PMA Monthly approvals from 10/1/2021 to 10/31/2021

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190012	10/15/2021	PMAO - PMA Origi	SPATZ3 ADJUSTABLE BALLOON SYSTEM	SPATZ FGIA INC.	Approval for the Spatz3 Adjustable Balloon System is indicated for temporary use for weight loss in adults with obesity Body Mass Index (BMI) of 35.0-40.0 kg/m2 or a BMI of 30.0 to 34.9 kg/m2 with one or more major obesity-related comorbid conditions who have failed to achieve and maintain weight-loss with a supervised weight control program. The Spatz3 Adjustable Balloon System is to be used in conjunction with a long-term supervised diet and behavior modification program designed to increase the possibility of long-term weight-loss maintenance. The maximum placement period for Spatz3 Adjustable Balloon System is 8 months.
P200040	10/06/2021	PMAO - PMA Origi	SOFTVUE¿ AUTOMATED WHOLE BREAST ULTRASOUND SYSTEM WITH SEQUR¿ BREAST INTERFACE ASSEMBLY	DELPHINUS MEDICAL TECHNOLOGIES	Approval for the SoftVue System. The device is indicated as an adjunct to mammography for breast cancer screening in asymptomatic women with dense breast parenchyma after confirmation that the breast density composition is BI-RADS c or d at the time of screening mammography. The device is intended to increase breast cancer detection in the described patient population relative to mammography alone. The device is not intended to be used as a replacement for screening mammography. The device can be used at the same visit as screening mammography and SoftVue images are intended to be interpreted with the mammogram results to enhance screening.
P210026	10/12/2021	PMAO - PMA Origi	KI-67 IHC PHARMDX	AGILENT TECHNOLOGIES, INC.	Approval of Ki-67 IHC MIB-1 pharmDx (Dako Omnis) For In Vitro Diagnostic Use. Ki-67 IHC MIB-1 pharmDx (Dako Omnis) is a qualitative immunohistochemical (IHC) assay using monoclonal mouse anti-Ki-67, Clone MIB-1, intended for use in the detection of Ki-67 protein in formalin-fixed, paraffin-embedded (FFPE) breast carcinoma tissue using the EnVision FLEX visualization system on Dako Omnis. Ki-67 protein expression in breast carcinoma is determined by using the Ki-67 pharmDx Score, which is the overall percentage of viable tumor cells in the invasive cancer component showing Ki-67 nuclear staining. The specimen should be considered to have Ki-67 expression if Ki-67 pharmDx Score is ? 20. Ki-67 IHC MIB-1 pharmDx (Dako Omnis) is indicated as an aid in identifying patients with early breast cancer at high risk of disease recurrence for whom adjuvant treatment with Verzenio® (abemaciclib) in combination with endocrine therapy is being considered.

