

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2013-M-1321, FDA-2013-M-1322, FDA-2013-M-1323, FDA-2013-M-1362, FDA-2013-M-1363, FDA-2013-M-1364, FDA-2013-M-1365, FDA-2013-M-1488, and FDA-2013-M-1605]

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 October 1, 2013, through December 31, 2013. 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 OCTOBER 1, 2013, THROUGH DECEMBER 31, 2013

| PMA No., Docket No. | Applicant | Trade Name | Approval Date |
|-------------------------------------|-----------------------------------|---|---------------------|
| P040043/S051, FDA-2013-M-1323 | W.L. Gore & Associates, Inc | GORE® TAG® Thoracic Endoprosthesis | September 10, 2013. |
| P970053/S011, FDA-2013-M-1362 | Nidek Co., Ltd | Nidek EC-5000 Excimer Laser System ... | September 30, 2013. |
| P020050/S012, FDA-2013-M-1321 | Alcon Research, Ltd | ALLEGRETTO WAVE® Eye-Q Excimer Laser System. | October 2, 2013. |
| H120005, FDA-2013-M-1322 | Kaneka Pharma America LLC | Kaneka Liposorber® LA-15 System | October 10, 2013. |
| P130005, FDA-2013-M-1363 | Cardiovascular Systems, Inc | Diamondback 360® Coronary Orbital Arthroctomy System. | October 21, 2013. |
| P110033, FDA-2013-M-1364 | Allergan | JUVÉDERM® VOLUMA™ XC | October 22, 2013. |
| P100009, FDA-2013-M-1365 | Abbott Vascular | MitraClip Clip Delivery System (MitraClip CDS). | October 24, 2013. |
| P100026, FDA-2013-M-1488 | NeuroPace, Inc | RNS® System | November 14, 2013. |
| P130006, FDA-2013-M-1605 | W.L. Gore & Associates, Inc | GORE® VIABAHN® Endoprosthesis & GORE® VIABAHB® Endoprosthesis with Heparin BioActive Surface. | December 5, 2013. |

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: March 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-05429 Filed 3-11-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2013-M-0851, FDA-2013-M-0987, FDA-2013-M-0988, FDA-2013-M-1017, FDA-2013-M-1095, FDA-2013-M-1159, and FDA-2013-M-1206]

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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, 2013, through September 30, 2013. 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, 2013, THROUGH SEPTEMBER 30, 2013

| PMA No., Docket No. | Applicant | Trade name | Approval date |
|--------------------------------|-----------------------------|--|---------------------|
| P120022, FDA-2013-M-0851 | QIAGEN Manchester Ltd | <i>therascreen</i> [®] EGFR RQ PCR Kit | July 12, 2013. |
| P110002, FDA-2013-M-0987 | LDR Spine USA, Inc | Mobi-C [®] Cervical Disc Prosthesis | August 7, 2013. |
| P120009, FDA-2013-M-0988 | PFM Medical AG | Nit-Occlud [®] PDA | August 16, 2013. |
| P120004, FDA-2013-M-1017 | Parascript, LLC | Parascript [®] AccuDetect [®] 6.1.0 | August 22, 2013. |
| P110009, FDA-2013-M-1095 | LDR Spine USA, Inc | Mobi-C [®] Cervical Disc Prosthesis | August 23, 2013. |
| P110040, FDA-2013-M-1159 | Medtronic Vascular | Medtronic Vascular Complete [®] SE Vascular Stent System. | September 19, 2013. |
| P120010, FDA-2013-M-1206 | Medtronic, Inc | MiniMed 530G System | September 26, 2013. |

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: March 6, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-05347 Filed 3-11-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0253]

Methods for Thrombogenicity Testing; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled “Workshop on Methods for Thrombogenicity Testing.” Planned topics of discussion include the optimization of in vitro and in vivo thrombogenicity test methods and the

identification of alternative in vitro tests.

Date and Time: The public workshop will be held on April 14, 2014, from 9 a.m. to 5 p.m.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503, sections B and C), Silver Spring, MD 20993-0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

Contact Persons: Anchal Kaushiva, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1266, Silver Spring, MD 20993-0002, 301-796-6330, FAX: 301-847-8115, email: anchal.kaushiva@fda.hhs.gov, or James Kleinedler, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1102, Silver Spring, MD 20993-0002, 301-796-9448, FAX: 301-847-8115, email: james.kleinedler@fda.hhs.gov.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending

this public workshop must register online by April 4, 2014, at 5 p.m., EST. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the workshop will be provided beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, 301-796-5661, email: susan.monahan@fda.hhs.gov no later than April 4, 2014.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm> and select this public workshop from the posted events list. Please provide complete contact information for each attendee, including name, title, and affiliation, email, and telephone number. Those without Internet access should contact Susan Monahan to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by April 4, 2014, at 5 p.m. Early registration is recommended because