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

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S085	01/21/2022	Y - 135 Review Tra	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Approval for the introduction of a new replacement metal detector for detecting metal particles in the cut Oxidized Regenerated Cellulose (ORC) at San Lorenzo, Puerto Rico manufacturing site.
P830063/S020	01/27/2022	R - Real-Time Proc	GAMBRO FIBER PLASMAFILTER	BAXTER INTERNATIONAL, INC.	Approval for a change in the polyvinyl chloride (PVC) material used for the production of the joint connectors in the Prismaflex TPE2000 Set.
P840001/S469	01/21/2022	P - Panel Track	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Approval for expanding the indications to include the management of chronic intractable pain of the lower limbs, including unilateral or bilateral pain, due to diabetic peripheral neuropathy of the lower extremities.
P880047/S043	01/21/2022	Y - 135 Review Tra	INTERCEED TC7 ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Approval for the introduction of a new replacement metal detector for detecting metal particles in the cut Oxidized Regenerated Cellulose (ORC) at your San Lorenzo, Puerto Rico manufacturing site.
P880086/S322	01/07/2022	R - Real-Time Proc	ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS	ABBOTT MEDICAL	Approval for Merlin PCS 3650 Programmer Model 3330 Software v25.41.
P900056/S196	01/25/2022	R - Real-Time Proc	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Approval for a new adhesive.
P910018/S032	01/14/2022	S - Special CBE	LIPOSORBER(R) LA-15 SYSTEM ADSORPTION COLUMN, SULFUX(R) FS-05 PLASMA SEPARATOR, AND TUB. SYST. FOR PLASMAPHER. (LT-MA2).	KANEKA PHARMA AMERICA CORP.	Approval for modification to the labeling (within the Instructions for Use and Operators Manual) for the LIPOSORBER LA-15 System.
P910023/S441	01/07/2022	R - Real-Time Proc	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ABBOTT MEDICAL	Approval for Merlin PCS 3650 Programmer Model 3330 Software v25.41.
P910023/S442	01/13/2022	R - Real-Time Proc	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ABBOTT MEDICAL	Approval for firmware updates for Avant, Neutrino NxT, Gallant, and Entrant families of ICDs and CRT-Ds.
P920046/S012	01/06/2022	S - Special CBE	FILSHIE CLIP (MARK VI) SYSTEM	FEMCARE LTD.	Approval for revisions to the Instructions for Use to clarify symptomatic versus asymptomatic clip migration rates for the Filshie Clip (Mark VI) System.
P970013/S089	01/07/2022	R - Real-Time Proc	MICRONY PACEMAKERS	ABBOTT MEDICAL	Approval for Merlin PCS 3650 Programmer Model 3330 Software v25.41.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970051/S205	01/10/2022	P - Panel Track	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for the Cochlear Nucleus 24 cochlear implant system. The device is indicated for individuals with unilateral hearing loss who meet the following criteria: 1) Individuals 5 years or older who have one ear with a severe to profound sensorineural hearing loss and obtain limited benefit from an appropriately fitted unilateral hearing device and one ear with normal or near normal hearing. a) In the ear to be implanted, a severe to profound sensorineural hearing loss defined as a PTA at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz of > 80 dB HL; and b) In the contralateral ear, normal or near normal hearing is defined as a PTA at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz <= 30 dB HL. 2) Limited benefit from an appropriately fit unilateral hearing device is defined as a score of less than or equal to 5% on a Consonant Nucleus Consonant (CNC) word test. For individuals between 5 years and 18 years of age, insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of 10% or less on developmentally appropriate word lists when tested in the ear to be implanted alone. 3) It is recommended that prior to cochlear implantation, individuals with SSD have at least two (2) weeks to one (1) month experience wearing appropriately fit Contralateral Routing of Signal (CROS) hearing aid or another suitable hearing device.
P980035/S694	01/12/2022	R - Real-Time Proc	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Approval for changes to the device feedthrough design and the pressure sensitive adhesive.
P990046/S060	01/20/2022	Y - 135 Review Tra	ATS OPEN PIVOT BILEAFLET HEART VALVE	MEDTRONIC ATS MEDICAL, INC.	Approval for a change to the formulation of a detergent used to clean valve orifices and leaflets.