Total: 3

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement

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P840001/S497	10/26/2021	R - Real-Time Proc	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Approval for minor labeling changes for the Models 97715 and 97716 Intellis implantable neurostimulators, Model 977Axxx and 977Dxxx Vectris lead kits, Model 977Cxxx Specify lead kits, and Model 9779x Injex anchor accessory kits which includes removing storage temperature limits from the labeling.
P840062/S081	10/07/2021	Y - 135 Review Tra	COLLACOTE(TM)	INTEGRA LIFESCIENCES CORP.	Approval for a change in the manufacturing site of the product package supplier to Carolina, Puerto Rico.
P850010/S097	10/07/2021	Y - 135 Review Tra	HELISTAT(TM) ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	INTEGRA LIFESCIENCES CORPORATION	Approval for a change in the manufacturing site of the product package supplier to Carolina, Puerto Rico
P850064/S045	10/13/2021	Y - 135 Review Tra	MODEL 203 LIFE PULSE HIGH FREQUENCY VENTILATOR	BUNNELL, INC.	Approval for a change to the manufacturing process of cutting the heater wire, including the process of stripping the ends of the cut heater wire. It is proposed that an approved vendor perform the requested tasks.
P860004/S377	10/12/2021	R - Real-Time Proc	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval for: a change in the raw material used to manufacture the rivet-support subcomponent in the roller arm and support assembly of the pumphead in SynchroMed II Drug Infusion Pump Model 8637 (SynchroMed II pump).
P940015/S047	10/27/2021	Y - 135 Review Tra	SYNVISC ONE	SANOFI GENZYME CORP.	Approval for the use of existing filling and parts washing machines to manufacture a biologic when not in use for the manufacture of Synvisc and Synvisc-One.
P960040/S459	10/07/2021	N - Normal 180 Day	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Approval for hardware, software, and firmware changes to NG3/NG4 Pulse Generators.
P960040/S466	10/07/2021	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 reflect findings of the Strategic Management to Improve CRT (SMART) Multi-Site Pacing (MSP) clinical study.
P970051/S207	10/08/2021	R - Real-Time Proc	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for a Remote Assist, a new software feature intended to enable clinicians to make select programming adjustments, enable processor settings, and provide counselling via a live video session with their cochlear implant patients.
P990004/S039	10/19/2021	O - Normal 180 Day	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Approval for addition of an alternate sterilization site and a change to the sterilization dosage for SURGIFOAM Absorbable Gelatin Sponge (Oral Sponge and Hemorrhoidectomy Sponge) and SURGIFOAM® Absorbable Gelatin Powder
P990074/S045	10/27/2021	N - Normal 180 Day	NATRELLE SALINE BREAST IMPLANTS	ALLERGAN	Approval for changes to the patient and physician labeling including a boxed warning and a patient decision checklist.
P990075/S051	10/27/2021	N - Normal 180 Day	MENTOR CORPORATION SALINE-FILLED AND SPECTRUM (R) MAMMARY PROSTHESES	MENTOR WORLDWIDE LLC	Approval for changes to the patient and physician labeling including a boxed warning and a patient decision checklist.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000021/S042	10/08/2021	Y - 135 Review Tra	DIMENSION(R) RXL PSA FLEX(R) REAGENT CARTRIDGE	SIEMENS HEALTHCARE DIAGNOSTICS	Approval for a change in the manufacturing process of streptavidin.
P000037/S056	10/13/2021	N - Normal 180 Day	ON-X (R) PROSTHETIC HEART VALVE, MODEL ONXA	ON-X LIFE TECHNOLOGIES, INC.	Approval for several changes to the On-X Ascending Aortic Prosthesis including changes to the yarn and gelatin component manufacturing and changes to device labeling.
P000046/S029	10/21/2021	O - Normal 180 Day	STAARVISC II	ANIKA THERAPEUTICS, INC.	Approval for request of an additional tradename, OPHTHALIN®
P010012/S528	10/07/2021	N - Normal 180 Day	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Approval for hardware, software, and firmware changes to NG3/NG4 Pulse Generators.
P010012/S540	10/07/2021	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 reflect findings of the Strategic Management to Improve CRT (SMART) Multi-Site Pacing (MSP) clinical study.
P010030/S152	10/18/2021	R - Real-Time Proc	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Approval for an additional software application (Service Interface V1.0.0) to be installed on the LifeVest 4000 Monitor
P020027/S037	10/08/2021	Y - 135 Review Tra	DIMENSION FPSA FLEX REAGENT CARTRIDGE AND DIMENSION T/F PSA CALIBRATOR FOR DIMENSION RXL AND XPAND SYSTEMS	SIEMENS HEALTHCARE DIAGNOSTICS	Approval for a change in the manufacturing process of streptavidin.
P020045/S095	10/12/2021	N - Normal 180 Day	7F FREEZOR CARDIAC CRYOABLATION CATHETER AND CCT.2 CRYOCONSOLE SYSTEM	MEDTRONIC CRYOCATH LP	Approval for an alternate packaging site; a new sterilization method and site; and packaging improvements for the electrical umbilical.
P020056/S054	10/27/2021	N - Normal 180 Day	NATRELLE SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Approval for changes to the patient and physician labeling including a boxed warning and a patient decision checklist.
P030053/S062	10/27/2021	N - Normal 180 Day	MEMORYGEL SILICONE GEL -FILLED BREAST IMPLANTS	MENTOR CORP.	Approval for changes to the patient and physician labeling including a boxed warning and a patient decision checklist.
P040024/S124	10/22/2021	R - Real-Time Proc	RESTYLANE INJECTABLE GEL	Q-MED AB	Approval to change the bacterial endotoxin specification limit of the Terumo needle co-packed with RESTYLANE® Injectable Gels.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P050037/S112	10/21/2021	S - Special CBE	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Approval for inclusion of additional elemental impurities testing in accordance with USP <232>.
P050038/S038	10/22/2021	Y - 135 Review Tra	ARISTA AH ABSORBABLE HEMOSTAT	DAVOL, INC.	Approval for a change in the amount of hydrochloric acid used during the hydrolysis step of the Arista AH manufacturing process.
P050052/S132	10/21/2021	S - Special CBE	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval for inclusion of additional elemental impurities testing in accordance with USP <232>
P060028/S041	10/27/2021	N - Normal 180 Day	MENTOR MEMORYSHAPE BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Approval for changes to the patient and physician labeling including a boxed warning and a patient decision checklist.
P070004/S033	10/27/2021	N - Normal 180 Day	SIENTRA SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Approval for changes to the patient and physician labeling including a boxed warning and a patient decision checklist.
P100014/S031	10/27/2021	O - Normal 180 Day	SOLESTA INJECTABLE GEL	PALETTE LIFE SCIENCES	Approval to implement electronic labeling and changes to the labeling including revised contraindication, new warnings and new precautions.
P100045/S057	10/05/2021	R - Real-Time Proc	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ST. JUDE MEDICAL	Approval for a software revision update to the CardioMEMS Web Application.
P100047/S189	10/15/2021	R - Real-Time Proc	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for dimensional changes to 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 manufacturing changes.
P120011/S022	10/27/2021	O - Normal 180 Day	IDEAL IMPLANT SALINE-FILLED BREAST IMPLANT	IDEALIMPLANT	Approval for changes to the patient and physician labeling including a boxed warning and a patient decision checklist.
P130021/S104	10/21/2021	S - Special CBE	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Approval for updates regarding flush port orientation, handle rotation, and valve deployment/retrieval timing to the Evolut R, Evolut PRO, and Evolut PRO+ Instructions for Use (IFU) to align to physician training materials and risk documentation.
P140003/S086	10/15/2021	R - Real-Time Proc	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for a revision of the Automated Impella Controller software related to the detection of obstructions of purge flow in the Impella 5.5 with Smart Assist.
P140029/S040	10/19/2021	Y - 135 Review Tra	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Approval for a new alternative bulk process on one manufacturing line to produce flexible batch sizes.

