January 12, 2024

W. L. Gore & Associates, Inc.
Edward Newton
Regulatory Affairs
3450 W. Kiltie Lane
Flagstaff, Arizona 86005

Re: P230023
Trade/Device Name: GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE)
Product Code: QZK
Filed: July 19, 2023

Dear Edward Newton:

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 GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis. This device is indicated for endovascular repair in patients with thoracoabdominal aortic aneurysms and high-surgical risk patients with pararenal aortic aneurysms who have appropriate anatomy as described below.

1. Adequate iliac / femoral access and brachial / axillary access
2. Proximal (supraceliac) aortic neck treatment diameter range over 2 cm seal zone of 22 - 34 mm for aneurysms extending up to 6.5 cm or less above the origin of the most proximal branch vessel
3. Aortic neck angle ≤ 60° at the Aortic Component proximal seal zone
4. Iliac artery treatment diameter range of 8 - 25 mm and iliac artery seal zone length of at least 10 mm
5. Renal artery seal zone diameters between 4.0 - 10.0 mm
6. Celiac and superior mesenteric artery seal zone diameters between 5.0 - 12.0 mm
7. ≥ 15 mm seal zone length in renal arteries, superior mesenteric artery, and celiac artery
8. Visceral segment of aorta (3 cm proximal through 9.5 cm distal to the most proximal visceral artery) must be ≥ 20 mm in diameter

Based upon the information submitted, 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 available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

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 all other applicable requirements, including those governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device (Aortic Component) 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 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 must include the information required by 21 CFR 814.84.

You have agreed to provide a Clinical Update to physician users at least annually. At a minimum, this update will include, for the IDE and Post-Approval studies, respectively, a summary of the number of patients for whom data are available, with the rates of mortality (device-and lesion-related), aortic rupture, stroke, paraplegia/paraparesis, renal events, mesenteric events, respiratory events, cardiac dysfunction, aortic enlargement, Type I/III endoleaks, loss of device integrity, loss of aortic/aortic branch patency, device migration, and additional surgical or interventional procedures related to the device or procedure. Reasons for secondary interventions and conversion to open surgery, as well as causes of lesion-related death and rupture are to be described. Additional relevant information from commercial experience within and outside the United States is to be included. A summary of any explant analysis findings is also 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 above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, under 21 CFR 814.82(a)(9), 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 must obtain approval of your post-approval study (PAS) protocol(s) within 60 days from the date of this order. 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 below. Your PMA supplement should be clearly labeled as a "PMA Post-Approval Study Protocol" as noted below 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.

In addition to the Annual Report requirements, you must provide the following data in post-approval study (PAS) reports for each PAS listed below.

1. Continued Follow-up of the IDE Study Subjects: This study is a non-randomized, multicenter, prospective study that consists of continued follow-up of all available subjects from the IDE Pivotal Study and the continued access subjects. The study design includes the assessment of the TAMBE Device in treating patients with thoracoabdominal and pararenal aortic aneurysms. A total of 102 subjects were enrolled in the Primary Arm and eligible for analysis in the pivotal study and 65 subjects have been approved for the continued access cohort. The remaining subjects will be followed annually for 5 years. Clinical endpoints include a composite of Uncomplicated Technical Success and Procedural Safety, as well as a composite of Clinically Significant Reintervention and Lesion-related Mortality. In addition, technical, treatment and clinical success as defined in the Society for Vascular Surgery "Reporting standards for endovascular aortic repair of aneurysms involving the renal-mesenteric arteries" will be presented. These endpoints will be analyzed descriptively.

   PAS Progress Reports must be submitted annually from the date of the PMA approval letter. The Final PAS Report should be submitted no later than three (3) months after study completion (i.e., last subject's last follow-up date).

2. GORE TAMBE Post Approval Study: This is a prospective, non-randomized, multi-center study collecting data from consecutively treated patients. The objective of the study is to capture longer term outcome data on use of TAMBE in real-world use and to assess the adequacy of the TAMBE training program. This study will enroll a minimum of 300 all comer subjects treated with TAMBE with at least 100 subjects evaluable at 5 years post-implantation. Follow-up will occur at 30 days, 6 months, 1 year and yearly thereafter through 10 years or until lost to follow-up including subject death. This study will have a minimum of 10 new sites without prior TAMBE Device implant experience, and at least 70 subjects will be enrolled at these new sites. Core Lab imaging analysis will be conducted through 5 years follow-up. The data collection will include: patient and anatomical characteristics, procedural characteristics and outcomes. The co-primary endpoints will be technical success and clinical success. The following secondary outcomes will be also reported: procedure and lesion-related mortality, primary/assisted primary clinical success and secondary clinical success, and target vessel related outcomes. Outcomes will be reported using descriptive statistics and definitions will align with the reporting standards. A subset analysis of select outcomes will be conducted to assess whether the training program is adequate to support the safe use of TAMBE in the real-world. The results of this subgroup analysis, as well as learnings and any resulting modifications to the training program will be included in the post approval study reports.

   From the date of study protocol approval, you must meet the following timelines for the Gore TAMBE Post Approval Study:

   - First subject enrolled within 9 months
   - 20% of subjects enrolled within 18 months
   - 50% of subjects enrolled within 27 months
   - 100% of subjects enrolled within 36 months

In addition, you must submit separate periodic reports on the progress of Gore TAMBE Post Approval Study as follows:

- PAS Progress Reports every six (6) months until subject enrollment has been completed, and annually thereafter, from the date of the PMA approval letter, unless otherwise specified by FDA.
- If any enrollment milestones are not met, you must begin submitting quarterly enrollment status reports every 3 months in addition to your periodic (6-month) PAS Progress Reports, until FDA notifies you otherwise.
- Submit the Final PAS Report three (3) months from study completion (i.e., last subject's last follow-up date).

Each PAS report should be submitted to the address below identified as a "PMA Post-Approval Study Report" in accordance with how the study is identified above and bearing the applicable PMA reference number.

Be advised that failure to comply with any post-approval requirement, including initiation, enrollment, and completion requirements outlined above, constitutes grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.82(c) and 814.46(a)(2).

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 accordance with 21 CFR 814.46(a)(3)-(4).

Be advised that protocol information, interim and final results will be published on the Post-Approval Studies Program Database Webpage, available at 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. Under 21 CFR 814.39, 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 Premarket Approval Application Order" (https://www.fda.gov/media/71327/download).

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 Part 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 available at 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. Additional information about changes that may require a PMA supplement are provided in 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.

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production and process controls (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 post-marketing safety reporting (21 CFR Part 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 post-marketing safety reporting is available at 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 post-marketing safety reporting requirements (21 CFR Part 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 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 Rohini Retarekar at 240-402-3750 or Rohini.Retarekar@fda.hhs.gov.

Sincerely,

Rachel E. Neubrander -S

Rachel Neubrander, PhD
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