P010031/S725	12/16/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement a new software check system that occurs after the wafer test steps at Medtronic Tempe Campus.

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P010031/S726	12/15/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the manufacturing execution system to FACTORYworks Release 9.8.
P010031/S727	12/18/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update wire bond manufacturing and test process documentation with Wire Bond Destructive Test Coupon requirements.
P020050/S036	12/22/2020	X - 30-Day Notice	WAVELIGHT ALLEGRETTO WAVE EXCIMER LASER SYSTEM	ALCON LABORATORIES, INC.	Alternate suppliers for the electronic modules and printed circuit boards contained in the WaveLight EX500 Excimer Laser.
P030005/S206	12/11/2020	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Move the Incoming Quality Assurance Acceptance Activity for testing levels of elements in Lithium Hydroxide from an external laboratory to the material supplier.
P030008/S032	12/22/2020	X - 30-Day Notice	WAVELIGHT ALLEGRETTO WAVE EXCIMER LASER SYSTEM	ALCON LABORATORIES, INC.	Alternate suppliers for the electronic modules and printed circuit boards contained in the WaveLight EX500 Excimer Laser.
P030019/S025	12/08/2020	X - 30-Day Notice	ORTHOVISC HIGH MOLECULAR WEIGHT HYALURONAN	ANIKA THERAPEUTICS, INC.	Alternate supplier of the glass syringes used in manufacture of the 2.25 and 3 mL sizes of ORTHOVISC.
P030035/S183	12/15/2020	X - 30-Day Notice	ANTHEM AND FRONTIER II CRT-P'S	ST. JUDE MEDICAL, INC.	Implement a new Sterilizer #2R at the Sylmar, CA facility.
P030036/S125	12/10/2020	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Change the current Particle Size Distribution (PSD) analytical test method from a PSD wet method to a dry PSD method at the supplier.
P030036/S126	12/03/2020	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement new wire take-up equipment in the supplier's manufacturing process.

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P030036/S127	12/15/2020	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the manufacturing execution system to FACTORYworks Release 9.8.
P030036/S128	12/08/2020	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Reduce the sampling monitoring plan for non-viable air particles in controlled environment areas.
P030050/S033	12/18/2020	X - 30-Day Notice	SCULPTRA AND SCULPTRA AESTHETIC	Q-MED AB	Addition of an alternate sterilization site for the flip-off seal used for Sculptra and Sculptra Aesthetic products.
P030052/S027	12/11/2020	X - 30-Day Notice	UROVYSION BLADDER CANCER KIT	ABBOTT MOLECULAR	Use of alternative parts for in-process testing.
P030054/S388	12/15/2020	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ST. JUDE MEDICAL	Implement a new Sterilizer #2R at the Sylmar, CA facility.
P040020/S097	12/17/2020	X - 30-Day Notice	ACRYSOF RESTOR APODIZED DIFFRACTIVE OPTIC POSTERIOR CHAMBER IOL	ALCON RESEARCH, LTD.	Introduction of the Turbidimetric Test Method for the Detection of Endotoxin levels for PMMA, AcrySof and AcrySof ReSTOR Intraocular Lenses (IOLs), AcrySert and UltraSert Lens Delivery Systems and Purified Water at Alcon Huntington West Virginia.
P040021/S045	12/10/2020	X - 30-Day Notice	SJM BIOCOR VALVE / SJM BIOCOR SUPRA VALVE	ST. JUDE MEDICAL, INC.	Modifications to the Steady Flow Hydrodynamic Tester.
P040027/S081	12/04/2020	X - 30-Day Notice	GORE VIATORR TIPS	W. L. GORE & ASSOCIATES, INC.	Implementation of process changes in the manufacturing of the Controlled Expansion Sleeve of the GORE VIATORR TIPS Endoprosthesis with Controlled Expansion.
P050006/S087	12/04/2020	X - 30-Day Notice	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Modifications to the automated inspection equipment used during packaging inspection of the device.
P050007/S040	12/04/2020	X - 30-Day Notice	STARCLOSE VASCULAR CLOSURE SYSTEM	ABBOTT VASCULAR DEVICES	Addition of a third sterilization chamber at the Synergy Health Ireland Facility.
P050023/S152	12/01/2020	X - 30-Day Notice	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Replace 100% Bake and Out Gas testing of electronic module components with lot sampling.
P050023/S153	12/18/2020	X - 30-Day Notice	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Implement automated cleaning equipment during an intermediate cleaning step.
P050050/S015	12/01/2020	X - 30-Day Notice	SCANDINAVIAN TOTAL ANKLE REPLACEMENT SYSTEM (S.T.A.R.ANKLE)	STRYKER CORPORATION	Modification to the gamma sterilization load configuration, positioning in the sterilization chamber and subsequent dose map validation.
P060022/S028	12/21/2020	X - 30-Day Notice	AKREOS POSTERIOR CHAMBER INTRAOCULAR LENS,MODEL ADAPT	BAUSCH & LOMB, INC.	Transfer of the bioburden and endotoxin testing methods from Nelson Laboratories Inc. to in-house at the B+L Clearwater, FL facility.