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P150025/S014	10/18/2021	N - Normal 180 Day	PD-L1 IHC 28-8 PHARMDX	AGILENT TECHNOLOGIES, INC.	Approval to update the current approved urothelial carcinoma (UC) indication of PD-L1 IHC 28-8 pharmDx: to include enhanced disease-free survival and new clinical data from Bristol-Myers Squibb (BMS) clinical study CA209274 (CHECKMATE-274) in this existing indication. PD-L1 IHC 28-8 pharmDx is a qualitative immunohistochemical assay using Monoclonal Rabbit Anti-PD-L1, Clone 28-8 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC), squamous cell carcinoma of the head and neck (SCCHN), and urothelial carcinoma (UC) tissues using EnVision FLEX visualization system on Autostainer Link 48. PD-L1 protein expression is defined as the percentage of evaluable tumor cells exhibiting partial or complete membrane staining at any intensity. Companion Diagnostic Indication Tumor Indication PD-L1 Expression Clinical Cutoff Intended Use NSCLC >= 1% tumor cell expression PD-L1 ICH 28-8 pharmDx is indicated as an aid in identifying NSCLC patients for treatment with OPDIVO (nivolumab) in combination with YERVOY (ipilimumab). When used in accordance with approved therapeutic labeling: PD-L1 expression (>= 1% or >= 5% or >= 10% tumor cell expression), as detected by PD-L1 IHC 28-8 pharmDx in non-squamous NSCLC (nsNSCLC) may be associated with enhanced survival from OPDIVO. PD-L1 expression (>= 1% tumor cell expression), as detected by PD-L1 IHC 28-8 pharmDx in SCCHN may be associated with enhanced survival from OPDIVO. PD-L1 expression (>= 1% tumor cell expression), as detected by PD-L1 IHC 28-8 pharmDx in UC may be associated with enhanced response rate and enhanced disease-free survival from OPDIVO®. See the OPDIVO® and YERVOY® product labels for specific clinical circumstances guiding PD-L1 testing.
P150031/S040	10/20/2021	P - Panel Track	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval to expand the current IFU to include: "Unilateral thalamic stimulation of the ventral intermediate nucleus (VIM). The device is indicated for the suppression of tremor in the upper extremity. The system is intended for use in patients who are diagnosed with essential tremor or parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability."
P150038/S014	10/29/2021	P - Panel Track	EXABLATE	INSIGHTEC	Approval for the Exablate Neuro. The device is indicated for use in the unilateral pallidotomy of patients with advanced, idiopathic Parkinsons disease with medication-refractory moderate to severe motor complications as an adjunct to Parkinsons disease medication treatment. Patients must be at least age 30. The designated area in the brain responsible for the movement disorder symptoms [globus pallidus (GPi)] must be identified and accessible for targeted thermal ablation by the Exablate device.
P160014/S018	10/12/2021	O - Normal 180 Day	COBRA PZF NANOCOATED CORONARY STENT SYSTEM	CELONOVA BIOSCIENCES, INC.	Approval for the updated final labeling to reflect the 5-year data obtained in the PzF SHIELD PAS study.
P160033/S006	10/07/2021	R - Real-Time Proc	POWERHEART® G5 AED, POWERHEART® AED G3 PLUS, AND POWERHEART® AED G3	ZOLL MEDICAL CORPORATION	Approval for a new supplier for the pediatric electrode for the Powerheart G5 Automated External Defibrillator.

