4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2015-M-1064, FDA-2015-M-1065, FDA-2015-M-1177, FDA-2015-M-1178, FDA-2015-M-1325, FDA-2015-M-1326, FDA-2015-M-1460, FDA-2015-M-1461, FDA-2015-M-1557, FDA-2015-M-1708, FDA-2015-M-1709, FDA-2015-M-1956, FDA-2015-M-1957, FDA-2015-M-1958, FDA-2015-M-1959, FDA-2015-M-2077, FDA-2015-M-2078, FDA-2014-M-2247]

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 April 1, 2015, through June 30, 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 April 1, 2015, through June 30, 2015

PMA No., Docket No.	Applicant	Trade Name	Approval Date
P140003, FDA-2015-M-1177	ABIOMED, Inc.	Impella® 2.5 System	3/23/2015
P130014, FDA-2015-M-1065	HyperBranch Medical Technology, Inc.	Adherus® AutoSpray Dural Sealant	3/30/2015
P130021/S010, FDA-2015-M-1064	Medtronic CoreValve, LLC	Medtronic CoreValve® System	3/30/2015
P110015, FDA-2015-M-1178	Advanced Breath Diagnostics, LLC	Gastric Emptying Breath Test (GEBT)	4/6/2015
P040020/S050, FDA-2015-M-1325	Alcon Research, Ltd.	AcrySof IQ ReSTOR +2.5 D Multifocal Intraocular Lens	4/13/2015
P120023, FDA-2015-M-1326	AcuFocus™, Inc.	KAMRA™ inlay	4/17/2015
H130007, FDA-2014-M-2247	CVRx®, Inc.	Barostim neo™ Legacy System	12/12/2014
P140011, FDA-2015-M-1460	Siemens Medical Solutions USA, Inc.	MAMMOMAT Inspiration with Tomosynthesis Option	4/21/2015
P120017, FDA-2015-M-1461	Medtronic, Inc.	Model 5071 Lead	4/27/2015
P130012, FDA-2015-M-1557	Greatbatch Medical	Myopore Sutureless Myocardial Pacing Lead	4/30/2015
P140023, FDA-2015-M-1708	Roche Molecular Systems, Inc.	cobas® KRAS Mutation Test	5/7/2015
P130022, FDA-2015-M-1709	Nevro Corp.	Nevro Senza Spinal Cord Stimulation (SCS) System	5/8/2015
P140026, FDA-2015-M-1956	Silk Road Medical, Inc.	ENROUTE™ Transcarotid Stent System	5/18/2015
P140004, FDA-2015-M-1957	Vertiflex®, Inc.	Superion® InterSpinous Spacer	5/20/2015
P140002, FDA-2015-M-1958	Terumo Medical Corp.	Misago® Peripheral Self-expanding Stent System	5/22/2015
P120005/S031, FDA-2015-M-1959	Dexcom, Inc.	Dexcom G4®PLATINUM (Pediatric) Continuous Glucose Monitoring System	5/22/2015
P110010/S096, FDA-2015-M-2077	Boston Scientific Corp.	PROMUS® Element™ Plus and Promus PREMIER™ Everolimus-Eluting Platinum Chromium Coronary Stent System (Monorail™ and Over-the-Wire)	6/1/2015
P050052/S049, FDA-2015-M-2078	Merz North America	Radiesse® Injectable Implant	6/4/2015

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 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-25352 Filed: 10/5/2015 08:45 am; Publication Date: 10/6/2015]