4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2016-M-1122, FDA-2016-M-1123, FDA-2016-M-1124, FDA-2016-M-1125, FDA-2016-M-1165, FDA-2016-M-1166, FDA-2016-M-1167, FDA-2016-M-1168, FDA-2016-M-1222, FDA-2016-M-1223, FDA-2016-M-1400, FDA-2016-M-1401, FDA-2016-M-1455, FDA-2016-M-1459, FDA-2016-M-1754, and FDA-2016-M-1755]

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: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may

not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket Nos. FDA-2016-M-1122, FDA-2016-M-1123, FDA-2016-M-1124, FDA-2016-M-1125, FDA-2016-M-1165, FDA-2016-M-1166, FDA-2016-M-1167, FDA-2016-M-1168, FDA-2016-M-1222, FDA-2016-M-1223, FDA-2016-M-1400, FDA-2016-M-1401, FDA-2016-M-1455, FDA-2016-M-1459, FDA-2016-M-1754, and FDA-2016-M-1755 for "Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications." Received comments will be

placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joshua Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1650, Silver Spring, MD 20993-0002, 301-796-6524.

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 April 1, 2016, through June 30, 2016. 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, 2016, through June 30, 2016

PMA No., Docket No.	Applicant	Trade Name	Approval Date
P100044/S018, FDA-2016-M-1123	Intersect ENT	PROPEL® Mini Sinus Implant	3/23/2016
P150028, FDA-2016-M-1122	NuMed, Inc.	Cheatham Platinum Stent System	3/25/2016
P150026, FDA-2016-M-1124	Cardiofocus, Inc.	HeartLight Endoscopic Ablation System	4/1/2016
P150033, FDA-2016-M-1125	Medtronic, Inc.	Medtronic Micra™ Transcatheter Pacemaker System	4/6/2016
P140003/S005, FDA-2016-M-1165	Abiomed, Inc.	Impella Left Ventricular Support System	4/7/2016
P150041, FDA-2016-M-1167	Abbott Molecular, Inc.	Vysis CLL FISH Probe Kit	4/11/2016
P150016, FDA-2016-M-1166	Neomend, Inc.	TRIDYNE™ Vascular Sealant	4/11/2016
P130001, FDA-2016-M-1168	Epigenomics AG	Epi proColon	4/12/2016
P150012, FDA-2016-M-1222	Boston Scientific Corporation	ImageReady MR Conditional Pacing System and Ingevity Pace/Sense Lead	4/25/2016
P130029/S002, FDA-2016-M-1223	Bard Peripheral Vascular, Inc.	Fluency® Plus Endovascular Stent Graft	4/26/2016
P160002, FDA-2016-M-1400	Ventana Medical Systems, Inc.	VENTANA PD-L1(SP142) Assay	5/18/2016
P070014/S037, FDA-2016-M-1455	Bard Peripheral Vascular, Inc.	Bard® LifeStent Vascular Stent System	5/31/2016
P110033/S018, FDA-2016-M-1401	Allergan	JUVÉDERM VOLBELLA® XC	5/31/2016
P150047, FDA-2016-M-1459	Roche Molecular Systems, Inc.	cobas® EGFR Mutation Test v2	6/1/2016
P150024, FDA-2016-M-1754	Aspire Bariatrics, Inc.	AspireAssist®	6/14/2016
P150029, FDA-2016-M-1755	Medtronic Minimed, Inc.	iPro2 Continuous Glucose Monitoring System With Enlite Sensor	6/17/2016

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 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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