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P160036/S003	10/15/2021	O - Normal 180 Day	HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM	DT MEDTECH LLC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P160046/S010	10/15/2021	P - Panel Track	VENTANA PD-L1 (SP263) ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the VENTANA PD-L1 (SP263) Assay as a CDx for identifying patients with NSCLC tumors with PD-L1 status of >= 1% TC who may benefit from treatment with TECENTRIQ.
P160049/S010	10/28/2021	O - Normal 180 Day	STELLAREX 0.035 OTW DRUG-COATED ANGIOPLASTY BALLOON	THE SPECTRANETICS CORP.	Approval for a manufacturing site located at Philips Image Guided Therapy Devices, 5905 Nathan Lane North, Plymouth, MN for a site change of the analytical laboratory for stability testing of Stellarex 0.035¿ Drug Coated Angioplasty Balloon.
P160049/S012	10/28/2021	O - Normal 180 Day	STELLAREX 0.035 OTW DRUG-COATED ANGIOPLASTY BALLOON	THE SPECTRANETICS CORP.	Approval for a manufacturing site located at Philips Image Guided Therapy Corporation, 5905 Nathan Lane North Plymouth, MN 55442, for manufacturing, including finished lot release testing and finished product testing, for the Stellarex 035 Drug Coated balloon.
P160055/S021	10/05/2021	O - Normal 180 Day	LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P170002/S019	10/22/2021	R - Real-Time Proc	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Approval for the increase in syringe volume from 1.0 mL to 1.2 mL of RHA®4 Dermal Filler.
P170012/S026	10/28/2021	Y - 135 Review Tra	HEMOBLAST¿ BELLOWS	BIOM'UP FRANCE SAS	Approval for modifications to the production equipment used in the Basic Fibrous Collagen (FB05) manufacturing process for the manufacture of HEMOBLAST¿ Bellows Hemostatic Powder.
P170013/S007	10/08/2021	O - Normal 180 Day	LOW-PROFILE VISUALIZED INTRALUMINAL SUPPORT (LVIS) AND LVIS JR.	MICROVENTION, INC.	Approval of the revised protocol for the post-approval study (PAS).
P170032/S009	10/14/2021	R - Real-Time Proc	WOVEN ENDOBRIDGE (WEB) ANEURYSM EMBOLIZATION SYSTEM	MICROVENTION, INC.	Approval for electron beam (E-beam) radiation as an additional sterilization method for the Woven EndoBridge (WEB) Aneurysm Embolization System.
P170038/S008	10/22/2021	Y - 135 Review Tra	CENTRIMAG CIRCULATORY SUPPORT SYSTEM	ABBOTT	Approval for the transfer of injection molding equipment and processes for the pump components to a new facility location
P180036/S008	10/06/2021	N - Normal 180 Day	OPTIMIZER SMART SYSTEM	IMPULSE DYNAMICS (USA), INC.	Approval for removing the Indications For Use requirement for patients to be in normal sinus rhythm.
P180036/S010	10/15/2021	O - Normal 180 Day	OPTIMIZER SMART SYSTEM	IMPULSE DYNAMICS (USA), INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P200023/S001	10/01/2021	S - Special CBE	ZILVER VENA VENOUS SELF-EXPANDING STENT	COOK IRELAND LTD.	Approval for updates to the Instructions for Use.

Total: 53

30-Day Notice

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N12159/S087	10/21/2021	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Changes to the packaging and Bergami process manufacturing steps related to the addition of automated packaging equipment.
N970003/S269	10/21/2021	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Automate a battery component cleaning process.
P810002/S114	10/20/2021	X - 30-Day Notice	BILEAFLET-CENTER OPENING CARDIAC VALVE	ABBOTT MEDICAL	New detergent in the manufacture of cuff fabric and vascular graft components.
P830055/S275	10/01/2021	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	DePuy Ireland (Cork, Ireland) as an alternate casting supplier.
P830060/S087	10/04/2021	X - 30-Day Notice	VENTAK AND AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (AICD) SYSTEMS	BOSTON SCIENTIFIC	Alternate stylet tip forming and inspection manufacturing processes that are performed at the supplier.
P860003/S104	10/01/2021	X - 30-Day Notice	UVAR PHOTOPHERESIS SYSTEM	MALLINCKRODT PHARMACEUTICALS IRELAND LIMITED	Moving production of the Servo Isolation Module PCBA (Printed Circuit Board Assembly) Assembly (PN-1260019) from EAS to a new supplier, Saline Lectronics.
P860003/S105	10/01/2021	X - 30-Day Notice	UVAR PHOTOPHERESIS SYSTEM	MALLINCKRODT PHARMACEUTICALS IRELAND LIMITED	Moving production of the Ballast Monitor PCBA and Bracket Assembly from EAS to new supplier Saline Lectronics.
P860004/S381	10/28/2021	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Reduce motor lead wire length to limit risk of short circuits
P860057/S204	10/12/2021	X - 30-Day Notice	EDWARDS LIFESCIENCES PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Increased manning and a relocation of component manufacturing activities to cleanroom #2-1.
P880047/S044	10/21/2021	X - 30-Day Notice	INTERCEED TC7 ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Changes to the packaging and Bergami process manufacturing steps related to the addition of automated packaging equipment.
P880047/S045	10/29/2021	X - 30-Day Notice	INTERCEED TC7 ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Changes to the sampling frequency of Bacterial Endotoxin Test (BET) lot release testing of the GYNECARE INTERCEED Absorbable Adhesion Barrier device, manufactured at ETHICON SARL, from 100% batch release testing to audit testing on a monthly basis.
P900056/S194	10/05/2021	X - 30-Day Notice	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Addition of a new plasma welding machine.