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P060037/S070	12/17/2020	X - 30-Day Notice	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Case for Quality Modified 30-Day Notice for the addition of the validated in-house testing system at the ZOML Shannon microbiology laboratory for the completion of Bacterial Endotoxin, Total Viable Count testing and TOC and conductivity testing of ZOML Shannon water samples. Also, the Firm proposed the addition of microbiological laboratories at the Zimmer GmbH facility in Winterthur, Switzerland site and an external contractor Accugenix for testing of all ZOML Shannon microbial samples requiring species/genus level identification testing.
P060039/S103	12/10/2020	X - 30-Day Notice	ATTAIN STARFIX MODEL 4195 LEAD	MEDTRONIC INC.	Change the current Particle Size Distribution (PSD) analytical test method from a PSD wet method to a dry PSD method at the supplier.
P060039/S104	12/15/2020	X - 30-Day Notice	ATTAIN STARFIX MODEL 4195 LEAD	MEDTRONIC INC.	Update the manufacturing execution system to FACTORYworks Release 9.8.
P060039/S105	12/08/2020	X - 30-Day Notice	ATTAIN STARFIX MODEL 4195 LEAD	MEDTRONIC INC.	Reduce the sampling monitoring plan for non-viable air particles in controlled environment areas.
P070008/S120	12/01/2020	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.	Replace 100% Bake and Out Gas testing of electronic module components with lot sampling.
P070008/S121	12/18/2020	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.	Implement automated cleaning equipment during an intermediate cleaning step.
P080006/S153	12/15/2020	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Update the manufacturing execution system to FACTORYworks Release 9.8.
P080006/S154	12/08/2020	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	New mold and press equipment at a sub-tier supplier.
P080006/S155	12/08/2020	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Reduce the sampling monitoring plan for non-viable air particles in controlled environment areas.
P080025/S218	12/16/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Reduction in the sample size of an acceptance activity.
P080025/S219	12/16/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Additional manufacturing equipment.
P080025/S220	12/18/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Update of the manufacturing execution system to FACTORYWorks Release 9.8.
P080025/S221	12/16/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Transfer of manufacturing activities of the lead assembly to the Heraeus Costa Rica manufacturing facility and minor manufacturing equipment changes at the facility to support the proposed transfer. Also, changes to a processing aid used during the manufacturing process of the material that is used at Heraeus Medical Components to coat the lead assembly.