P000039/S076	01/13/2022	R - Real-Time Proc	THE AMPLATZER(R) SEPTAL OCCLUDER (ASO) AND THE AMPLATZER EXCHANGE SYSTEM	ABBOTT MEDICAL	Approval for labeling changes to update the MRI Conditional information in the Instructions for Use (IFU) and Patient Implant Cards (PIC) supplied with the impacted Amplatzer Occluder devices.
P010013/S085	01/04/2022	O - Normal 180 Day	NOVASURE IMPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM	HOLOGIC, INC.	Approval for a revision to the NovaSure post approval study protocol, S0112003.
P010030/S155	01/26/2022	R - Real-Time Proc	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Approval for a minor design change to the plastic therapy electrode enclosures and the therapy electrode laminate on the LifeVest 4000 electrode belt
P010031/S762	01/24/2022	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for updates to the CareLink SmartSync Cobalt Crome Application software.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P020004/S185	01/28/2022	R - Real-Time Proc	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES, INC	Approval for a change in manufacturing of delivery system construct of C3 Catheter Delivery System of the 28.5mm, 31mm, and 35mm configurations of the Gore Excluder AAA Trunk Endoprosthesis
P020012/S040	01/21/2022	Y - 135 Review Tra	ARTEFILL, BELLAFILL PMMA COLLAGEN PERMANENT DERMAL FILLER	SUNEVA MEDICAL, INC.	Approval to add an alternate supplier for NaOH used in the manufacture of the device.
P020018/S060	01/20/2022	O - Normal 180 Day	ZENITH AAA ENDOVASCULAR GRAFT AND H&L-B ONE-SHOT INTRODUCTINO SYSTEM	COOK, INC.	Approval of the labeling updates for the post-approval study (PAS) protocol.
P020024/S066	01/13/2022	R - Real-Time Proc	AMPLATZER DUCT OCCLUDER AND 180 DEGREE DELIVERY SYSTEM	ABBOTT MEDICAL	Approval for labeling changes to update the MRI Conditional information in the Instructions for Use (IFU) and Patient Implant Cards (PIC) supplied with the impacted Amplatzer Occluder devices.
P030009/S104	01/27/2022	Y - 135 Review Tra	DRIVER OVER-THE-WIRE, RAPID EXCHANGE, AND MULTI-EXCHANGE CORONARY STENT SYSTEMS	MEDTRONIC IRELAND	Approval for using calculations of spore log resistance to evaluate lethality challenges of the requalification microbiological performance qualification for process development.
P030035/S188	01/07/2022	R - Real-Time Proc	ANTHEM AND FRONTIER II CRT-P'S	ABBOTT MEDICAL	Approval for Merlin PCS 3650 Programmer Model 3330 Software v25.41.
P030050/S038	01/21/2022	O - Normal 180 Day	SCULPTRA AND SCULPTRA AESTHETIC	Q-MED AB	Approval of the protocol for the post-approval study (PAS) protocol.
P030054/S396	01/07/2022	R - Real-Time Proc	ST JUDE MEDICAL EPIC HF SYSTEM	ABBOTT MEDICAL	Approval for Merlin PCS 3650 Programmer Model 3330 Software v25.41.
P030054/S397	01/13/2022	R - Real-Time Proc	ST JUDE MEDICAL EPIC HF SYSTEM	ABBOTT MEDICAL	Approval for firmware updates for Avant, Neutrino NxT, Gallant, and Entrant families of ICDs and CRT-Ds.
P040037/S148	01/28/2022	R - Real-Time Proc	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Approval for minor labeling changes.
P040040/S045	01/13/2022	R - Real-Time Proc	AMPLATZER MUSCULAR VSD OCCLUDER	ABBOTT MEDICAL	Approval for labeling changes to update the MRI Conditional information in the Instructions for Use (IFU) and Patient Implant Cards (PIC) supplied with the impacted Amplatzer Occluder devices.
P050023/S164	01/27/2022	R - Real-Time Proc	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval for a new version of the cellular modem used in the CardioMessenger Smart 4G device.
P060040/S082	01/12/2022	S - Special CBE	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Approval for addendums to Instructions for Use and Patient Handbook for HeartMate 3 Left Ventricular Assist System (LVAS) and HeartMate II Left Ventricular Assist System (LVAS)
P060040/S083	01/28/2022	R - Real-Time Proc	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Approval for the HeartMate Touch App software upgrade from version 1.0.17 to version 1.0.32.