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P910056/S048	10/14/2021	X - 30-Day Notice	SOFLEX UV-ABSORBING SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS	BAUSCH & LOMB, INC.	Change to the metrology equipment used for dioptric power and image quality measurements of enVista® Hydrophobic Acrylic Intraocular Lenses.
P910073/S166	10/04/2021	X - 30-Day Notice	ENDOTAK LEAD SYSTEM	BOSTON SCIENTIFIC	Alternate stylet tip forming and inspection manufacturing processes that are performed at the supplier.
P910073/S167	10/06/2021	X - 30-Day Notice	ENDOTAK LEAD SYSTEM	BOSTON SCIENTIFIC	Add an alternate thermal transfer ribbon for improved legibility for use in the Dorado, Puerto Rico facility.
P930039/S231	10/01/2021	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Eliminate the use of the clean bench in the manufacturing process of the J Stylet Package.
P930039/S232	10/01/2021	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Modifications to the backfill/bonding processes for CapSureFix Novus leads.
P950024/S100	10/19/2021	X - 30-Day Notice	MEDTRONIC(R) CAPSURE (R) EPI PACING LEAD MODEL 4695	MEDTRONIC INC.	Remove air-drying time at Final Wash Operation of a CapSure Epicardial Pacing Lead model 4968.
P950037/S230	10/29/2021	X - 30-Day Notice	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Optimize the sterilization process parameters for P01 and P02 and propose a load change for P01.
P960004/S097	10/04/2021	X - 30-Day Notice	THINLINE ENDOCARDIAL PACING LEADS	BOSTON SCIENTIFIC	Alternate stylet tip forming and inspection manufacturing processes that are performed at the supplier.
P960004/S098	10/06/2021	X - 30-Day Notice	THINLINE ENDOCARDIAL PACING LEADS	BOSTON SCIENTIFIC	Add an alternate thermal transfer ribbon for improved legibility for use in the Dorado, Puerto Rico facility.
P960006/S054	10/04/2021	X - 30-Day Notice	SWEET TIP(R) RX STEROID ELUTING LEAD	BOSTON SCIENTIFIC	Alternate stylet tip forming and inspection manufacturing processes that are performed at the supplier.
P960009/S410	10/27/2021	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Changes to the Proximal Body Assembly (PBA), which includes increasing the PBA core pin outer diameter tolerance and allowing replacement of PBA tensile test samples when there is a tubing break below the required acceptance criteria, for the SenSight Directional Lead System (Octave) extension subassemblies at the Medtronic Danvers, MA facility.
P960016/S088	10/14/2021	X - 30-Day Notice	LIVEWIRE(R) CARDIAC ABLATION SYSTEM	ST. JUDE MEDICAL	Implement non-product software changes to the Ampere Generator and Remote Control Calibration and Functional Tests, and the Best Electrical Automated Safety Tester (BEAST) electrical test processes involved in the manufacture of Ampere Generator and Remote Control.
P960040/S472	10/21/2021	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Automate a battery component cleaning process.
P960043/S115	10/27/2021	X - 30-Day Notice	PROSTAR 9 FR. PERCUTANEOUS VASCULAR SURGICAL (PVS) SYSTEM	ABBOTT VASCULAR INC.	Modification to the grit blasting process on the push mandrel component of the Perclose ProStyle device.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S794	10/14/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Updates to inspection and acceptance criteria for high energy transformers.
P980023/S109	10/29/2021	X - 30-Day Notice	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Optimize the sterilization process parameters for P01 and P02 and propose a load change for P01.
P980035/S693	10/27/2021	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Update the rework wire extension process.
P990004/S050	10/28/2021	X - 30-Day Notice	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Use of an additional dry oven for the SURGIFOAM® pouch-packed sponge products to increase production capacity.
P010001/S024	10/07/2021	X - 30-Day Notice	CERAMIC TRANSCEND HIP ARTICULATION SYSTEM	CERAMTEC GMBH	Addition of a laser system for laser marking of ceramic components of the Transcend Hip Articulation System.
P010012/S546	10/06/2021	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Add an alternate thermal transfer ribbon for improved legibility for use in the Dorado, Puerto Rico facility.
P010012/S547	10/21/2021	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Automate a battery component cleaning process.
P010030/S153	10/12/2021	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTUR ING CORPORATIO N	Alternate tier II suppliers of raw material components for assembly onto the LifeVest 4000 Monitor Printed Circuit Assembly.
P010031/S759	10/14/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Updates to inspection and acceptance criteria for high energy transformers.
P020004/S184	10/22/2021	X - 30-Day Notice	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,I NC	Changes to the lot acceptance sampling plan methodology.