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P080026/S023	12/04/2020	X - 30-Day Notice	ABBOTT REALTIME HBV ASSAY	ABBOTT MOLECULAR, INC.	Implementation of an in-process QC test.
P090013/S311	12/15/2020	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Update the manufacturing execution system to FACTORYworks Release 9.8.
P090013/S312	12/08/2020	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Reduce the sampling monitoring plan for non-viable air particles in controlled environment areas.
P090029/S015	12/01/2020	X - 30-Day Notice	PRESTIGE LP CERVICAL DISC	MEDTRONIC SOFAMOR DANEK USA, INC.	Replace the current deionized water system to a new reverse osmosis & deionized water system with new piping and fixtures. This change applies to the water system is being replaced by a new reverse osmosis & deionized water system with new piping and fixtures. The following manufacturing facility is affected by the change(s): Orchid Orthopedics Solutions, 23149 Commerce Drive, Farmington Hills, MI 48335 USA.
P100010/S111	12/15/2020	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Implement two alternate manufacturing Cell Operating System (COS) stations and to update associated equipment and inspection procedures
P100010/S112	12/15/2020	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Update the manufacturing execution system to FACTORYworks Release 9.8.
P100014/S029	12/11/2020	X - 30-Day Notice	SOLESTA INJECTABLE GEL	PALETTE LIFE SCIENCES	Change in water source during the washing process.
P100014/S030	12/18/2020	X - 30-Day Notice	SOLESTA INJECTABLE GEL	PALETTE LIFE SCIENCES	Modify the microbiological control set sampling plan in accordance with ISO 146981:2003 by replacing batch-related air sample testing to air sampling testing twice a month is acceptable.
P100017/S023	12/08/2020	X - 30-Day Notice	ABBOTT REALTIME HCV, ABBOTT REALTIME HCV AMPLIFICATION REAGENT KIT, ABBOTT REALTIME HVC CONTROL KIT, ABBOTT REALTIME HCV	ABBOTT MOLECULAR, INC.	Implementation of an in-process QC test.
P100018/S030	12/21/2020	X - 30-Day Notice	PIPELINE EMBOLIZATION DEVICE	MICRO THERAPEUTICS, INC. D/B/A EV3 NEUROVASCULAR	Implementation of a statistical process monitoring control limit for the Pipeline Flex Embolization Device proximal delivery system hypotube subassembly.
P100022/S037	12/22/2020	X - 30-Day Notice	ZILVER PTX DRUG-ELUTING PERIPHERAL STENT	COOK IRELAND, LTD.	Change to delivery system handle manufacturing processes.
P100045/S046	12/22/2020	X - 30-Day Notice	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ST. JUDE MEDICAL	Rework the LCD screens from the CardioMEMS I3 Patient Electronic System (PES) returns inventory and use them in the new PES manufacturing builds.
P110002/S026	12/15/2020	X - 30-Day Notice	MOBI-C CERVICAL DISC PROSTHESIS (ONE-LEVEL INDICATION)	ZIMMER BIOMET SPINE, INC.	Additional sealing machine for the secondary packaging/outer pouch for the Mobi-C implant.

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P110005/S007	12/28/2020	X - 30-Day Notice	SINOVIAL (SODIUM HYALURONATE 0.8%)	IBSA INSTITUT BIOCHIMIQUE SA	Change in the holding times for which filtered solution and bulk solution are kept during the manufacturing process.
P110007/S013	12/02/2020	X - 30-Day Notice	HEALON ENDOCOAT OPVISCOSURGICAL OPHTHALMIC DEVICE (OVD) (3% SODIUM HYALURONATE)	JOHNSON & JOHNSON SURGICAL VISION, INC.	Expansion of the Lifecore Biomedical quality control (QC) laboratory.
P110009/S026	12/15/2020	X - 30-Day Notice	MOBI-C CERVICAL DISC PROSTHESIS (TWO-LEVEL INDICATION)	ZIMMER BIOMET SPINE, INC.	Additional sealing machine for the secondary packaging/outer pouch for the Mobi-C implant.
P110010/S185	12/16/2020	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of a new ISO class 8 Cleanroom to support expansion of the Stent Delivery Catheter production unit.
P110010/S186	12/08/2020	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Integration of automated stent visual inspection process steps.
P110012/S021	12/11/2020	X - 30-Day Notice	VYSIS ALK BREAK APART FISH PROBE KIT, VYSIS PARAFFIN PRETREATMENT IV & POST HYBRIDIZATION WASH BUFFER KIT PROBECHEK ALK	ABBOTT MOLECULAR, INC.	Use of alternative parts for in-process testing.
P110013/S105	12/21/2020	X - 30-Day Notice	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Introduction of a robotic aid for the packaging and labeling workstep
P110035/S064	12/17/2020	X - 30-Day Notice	EPIC SELF-EXPANDING NITINOL STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Updates to the software for sterilization aeration at the BSC Coventry, Rhode Island facility.
P110038/S025	12/17/2020	X - 30-Day Notice	RELAY THORACIC STENT-GRAFT WITH PLUS DELIVERY SYSTEM	BOLTON MEDICAL, INC.	Change to the nylon sub-supplier, the anti-block additive used, and the extrusion process used in the manufacturing of the product pouches for the Treo Abdominal Stent-Graft System and the Relay Thoracic Stent-Graft with Plus Delivery System.
P110042/S148	12/01/2020	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Updates to the acrylic adhesive application process.

