4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2014-M-0867, FDA-2014-M-0874, FDA-2014-M-0875, FDA-2014-M-1060, FDA-2014-M-1064, FDA-2014-M-1113, FDA-2014-M-1114, FDA-2014-M-1193, FDA-2014-M-1265, FDA-2014-M-1279, and FDA-2014-M-1280]

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 July 1, 2014, through September 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 July 1, 2014, Through September 30, 2014

PMA No., Docket No.	Applicant	Trade Name	Approval Date
P130021/S002, FDA-2014-M-0867	Medtronic CoreValve LLC	Medtronic CoreValve™ System (MCS)	June 12, 2014

PMA No., Docket No.	Applicant	Trade Name	Approval Date
P130009, FDA-2014-M-0874	Edwards Lifesciences, LLC	Edwards SAPIEN XT™ Transcatheter Heart Valve and Accessories	June 16, 2014
P130029, FDA-2014-M-0875	Bard Peripheral Vascular, Inc.	Fluency® Plus Endovascular Stent Graft	June 17, 2014
P130011, FDA-2014-M-1064	Sorin Group Canada, Inc.	Freedom SOLO Stentless Heart Valve and SOLO Smart Heart Valve	June 24, 2014
P130030, FDA-2014-M-1060	Boston Scientific Corp.	REBEL™ Platinum Chromium Coronary Stent System (Monorail™ and Over-The-Wire)	June 27, 2014
P090029, FDA-2014-M-1113	Medtronic Sofamor Danek USA, Inc.	Prestige® LP Cervical Disc	July 24, 2014
H130005, FDA-2014-M-1114	MicroVention, Inc.	Low-Profile Visualized Intraluminal Support Device (LVIS and LVIS Jr.)	July 25, 2014
P130017, FDA-2014-M-1193	Exact Sciences, Inc.	COLOGUARD™	August 11, 2014
H120003, FDA-2014-M-1265	XVIVO Perfusion, Inc.	XVIVO Perfusion System (XPS™) with STEEN Solution™ Perfusate	August 12, 2014
H130004, FDA-2014-M-1280	Plexision, Inc.	Pleximmune™	August 26, 2014
P130020, FDA-2014-M-1279	GE Healthcare	SenoClaire	August 26, 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: February 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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