P080011/S130	01/04/2022	O - Normal 180 Day	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Approval for a new private label brand name.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P080012/S068	01/12/2022	P - Panel Track	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Approval for the Prometra® Programmable Infusion Pump System. The device is indicated for intrathecal infusion of drug therapy, including: Infumorph ® (preservative free morphine sulfate sterile solution), preservative-free sterile 0.9% saline solution (Sodium Chloride Injection, USP), and baclofen (baclofen injection, intrathecal, 500-2000 mcg/mL). For Infumorph, the pump system is indicated for use in patient populations of 22 years and older (adults). For baclofen, the pump system is indicated for use in patient populations of 12 years and older (pediatric adolescents and adults).
P100021/S093	01/27/2022	Y - 135 Review Tra	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Approval for using calculations of spore log resistance to evaluate lethality challenges of the requalification microbiological performance qualification for process development.
P100026/S088	01/18/2022	R - Real-Time Proc	NEUROPACE RNS SYSTEM	NEUROPACE INC	Approval to modify the labeling for the NeuroPace® RNS® Neurostimulator model RNS-320 to provide updated estimates for battery longevity.
P110013/S112	01/27/2022	Y - 135 Review Tra	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for using calculations of spore log resistance to evaluate lethality challenges of the requalification microbiological performance qualification for process development.
P120005/S088	01/20/2022	O - Normal 180 Day	DEXCOM G4 PLATINUM CONTIUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Approval of continuous pediatric enrollment for the post-approval study (PAS) protocol.
P120021/S022	01/13/2022	R - Real-Time Proc	AMPLATZER PFO OCCLUDER	ABBOTT MEDICAL	Approval for labeling changes to update the MRI Conditional information in the Instructions for Use (IFU) and Patient Implant Cards (PIC) supplied with the impacted Amplatzer Occluder devices.
P130006/S087	01/28/2022	R - Real-Time Proc	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,I NC	Approval for minor labeling changes.
P130021/S095	01/27/2022	Y - 135 Review Tra	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Approval for using calculations of spore log resistance to evaluate lethality challenges of the requalification microbiological performance qualification for process development.
P130022/S042	01/18/2022	P - Panel Track	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATIO N	Approval for the Senza Spinal Cord Stimulation (SCS) System for expanding the indications to add the following: The Senza®, Senza II and Senza Omnia neuromodulation systems, when programmed to include a frequency of 10 kHz, are indicated as aids in the management of non-surgical refractory back pain (intractable back pain without prior surgery and not a candidate for back surgery).
P140010/S061	01/27/2022	Y - 135 Review Tra	IN PACT ADMIRAL PACLITAXEL-ELUTING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Approval for using calculations of spore log resistance to evaluate lethality challenges of the requalification microbiological performance qualification for process development.
P140018/S026	01/27/2022	Y - 135 Review Tra	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Approval for using calculations of spore log resistance to evaluate lethality challenges of the requalification microbiological performance qualification for process development.

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P140031/S138	01/04/2022	O - Normal 180 Day	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for the Edwards Añasco Puerto Rico manufacturing site to manufacture the Crimper 9600CR, located at State Road 402, KM 1.4, Industrial Park, Añasco, PR 00610.
P140033/S071	01/07/2022	R - Real-Time Proc	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ABBOTT MEDICAL	Approval for Merlin PCS 3650 Programmer Model 3330 Software v25.41.
P150013/S022	01/31/2022	O - Normal 180 Day	PD-L1 IHC 22C3 PHARMDX	AGILENT TECHNOLOGIES, INC.	Approval of the final report for the External Reproducibility Study (Part B ¿ Inter-Observer) using the PD-L1 IHC 22C3 pharmDx in esophogeal squamous cell carcinoma specimens and the proposed changes to the labeling to include the results of this study.
P150033/S107	01/27/2022	Y - 135 Review Tra	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval for using calculations of spore log resistance to evaluate lethality challenges of the requalification microbiological performance qualification for process development.
P150034/S009	01/04/2022	O - Normal 180 Day	RAINDROP NEAR VISION INLAY	RVO 2.0, INC. (D.B.A. OPTICS MEDICAL)	Approval to place the study on hold for the post-approval study (PAS) protocol.