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P110042/S151	12/11/2020	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Add a new X-ray System to the battery manufacturing process.
P120010/S138	12/01/2020	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Manufacturing changes related to bioburden testing for the Enlite Sensor and Guardian Sensor (3). The Enlite Sensor is component of the MiniMed 530G System, the MiniMed 630G System, the Paradigm Real-Time Revel System, and the iPro2 CGM System. The Guardian Sensor (3) is component of the MiniMed 670G System, the Guardian Connect System, and the MiniMed 630G System with SmartGuard.
P120017/S025	12/15/2020	X - 30-Day Notice	MODEL 5071 LEAD	MEDTRONIC INC.	Update the manufacturing execution system to FACTORYworks Release 9.8.
P120017/S026	12/08/2020	X - 30-Day Notice	MODEL 5071 LEAD	MEDTRONIC INC.	Reduce the sampling monitoring plan for non-viable air particles in controlled environment areas.
P120020/S025	12/14/2020	X - 30-Day Notice	SUPERA PERIPHERAL STENT SYSTEM	ABBOTT VASCULAR (IDEF TECHNOLOGIES INC)	Addition of three in-process inspection tests of assembly units for flushing path blockages and leaks.
P130004/S010	12/17/2020	X - 30-Day Notice	RESURE SEALANT	OCULAR THERAPEUTIX, INC.	Modify the test method for the ReSure Sealant Hydrogel and Dropper Bottle Performance.
P130013/S040	12/17/2020	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Updates to the software for sterilization aeration at the BSC Coventry, Rhode Island facility.
P130014/S009	12/01/2020	X - 30-Day Notice	ADHERUS AUTOSPRAY DURAL SEALANT	HYPERBRANCH MEDICAL TECHNOLOGY, INC.	Replacement mold for the Housing Top and Housing Bottom of the device applicator.
P130016/S045	12/08/2020	X - 30-Day Notice	NUCLEUS HYBRID L24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	New lower limit for the wireless power test system used for testing the bidirectional wireless link for the CP1000 (Nucleus 7) sound processor.
P130026/S067	12/18/2020	X - 30-Day Notice	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Changes to the TactiCath SE process aid to prevent adhesive contamination on the tip electrode.
P130030/S071	12/08/2020	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE	BOSTON SCIENTIFIC CORP.	Integration of automated stent visual inspection process steps.
P140028/S065	12/08/2020	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Integration of automated stent visual inspection process steps.
P140028/S066	12/17/2020	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Updates to the software for sterilization aeration at the BSC Coventry, Rhode Island facility.

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P140031/S123	12/13/2020	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Implementation of an autoclave for laboratory supplies and equipment sterilization.
P140031/S124	12/16/2020	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Addition of an alternative crimping accessory packaged with the Edwards delivery systems.
P140032/S064	12/18/2020	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Update of the manufacturing execution system to FACTORYWorks Release 9.8.
P140033/S064	12/15/2020	X - 30-Day Notice	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ST. JUDE MEDICAL, INC.	Implement a new Sterilizer #2R at the Sylmar, CA facility.
P150001/S089	12/01/2020	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	Manufacturing changes related to bioburden testing for the Enlite Sensor and Guardian Sensor (3). The Enlite Sensor is component of the MiniMed 530G System, the MiniMed 630G System, the Paradigm Real-Time Revel System, and the iPro2 CGM System. The Guardian Sensor (3) is component of the MiniMed 670G System, the Guardian Connect System, and the MiniMed 630G System with SmartGuard.
P150003/S068	12/16/2020	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Addition of a new ISO class 8 Cleanroom to support expansion of the Stent Delivery Catheter production unit.
P150003/S069	12/08/2020	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Integration of automated stent visual inspection process steps.
P150005/S059	12/11/2020	X - 30-Day Notice	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Add a new proximal shaft inspection step during the manufacturing process.
P150005/S060	12/15/2020	X - 30-Day Notice	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Modify the Cooling Handle Assembly manufacturing process.
P150009/S004	12/22/2020	X - 30-Day Notice	ANGELMED GUARDIAN SYSTEM	ANGEL MEDICAL SYSTEMS INC.	Component change the implantable and external device components of the AngelMed Guardian System.
P150012/S105	12/11/2020	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Move the Incoming Quality Assurance Acceptance Activity for testing levels of elements in Lithium Hydroxide from an external laboratory to the material supplier.
P150014/S040	12/10/2020	X - 30-Day Notice	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Implement an automated QC test for a kit component.

