4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2012-M-0712, FDA-2012-M-0713, FDA-2012-M-0734, FDA-2012-M-0735, FDA-2012-M-0814, FDA-2012-M-0833, FDA-2012-M-0893, FDA-2012-M-0965, FDA-2012-M-0968, FDA-2012-M-1011, and FDA-2012-M-1013]

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:

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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 July 1, 2012, through September 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 July 1, 2012, Through September 30, 2012

PMA No., Docket No.	Applicant	Trade Name	Approval Date
P980022/S010, FDA-2012-M-0965	Medtronic MiniMed, Inc.	Guardian Telemetered Glucose Monitoring System (TGMS)	January 7, 2004
P000008/S017, FDA-2012-M-1013	Allergan, Inc.	LAP-BAND™ Adjustable Gastric Banding System	February 16, 2011
P100049, FDA-2012-M-0893	Torax Medical, Inc.	LINX™ Reflux Management System	March 22, 2012
P010031/S232, FDA-2012-M-0814	Medtronic, Inc.	Concerto/Concerto II; Consulta; Maximo II; and Protecta/Protecta XT Families of CRT-Ds	April 4, 2012
P080030, FDA-2012-M-0712	Glaukos Corp.	Glaukos iStent® Trabecular Micro-Bypass Stent and Inserter	June 25, 2012
P110007, FDA-2012-M-0734	Abbott Medical Optics, Inc.	Healon® EndoCoat OpViscosurgical Ophthalmic Device (OVD) (3% Sodium Hyaluronate)	July 2, 2012
P110037, FDA-2012-M-0713	Roche Molecular Systems, Inc.	COBAS® AmpliPrep/COBAS® TaqMan® CMV Test	July 5, 2012
P110030, FDA-2012-M-0735	QIAGEN Manchester, Ltd.	therascreen® KRAS RGQ PCR Kit	July 6, 2012
P110043, FDA-2012-M-0833	Abbott Vascular	Omnilink Elite Vascular Balloon-Expandable Stent System	July 31, 2012
P040024/S056, FDA-2012-M-0968	Medicis Aesthetics Holdings, Inc.	Restylane L Injectable Gel	August 30, 2012
P110006, FDA-2012-M-1011	U-Systems, Inc.	somo-v® Automated Breast Ultrasound System (ABUS)	September 18, 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: December 31, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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