



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

NOV - 1 2011

Ms. Meg Carr
Director, Regulatory Affairs
TriVascular, Inc.
3910 Brickway Blvd.
Santa Rosa, CA 95403

Re: H100008
HUD #04-0145
Ovation Abdominal Stent Graft System
Filed: December 17, 2010
Amended: February 11, 2011, March 28, 2011, March 30, 2011, and April 4, 2011
Product Code: MIH

Dear Ms. Carr:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your humanitarian device exemption (HDE) application for the Ovation Abdominal Stent Graft System. This device is indicated for use in subjects diagnosed with an aneurysm in the abdominal aorta with small aortic diameters and access vessels of less than 7 mm in diameter, and having vascular morphology suitable for endovascular repair, including:

- Adequate iliac/femoral access compatible with vascular access techniques, devices, and/or accessories,
- Non-aneurysmal proximal aortic neck:
 - with a length of at least 7 mm proximal to the aneurysm,
 - with an inner wall diameter of no less than 15.5 mm and no greater than 17.4 mm, and,
 - with an aortic angle of ≤ 60 degrees if proximal neck is ≥ 10 mm and ≤ 45 degrees if proximal neck is < 10 mm,
- Adequate distal iliac landing zone:
 - with a length of at least 10 mm, and
 - with an inner wall diameter of no less than 8 mm and no greater than 17 mm.

CDRH is pleased to inform you that your HDE is approved subject to the enclosed "Conditions of Approval." You may begin commercial distribution of the device after you have submitted an amendment to this HDE with copies of the approved labeling in final printed form.

In addition to the postapproval requirements in the enclosure, the postapproval reports must include the following information:

1. In addition to the periodic report requirements outlined in the enclosure (per 21 CFR 814.126(b)), you have agreed to provide the following data in a separate post-approval study report:

You have agreed to perform a primary post-approval study for the Ovation Abdominal Stent Graft System to evaluate the longer-term safety and benefit of the Ovation Abdominal Stent Graft System through five years of implantation. The primary safety endpoint for this study is freedom from aneurysm-related mortality at 5 years and the primary benefit endpoint is freedom from aneurysm rupture and conversion to open repair through 12 months. Aneurysm-related mortality is defined as:

Death from a rupture of the abdominal aortic aneurysm (AAA) or from any procedure intended to treat the AAA. If a death occurred within 30 days of any procedure, or within the hospital stay if the patient was not discharged within 30 days, then it is presumed to be aneurysm related.

This study will enroll 180 subjects:

- 157 pivotal cohort subjects (implanted with any size other than the 20mm device under IDE G090239);
- up to 30 subjects (implanted with the 20mm device from the HDE de novo study, pivotal study or Continued Access study, as described in item 2 below); and
- if needed to reach the 180 subjects as of the date of a Premarket Approval Application (PMA) approval for the Ovation Abdominal Stent Graft System: up to 30 of the first consecutively enrolled Continued Access subjects (implanted with any other size device other than the 20mm device under IDE G090239).

At 12 months and at each annual visit, a contrast-enhanced CT scan, abdominal x-ray, physical exam, and a clinical assessment of adverse events will be conducted. All data will be entered into a database, analyzed, and submitted in post-approval study reports to the FDA, and a final report will be submitted after completion of the follow-up and analysis. This follow-up plan will enable an evaluation of aneurysm-related mortality, major adverse events, migration, patency, endoleaks, device integrity, aneurysm enlargement, aneurysm rupture, secondary endovascular procedures and conversion to open surgical repair over time.

Upon completion of this post-approval study, you must provide an HDE supplement with revised labeling that reflects the study findings.

2. You have agreed to evaluate any differences in outcomes by gender for your primary post-approval study subjects using descriptive statistics and to include this information in your post-

approval study reports. The outcomes that are to be compared include those listed in item 1 above.

3. As a secondary post-approval study, you have agreed to evaluate the operative, 30-day, and yearly outcomes for 30 subjects implanted with the 20mm device as compared to the outcomes for subjects treated with any other size of the Ovation Abdominal Stent Graft System from the primary post-approval study described in item 1 above using descriptive statistics. The outcomes that are to be compared include those listed in item 1. These 30 patients will have been enrolled in the pivotal or Continued Access studies or under the HDE de novo study. The de novo study will include a minimum of 3 and up to 15 investigational sites. These data will be included in your post-approval study reports.
4. You have agreed to evaluate your physician training program by comparing the incidence of technical failure at implant and type I endoleak, secondary endovascular procedures, and device-related serious adverse events through 30 days for two categories of physicians who enrolled subjects in your pivotal study. The categories will include physicians with either more or less than 20 AAA cases in the 2 years following participation in the Ovation physician training program. This analysis will be included in a post-approval study report. Any additional insight obtained regarding your training program based on the outcomes of de novo subjects will also be reported in a post-approval study report. Should modifications be necessary to the training program, you will describe and provide the appropriate rationale for each modification within an annual report to your HDE.
5. You have agreed to provide a clinical update to physician users at least annually. At a minimum this update will include for your post-approval study cohort and all patients enrolled in the 20mm de novo cohort (i.e., regardless as to whether they are included in the primary post-approval study), a summary of the number of patients for whom data are available, with a summary describing the occurrence of the outcomes described in item 1 above. Reports of losses of device integrity, reasons for conversion and causes of aneurysm-related death and rupture 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 US is also to be included. The clinical updates for physician users and the information supporting the updates must be provided at least annually in periodic reports to your HDE.