P160030/S048	01/19/2022	O - Normal 180 Day	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval of the revised protocol for the post-approval study
P160037/S010	01/24/2022	R - Real-Time Proc	BD ONCLARITY HPV ASSAY	BECTON, DICKINSON AND COMPANY	Approval for the use of a new molecular sample tube closure cap in the BD Onclarity HPV Assay kits, when used on the BD Viper LT Instrument and BD COR System.
P160039/S007	01/10/2022	N - Normal 180 Day	REMEDE® SYSTEM	RESPICARDIA	Approval of a change to the GEN 1.5 IPG firmware (FW) from version 1.13 to version 1.14.
P160043/S048	01/27/2022	Y - 135 Review Tra	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for using calculations of spore log resistance to evaluate lethality challenges of the requalification microbiological performance qualification for process development.
P160043/S057	01/13/2022	S - Special CBE	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for additional visual verification at the attach bifurcate luer workstep.
P160045/S034	01/21/2022	O - Normal 180 Day	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Approval of the clinical protocol titled Oncomine Dx Target Test Clinical Validation Protocol: Biomarker EGFR Exon 20 Insertions (Olympic) - PRJ0002127 Supplemental Sample Study, for the post-approval study (PAS) protocol.
P160054/S044	01/12/2022	S - Special CBE	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Approval for addendums to Instructions for Use and Patient Handbook for HeartMate 3 Left Ventricular Assist System (LVAS) and HeartMate II Left Ventricular Assist System (LVAS)

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P160054/S045	01/28/2022	R - Real-Time Proc	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Approval for the HeartMate Touch App software upgrade from version 1.0.17 to version 1.0.32.
P170019/S030	01/19/2022	N - Normal 180 Day	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval to expand the intended use of FoundationOne CDx (F1CDx) to expand the intended use of FoundationOne CDx (F1CDx) to include a companion diagnostic indication for identifying patients with BRAF V600 mutation-positive unresectable or metastatic melanoma, who may benefit from treatment with atezolizumab (Tecentriq) in combination with cobimetinib and vemurafenib.
P170035/S014	01/24/2022	O - Normal 180 Day	BAUSCH + LOMB ULTRA (SAMFILCON A) CONTACT LENSES	BAUSCH AND LOMB, INC.	Approval for addition of a private label trade name.
P180038/S006	01/21/2022	R - Real-Time Proc	LIAISON XL MUREX ANTI-HBC, LIAISON MUREX CONTROL ANTI-HBC	DIASORIN INC.	Approval to allow an additional supplier of reaction cuvettes used with the assays on the LIAISON XL Analyzer.
P180039/S005	01/21/2022	R - Real-Time Proc	LIAISON® XL MUREX ANTI-HBS, LIAISON® XL MUREX CONTROL ANTI-HBS AND LIAISON® XL MUREX ANTI-HBS VERIFIERS	DIASORIN INC.	Approval to allow an additional supplier of reaction cuvettes used with the assays on the LIAISON XL Analyzer.
P180045/S003	01/21/2022	R - Real-Time Proc	LIAISON® XL MUREX HBC IGM, LIAISON® XL MUREX CONTROL HBC IGM	DIASORIN INC.	Approval to allow an additional supplier of assay reaction cuvettes used with these assays on the LIAISON XL Analyzer.
P180046/S041	01/04/2022	R - Real-Time Proc	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval to update the RF conditions in the 3T MRI conditional labeling.
P180047/S011	01/21/2022	R - Real-Time Proc	LIAISON QUANTIFERON - TB GOLD PLUS, LIAISON CONTROL QUANTIFERON - TB GOLD PLUS AND LIAISON QUANTIFERON SOFTWARE	DIASORIN, INC.	Approval to allow an additional supplier of reaction cuvettes used with the assays on the LIAISON XL Analyzer.
P180048/S003	01/21/2022	R - Real-Time Proc	LIAISON® XL MUREX HBEAG, LIAISON® XL MUREX CONTROL HBEAG	DIASORIN INC.	Approval to allow an additional supplier of reaction cuvettes used with the assays on the LIAISON XL Analyzer.
P180049/S003	01/21/2022	R - Real-Time Proc	LIAISON® XL MUREX ANTI-HBE, LIAISON® XL MUREX CONTROL ANTI-HBE	DIASORIN INC.	Approval to allow an additional supplier of reaction cuvettes used with the assays on the LIAISON XL Analyzer.
