4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2017-M-6970, FDA-2017-M-6971, FDA-2017-M-6983, FDA-2017-M-6984, FDA-2017-M-7004, FDA-2018-M-0411, FDA-2018-M-0528, FDA-2018-M-0620, FDA-2018-M-0736, FDA-2018-M-0737, FDA-2018-M-00-0738, FDA-2018-M-0792, FDA-2018-M-1371, FDA-2018-M-1215, FDA-2018-M-1237, FDA-2018-M-1372, FDA-2018-M-1446, FDA-2018-M-1447, FDA-2018-M-1580, FDA-2018-M-1581, FDA-2018-M-1634, FDA-2018-M-1727, FDA-2018-M-1791, FDA-2018-M-1753, FDA-2018-M-1970, FDA-2018-M-2118, FDA-2018-M-2119, FDA-2018-M-2237, FDA-2018-M-2269, FDA-2018-M-2335, FDA-2018-M-2460, FDA-2018-M-2461, FDA-2018-M-2462, FDA-2018-M-2463, FDA-2018-M-2571, FDA-2018-M-2883, FDA-2018-M-2884, FDA-2018-M-2885, FDA-2018-M-2886, FDA-2018-M-2887, FDA-2018-M-2983, FDA-2018-M-3131, FDA-2018-M-3153, FDA-2018-M-3212, FDA-2018-M-3503, FDA-2018-M-3505, and FDA-2018-M-3548]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) and humanitarian device exemption applications (HDEs), that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the internet and the Agency's Dockets Management Staff.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted,

marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket Nos. FDA-2017-M-6970, FDA-2017-M-6971, FDA-2017-M-6983, FDA-2017-M-6984, FDA-2017-M-7004, FDA-2018-M-0411, FDA-2018-M-0528, FDA-2018-M-0620, FDA-2018-M-0736, FDA-2018-M-0737, FDA-2018-M-00-0738, FDA-2018-M-0792, FDA-2018-M-1371, FDA-2018-M-1215, FDA-2018-M-1237, FDA-2018-M-1372, FDA-2018-M-1446, FDA-2018-M-1447, FDA-2018-M-1580, FDA-2018-M-1581, FDA-2018-M-1634, FDA-2018-M-1727, FDA-2018-M-1791, FDA-2018-M-1753, FDA-2018-M-1970, FDA-2018-M-2118, FDA-2018-M-2119, FDA-2018-M-2237, FDA-2018-M-2269, FDA-2018-M-2335, FDA-2018-M-2460, FDA-2018-M-2461, FDA-2018-M-2462, FDA-2018-M-2463, FDA-2018-M-2571, FDA-2018-M-2883, FDA-2018-M-2884, FDA-2018-M-2885, FDA-2018-M-2886, FDA-2018-M-2887, FDA-2018-M-2983, FDA-2018-M-3131, FDA-2018-M-3153, FDA-2018-M-3212, FDA-2018-M-3503, FDA-2018-M-3505, and FDA-2018-M-3548 for "Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its

consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf .

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joshua Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993-0002, 301-796-6524.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying,

or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the internet from January 1, 2018, through September 18, 2018. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

Table 1.--List of Safety and Effectiveness Summaries for Approved PMAs and Safety and Probable Benefit Summaries for Approved HDEs Made Available from January 1, 2018, Through September 18, 2018

PMA No., Docket No.	Applicant	Trade Name	Approval Date
P150005/S014, FDA-2017-M-6970	Boston Scientific	Blazer® Open-Irrigated Ablation Catheter and IntellaNav™ Open-Irrigated Ablation Catheter	12/21/2017
P100030/S008, FDA-2017-M-6971	Mallinckrodt Pharma IP Trading DAC	PREVELEAK Surgical Sealant	12/21/2017
P160012, FDA-2017-M-6983	Physio-Control, Inc.	LIFEPAK CR® Plus Defibrillator, LIFEPAK EXPRESS® Defibrillator and CHARGE-PAK® Battery Charger	12/21/2017
P140032, FDA-2017-M-6984	Medtronic, Inc.	Implantable System for Remodulin®	12/22/2017
P160022, FDA-2017-M-7004	ZOLL Medical Corp.	X Series®, R Series®, AED Pro®, and 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	12/27/2017
P170025, FDA-2018-M-0411	Hologic, Inc.	Aptima® HBV Quant Assay	1/23/2018

