4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2015-M-4474, FDA-2016-M-1915, FDA-2016-M-1837, FDA-2016-M-1916, FDA-2016-M-1914, FDA-2016-M-1917, FDA-2016-M-2182, FDA-2016-M-2183, FDA-2016-M-2184, FDA-2016-M-2185, FDA-2016-M-2332, FDA-2016-M-2334, FDA-2016-M-2333, FDA-2016-M-2485, FDA-2016-M-2498, FDA-2016-M-2499, FDA-2016-M-2500, FDA-2016-M-2649, FDA-2016-M-2650, FDA-2016-M-2651, FDA-2016-M-2735, FDA-2016-M-2974, FDA-2016-M-2971, FDA-2016-M-1972, FDA-2016-M-2973, FDA-2016-M-2975, FDA-2016-M-3430, FDA-2016-M-3431, FDA-2016-M-3913, FDA-2016-M-3653, FDA-2016-M-3914, FDA-2016-M-3915, FDA-2016-M-4046, FDA-2016-M-4344, FDA-2016-M-4458, FDA-2016-M-4459, FDA-2016-M-4483, FDA-2016-M-4657, FDA-2016-M-4530, FDA-2016-M-4653, FDA-2017-M-0180, FDA-2017-M-0181, FDA-2017-M-0229, FDA-2017-M-0560, FDA-2017-M-0831, FDA-2017-M-0661, FDA-2017-M-0971, FDA-2017-M-2652, FDA-2017-M-1121, FDA-2017-M-1122, FDA-2017-M-1228, FDA-2017-M-1845, FDA-2017-M-1227, FDA-2017-M-1713, FDA-2017-M-1714, FDA-2017-M-1950, FDA-2017-M-2594, FDA-2017-M-2766, FDA-2017-M-2767, FDA-2017-M-2768, FDA-2017-M-3103, FDA-2017-M-3200, FDA-2017-M-3430, FDA-2017-M-3579, FDA-2017-M-3580, FDA-2017-M-3778, FDA-2017-M-3839, FDA-2017-M-3928, FDA-2017-M-3982, FDA-2017-M-3990, and FDA-2017-M-3983]

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) 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-2015-M-4474, FDA-2016-M-1915, FDA-2016-M-1837, FDA-2016-M-1916, FDA-2016-M-1914, FDA-2016-M-1917, FDA-2016-M-2182, FDA-2016-M-2183, FDA-2016-M-2184, FDA-2016-M-2185, FDA-2016-M-2332, FDA-2016-M-2334, FDA-2016-M-2333, FDA-2016-M-2485, FDA-2016-M-2498, FDA-2016-M-2499, FDA-2016-M-2500, FDA-2016-M-2649, FDA-2016-M-2650, FDA-2016-M-2651, FDA-2016-M-2735, FDA-2016-M-2974, FDA-2016-M-2971, FDA-2016-M-1972, FDA-2016-M-2973, FDA-2016-M-2975, FDA-2016-M-3430, FDA-2016-M-3431, FDA-2016-M-3913, FDA-2016-M-3653, FDA-2016-M-3914, FDA-2016-M-3915, FDA-2016-M-4046, FDA-2016-M-4344, FDA-2016-M-4458, FDA-2016-M-4459, FDA-2016-M-4483, FDA-2016-M-4657, FDA-2016-M-4530, FDA-2016-M-4653, FDA-2017-M-0180, FDA-2017-M-0181, FDA-2017-M-0229, FDA-2017-M-0560, FDA-2017-M-0831, FDA-2017-M-0661, FDA-2017-M-0971, FDA-2017-M-2652, FDA-2017-M-1121, FDA-2017-M-1122, FDA-2017-M-1228, FDA-2017-M-1845, FDA-2017-M-1227, FDA-2017-M-1713, FDA-2017-M-1714, FDA-2017-M-1950, FDA-2017-M-2594, FDA-2017-M-2766, FDA-2017-M-2767, FDA-2017-M-2768, FDA-2017-M-3103, FDA-2017-M-3200, FDA-2017-M-3430, FDA-2017-M-3579, FDA-2017-M-3580, FDA-2017-M-3778, FDA-2017-M-3839, FDA-2017-M-3928, FDA-2017-M-3982, FDA-2017-M-3990, and FDA-2017-M-3983 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 (the 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 quarterly 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 July 1, 2016, through June 30, 2017. 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 Made Available from July 1, 2016, through June 30, 2017