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P030005/S214	10/21/2021	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Automate a battery component cleaning process.
P030017/S347	10/07/2021	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Update to the Implantable Pulse Generator (IPG) Automatic Test Equipment (ATE) software to widen the acceptance criteria limits during the (PCBA) manufacturing process.
P030039/S027	10/27/2021	X - 30-Day Notice	COSEAL SURGICAL SEALANT	BAXTER BIO SCIENCE	Several manufacturing changes to the syringe clip component of the Coseal Surgical Sealant product.
P040012/S062	10/12/2021	X - 30-Day Notice	ACCULINK CAROTID STENT SYSTEM AND RX ACCULINK CAROTID STENT SYSTEM	ABBOTT VASCULAR	Manufacturing site change for a hypotube supplier.
P040014/S045	10/14/2021	X - 30-Day Notice	IBI THERAPY CARDIAC ABLATION SYSTEM ERS/ 1500T RF GENERATOR	IRVINE BIOMEDICAL, INC.	Implement non-product software changes to the Ampere Generator and Remote Control Calibration and Functional Tests, and the Best Electrical Automated Safety Tester (BEAST) electrical test processes involved in the manufacture of Ampere Generator and Remote Control.
P040020/S101	10/01/2021	X - 30-Day Notice	ACRYSOF RESTOR APODIZED DIFFRACTIVE OPTIC POSTERIOR CHAMBER IOL	ALCON RESEARCH, LTD.	Replacement of obsolete components and a minor software upgrade for the optical inspection equipment used to measure AcrySof PanOptix and PanOptix Toric intraocular lenses.
P040042/S051	10/14/2021	X - 30-Day Notice	THERAPY DUAL 8 CARDIAC ABLATION SYSTEM,THERAM 8MM THERMISTER ABLATION CATHETER SAFIRE TX ABLATION CATHETER	IRVINE BIOMEDICAL,INC.(IBI)	Implement non-product software changes to the Ampere Generator and Remote Control Calibration and Functional Tests, and the Best Electrical Automated Safety Tester (BEAST) electrical test processes involved in the manufacture of Ampere Generator and Remote Control.
P050023/S163	10/29/2021	X - 30-Day Notice	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Optimize the sterilization process parameters for P01 and P02 and propose a load change for P01.
P050027/S029	10/13/2021	X - 30-Day Notice	KARL STORZ PHOTODYNAMIC DIAGNOSTIC D-LIGHT C (PDD) SYSTEM	KARL STORZ ENDOSCOPY-AMERICA, INC.	Change in an epoxy manufacturing material used in the manufacturing process of the transformer in the Telecam and Tricam.
P060019/S054	10/14/2021	X - 30-Day Notice	IBI THERAPY COOL PATH ABLATION CATHETER & IBI-1500T9 RF	IRVINE BIOMEDICAL, INC.	Implement non-product software changes to the Ampere Generator and Remote Control Calibration and Functional Tests, and the Best Electrical Automated Safety Tester (BEAST) electrical test processes involved in the manufacture of Ampere Generator and Remote Control.
P060037/S075	10/07/2021	X - 30-Day Notice	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Changes to the heat sealing process parameters of the sterile package lidding.
P060040/S080	10/07/2021	X - 30-Day Notice	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORP.	Alternate leakage Test Analyzer for HeartMate Power Module (PM) and HeartMate Universal Battery Charger (UBC).

