



May 4, 2020

Bolton Medical, Inc.
Miriam Paret
Regulatory Affairs Manager
799 International Parkway
Sunrise, Florida 33325

Re: P190015

Trade/Device Name: TREO[®] Abdominal Stent-Graft System

Product Code: MIH

Filed: July 11, 2019

Amended: July 11, 2019; February 3, 2020; March 3, 2020

Dear Miriam Paret:

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 TREO[®] Abdominal Stent-Graft System. This device is indicated for use in the endovascular treatment of patients with infrarenal abdominal aortic and aorto-iliac aneurysms with the following characteristics:

- Adequate iliac or femoral access compatible with the required delivery systems and accessories
- Proximal aortic landing zone with:
 - Infrarenal landing neck length of ≥ 15 mm
 - Aortic neck diameters ≥ 17 mm and ≤ 32 mm
 - Suprarenal neck angle of ≤ 45 degrees
 - Infrarenal neck angle of ≤ 60 degrees
- Distal iliac landing zone with:
 - an inside diameter of 8 mm – 13 mm and a length of ≥ 10 mm or
 - an inside diameter of > 13 mm – 20 mm and a length of ≥ 15 mm
- Minimum overall AAA treatment length (proximal landing location to distal landing location) of 13 cm
- Minimum overall length from the lowest renal artery to the aortic bifurcation of 9 cm

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. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm> identifies combination product submissions.

The sale and distribution of this device is 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 2 years for the Main Bifurcated Stent-Grafts, the Proximal Cuff, and the Straight Extension Stent-Grafts; and 3 years for the Leg Extension Stent-Grafts. 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 the 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. 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.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA 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.

You have agreed to provide a Clinical Update to physician users at least annually. At a minimum, this update will include, for your IDE study cohort and post-approval study cohort, respectively, a summary of the number of patients for whom data are available, with the rates of major adverse events, aneurysm-related mortality, aneurysm rupture, secondary endovascular procedures, conversions to surgical repair, endoleaks, aneurysm enlargement, prosthesis migration, occlusions, stenoses, losses of device integrity, and other procedure or device-related events. Reasons for secondary interventions and conversion to open surgery as well as causes of aneurysm-related death and rupture are to be described. Additional relevant information from commercial experience within and outside the United States is also to be included. A summary of any explant analysis findings is to be included. The clinical update 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 each PAS listed below. Separate PAS Progress Reports must be submitted for each study every six (6) months during the first two (2) years of the study and annually thereafter, unless otherwise specified by FDA. Each report, identified as a 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.

1. *Continued Follow-up of the IDE Study Subjects:* This is a prospective, single-arm, multi-center study that consists of continued follow-up of all available subjects from the IDE Pivotal and Continued Access studies. A total of 158 subjects were enrolled in the study and remaining subjects will be followed for 5 years, with the exception of subjects identified with fracture(s) within the first 5 years who will be followed for an additional 5 years (total of 10 years of follow-up). Secondary endpoints through 5 years (or 10 years for patients with fracture(s)) will include major adverse events, all-cause mortality, aneurysm-related mortality, aneurysm rupture, secondary interventions, conversion to open surgery, losses of device integrity, device occlusions, stenosis or kink, aneurysm enlargement (> 5 mm), stent graft migration (> 10 mm), all types of endoleaks, and other device-related events. No formal hypothesis testing will be performed for the longer-term follow-up. Outcomes will be reported using descriptive statistics annually.
2. *TREO Post Approval Study:* This is a prospective, multi-center, non-randomized, single arm, post approval study. The objective of the study is to collect confirmatory safety and effectiveness data of the TREO® Abdominal Stent-Graft System with emphasis on subjects that may experience a device strut or barb fracture in routine clinical practice. The study will prospectively enroll a minimum of 300 subjects at up to 40 U.S. sites. Follow-up will occur at 30 days, 1 year, and annually thereafter through 5 years. The primary endpoints are stent fracture, barb separation, and secondary intervention for adverse events related to stent fracture or barb separation. Additional endpoints will be collected and reported at each follow-up point through 5 years post-procedure, including but not limited to the following: technical success, major adverse events, all-cause mortality, aneurysm-related mortality, aneurysm rupture, secondary interventions, conversion to open surgery, losses of device integrity, device occlusions, stenosis or kink, aneurysm enlargement (> 5 mm), stent graft migration (> 10 mm), all types of endoleaks, and other device-related events. Outcomes will be reported using descriptive statistics every six months during the first two years of the study and annually thereafter.

Be advised that failure to comply with any post-approval requirement, including complying with the PAS requirements outlined above, constitutes grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.82(c).

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.

Be advised that protocol information, interim and final results will be published on the Post Approval Study Webpage https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm.

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" (<https://www.fda.gov/media/71327/download>).

Within 30 days of your receipt of this letter, you must submit a PMA supplement that includes a complete protocol of your post-approval study described above. Your PMA supplement should be clearly labeled as a PMA Post-Approval Study Protocol" as noted above and submitted to the address below. Please reference the PMA number above to facilitate processing. If there are multiple protocols being finalized after PMA approval, please submit each protocol as a separate PMA supplement.

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identification (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. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI website, <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-udi-system>.

Before making any change affecting the safety or effectiveness of the PMA 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" <https://www.fda.gov/media/81431/download>.

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 for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products, 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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems> and on combination product postmarketing safety reporting is available at (see

<https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>).

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the postmarketing safety reporting requirements (21 CFR 4, Subpart B) for combination products, 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

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls>.

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

<https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals>. 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 a copy of all final labeling. Final 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 labeling is identical to the labeling approved in draft form. If the final 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, 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
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 Charlie Yongpravat at 240-402-6652 or Charlie.Yongpravat@fda.hhs.gov.

Sincerely,

Nicole G. Ibrahim -S

Nicole Ibrahim, Ph.D.

Director

DHT2B: Division of Circulatory Support,
Structural and Vascular Devices

OHT2: Office of Cardiovascular Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health