P190006/S041	01/04/2022	R - Real-Time Proc	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval to update the RF conditions in the 3T MRI conditional labeling.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190008/S015	01/27/2022	Y - 135 Review Tra	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Approval for using calculations of spore log resistance to evaluate lethality challenges of the requalification microbiological performance qualification for process development.
P190017/S003	01/21/2022	R - Real-Time Proc	LIAISON® XL MUREX HBSAG QUAL, LIAISON® MUREX CONTROL HBSAG, AND LIAISON® XL MUREX HBSAG CONFIRMATORY TEST	DIASORIN INC	Approval to allow an additional supplier of reaction cuvettes used with the assays on the LIAISON XL Analyzer.
P190018/S013	01/26/2022	R - Real-Time Proc	CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM, CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM	ALCON RESEARCH, LTD.	Approval for the Clareon Vivity Extended Vision Hydrophobic IOL and the Clareon Vivity Toric Extended Vision Hydrophobic IOL in lens case and AutonoMe Automated Pre-loaded Delivery System configurations.
P200002/S001	01/10/2022	O - Normal 180 Day	EPI-SENSE GUIDED COAGULATION SYSTEM	ATRICURE, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P200015/S016	01/04/2022	O - Normal 180 Day	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Approval for the Edwards Añasco Puerto Rico manufacturing site to manufacture the Crimper 9600CR, located at State Road 402, KM 1.4, Industrial Park, Añasco, PR 00610.
P200017/S001	01/06/2022	N - Normal 180 Day	ADVIA CENTAUR ANTI-HBE2 (AHBE2) ASSAY	SIEMENS HEALTHCARE DIAGNOSTICS, INC.	Approval for migration of the ADVIA Centaur Anti-HBe2 (aHBe2) assay to the Atellica IM analyzer. The device, as modified, will be marketed under the trade name Atellica IM Anti-HBe2 (aHBe2).
P200021/S010	01/14/2022	O - Normal 180 Day	NEURO COCHLEAR IMPLANT SYSTEM	OTICON MEDICAL	Approval of the changes to approved protocol and enromment timeline for the post-approval study (PAS) protocol.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P200039/S004	01/04/2022	R - Real-Time Proc	SHOCKWAVE INTRAVASCULAR LITHOTRIPSY (IVL) SYSTEM WITH SHOCKWAVE C2 CORONARY INTRAVASCULAR LITHOTRIPSY (IVL) CATHETER	SHOCKWAVE MEDICAL, INC.	Approval for use of the 1-wire printed circuit board in the catheter connector.
P200046/S003	01/27/2022	Y - 135 Review Tra	HARMONY¿ TPV SYSTEM	MEDTRONIC, INC.	Approval for using calculations of spore log resistance to evaluate lethality challenges of the requalification microbiological performance qualification for process development.
P210020/S001	01/19/2022	O - Normal 180 Day	OPTILUME URETHRAL DRUG COATED BALLOON	UROTRONIC, INC.	Approval of the protocol for the post-approval study (PAS) protocol.
P210020/S002	01/27/2022	O - Normal 180 Day	OPTILUME URETHRAL DRUG COATED BALLOON	UROTRONIC, INC.	Approval of the protocol for the post-approval study (PAS) protocol.

Total: 78

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S090	01/20/2022	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Changes to inks used on the packaging components (Tyvek wrapper, foil pouch, carton) of the SURGICEL Family of Absorbable Hemostats, manufactured at the Ethicon LLC site (Puerto Rico).
N12159/S091	01/19/2022	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Duplication of the existing dehumidification process for SURGICEL SNoW products in Dehumidification Chamber #3 at Ethicon LLC San Lorenzo, Puerto Rico facility.
P830055/S278	01/19/2022	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Removal of the post irradiation heat treatment process step for the Attune Revision Cruciate Retaining System (CRS) Rotating Platform (RP) Tibial Inserts that are manufactured in Cork, Ireland.
P830055/S279	01/20/2022	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Introducing an additional Final Cleanline to the process for capacity purposes.
P830061/S202	01/28/2022	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Minor modifications to combination product processes at Medtronic Rice Creek.
P840001/S507	01/19/2022	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Change in the ceramic material for multi-layer ceramic capacitors (MLCC) at Medtronics supplier. The components impacted are used within the hybrid electronic modules manufactured by Medtronics internal supplier.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P850089/S160	01/28/2022	X - 30-Day Notice	CAPSURE SP, CAPSURE, CAPSURE 2 LEADS, EXCELLENCE S, IMPULSE, IMPLUSE II EXCELLENCE SS, LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Minor modifications to combination product processes at Medtronic Rice Creek.