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P070001/S021	10/28/2021	X - 30-Day Notice	PRODISC TM-C TOTAL DISC REPLACEMENT	CENTINEL SPINE, LLC	Expand the responsibilities of Hammill Medical (360 Tomahawk Drive Maumee, OH 43537) to perform the following for the prodisc -C modified endplates (-SK, -NOVO, and -VIVO) once the modified endplates are approved: acquire the raw material, machine the endplate components, polish the superior endplates, complete inspections and bead blast the endplates.
P070008/S132	10/29/2021	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.	Optimize the sterilization process parameters for P01 and P02 and propose a load change for P01.
P080006/S163	10/19/2021	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Replace two injection molding presses at external supplier - Integer.
P080020/S045	10/04/2021	X - 30-Day Notice	GEL-ONE	SEIKAGAKU CORP.	Addition of a new supplier for a raw material used in the manufacture of Gel-One.
P090016/S046	10/13/2021	X - 30-Day Notice	BELOTERO BALANCE	MERZ NORTH AMERICA, INC	Qualification of an alternative supplier of needles and modification of associated secondary packaging components to accommodate the new needles.
P090031/S011	10/13/2021	X - 30-Day Notice	MONOVISC	ANIKA THERAPEUTICS, INC.	Alternate plastic formulation for components of the syringe.
P090031/S012	10/13/2021	X - 30-Day Notice	MONOVISC	ANIKA THERAPEUTICS, INC.	Change from an automatic to manual drainage step in manufacture of Monovisc.
P100009/S044	10/22/2021	X - 30-Day Notice	MITRACLIP DELIVERY SYSTEM	ABBOTT VASCULAR INC.	New cleanroom in an existing facility to manufacture Delivery Catheter sub-assemblies.
P100047/S190	10/18/2021	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Change to the coating chemistry/process for the Vent Patch on the Controller and Battery Pack.
P110001/S016	10/26/2021	X - 30-Day Notice	RX HERCULINK ELITE RENAL STENT SYSTEM	ABBOTT VASCULAR	Change to the resin supplier for material used in the inner member subassembly of the RX Herculink Elite Renal and Biliary Stent System.
P110016/S079	10/14/2021	X - 30-Day Notice	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Implement non-product software changes to the Ampere Generator and Remote Control Calibration and Functional Tests, and the Best Electrical Automated Safety Tester (BEAST) electrical test processes involved in the manufacture of Ampere Generator and Remote Control.
P110028/S022	10/12/2021	X - 30-Day Notice	ABSOLUTE PRO VASCULAR SELF-EXPANDING STENT SYSTEM	ABBOTT VASCULAR INC.	Manufacturing site change for a hypotube supplier.
P110042/S160	10/19/2021	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Add second suppliers for the PCB and RF Crystal components; modification to the manufacturing material of the RF Crystal component from the new supplier, and correction to design specification for the EMBLEM S-ICD PG models A209 and A219.

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P110042/S163	10/06/2021	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Add an alternate thermal transfer ribbon for improved legibility for use in the Dorado, Puerto Rico facility.
P110042/S165	10/21/2021	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Automate a battery component cleaning process.
P130017/S049	10/06/2021	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Manufacturing changes for a capture bead reagent.
P130021/S105	10/19/2021	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Additional visual inspection for the delivery catheter system sub-assembly component.
P130026/S076	10/14/2021	X - 30-Day Notice	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Implement non-product software changes to the Ampere Generator and Remote Control Calibration and Functional Tests, and the Best Electrical Automated Safety Tester (BEAST) electrical test processes involved in the manufacture of Ampere Generator and Remote Control.
P140004/S026	10/07/2021	X - 30-Day Notice	SUPERION INTERSPINOUS SPACER	BOSTON SCIENTIFIC NEUROMODULATION	Distribute the device incorporating the change as requested in this supplement. This change adds an additional supplier for the Superion Indirect Decompression System (IDS) instrument kits tray retainer lid. The following manufacturing facility is affected by the change; New supplier: Nelipak- Mervue, Galway, Ireland.
P140018/S028	10/06/2021	X - 30-Day Notice	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Use of an alternative biological indicator (BI) for use in sterilization of the VenaSeal Closure System.
P140028/S071	10/07/2021	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Addition of an alternate pouch supplier.
P140029/S042	10/27/2021	X - 30-Day Notice	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Alternate sterility testing laboratory.
P140030/S014	10/14/2021	X - 30-Day Notice	ASTRON PERIPHERAL SELF-EXPANDING NITINOL STENT SYSTEM	BIOTRONIK, INC.	Modifications to the ultrasonic pre-cleaning process and replacement of the ultrasonic cleaning machine.
P140031/S135	10/12/2021	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Increased manning and a relocation of component manufacturing activities to cleanroom #2-1.
P140031/S136	10/28/2021	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Changes to the manufacturing process for several components of the Edwards Commander delivery system.
P150001/S092	10/05/2021	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	Addition of equivalent e-beam sterilization equipment at an approved site of a current contract sterilizer.

