4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2015-M-1707, FDA-2015-M-2218, FDA-2015-M-2217, FDA-2015-M-2497, FDA-2015-M-2219, FDA-2015-M-2499, FDA-2015-M-2634, FDA-2015-M-2584, FDA-2015-M-2618, FDA-2015-M-2739, FDA-2015-M-2740, and FDA-2015-M-2964]

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-2015-M-1707, FDA-2015-M-2218, FDA-2015-M-2217, FDA-2015-M-2497, FDA-2015-M-2219, FDA-2015-M-2499, FDA-2015-M-2634, FDA-2015-M-2584, FDA-2015-M-2618, FDA-2015-M-2739, FDA-2015-M-2740, and FDA-2015-M-2964 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: Melissa Torres, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1650, Silver Spring, MD 20993-0002, 301-796-5576.

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, 2015, through September 30, 2015. 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, 2015, through September 30, 2015

PMA No., Docket No.	Applicant	Trade Name	Approval Date
P930016/S044, FDA-2015-M-1707	AMO Manufacturing USA, LLC	STAR S4 IR Exciter Laser System and iDesign WaveScan Studio System	5/6/2015
P120024, FDA-2015-M-2218	Aesculap Implant Systems, LLC	activL® Artificial Disc	6/11/2015
P140021, FDA-2015-M-2217	Roche Diagnostics Operations, Inc.	Elecsys® Anti-HCV II Immunoassay and Elecsys® PreciControl Anti-HCV	6/11/2015
P140009, FDA-2015-M-2497	St. Jude Medical Neuromodulation	Brio Neurostimulation System	6/12/2015
P140025, FDA-2015-M-2219	Ventana Medical Systems, Inc.	VENTANA ALK (D5F3) CDx Assay	6/12/2015
P140031, FDA-2015-M-2499	Edwards Lifesciences, LLC.	SAPIEN 3™ Transcatheter Heart Valve and Accessories	6/17/2015
P040024/S073, FDA-2015-M-2634	Galderma Laboratories L.P.	Restylane Lyft with Lidocaine	7/1/2015
H080004, FDA-2015-M-2584	Integrum AB	Osseoanchored Prostheses for the Rehabilitation of Amputees (OPRA)	7/16/2015
P140028, FDA-2015-M-2618	Boston Scientific Corporation	Innova™ Vascular Self-Expanding Stent System	7/21/2015
P140013, FDA-2015-M-2739	Minerva Surgical, Inc.	Minerva™ Endometrial Ablation System	7/27/2015
P140012, FDA-2015-M-2740	ReShape Medical, Inc.	ReShape Integrated Dual Balloon System	7/28/2015
P140008, FDA-2015-M-2964	Apollo Endosurgery, Inc.	ORBERA™ Intragastric Balloon System	8/5/2015

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: November 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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