P880047/S049	01/20/2022	X - 30-Day Notice	INTERCEED TC7 ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Changes to inks used on the packaging components (Tyvek wrapper, foil pouch, carton) of the GYNECARE INTERCEED Absorbable Adhesion Barrier, manufactured at the Ethicon LLC site (Puerto Rico).
P890003/S451	01/28/2022	X - 30-Day Notice	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Minor modifications to combination product processes at Medtronic Rice Creek.
P890055/S079	01/27/2022	X - 30-Day Notice	MEDSTREAM PROGRAMMABLE INFUSION PUMP SYSTEM	INTERA ONCOLOGY	Change in the supplier of Can component of the Intera 3000 pump.
P900009/S048	01/07/2022	X - 30-Day Notice	SONIC ACCELERATED FRACTURE HEALING SYSTEM MODEL 2A	BIOVENTUS LLC	Use an additional supplier for the plastic housing components of the Main Operating Unit of the EXOGEN® Ultrasound Bone Healing System.
P910056/S049	01/19/2022	X - 30-Day Notice	SOFLEX UV-ABSORBING SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS	BAUSCH & LOMB, INC.	Updating the raw material specification for one chemical used in the formulation of the polishing slurry for the intraocular lenses.
P910061/S027	01/19/2022	X - 30-Day Notice	MODEL LI30U SOFLEX(TM) UV-ABSORB. INTRAOCULAR LENS	BAUSCH & LOMB	Updating the raw material specification for one chemical used in the formulation of the polishing slurry for the intraocular lenses.
P920015/S264	01/28/2022	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Minor modifications to combination product processes at Medtronic Rice Creek.
P930039/S236	01/28/2022	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Minor modifications to combination product processes at Medtronic Rice Creek.
P950024/S102	01/28/2022	X - 30-Day Notice	MEDTRONIC(R) CAPSURE (R) EPI PACING LEAD MODEL 4695	MEDTRONIC INC.	Minor modifications to combination product processes at Medtronic Rice Creek.
P960009/S416	01/19/2022	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Change in the ceramic material for multi-layer ceramic capacitors (MLCC) at Medtronics supplier. The components impacted are used within the hybrid electronic modules manufactured by Medtronics internal supplier.
P960058/S154	01/14/2022	X - 30-Day Notice	CLARION MULTI-STRATEGY COCHLEAR IMPLANT	ADVANCED BIONICS	Introduction of new roll-band sealers used by the supplier for preparing seal pouches for sterilization.
P970004/S351	01/13/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Use of a new Distribution Center Sorter Tool (DCST) to check unopened active implantable devices returned from customers.
P980006/S033	01/13/2022	X - 30-Day Notice	PURE VISION VISIBILITY TINTED CONTACT LENS FOR EXTENDED WEAR	BAUSCH & LOMB, INC.	Adding an alternate supplier of a raw material for the Ultra (samfilcon A) and Pure Vision (balafilcon A) contact lens products.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S802	01/31/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Modifications to the plasma cleaning process at Medtronic's internal supplier.
P980016/S803	01/21/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update the final clean process used in manufacturing at internal supplier.
P980016/S804	01/28/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Change in the ceramic material for multi-layer ceramic capacitors used by supplier.
P980035/S699	01/10/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implement a vision system at Medtronic's Swiss Manufacturing Operations facility.
P980035/S700	01/18/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	New cleaning basket and transport bin used in manufacturing at Medtronic Tempe Campus.
P980035/S701	01/21/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Update the final clean process used in manufacturing at internal supplier.
P980035/S702	01/28/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Change in the ceramic material for multi-layer ceramic capacitors used by supplier.
P990004/S052	01/19/2022	X - 30-Day Notice	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Implementation of a new clean room, HVAC and utility systems at the Ferrosan manufacturing facility to be used in the production of all SURGIFOAM and SURGIFLO devices.
P990004/S053	01/21/2022	X - 30-Day Notice	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Addition of a 8-pallet chamber at the same site for the surface sterilization of the Thrombin Kit Package of the Surgiflo® Hemostatic Matrix Kit with Thrombin.
P010015/S488	01/10/2022	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implement a vision system at Medtronic's Swiss Manufacturing Operations facility.