The sale, distribution, and use of this device are limited to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. In addition, in order to ensure the safe use of the device, FDA has further restricted the device within the meaning of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act insofar as (1) the labeling shall specify the training requirements for practitioners who may use the device as approved in this order and (2) the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

Expiration dating for the Ovation Abdominal Stent Graft System and Iliac Extensions has been established and approved at 3 years and 1 year, respectively. 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).

Under section 519(e) of the act, as amended by the Safe Medical Devices Act in 1990, manufacturers of certain devices must track their products to the final user or patient so that these devices can be located quickly if serious problems occur with the products. The tracking requirements apply to: (1) permanent implants, the failure of which would be reasonably likely to have serious adverse health consequences; (2) life-sustaining or life-supporting devices that are used outside of device user facilities, the failure of which would be reasonably likely to have serious adverse health consequences; and (3) other devices that FDA has designated as requiring tracking.

Under section 519(e)(1) of the act, FDA believes that your device is a device that is subject to tracking because it is a permanent implant, the failure of which would be reasonably likely to have serious adverse health consequences.

FDA's tracking regulation published in the Federal Register of August 16, 1993 (58 FR 43442) and appears at 21 CFR Part 821. The regulation describes your responsibilities in tracking a device. In addition, 21 CFR 821.20(b) lists examples of permanent implants and life-sustaining or life-supporting devices that FDA believes must be tracked, and 21 CFR 821.20(c) lists devices that FDA has designated for tracking. FDA's rationale for identifying these devices is set out in the Federal Register of March 27, 1991 (57 FR 10705-10709); May 29, 1992 (57 FR 22973-22975), and August 16, 1992 (58 FR 43451-43455).

FDA wishes to remind you that failure to comply with any postapproval requirement constitutes a ground for withdrawal of the HDE. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

CDRH will notify the public of its decision to approve your HDE by making available a summary of the safety and probable benefit of the device upon which the approval was based. The information can be found on the FDA CDRH Internet HomePage located at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm>. Written requests for this information can also be made to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the HDE 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 requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you

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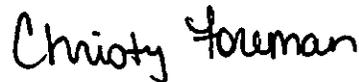
must submit an amendment to this HDE submission with copies of all approved labeling in final printed form. The labeling will not routinely be reviewed by FDA staff when HDE applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is 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.

Any information to be submitted to FDA regarding this HDE should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above HDE number to facilitate processing:

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

If you have any questions concerning this approval order, please contact Tina M. Morrison, Ph.D. at (301) 796-6310.

Sincerely yours,



Christy Foreman
Director
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure
Conditions of Approval

CONDITIONS OF APPROVAL FOR AN HDE

I. APPROVED LABELING

As soon as possible and before commercial distribution of the device, the holder of an HDE should submit three copies of the approved labeling in final printed form as an amendment (if submitted prior to HDE approval) or supplement (if submitted after HDE approval) to the HDE. The amendment/supplement should be submitted to the U.S. Food and Drug Administration, Center for Devices and Radiological Health, HDE Document Mail Center – WO66-G609, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002.

II. ADVERTISEMENTS

Advertisements and other descriptive printed materials issued by the HDE holder or private label distributor with respect to this device should not recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(e)) under the authority of section 515(d)(1)(B)(ii) of the act (21 U.S.C. 360e(d)(1)(B)(ii)), all advertisements and other descriptive printed material issued by the holder or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications.

III. HDE SUPPLEMENTS

Before making any change affecting the safety or probable benefit of the device, the HDE holder should submit a supplement for review and approval by FDA unless a "Special HDE Supplement" is permitted as described under 21 CFR 814.39(d)(2) or an alternate submission is permitted as described under 21 CFR 814.39(e). All HDE supplements or alternate submissions must comply with the applicable requirements under 21 CFR 814.39 of the Premarket Approval (PMA) regulation and under 21 CFR 814.108 of the Humanitarian Device Exemption regulation. The review timeframe for HDE supplements is 75 days except for those submitted under 21 CFR 814.39(e).

