4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2011-M-0726, FDA-2011-M-0919, FDA-2012-M-0024, FDA-2012-M-0056, FDA-2012-M-0074, FDA-2012-M-0075, FDA-2012-M-0082, FDA-2012-M-0112, FDA-2012-M-0172, FDA-2012-M-0173, FDA-2012-M-0177, FDA-2012-M-0180, FDA-2012-M-0181, FDA-2012-M-0207, FDA-2012-M-0208, FDA-2012-M-0209, FDA-2012-M-0210, FDA-2012-M-0221, and FDA-2012-M-0250]

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 section 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, 2012, through March 31, 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 January 1, 2012, Through March 31, 2012

PMA No., Docket No.	Applicant	Trade Name	Approval Date
P090012, FDA-2012-M-0074	Mela Sciences, Inc.	MelaFind	November 1, 2011
H100008, FDA-2011-M-0726	TriVascular, Inc.	OVATION Abdominal Stent Graft System	November 1, 2011
H090002, FDA-2011-M-0848	BSD Medical Corporation	BSD-2000 Hyperthermia System	November 18, 2011
H100004, FDA-2011-M-0919	Berlin Heart, Inc.	Berlin Heart EXCOR Pediatric Ventricular Assist Device	December 16, 2011
P110031, FDA-2012-M-0024	Roche Diagnostics Corp.	Elecsys Anti-HBc IgM Immunoassay and Elecsys PreciControl Anti-HBc IgM	January 3, 2012
P040043.S040, FDA-2012-M-0056	W.L. Gore & Associates, Inc.	Gore TAG Thoracic Endoprosthesis	January 13, 2012
P100039, FDA-2012-M-0075	Siemens Healthcare Diagnostics Inc.	ADVIA Centaur Anti-HBs2 Assay and Quality Control Material	January 20, 2012
P100005, FDA-2012-M-0082	Vucomp, Inc.	M-Vu Algorithm Engine	January 23, 2012
P110016, FDA-2012-M-0112	St. Jude Medical, Inc. (parent company for Irvine Biomedical, Inc.)	Therapy Cool Path Duo/ Safire BLU Duo Ablation Catheter and IBI 1500T9-CP V1.6 Cardiac Ablation Generator	January 25, 2012
P080012, FDA-2012-M-0180	Flowonix Medical, Inc. (approved under Medasys, Inc.)	Prometra Programmable Infusion Pump System	February 7, 2012
P100007, FDA-2012-M-0172	Almen Laboratories, Inc.	Breast Companion Software System	February 10, 2012
P100033, FDA-2012-M-0173	Gen-Probe Inc.	PROGENSA PCA3 Assay	February 13, 2012
P110013, FDA-2012-M-0177	Medtronic Vascular	Resolute MicroTrac/Resolute Integrity Zotarolimus-Eluting Coronary Stent System	February 17, 2012
P110028, FDA-2012-M-0181	Abbott Vascular Inc.	Absolute Pro Vascular Self-Expanding Stent System	February 22, 2012
P100025, FDA-2012-M-0207	Otsuka America Pharmaceutical, Inc.	BreathTek UBT H. pylori Kit and Pediatric Urea Hydrolysis Rate Calculation Application (PUHR-CA), Version 1.0	February 22, 2012

Table 1.--List of Safety and Effectiveness Summaries for Approved PMAs Made Available From January 1, 2012, Through March 31, 2012

PMA No., Docket No.	Applicant	Trade Name	Approval Date
P100023.S015, FDA-2012-M-0208	Boston Scientific Corp.	ION Paclitaxel-Eluting Coronary Stent System (Monorail and Over-The-Wire Delivery Systems)	February 22, 2012
P060008.S046, FDA-2012-M-0210	Boston Scientific Corp.	TAXUS Liberté Paclitaxel-Eluting Coronary Stent System (Monorail and Over-The-Wire Delivery Systems)	February 22, 2012
P030025.S086, FDA-2012-M-0209	Boston Scientific Corp.	TAXUS Express2 Paclitaxel-Eluting Coronary Stent System (Monorail and Over-The-Wire Delivery Systems)	February 22, 2012
P110023, FDA-2012-M-0221	ev3, Inc.	Everflex Self-Expanding Peripheral Stent System (Everflex)	March 7, 2012
P070004, FDA-2012-M-0250	Sientra, Inc.	SIENTRA Silicone Gel Breast Implants	March 9, 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 and http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm.

Dated: June 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-14486 Filed 06/13/2012 at 8:45 am; Publication Date: 06/14/2012]