P010015/S489	01/21/2022	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Update the final clean process used in manufacturing at internal supplier.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S490	01/28/2022	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Minor modifications to combination product processes at Medtronic Rice Creek.
P010015/S491	01/28/2022	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Change in the ceramic material for multi-layer ceramic capacitors used by supplier.
P010019/S081	01/12/2022	X - 30-Day Notice	FOCUS NIGHT AND DAY (LOTRAFILCON A) SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Moving the 'lens rinsing' process step to an earlier position of the manufacturing process flow for production of lotrafilcon A and B material soft contact lenses for extended wear at the Alcon Batam, Indonesia facility.
P010030/S157	01/25/2022	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Update to the Automated Belt Test System, Version 2.2.
P010031/S768	01/31/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modifications to the plasma cleaning process at Medtronic's internal supplier.
P010031/S769	01/21/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the final clean process used in manufacturing at internal supplier.
P010031/S770	01/28/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Change in the ceramic material for multi-layer ceramic capacitors used by supplier.
P010054/S042	01/11/2022	X - 30-Day Notice	ELECSYS ANTI-HBS	ROCHE DIAGNOSTICS CORP.	Expand and improve the manufacturing packaging process.
P030002/S040	01/19/2022	X - 30-Day Notice	CRYSTALENS MODEL AT-45 ACCOMMODATING POSTERIOR CHAMBER INTRAOCULAR LENS (IOL)	BAUSCH & LOMB, INC.	Updating the raw material specification for one chemical used in the formulation of the polishing slurry for the intraocular lenses.
P050006/S097	01/27/2022	X - 30-Day Notice	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Changes to the inspection method and equipment used to measure the guidewire port dimensions on the delivery catheter for Gore CARDIOFORM Septal Occluder.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P060022/S029	01/19/2022	X - 30-Day Notice	AKREOS POSTERIOR CHAMBER INTRAOCULAR LENS,MODEL ADAPT	BAUSCH & LOMB, INC.	Updating the raw material specification for one chemical used in the formulation of the polishing slurry for the intraocular lenses.
P060037/S076	01/05/2022	X - 30-Day Notice	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Reduction in the number of biological indicators (BIs) for performance requalification and routine monitoring for hydrogen peroxide (VHP) gas plasma sterilization of their subject device, NexGen® LPS Flex/LPS Mobile Bearing Knee System, Cross-linked Polyethylene Prolong Articular Surface.
P070026/S089	01/21/2022	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Installation of a new grinder for use in grinding BIOLOX Ceramic inserts.
P080006/S168	01/28/2022	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Minor modifications to combination product processes at Medtronic Rice Creek.
P080011/S137	01/06/2022	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Modification to the lens transfer process for the Biofinity XR Toric product at the CooperVision Manufacturing Ltd. facility in Hamble, United Kingdom.
P080025/S246	01/13/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Use of a new Distribution Center Sorter Tool (DCST) to check unopened active implantable devices returned from customers.
P090013/S319	01/28/2022	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Minor modifications to combination product processes at Medtronic Rice Creek.
P100010/S124	01/20/2022	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Minor manufacturing changes to the Arctic Front Advance and Arctic Front Advance Pro to improve manufacturing yield.
P100021/S099	01/03/2022	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Replacement of the laser welder for the collar hypotube assembly of the Iliac Delivery System Taper Tip.
P100042/S033	01/28/2022	X - 30-Day Notice	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Relocate manufacturing processes from one facility to another.
P100049/S030	01/07/2022	X - 30-Day Notice	LINX REFLUX MANAGEMENT SYSTEM	TORAX MEDICAL	30-Day Notice Supplement in accordance with the letter from FDA following review of the Annual Report.
P100049/S031	01/07/2022	X - 30-Day Notice	LINX REFLUX MANAGEMENT SYSTEM	TORAX MEDICAL	Changes regarding DCO 3814 & DCO 3780.
P100049/S032	01/07/2022	X - 30-Day Notice	LINX REFLUX MANAGEMENT SYSTEM	TORAX MEDICAL	Changes regarding DCOs 3872, 3893, 3876, 3753, 3792, and 3860.
P110022/S028	01/11/2022	X - 30-Day Notice	ELECSYS ANTI-HBC IGM IMMUNOASSAY AND ELECSYS PRECICONTROL ANTI-HBC IGM	ROCHE DIAGNOSTICS CORP.	Expand and improve the manufacturing packaging process.
