4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2014-M-2375, FDA-2015-M-0909, FDA-2015-M-0199, FDA-2015-M-0200, FDA-2015-M-0201, FDA-2015-M-0228, FDA-2015-M-0266, FDA-2015-M-0267, FDA-2015-M-0431, FDA-2015-M-0502, FDA-2015-M-0690, FDA-2015-M-0738, FDA-2015-M-0910]

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 Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 when submitting a written request. See the SUPPLEMENTARY INFORMATION section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Melissa Torres, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1650, Silver Spring, MD 20993-0002, 301-796-5576.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with sections 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 January 1, 2015, through March 31, 2015. 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 January 1, 2015, through March 31, 2015

PMA No., Docket No.	Applicant	Trade Name	Approval Date
P980040/S049, FDA-2014-M-2375	Abbott Medical Optics, Inc.	TECNIS® multifocal 1-piece intraocular lens	12/17/2014
P140010, FDA-2015-M-0199	Medtronic, Inc.	IN.PACT™ Admiral™ Paclitaxel-coated Percutaneous Transluminal Angioplasty Balloon Catheter	12/30/2014
P130019, FDA-2015-M-0201	EnteroMedics, Inc.	Maestro® Rechargeable System	1/14/2015
P130025, FDA-2015-M-0200	Koning Corp.	Koning Breast CT (Model CBCT 1000)	1/14/2015
P060001/S020, FDA-2015-M-0228	ev3, Inc.	Protégé™ GPS Self-Expanding Peripheral Stent System	1/21/2015
H140001, FDA-2015-M-0267	ABIOMED, Inc.	Impella RP System	1/23/2015
P140017, FDA-2015-M-0266	Medtronic, Inc.	Melody™ Transcatheter Pulmonary Valve (TPV) and Ensemble™ Transcatheter Valve Delivery System	1/27/2015
P130023, FDA-2015-M-0431	Cohera Medical, Inc.	TissuGlu® Surgical Adhesive	2/3/2015
P010047/S036, FDA-2015-M-0502	NeoMend, Inc.	ProGel™ Pleural Air Leak Sealant	2/13/2015
P140018, FDA-2015-M-0690	Covidien, LLC	VenaSeal™ Closure System	2/20/2015
H130001, FDA-2015-M-0909	Biologics Consulting Group, Inc.	Lixelle Beta 2-microglobulin Apheresis Column	3/5/2015
P110024, FDA-2015-M-0738	Advanced Circulatory Systems, Inc.	ResQCPR™ System	3/6/2015
P130013, FDA-2015-M-0910	Boston Scientific Corp.	WATCHMAN™ Left Atrial Appendage (LAA) Closure Technology	3/13/2015

II. Electronic Access

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

Dated: September 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-24625 Filed: 9/28/2015 08:45 am; Publication Date: 9/29/2015]