P160032, FDA-2018-M-0528	Defibtech, LLC	Lifeline/ReviveR DDU-100, Lifeline/ReviveR AUTO DDU-120, Lifeline/ReviveR VIEW DDU-2300, Lifeline/ReviveR VIEW AUTO DDU-2200, Lifeline/ReviveR ECG DDU-2450, and Lifeline/ReviveR ECG+ DDU-2475 Automated External Defibrillators	2/1/2018
P140003/S018, FDA-2018-M-0620	Abiomed, Inc.	Impella Ventricular Support Systems	2/7/2018
P160037, FDA-2018-M-0736	Becton, Dickinson and Co.	BD Onclarity HPV Assay	2/12/2018
P150001/S021, FDA-2018-M-0737	Medtronic MiniMed, Inc.	MiniMed 630G System	2/13/2018
P160017/S017, FDA-2018-M-0738	Medtronic MiniMed, Inc.	MiniMed 670G System	2/13/2018
P960043/S097, FDA-2018-M-0792	Abbott Vascular	Perclose ProGlide® Suture-Mediated Closure System	2/16/2018
P160007, FDA-2018-M-1371	Medtronic MiniMed, Inc.	Guardian Connect System	3/8/2018
H170002, FDA-2018-M-1215	Kaneka Pharma America LLC	LIPOSORBER® LA-15 System	3/20/2018
P160013, FDA-2018-M-1237	TransMedics, Inc.	Organ Care System (OCS™) Lung System	3/22/2018
P050006/S060, FDA-2018-M-1372	W.L. Gore & Associates, Inc.	GORE® CARDIOFORM Septal Occluder	3/30/2018
P160018/S001, FDA-2018-M-1446	Foundation Medicine, Inc.	FoundationFocus™CDx *BRCA* LOH	4/6/2018
P150009, FDA-2018-M-1447	Angel Medical Systems, Inc.	AngelMed Guardian System	4/9/2018
P160052, FDA-2018-M-1581	Parsagen Diagnostics, Inc.	PartoSure Test	4/11/2018
P950039/S036, FDA-2018-M-1580	Hologic, Inc.	ThinPrep Integrated Imager	4/18/2018
P140010/S037, FDA-2018-M-1634	Medtronic Vascular, Inc.	IN.PACT™ Admiral™ Paclitaxel-Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter	4/19/2018
P960009/S219, FDA-2018-M-1727	Medtronic, Inc.	Medtronic DBS System for Epilepsy	4/27/2018
P170035, FDA-2018-M-1791	Bausch + Lomb, Inc.	Bausch + Lomb ULTRA (samfilcon A) Contact Lenses	4/30/2018
P170016, FDA-2018-M-1753	Teva Pharmaceuticals USA, Inc.	SYNOJOYNT™	5/8/2018
P040024/S099, FDA-2018-M-1970	Galderma Laboratories, LP	*Restylane® Lyft with Lidocaine*	5/18/2018
P170013, FDA-2018-M-2118	MicroVention, Inc.	Low-Profile Visualized Intraluminal Support (LVIS) and LVIS Jr.	5/30/2018
P170039, FDA-2018-M-2119	Clinical Research Consultants, Inc.	CustomFlex™ Artificial Iris	5/30/2018
P910056/S027, FDA-2018-M-2237	Bausch + Lomb, Inc.	enVista® One-Piece Hydrophobic Acrylic Toric Intraocular Lens (Model MX60T)	6/8/2018
P150013/S009, FDA-2018-M-2269	Dako North America, Inc.	PD-L1 IHC 22C3 pharmDx	6/12/2018
P100006/S005, FDA-2018-M-2335	BioMimetic Therapeutics, LLC	AUGMENT® Injectable	6/12/2018

P170043, FDA-2018-M-2460	Glaukos Corp.	iStent *inject* Trabecular Micro-Bypass System (Model G2-M-IS)	6/21/2018
P160017/S031, FDA-2018-M-2461	Medtronic MiniMed, Inc.	MiniMed 670G System	6/21/2018
P160048, FDA-2018-M-2463	Senseonics, Inc.	Eversense Continuous Glucose Monitoring System	6/21/2018
P180008, FDA-2018-M-2462	Tandem Diabetes Care, Inc.	t:slim X2 Insulin Pump with Basal-IQ Technology	6/21/2018
P180002, FDA-2018-M-2571	Pulmonx Corp.	Zephyr® Endobronchial Valve System	6/29/2018
P160026, FDA-2018-M-2883	Physio-Control, Inc.	LIFEPAK® 1000 Defibrillator, LIFEPAK® 1000 Defibrillator Lithium-Ion Rechargeable Battery, LIFEPAK® 1000 Defibrillator Non-Rechargeable Battery, LIFEPAK® 20 Defibrillator/Monitor (Refurbished), LIFEPAK® 20e Defibrillator/Monitor, LIFEPAK® 15 Monitor/Defibrillator, LIFEPAK® Lithium-ion Rechargeable Battery (for use with the LIFEPAK® 15 Monitor/Defibrillator)	7/2/2018
P170024, FDA-2018-M-2884	Stryker Neurovascular	Surpass Streamline Flow Diverter	7/13/2018
P170041, FDA-2018-M-2885	Abbott Molecular, Inc.	Abbott RealTi*me* IDH1	7/20/2018
P160030/S017, FDA-2018-M-2886	Abbott Diabetes Care Inc.	FreeStyle Libre 14 Day Flash Glucose Monitoring System	7/23/2018
P160053, FDA-2018-M-2887	Endomagnetics Ltd.	Magtrace™ and Sentimag® Magnetic Localization System	7/24/2018
P170042, FDA-2018-M-2983	C.R. Bard, Inc.	COVERA™ Vascular Covered Stent	7/30/2018
P150048/S012, FDA-2018-M-3131	Edwards Lifesciences LLC	Edwards Pericardial Mitral Bioprosthesis, Model 11000M	8/9/2018
P170034, FDA-2018-M-3153	Ivantis, Inc.	Hydrus® Microstent	8/10/2018
P150013/S011, FDA-2018-M-3212	Dako North America, Inc.	PD-L1 IHC 22C3 pharmDx	8/16/2018
P030016/S001, FDA-2018-M-3503	STAAR Surgical Co.	Visian® TORIC ICL (Implantable Collamer® Lens)	9/13/2018
H170004, FDA-2018-M-3505	BIOTRONIK, Inc.	PK Papyrus Covered Coronary Stent System	9/14/2018
P180011, FDA-2018-M-3548	Boston Scientific Corp.	ELUVIA™ Drug-Eluting Vascular Stent System	9/18/2018

II. Electronic Access

Persons with access to the internet may obtain the documents at https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm.

Dated: November 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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