PMA No., Docket No.	Applicant	Trade Name	Approval Date
P130018, FDA-2015-M-4474	Uromedica, Inc.	ProACT™ Adjustable Continence Therapy for Men	11/24/15
P140003/S004, FDA-2016-M-1915	Abiomed, Inc.	Impella Ventricular Support	4/7/2016
P150034, FDA-2016-M-1837	Revision Optics, Inc.	Raindrop Near Vision Inlay	6/29/2016
P150017, FDA-2016-M-1916	Cartiva, Inc.	Cartiva Synthetic Cartilage Implant	7/1/2016
P150023, FDA-2016-M-1914	Abbott Vascular	Absorb GT1™ Bioresorbable Vascular Scaffold (BVS) System	7/5/2016
P100020/S017, FDA-2016-M-1917	Roche Molecular Systems, Inc.	cobas® HPV Test	7/7/2016
P090029/S003, FDA-2016-M-2182	Medtronic Sofamor Danek USA, Inc.	Prestige LP™ Cervical Disc	7/7/2016
P150038, FDA-2016-M-2183	InSightec, Inc.	ExAblate Model 4000 Type 1.0 System (ExAblate Neuro)	7/11/2016
P980040/S065, FDA-2016-M-2184	Abbott Medical Optics, Inc.	TECNIS® Symfony Extended Range of Vision Intraocular Lens	7/15/2016
P150006, FDA-2016-M-2185	Vasorum, Ltd.	Celt ACD Vascular Closure Device	7/20/2016
P160004, FDA-2016-M-2332	W.L. Gore & Associates, Inc.	Gore TIGRIS Vascular Stent	7/27/2016
P150003/S003, FDA-2016-M-2334	Boston Scientific Corp.	SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (Over-The-Wire & Monorail)	7/29/2016
P150037, FDA-2016-M-2333	Alcon Laboratories, Inc.	CyPass® System (Model 241-S)	7/29/2016
P150001, FDA-2016-M-2500	Medtronic MiniMed	MiniMed 630G System with SmartGuard	8/10/2016
P150036, FDA-2016-M-2485	Edwards Lifesciences, LLC	Edwards INTUITY Elite Valve System	8/12/2016
P130009/S057, FDA-2016-M-2498	Edwards Lifesciences LLC	Edwards SAPIEN XT Transcatheter Heart Valve	8/18/2016
P140031/S010, FDA-2016-M-2499	Edwards Lifesciences LLC	Edwards SAPIEN 3 Transcatheter Heart Valve	8/18/2016
P020045/S073, 2016-M-2649	Medtronic, Inc.	Freezor® *Xtra* Cardiac Cryoablation Catheter	8/31/2016
P140010/S015, FDA-2016-M-2650	Medtronic Vascular, Inc.	In Pact™ Admiral™ Paclitaxel-Coated Percutaneous Transluminal Angioplasty Balloon Catheter	9/7/2016
P160001, FDA-2016-M-2651	Obalon Therapeutics, Inc.	Obalon Balloon System	9/8/2016
P150040, FDA-2016-M-2735	Carl Zeiss Meditec, Inc.	VisuMax® Femtosecond Laser	9/13/2016
P000025/S084, FDA-2016-M-2974	MED-EL Corp.	MED-EL Cochlear Implant System	9/15/2016
P150021, FDA-2016-M-2971	Abbott Diabetes Care, Inc.	Freestyle Libre Pro Flash Glucose Monitoring System	9/23/2016