Since all situations which require an HDE supplement cannot be briefly summarized, please consult the HDE regulation for further guidance. The guidance provided below is only for several key instances. In general, an HDE supplement must be submitted:

- 1) When unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification; or
- 2) If the device is to be modified, and animal/laboratory or clinical testing is needed to determine if the modified device remains safe and continues to provide probable benefit.

HDE supplements submitted under 21 CFR 814.39(d)(2) "Special HDE Supplement - Changes Being Effected" are limited to the labeling, quality control, and manufacturing process changes as specified under this section of the regulation. This provision allows for the addition of, but not the

replacement of previously approved, quality control specifications and test methods. These changes may be implemented upon acknowledgment by FDA that the submission is being processed as a "Special HDE Supplement - Changes Being Effected." Please note that this acknowledgment is in addition to that issued by the Document Mail Center for all HDE supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software, or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of an HDE supplement before implementation and include the use of a *30-day HDE supplement or periodic postapproval report*. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence to the HDE holder that the alternate submission is permitted for the change. Before this can occur, FDA and the HDE holder must agree upon any needed testing, the testing protocol, the test results, the reporting format, the information to be reported, and the alternate submission to be used.

Please note that unlike the PMA process, a supplement may not be submitted for a new indication for use for a humanitarian use device (HUD). An HDE holder seeking a new indication for use for an HUD approved under the provisions of Subpart H of 21 CFR 814, must obtain a new designation of HUD status for the new indication for use and submit an original HDE application in accordance with §814.104. The application for the new indication for use may incorporate by reference any information or data previously submitted to the agency.

IV. POSTAPPROVAL RECORD KEEPING REQUIREMENTS

An HDE holder is required to maintain records of the names and addresses of the facilities to which the HUD has been shipped, correspondence with reviewing institutional review boards (IRBs), as well as any other information requested by a reviewing IRB or FDA.

V. POSTAPPROVAL REPORTING REQUIREMENTS Continued approval of the HDE is contingent upon the submission of postapproval reports required under 21 CFR 814.84 and 21 CFR 814.126.

A. ANNUAL REPORT

Annual reports should be submitted at intervals of 1 year from the date of approval of the original HDE. Reports for supplements approved under the original HDE should be included in the next and subsequent periodic reports for the original HDE unless otherwise specified in the approval order for the HDE supplement. Three copies identified as "Annual Report" and bearing the applicable HDE reference number are to be submitted to the U.S. Food and Drug Administration, Center for Devices and Radiological Health, HDE Document Mail Center – WO66-G609, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002. Reports should indicate the beginning and ending date of the period covered by the report and include the following information required by 21 CFR 814.126(b)(1):

1. An update of the information required under §814.102(a) in a separately bound volume;

2. An update of the information required under §814.104(b)(2), (b)(3), and (b)(5);
3. The number of devices that have been shipped or sold and, if the number shipped or sold exceeds 4,000, an explanation and estimate of the number of devices used per patient. If a single device is used on multiple patients, an estimate of the number of patients treated or diagnosed using the device together with an explanation of the basis for the estimate;
4. Information describing the applicant's clinical experience with the device. This shall include safety information that is known or reasonably should be known to the applicant, a summary of medical device reports made pursuant to 21 CFR 803, any data generated from postmarketing studies, and information (whether published or unpublished) that is known or reasonably expected to be known by the applicant that may affect an evaluation of the safety of the device or that may affect the statement of contraindications, warnings, precautions, and adverse reactions in the device labeling; and
5. A summary of any changes made to the device in accordance with supplements submitted under §814.108 and any changes required to be reported to FDA under §814.39(b).

B. ADVERSE REACTION AND DEVICE DEFECT REPORTING

As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and probable benefit of the device, the holder shall submit three copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the U.S. Food and Drug Administration, Center for Devices and Radiological Health, HDE Document Mail Center – WO66-G609, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002. Such reports should be submitted within 10 days after the HDE holder receives or has knowledge of information concerning:

- (1) A mixup of the device or its labeling with another article.
- (2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and
 - (a) has not been addressed by the device's labeling or
 - (b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.
- (3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved HDE that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the HDE holder's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the firm. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the holder shall be

included in the "Annual Report" described under "Postapproval Reports" above unless otherwise specified in the conditions of approval for this HDE. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of occurrence for each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the HDE holder when determined by FDA to be necessary to provide continued reasonable assurance of the safety and probable benefit of the device for its intended use.

C. **REPORTING UNDER THE MEDICAL DEVICE REPORTING REGULATION**

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 www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.