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P150003/S079	10/04/2021	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Change to manufacturing site and pouch attributes.
P150012/S118	10/04/2021	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Alternate stylet tip forming and inspection manufacturing processes that are performed at the supplier.
P150012/S119	10/21/2021	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Automate a battery component cleaning process.
P150031/S044	10/07/2021	X - 30-Day Notice	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Update to the Implantable Pulse Generator (IPG) Automatic Test Equipment (ATE) software to widen the acceptance criteria limits during the (PCBA) manufacturing process.
P150033/S120	10/01/2021	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Implement a rework step for top shield disassembly, desiccant removal and control the time of rebaking process.
P150033/S121	10/26/2021	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Update equipment on the battery manufacturing line.
P150033/S122	10/13/2021	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Update the laser marking process at Medtronics Swiss Manufacturing Operations.
P150033/S123	10/13/2021	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Updates to the masking, demasking and interplant shipping and final visual inspection processes.
P150033/S124	10/14/2021	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Updates to the feedthrough potting, curing and inspection processes at Medtronics Swiss Manufacturing Operations.
P150033/S125	10/15/2021	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Updates to the monitoring plan for diameter and length inspections at Medtronic's Swiss Manufacturing Operations.
P150036/S058	10/12/2021	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Increased manning and a relocation of component manufacturing activities to cleanroom #2-1.
P150048/S058	10/12/2021	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Increased manning and a relocation of component manufacturing activities to cleanroom #2-1.
P160007/S041	10/05/2021	X - 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Addition of equivalent e-beam sterilization equipment at an approved site of a current contract sterilizer.
P160017/S094	10/05/2021	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Addition of equivalent e-beam sterilization equipment at an approved site of a current contract sterilizer.

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P160025/S012	10/14/2021	X - 30-Day Notice	ASTRON PULSAR STENT SYSTEM, PULSAR-18 STENT SYSTEM	BIOTRONIK, INC.	Modifications to the ultrasonic pre-cleaning process and replacement of the ultrasonic cleaning machine.
P160035/S020	10/14/2021	X - 30-Day Notice	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Implementation of mobile test unit version 2 (MTU 2) with Hardware Extension for the pairing of batteries for the Ikus driving unit.
P160035/S021	10/20/2021	X - 30-Day Notice	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	changes to the test program in the software used to determine the roughness of sloping and curved surfaces of the titanium connectors and adapters of the connecting and extension sets for the EXCOR blood pumps
P160047/S025	10/29/2021	X - 30-Day Notice	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	COOPERSURGICAL, INC.	Changes made to Mara Water Vapor Probe Handle, Handle Plug, and Protective Sheath Assembly.
P160054/S038	10/07/2021	X - 30-Day Notice	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATION	Alternate leakage Test Analyzer for HeartMate Power Module (PM) and HeartMate Universal Battery Charger (UBC).
P170012/S027	10/13/2021	X - 30-Day Notice	HEMOBLAST¿ BELLOWS	BIOM'UP FRANCE SAS	Change the location of performing Differential Scanning Calorimetry testing on the finished HEMOBLAST Bellows hemostatic powder to Biom'Up's manufacturing facility in St-Priest, France.
P170036/S009	10/12/2021	X - 30-Day Notice	M6-C ARTIFICIAL CERVICAL DISC	SPINAL KINETICS LLC	Add a new burst tester.
P180011/S047	10/07/2021	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of an alternate pouch supplier.
P190027/S002	10/08/2021	X - 30-Day Notice	TACK ENDOVASCULAR SYSTEM (4F, 1.5-4.5MM)	PHILIPS IMAGE GUIDED THERAPY CORPORATION (FORMERLY INTACT)	Alternate supplier for the tip component of the delivery system.
P200015/S014	10/28/2021	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Changes to the manufacturing process for several components of the Edwards Commander delivery system.
P200021/S006	10/26/2021	X - 30-Day Notice	NEURO COCHLEAR IMPLANT SYSTEM	OTICON MEDICAL	Oticon Medical LLC as the initial importer with responsibility for certain manufacturing activities
P200021/S007	10/26/2021	X - 30-Day Notice	NEURO COCHLEAR IMPLANT SYSTEM	OTICON MEDICAL	Changes related to the shipment configuration of the Sound Processor and Operating Room Kit.
P200023/S002	10/26/2021	X - 30-Day Notice	ZILVER VENA VENOUS SELF-EXPANDING STENT	COOK IRELAND LTD.	Adding a manufacturing site for delivery system tips and process changes for inner catheters.

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P200028/S007	10/27/2021	X - 30-Day Notice	DIAMONDTEMP ABLATION SYSTEM	MEDTRONIC INC.	Changes in the bioburden sampling plan and an expansion in the number of sterilization chambers and pallets.
	10/06/2021	X - 30-Day Notice	GORE EXCLUDER CONFORMABLE AAA ENDOPROSTHESIS (CEXC)	W. L. GORE AND ASSOCIATES, INC.	Removal of tensile sample testing for the constraining loop subassembly.
Total: 103					