P110023/S033	01/11/2022	X - 30-Day Notice	EVERFLEX SELF-EXPANDING PERIPHERAL STENT SYSTEM (EVERFLEX)	MEDTRONIC VASCULAR INC	Additional supplier for laser cut and reamed long length stent implant components.
P120011/S024	01/26/2022	X - 30-Day Notice	IDEAL IMPLANT SALINE-FILLED BREAST IMPLANT	IDEALIMPLANT	Trelleborg Sealing Solutions US, Inc. to resume fabrication of silicone shells using new DipTech automated equipment.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140013/S013	01/11/2022	X - 30-Day Notice	MINERVA ENDOMETRIAL ABLATION SYSTEM	MINERVA SURGICAL	Transfer of the manifold assembly from the supplier to the contract manufacturer.
P140019/S005	01/07/2022	X - 30-Day Notice	I-FACTOR PEPTIDE ENHANCED BONE GRAFT	CERAPEDICS, LLC	Change in the type of Biological Indicators (BI) used in annual sterilization revalidation.
P140031/S139	01/23/2022	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Removal of inspections performed on the raw material tubing used to manufacture Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve frames.
P150014/S042	01/19/2022	X - 30-Day Notice	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Discontinue unnecessary testing for a kit component.
P150033/S130	01/18/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	New cleaning basket and transport bin used in manufacturing at Medtronic Tempe Campus.
P150033/S131	01/21/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Update the final clean process used in manufacturing at internal supplier.
P150033/S132	01/28/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Minor modifications to combination product processes at Medtronic Rice Creek.
P160041/S034	01/19/2022	X - 30-Day Notice	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Discontinue unnecessary testing for a kit component.
P160047/S026	01/25/2022	X - 30-Day Notice	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	COOPERSURGICAL, INC.	Change to the outer diameter of the internal balloon component to ensure final component meets specification.
P160054/S043	01/07/2022	X - 30-Day Notice	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Update the laser welding input parameters for the Heartmate 3 pump.
P170007/S011	01/25/2022	X - 30-Day Notice	DUROLANE	BIOVENTUS LLC	Use of the supplier's new facility for manufacture of the syringe component.
P170032/S011	01/14/2022	X - 30-Day Notice	WOVEN ENDOBRIDGE (WEB) ANEURYSM EMBOLIZATION SYSTEM	MICROVENTION, INC.	Relocation of the supplier of several WEB System components, Creganna Medical, from the manufacturing location in Tualatin, Oregon, to Wilsonville, Oregon.
P170035/S015	01/13/2022	X - 30-Day Notice	BAUSCH + LOMB ULTRA (SAMFILCON A) CONTACT LENSES	BAUSCH AND LOMB, INC.	Adding an alternate supplier of a raw material for the Ultra (samfilcon A) and Pure Vision (balafilcon A) contact lens products.
P180035/S009	01/26/2022	X - 30-Day Notice	MISIGHT 1 DAY (OMAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES FOR DAILY WEAR	COOPERVISION, INC.	Adding additional three packaging and labeling lines for MiSight 1 day (omafilcon A) product at the CooperVision, Inc., Distribution Facility at West Henrietta, NY, USA.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180046/S047	01/14/2022	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Increasing the maximum sterilization load.
P180046/S049	01/25/2022	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Change to the Breathoprene material used in the construction of the charging belt due to component obsolescence.
P190006/S047	01/14/2022	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Increasing the maximum sterilization load.
P190006/S049	01/25/2022	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Change to the Breathoprene material used in the construction of the charging belt due to component obsolescence.
P190019/S010	01/18/2022	X - 30-Day Notice	RANGER¿ PACLITAXEL-COATED PTA BALLOON CATHETER	BOSTON SCIENTIFIC CORPORATION	Adoption of the Ranger Paclitaxel-Coated PTA Balloon Catheter into the reduced EO gas concentration version of the BSC2000-2 sterilization cycle.
P190028/S006	01/19/2022	X - 30-Day Notice	COBAS HPV FOR USE ON THE COBAS 6800/8800 SYSTEMS	ROCHE MOLECULAR SYSTEMS, INC.	Discontinue unnecessary testing for a kit component.
P200015/S017	01/23/2022	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Removal of inspections performed on the raw material tubing used to manufacture Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve frames.
Total: 78					