DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 15, 2015

Cook Medical Incorporated
Mr. Scott Williams, MS, RAC
Director of Regulatory Affairs
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402-0489

Re: P140016
Trade/Device Name: Zenith Alpha Thoracic Endovascular Graft
Filed: March 20, 2015
Amended: June 19, 2015
Product Code: MIH

Dear Mr. Williams:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Zenith Alpha™ Thoracic Endovascular Graft. This device is indicated for the endovascular treatment of patients with isolated lesions of the descending thoracic aorta (not including dissections) having vascular anatomy suitable for endovascular repair, including:

- Iliac/femoral anatomy that is suitable for access with the required introduction systems,
- Nonaneurysmal aortic segments (fixation sites) proximal and distal to the thoracic lesion:
  - with a length of at least 20 mm, and
  - with a diameter measured outer wall to outer wall of no greater than 42 mm and no less than 15 mm.

We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 3 years. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

Continued approval of this PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84. This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identifier (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. For more information on these requirements, please see the UDI website, http://www.fda.gov/udi.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

As part of the Annual Report to your PMA Application, you will provide a clinical update to physician users at least annually with current information regarding the Zenith Alpha™ Thoracic Endovascular Graft device. All clinical updates are to include information from the two pivotal studies for the aneurysm/ulcer and blunt traumatic aortic injury indications, and continued access clinical studies for the aneurysm/ulcer indication. At a minimum, the information to be included regarding the clinical studies will include a summary of the number of patients for whom data are available, with the rates of death, aneurysm-related mortality, secondary endovascular procedures, conversion to open surgical repair, major device events, endoleak, aneurysm enlargement, prosthesis migration, losses of device integrity, aortic rupture and patency. Reports of losses of device integrity, reasons for secondary interventions and conversions to open surgical repair, and causes of death that may be associated with the lesion treated (e.g., death within 30 days of a secondary procedure to treat the index lesion and death from bleeding through the index lesion) are to be described. A summary of any explant analysis findings are to be included. Additional relevant information from commercial experience within and outside of the U.S. is also to be included. The clinical updates for physician users and the information supporting the updates must be provided in the Annual Report.

In addition to the Annual Report requirements, you must provide the following data in post-approval study (PAS) reports for the PAS listed below, to be provided annually. Two (2) copies of the report identified as an "ODE Lead PMA Post-Approval Study Report" in accordance with how the study is identified below and bearing the applicable PMA reference number, should be submitted to the address below.

ODE Lead PMA Post-Approval Study: The Office of Device Evaluation (ODE) will lead the review of the Post-Approval Study data that consists of the extended follow-up data out to 5 years for subjects enrolled in the aneurysm/ulcer clinical study initiated prior to device approval. This includes data from the pivotal study and continued access cohorts in accordance with the previously approved Investigational Device Exemption protocol. The data should include a summary of the number of patients for whom data are available and the rates of adverse events, such as death, aneurysm-related mortality, secondary endovascular procedures, conversion to open surgical repair, major device events, endoleak, aneurysm enlargement, prosthesis migration, losses of device integrity, aortic rupture and patency.

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA. In addition, the results from any post approval study should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a PMA Supplement. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm).

Before making any change affecting the safety or effectiveness of the device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes

aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm

CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. Final printed labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in 6 copies, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
PMA Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Tina Morrison, PhD at 301-796-6310 or Tina.Morrison@fda.hhs.gov.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

**Medical Device Tracking Order**

10/2/15

Mr. Scott Williams, MS, RAC
COOK MEDICAL INCORPORATED
750 DANIELS WAY
PO BOX 489
BLOOMINGTON, IN 47402-0489
UNITED STATES

Re: P140016
SYSTEM, ENDOVASCULAR GRAFT, AORTIC ANEURYSM TREATMENT (MIH)

Dear Mr. Scott Williams, MS, RAC:

You are notified by this letter of your obligation to adopt a method of tracking for the device referenced above, as authorized by section 519(g) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 360i(g). The implementation of section 519(g) of the Act requires the Food and Drug Administration (FDA) to issue an order to manufacturers when FDA determines that a person who manufactures and distributes a device meets the relevant statutory requirements and that tracking is required to protect the public health. This order is effective immediately.

Section 519(g) of the Act states that FDA, "may by order require a manufacturer to adopt a method of tracking a class II or class III device—

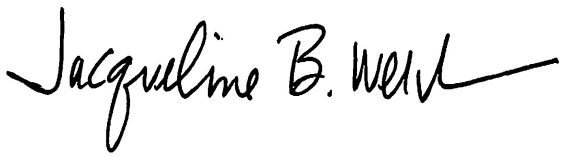
(A) the failure of which would be reasonably likely to have serious adverse health consequences; or
(B) which is—

(i) intended to be implanted in the human body for more than one year, or
(ii) a life sustaining or life supporting device used outside a device user facility."

The corresponding medical device tracking regulations, found in Title 21 Code of Federal Regulations (CFR) Part 821, are intended to ensure that tracked devices can be traced from the device manufacturing facility to the person for whom the device is intended when patient notification actions under section 518(a) of the Act, 21 U.S.C. § 360h(a), or device recall actions under section 518(e) of the Act, 21 U.S.C. § 360h(e), are ordered by the FDA. The device tracking requirements for exemptions and variances; system and content requirements of tracking; the obligations of persons other than device manufacturers; records and inspection requirements; and confidentiality requirements, which were published in the Federal Register on August 16, 1993, remain in effect. (21 CFR sections 821.2, 821.25, 821.30, 821.50, 821.55 and 821.60)

This order to adopt a tracking method does not change your firm's obligations concerning other FDA regulations affecting its device. FDA published in the Federal Register on February 28, 2002, an amendment to the final rule to revise the scope of the regulation and add certain patient confidentiality requirements and non-substantive changes to remove outdated references and simplify terminology. (67 FR 6943) If you need specific guidance, please contact the Office of Compliance, FDA Center for Devices and Radiological Health, at TrackedDevicesMailbox@fda.hhs.gov. Other general information about your firm's responsibilities under the Act, or more specific information, such as non-binding guidance on medical device tracking (link provided), may be obtained from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number, (800) 638-2041, or at the internet address www.fda.gov/cdrh.

Sincerely,



Jacqueline B. Welch
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosures/Links

Medical Device Tracking; Guidance for Industry and FDA Staff

cc: WO66 rm. 1644 DGarcia
WO66 rm. 2678 BYoung
HFR-CE740
~~D~~onna Headlee

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