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P150015/S042	12/10/2020	X - 30-Day Notice	COBAS HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Implement an automated QC test for a kit component.
P150019/S062	12/01/2020	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Manufacturing changes related to bioburden testing for the Enlite Sensor and Guardian Sensor (3). The Enlite Sensor is component of the MiniMed 530G System, the MiniMed 630G System, the Paradigm Real-Time Revel System, and the iPro2 CGM System. The Guardian Sensor (3) is component of the MiniMed 670G System, the Guardian Connect System, and the MiniMed 630G System with SmartGuard.
P150021/S051	12/16/2020	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Modifying an existing automated inspection process on the Sensor Applicator assembly line at an Abbott Diabetes Care supplier for the sensor component manufacturing process. The Sensor is a component of the FreeStyle Libre Pro Flash Glucose Monitoring System and Freestyle Libre Flash Glucose Monitoring System.
P150029/S035	12/01/2020	X - 30-Day Notice	IPRO2 CGM SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Manufacturing changes related to bioburden testing for the Enlite Sensor and Guardian Sensor (3). The Enlite Sensor is component of the MiniMed 530G System, the MiniMed 630G System, the Paradigm Real-Time Revel System, and the iPro2 CGM System. The Guardian Sensor (3) is component of the MiniMed 670G System, the Guardian Connect System, and the MiniMed 630G System with SmartGuard.
P150033/S089	12/16/2020	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Implement a new software check system that occurs after the wafer test steps at Medtronic Tempe Campus.
P150033/S091	12/15/2020	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Update the manufacturing execution system to FACTORYworks Release 9.8.
P150036/S054	12/13/2020	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Implementation of an autoclave for laboratory supplies and equipment sterilization.
P150041/S006	12/11/2020	X - 30-Day Notice	VYSIS CLL FISH PROBE KIT	ABBOTT MOLECULAR, INC.	Use of alternative parts for in-process testing.
P150048/S051	12/13/2020	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Implementation of an autoclave for laboratory supplies and equipment sterilization.
P160007/S039	12/01/2020	X - 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Manufacturing changes related to bioburden testing for the Enlite Sensor and Guardian Sensor (3). The Enlite Sensor is component of the MiniMed 530G System, the MiniMed 630G System, the Paradigm Real-Time Revel System, and the iPro2 CGM System. The Guardian Sensor (3) is component of the MiniMed 670G System, the Guardian Connect System, and the MiniMed 630G System with SmartGuard.
P160015/S007	12/21/2020	X - 30-Day Notice	AED PLUS AND FULLY AUTOMATIC AED PLUS	ZOLL MEDICAL CORPORATION	Use Fluke Impulse 6000/7000 Defibrillator Analyzers for defibrillation energy testing.

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P160015/S008	12/30/2020	X - 30-Day Notice	AED PLUS AND FULLY AUTOMATIC AED PLUS	ZOLL MEDICAL CORPORATION	New tin-to-wire machines used in the manufacture of electrode assemblies.
P160015/S009	12/30/2020	X - 30-Day Notice	AED PLUS AND FULLY AUTOMATIC AED PLUS	ZOLL MEDICAL CORPORATION	New ring terminal-to-tin machine used during electrode manufacturing.
P160017/S088	12/01/2020	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Manufacturing changes related to bioburden testing for the Enlite Sensor and Guardian Sensor (3). The Enlite Sensor is component of the MiniMed 530G System, the MiniMed 630G System, the Paradigm Real-Time Revel System, and the iPro2 CGM System. The Guardian Sensor (3) is component of the MiniMed 670G System, the Guardian Connect System, and the MiniMed 630G System with SmartGuard.
P160022/S023	12/07/2020	X - 30-Day Notice	X SERIES®, R SERIES®, AED PRO®, AED 3¿ BLS PROFESSIONAL DEFIBRILLATORS, PRO-PADZ RADIOTRANSPARENT ELECTRODE, SUREPOWER ¿ BATTERY PACK, SUREPOWER II¿ BATTERY PACK, AED PRO® NON-RECHARGEABLE LITHIUM BATTERY PACK, AED 3 ¿ BATTERY PACK, SUREPOWER¿ CHARGER, AND SUREPOWER ¿ SINGLE BAY CHARGER	ZOLL MEDICAL CORPORATION	New equipment used in the flex printed circuit board manufacturing line at a supplier.
P160028/S003	12/16/2020	X - 30-Day Notice	PHILIPS HEARTSTART FR3 DEFIBRILLATOR	PHILIPS MEDICAL SYSTEMS, INC.	Updates to the inspection process for various device components and sub-assemblies.
P160029/S007	12/16/2020	X - 30-Day Notice	HEARTSTART ONSITE DEFIBRILLATOR (MODEL M5066A) AND HEARTSTART HOME DEFIBRILLATOR (MODEL M5068A)	PHILIPS MEDICAL SYSTEMS, INC.	Updates to the inspection process for various device components and sub-assemblies.
P160030/S045	12/16/2020	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Modifying an existing automated inspection process on the Sensor Applicator assembly line at an Abbott Diabetes Care supplier for the sensor component manufacturing process. The Sensor is a component of the FreeStyle Libre Pro Flash Glucose Monitoring System and Freestyle Libre Flash Glucose Monitoring System.
P160038/S018	12/04/2020	X - 30-Day Notice	PRAXIS EXTENDED RAS PANEL	ILLUMINA, INC.	Changes to a bulk enzyme manufacturing process.

