4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2014-M-0326, FDA-2013-M-1324, FDA-2013-M-1693, FDA-2014-M-0069, FDA-2014-M-0166, FDA-2014-M-0167, FDA-2014-M-0224, and FDA-2014-M-0254]

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: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1650, Silver Spring, MD 20993-0002, 301-796-6570.

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, 2014, through March 31, 2014, and includes one denial action 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, 2014, Through March 31, 2014

PMA No., Docket No.	Applicant	Trade Name	Date of Action
P070023, FDA-2013-M-1324	Fzio Med, Inc.	Oxiplex®/SP Gel	Denied October 21, 2013
P110016/S008, FDA-2013-M-1693	St. Jude Medical, Inc.	Therapy Cool Flex Ablation Catheter	Approved December 18, 2013
P130004, FDA-2014-M-0069	Ocular Therapeutics, Inc.	ReSure® Sealant	Approved January 8, 2014

PMA No., Docket No.	Applicant	Trade Name	Date of Action
P130021, FDA-2014-M-0166	Medtronic CoreValve LLC	Medtronic CoreValve™ System	Approved January 17, 2014
P100040/S012, FDA-2014-M-0167	Medtronic Vascular	Valiant Thoracic Stent Graft with Captivia Delivery System	Approved January 22, 2014
P120005/S002, FDA-2014-M-0224	Dexcom, Inc.	Dexcom G4 PLATINUM (Pediatric) Continuous Glucose Monitoring System	Approved February 3, 2014
P090031, FDA-2014-M-0254	Anika Therapeutics, Inc.	MONOVISC™ Injectable Intra-articular Device	Approved February 25, 2014
P130015, FDA-2013-M-0326	Roche Diagnostics Operations, Inc.	Elecsys® HBeAg Immunoassay and Elecsys® PreciControl HBeAg	Approved March 14, 2014

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 19, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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