4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2014-M-0327, FDA-2014-M-0434, FDA-2014-M-0552, FDA-2014-M-0553, FDA-2014-M-0690; FDA-2014-M-0691, FDA-2014-M-0692, FDA-2014-M-0726, FDA-2014-M-0727, FDA-2014-M-0866, and FDA-2014-M-0872]

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 (21 U.S.C. 360e(g)). 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, 2014, through June 30, 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 April 1, 2014, Through June 30, 2014

PMA No., Docket No.	Applicant	Trade Name	Approval Date
P130016, FDA-2014-M-0327	Cochlear Americas	Nucleus® Hybrid™ L24 Cochlear Implant System	March 20, 2014
P120020, FDA-2014-M-0434	Abbott Vascular (IDEV Technologies, Inc.)	SUPERA® Peripheral Stent System	March 28, 2014
P010015/S205, FDA-2014-M-0553	Medtronic, Inc.	Cardiac Resynchronization Therapy Pacemaker (CRT-P) Devices	April 10, 2014
P010031/S381, FDA-2014-M-0553	Medtronic, Inc.	Cardiac Resynchronization Therapy Defibrillator (CRT-D) Devices	April 10, 2014

Table 1.--List of Safety and Effectiveness Summaries for Approved PMAs Made Available From April 1, 2014, Through June 30, 2014

PMA No., Docket No.	Applicant	Trade Name	Approval Date
P100020/S008, FDA-2014-M-0552	Roche Molecular Systems, Inc.	cobas® HPV Test	April 24, 2014
P130008, FDA-2014-M-0690	Inspire Medical Systems, Inc.	Inspire Upper Airway Stimulation (UAS) system	April 30, 2014
P110005, FDA-2014-M-0691	IBSA Institut Biochimique SA	Gel-Syn™ Sinovial (Sodium Hyaluronate 0.8%)	May 9, 2014
P110041, FDA-2014-M-0692	Siemens Healthcare Diagnostics	ADVIA Centaur® HBsAgII, ADVIA Centaur® HBsAg Confirmatory and ADVIA Centaur® HBsAg Quality Control Material	May 16, 2014
P110027, FDA-2014-M-0726	QIAGEN Manchester Ltd.	therascreen® KRAS RGQ PCR Kit	May 23, 2014
P100045, FDA-2014-M-0727	CardioMEMS, Inc.	CardioMEMS™ HF System	May 28, 2014
P130027, FDA-2014-M-0866	QIAGEN, Inc.	artus® CMV RGQ MDx Kit	June 2, 2014
P040024/S072, FDA-2014-M-0872	Valeant Pharmaceuticals North America LLC/Medicis	Restylane Silk Injectable Gel	June 13, 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: September 23, 2014

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-22987 Filed 09/25/2014 at 8:45 am; Publication Date: 09/26/2014]