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P160041/S032	12/10/2020	X - 30-Day Notice	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Implement an automated QC test for a kit component.
P160043/S040	12/21/2020	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Introduction of a robotic aid for the packaging and labeling workstep.
P160045/S024	12/01/2020	X - 30-Day Notice	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Manufacturing process and material changes.
P160048/S017	12/11/2020	X - 30-Day Notice	EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM	SENSEONICS, INCORPORATED	Adding a new component manufacturing line at a previously approved supplier.
P170006/S019	12/06/2020	X - 30-Day Notice	AVALUS(TM) BIOPROSTHESIS	MEDTRONIC INC.	Automation of the valve rinsing process before and after anti-mineralization treatment.
P170008/S030	12/08/2020	X - 30-Day Notice	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Changes to include an interim packaging phase for sterilized lots.
P170008/S031	12/21/2020	X - 30-Day Notice	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Change to EluNIRs sterilization process for the verification of successful sterilization.
P170023/S007	12/17/2020	X - 30-Day Notice	BULKAMID URETHRAL BULKING SYSTEM	CONTURA INTERNATIONAL A/S	Change in the sterilization site of the Bulkamid Needle, a component of the Bulkamid Urethral Bulking System.
P170024/S006	12/15/2020	X - 30-Day Notice	SURPASS STREAMLINE FLOW DIVERTER	STRYKER NEUROVASCULAR	Optimization changes to the ethylene oxide (EO) sterilization cycle used for sterilization of the Surpass Streamline Flow Diverter.
P180011/S039	12/08/2020	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Integration of automated stent visual inspection process steps.
P180011/S040	12/17/2020	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Updates to the software for sterilization aeration at the BSC Coventry, Rhode Island facility.
P180028/S004	12/16/2020	X - 30-Day Notice	HEARTSTART FRX DEFIBRILLATOR	PHILIPS MEDICAL SYSTEMS	Updates to the inspection process for various device components and sub-assemblies.
P190015/S008	12/17/2020	X - 30-Day Notice	TREO® ABDOMINAL STENT-GRAFT SYSTEM	BOLTON MEDICAL INC.	Change to the nylon sub-supplier, the anti-block additive used, and the extrusion process used in the manufacturing of the product pouches for the Treo Abdominal Stent-Graft System and the Relay Thoracic Stent-Graft with Plus Delivery System.
P190019/S001	12/02/2020	X - 30-Day Notice	RANGER¿ PACLITAXEL-COATED PTA BALLOON CATHETER	BOSTON SCIENTIFIC CORPORATION	Adopt Ranger into the reduced EO gas concentration version of the BSC2000-2 sterilization cycle.

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P190028/S004	12/10/2020	X - 30-Day Notice	COBAS HPV FOR USE ON THE COBAS 6800/8800 SYSTEMS	ROCHE MOLECULAR SYSTEMS, INC.	Implement an automated QC test for a kit component.
P200015/S003	12/16/2020	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Addition of an alternative crimping accessory packaged with the Edwards delivery systems.
P200015/S006	12/10/2020	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Implementation of a new inspection and a new cutting fixture related to the Commander Delivery System valve crimp section.
P200015/S007	12/18/2020	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Removal of two in-process dimensional inspections.

Total: 219					