P080020/S020, FDA-2016-M-2975	Seikagaku Corp.	Gel-One®	9/27/2016
P160017, FDA-2016-M-1972	Medtronic MiniMed, Inc.	MiniMed 670G System	9/28/2016

PMA No., Docket No.	Applicant	Trade Name	Approval Date
P150044, FDA-2016-M-2973	Roche Molecular Systems, Inc.	cobas® EGFR Mutation Test v2	9/28/2016
P150030, FDA-2016-M-3430	Smith & Nephew, Inc.	R3™ delta Ceramic Acetabular System	10/17/2016
P160006, FDA-2016-M-3431	Ventana Medical Systems, Inc.	VENTANA PD-L1 (SP142) Assay	10/18/2016
P150013/S001, FDA-2016-M-3913	Dako North America, Inc.	PD-L1 IHC 22C3 pharmDX	10/24/2016
P120021, FDA-2016-M-3653	St. Jude Medical, Inc.	Amplatzer™ PFO Occluder	10/28/2016
P150043, FDA-2016-M-3914	QView Medical, Inc.	QVCAD System	11/9/2016
P930016/S045, FDA-2016-M-3915	AMO Manufacturing USA, LLC	Star S4 IR Excimer Laser System and iDesign Advanced WaveScan Studio	11/14/2016
P020050/S023, FDA-2016-M-4046	Alcon Laboratories, Inc.	WaveLight® EX500 and ALLEGRETTO WAVE® EYE-Q Excimer Laser Systems	11/21/2016
P140029, FDA-2016-M-4344	Q-Med AB	Restylane® Refyne and Restylane® Defyne	12/9/2016
P130007/S016, FDA-2016-M-4458	Animas Corporation	OneTouch Vibe™ Plus System	12/16/2016
P160018, FDA-2016-M-4459	Foundation Medicine, Inc.	FoundationFocus™ CDx_{BRACA} Assay	12/19/2016
P120005/S041, FDA-2016-M-4483	Dexcom, Inc.	Dexcom G5 Mobile Continuous Glucose Monitoring System	12/20/2016
P040020/S049, FDA-2016-M-4657	Alcon Laboratories, Inc.	Acrysof® IQ ReSTOR® +3.0 D Multifocal Toric Intraocular Lens	12/22/2016
P160019, FDA-2016-M-4530	Roche Diagnostics	Elecsys HBsAg II/Elecsys HBsAg Confirmatory Test/PreciControl HBsAg II	12/23/2016
P100022/S020, FDA-2016-M-4653	Cook Medical Inc.	Zilver PTX Drug-Eluting Peripheral Stent	12/28/2016
H070005, FDA-2017-M-0180	AGA Medical Corp.	AMPLATZER™ Post-Infarct Muscular VSD Occluder	1/10/2017
P160031, FDA-2017-M-0181	FUJIFILM Medical Systems U.S.A., Inc.	ASPIRE Cristalle Digital Breast Tomosynthesis Option	1/10/2017
P160008, FDA-2017-M-0229	HeartSine Technologies LLC	HeartSine samaritan® SAM 350P, SAM 360P, and SAM 450P Public Access Automated External Defibrillators, Accessories and Saver EVO® Software Version 1.4.0.	1/12/2017
P160021, FDA-2017-M-0560	W.L. Gore & Associates, Inc.	Gore® Viabahn® VBX Balloon Expandable Endoprosthesis	1/27/2017
P130024/S009, FDA-2017-M-0831	Lutonix, Inc.	Lutonix® 035 Drug Coated Balloon PTA Catheter	2/7/2017
P140033, FDA-2017-M-0661	St. Jude Medical, Inc.	MR Conditional Pacemaker System--Assurity MRI™ and Endurity MRI™ Pacemakers and Tendril MRI™ 1200M LPA Lead	1/31/2017
P160023, FDA-2017-M-0971	Hologic, Inc.	Aptima® HCV Quant Dx Assay	2/13/2017

