4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2014-M-1452, FDA-2014-M-1596, FDA-2014-M-1597, FDA-2014-M-1599, FDA-2014-M-1735, FDA-2014-M-1736, FDA-2014-M-2042, FDA-2014-M-2246, FDA-2014-M-2248, and FDA-2014-M-2376]

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 October 1, 2014, through December 31, 2014. 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 October 1, 2014, Through December 31, 2014

PMA No., Docket No.	Applicant	Trade Name	Approval Date

PMA No., Docket No.	Applicant	Trade Name	Approval Date
P040037/S060, FDA-2014-M-1452	W.L. Gore & Associates, Inc.	GORE VIABAHN Endoprosthesis, GORE VIABAHN Endoprosthesis with Heparin	September 19, 2014
P070015/S122, FDA-2014-M-1596	Abbott Vascular, Inc.	XIENCE V® and XIENCE nano® Everolimus Eluting Coronary Stent System	October 3, 2014
P110019/S066, FDA-2014-M-1596	Abbott Vascular, Inc.	XIENCE PRIME® and XIENCE PRIME LL Everlimus Eluting Coronary Stent System	October 3, 2014
P130024, FDA-2014-M-1597	Lutonix, Inc.	Lutonix 035 Drug Coated Balloon PTA Catheter	October 9, 2014
P110023/S007, FDA-2014-M-1599	ev3, Inc.	EverFlex™ Self-Expanding Peripheral Stent System	October 10, 2014
P120005/S018, FDA-2014-M-1735	Dexcom, Inc.	Dexcom G4™ PLATINUM Continuous Glucose Monitoring System	October 21, 2014
P130026, FDA-2014-M-1736	St. Jude Medical	TactiCath Quartz® Catheter and TactiSysQuartz® Equipment	October 24, 2014
P120011, FDA-2014-M-2042	Ideal Implant, Inc.	IDEAL IMPLANT® Saline-filled Breast Implant	November 14, 2014
P130007, FDA-2014-M-2246	Animas Corp.	Animas Vibe System	November 25, 2014
P140020, FDA-2014-M-2248	Myriad Genetic Laboratories, Inc.	BRACAnalysis CDx™	December 19, 2014
P020012/S009, FDA-2014-M-2376	Suneva Medical, Inc.	Bellafill	December 23, 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: April 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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