4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2013-M-0462, FDA-2013-M-0463, FDA-2013-M-0464, FDA-2013-M-0549, FDA-2013-M-0592, FDA-2013-M-0594, FDA-2013-M-0595, FDA-2013-M-0709, FDA-2013-M-0724, FDA-2013-M-0738, and FDA-2013-M-0758]

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 April 1, 2013, through June 30, 2013. 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, 2013, Through June 30, 2013

PMA No., Docket No.	Applicant	Trade Name	Approval Date
P120016, FDA-2013-M-0592	Cardiva Medical, Inc.	VASCADE Vascular Closure System (VCS)	January 31, 2013
P070026/S004, FDA-2013-M-0462	DePuy Orthopaedics, Inc.	DuPuy Ceramax Ceramic Total Hip System	April 2, 2013
P960043/S080, FDA-2013-M-0464	Abbott Vascular	PERCLOSE PROGLIDE Suture Mediated Closure System	April 15, 2013
P980040/S039, FDA-2013-M-0463	Abbott Medical Optics, Inc.	TECNIS Toric 1-Piece Intraocular Lens (IOL) and the TECNIS Toric Calculator System	April 15, 2013
P080009, FDA-2013-M-0549	Ethicon Endo-Surgery, Inc.	SEDASYS Computer-Assisted Personalized Sedation System	May 3, 2013
P120019, FDA-2013-M-0594	Roche Molecular Systems, Inc.	COBAS EGFR Mutation Test	May 14, 2013
P080003/S001, FDA-2013-M-0595	Hologic, Inc.	Selenia Dimensions 3D System	May 16, 2013
P030002/S027, FDA-2013-M-0724	Bausch + Lomb, Inc.	TRULIGN Toric Posterior Chamber Intraocular Lens	May 20, 2013
P120014, FDA-2013-M-0709	bioMérieux, Inc.	THxID BRAF Kit for use on the ABI 7500 Fast DX Real-Time PCR Instrument	May 29, 2013
P060028, FDA-2013-M-0738	Mentor Worldwide LLC	MEMORYSHAPE Breast Implants	June 14, 2013
P120012, FDA-2013-M-0758	Abbott Molecular, Inc.	Abbott RealTime HCV Genotype II, Abbott RealTime HCV Genotype II Control Kit, and Uracil-N-Glycosylase (UNG)	June 20, 2013

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: August 13, 2013.
Leslie Kux,
Assistant Commissioner for Policy.

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