4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2012-M-0371, FDA-2012-M-0372, FDA-2012-M-0373, FDA-2012-M-0390, FDA-2012-M-0407, FDA-2012-M-0562, and FDA-2012-M-0638]

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 of this document 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 April 1, 2012, through June 30, 2012. 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, 2012, Through June 30, 2012

PMA No., Docket No.	Applicant	Trade Name	Approval Date
P020018/S040, FDA-2012-M-0371	Cook, Inc.	Zenith® Fenestrated AAA Endovascular Graft (with the adjunctive Zenith Alignment Stent)	April 4, 2012
P110029, FDA-2012-M-0372	Abbot Laboratories	ARCHITECT HBsAg Qualitative, ARCHITECT HBsAg Qualitative Confirmatory, ARCHITECT HBsAg Qualitative Confirmatory Manual Diluent, ARCHITECT HBsAg Qualitative Calibrators, and ARCHITECT HBsAg Qualitative Controls	April 12, 2012
P110004, FDA-2012-M-0407	Medinol Ltd.	Presillion™ plus CoCr Coronary Stent on RX System	April 12, 2012
P110035, FDA-2012-M-0373	Boston Scientific Corp.	Epic™ Vascular Self-Expanding Stent System	April 13, 2012
P090015, FDA-2012-M-0390	Leica Biosystems	BOND™ ORACLE™ HER2 IHC System	April 18, 2012
P110010/S001, FDA-2012-M-0562	Boston Scientific Corp.	PROMUS® Element™ Plus Everolimus-Eluting Platinum Chromium Coronary Stent System (Monorail™ and Over-the-Wire)	June 1, 2012
P090026, FDA-2012-M-0638	Beckman Coulter, Inc.	Access® Hybritech® p2PSA on the Access Immunoassay Systems	June 14, 2012

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 28, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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