PMA No., Docket No.	Applicant	Trade Name	Approval Date
P160003, FDA-2016-M-2652	Biotronik, Inc.	PRO-Kinetic Energy Cobalt Chromium Coronary Stent System	2/14/2017
P150039, FDA-2017-M-1121	Tryton Medical, Inc.	TRYTON Side Branch Stent	2/21/2017
P160014, FDA-2017-M-1122	CeloNova BioSciences, Inc.	COBRA PzF™ NanoCoated Coronary Stent System	2/21/2017
P100044/S023, FDA-2017-M-1228	Intersect ENT	PROPEL® Contour Sinus Implant	2/23/2017
P140017/S005, FDA-2017-M-1227	Medtronic, Inc.	Melody™ Transcatheter Pulmonary Valve, Ensemble™ Transcatheter Valve Delivery System and Ensemble™ II Transcatheter Valve Delivery System	2/24/2017
P160016, FDA-2017-M-1713	Siemens Healthcare Diagnostics, Inc.	VERSANT® HCV GENOTYPE 2.0 Assay (LiPA)	3/14/2017
P110033/S020, FDA-2017-M-1714	Allergan	Juvéderm Vollure™ XC	3/17/2017
P160025, FDA-2017-M-1845	Biotronik, Inc.	Astron Pulsar and Pulsar-18 Stent Systems	3/23/2017
P160009, FDA-2017-M-1950	iCAD, Inc.	PowerLook® Tomo Detection Software	3/24/2017
P160024, FDA-2017-M-2594	Bard Peripheral Vascular, Inc.	LifeStream Balloon Expandable Vascular Covered Stent	4/24/2017
P160043, FDA-2017-M-2767	Medtronic, Inc.	Resolute Onyx Zotarolimus- Eluting Coronary Stent System	4/28/2017
P160040, FDA-2017-M-2766	Invivoscribe Technologies, Inc.	LeukoStrat® CDx FLT3 Mutation Assay	4/28/2017
P160046, FDA-2017-M-2768	Ventana Medical Systems, Inc.	VENTANA PD-L1 (SP263) Assay	5/1/2017
H150003, FDA-2017-M-3103	Wilson-Cook Medical, Inc.	Flourish™ Pediatric Esophageal Atresia Device	5/12/2017
P160044, FDA-2017-M-3200	Abbott Molecular, Inc.	Abbott RealTime CMV	5/18/2017
P160041, FDA-2017-M-3430	Roche Molecular Systems, Inc.	cobas® CMV	6/1/2017
P140031/S028, FDA-2017-M-3579	Edwards Lifesciences LLC	Edwards SAPIEN 3™ Transcatheter Heart Valve and Accessories	6/5/2017
P160035, FDA-2017-M-3580	Berlin Heart, Inc.	EXCOR® Pediatric Ventricular Assist Device	6/6/2017
P160047, FDA-2017-M-3778	AEGEA Medical, Inc.	AEGEA Vapor System™	6/14/2017
H160002, FDA-2017-M-3839	Pulsar Vascular, Inc.	PulseRider® Aneurysm Neck Reconstruction Device ("PulseRider")	6/19/2017
P160045, FDA-2017-M-3928	Life Technologies Corp.	Oncomine™ Dx Target Test	6/22/2017
P150046, FDA-2017-M-3982	SciBase AB	Nevisense	6/28/2017
P150048, FDA-2017-M-3990	Edwards Lifesciences, LLC	Edwards Pericardial Aortic Bioprosthesis and Edwards INSPIRIS RESILIA Aortic Valve	6/29/2017
P160038, FDA-2017-M-3983	Illumina, Inc.	Praxis™ Extended RAS Panel	6/29/2017

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: September 12, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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