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

June 23, 2014

Michelle M. Peterson
Regulatory Affairs
W. L. Gore & Associates, Inc.
3450 W. Kiltie Lane
Flagstaff, AZ 86001

Re: P040043/S051
GORE TAG Thoracic Endoprosthesis

Dear Ms. Peterson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) completed its evaluation of your premarket approval application (PMA) Supplement and issued an approval order on September 10, 2013. Per our e-mail dated May 22, 2014, modifications to your conditions of approval were required to appropriately reflect that you will participate as a stakeholder in the Society for Vascular Surgery Patient Safety Organization governed Vascular Quality Initiative to provide surveillance on your device used to treat descending thoracic aortic dissections. The modified conditions of approval are as follows:

You have agreed to provide the following data as part of the annual report:

1. [Unmodified] You currently provide a clinical update to physician users at least annually, with information regarding your TAG device. Future clinical updates are to include information from your TAG 08-01 (dissection) clinical study. At a minimum, the information to be included for the dissection study will include a summary of the number of patients for whom data are available, with a summary of dissection-related deaths, aortic ruptures, aortic enlargements, extension of the dissection, major adverse events (i.e., paraparesis, paraplegia, new ischemia), losses of device integrity, and additional dissection-related interventions, including the reasons for the interventions. A summary of any explant analysis findings is to be included. Additional relevant information from commercial experience within and outside of the U.S. is also to be included.

2. [Modified] In addition to providing information regarding your dissection study in your clinical updates to physician users, you will report any significant observations from the surveillance described below of the use of the TAG device to repair Type B dissections in the descending thoracic aorta.

In addition to the conditions outlined above, you agree to support and actively participate as a stakeholder in the Society for Vascular Surgery Patient Safety Organization governed Vascular Quality Initiative and undertake such activities to ensure that surveillance occurs for the TAG device when used to repair Type B dissections in the descending thoracic aorta in at least 60 patients with acute dissections and 60 patients with chronic dissections.

This surveillance should monitor freedom from dissection-related mortality, additional dissection-related intervention, dissection treatment success, the individual elements of the composite endpoint dissection treatment success, all-cause mortality, false lumen patency, endovascular device penetration of the aortic wall, loss of device integrity, device technical success at the time of the procedure, and device procedural success.

We hope that this error has not inconvenienced you. If you have any questions about this corrective action, please contact Dorothy Abel at (301) 796-6366 or dorothy.abel@fda.hhs.gov.

Sincerely yours,

Nicole G. Ibrahim -S

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

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10903 New Hampshire Avenue
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September 10, 2013

Ms. Michelle Peterson
Regulatory Affairs
W.L. Gore & Associates, Inc.
3450 W. Kiltie Lane
Flagstaff, AZ 86001

Re: P040043/S051
GORE TAG Thoracic Endoprosthesis
Filed: March 14, 2013
Procode: MIH

Dear Ms. Peterson:

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) supplement for the GORE TAG Thoracic Endoprosthesis. This device is intended for endovascular repair of all lesions of the descending thoracic aorta, including:

- Isolated lesions in patients who have appropriate anatomy, including:
  - Adequate iliac / femoral access
  - Aortic inner diameter in the range of 16-42 mm
  - ≥ 20 mm non-aneurysmal aorta proximal and distal to the lesion

- Type B dissections in patients who have appropriate anatomy, including:
  - Adequate iliac / femoral access
  - ≥ 20 mm landing zone proximal to the primary entry tear; proximal extent of the landing zone must not be dissected
  - Diameter at proximal extent of proximal landing zone in the range of 16-42 mm.

We are pleased to inform you that the PMA supplement is approved. You may begin commercial distribution of the device as modified 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" (please use this title even if the specified interval is more frequent than one year) 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 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 the following data as part of the annual report:

1. You currently provide a clinical update to physician users at least annually, with information regarding your TAG Device. Future clinical updates are to include information from your TAG 08-01 (dissection) clinical study. At a minimum, the information to be included for the dissection study will include a summary of the number of patients for whom data are available, with a summary of dissection-related deaths, aortic ruptures, aortic enlargements, extension of the dissection, major adverse events (i.e., paraparesis, paraplegia, new ischemia), losses of device integrity, and additional dissection-related interventions, including the reasons for the interventions. A summary of any explant analysis findings is to be included. Additional relevant information from commercial experience within and outside of the U.S. is also to be included.

2. In addition to providing information regarding your dissection study in your clinical updates to physician users, you will provide information regarding the postapproval study (PAS) described below to physician users on a regular basis. The content and timing of these updates will be based on your PAS protocol.

In addition to the conditions outlined above, you must conduct a post-approval study (PAS) to evaluate freedom from dissection-related mortality in patients followed through 5 years post-implantation as described below:

TAG Post-Approval Study: The study will be a prospective, single-arm registry of patients treated for thoracic dissection, consecutively enrolled at multiple investigational centers treated with the TAG device or any other thoracic endovascular graft. The study

will consist of all patients treated at centers that agree to participate in the 5-year follow-up PAS.

The primary objective for the Post-Approval Study is to evaluate freedom from dissection-related mortality through 5 years post-implantation in patients treated for acute or chronic dissections with thoracic endovascular grafts.

The primary safety endpoint of the study is freedom from dissection-related mortality post-implantation at 5 years. The primary effectiveness endpoints will include device technical success at the time of the procedure and device procedural success at 30 days.

Secondary endpoints through 5 years include additional dissection-related intervention, dissection treatment success, the individual elements of the composite endpoint dissection treatment success, all-cause mortality, false lumen patency, endovascular device penetration of the aortic wall, and loss of device integrity.

Patients treated with the TAG device will be part of a total of 200 acute patients and 200 chronic patients treated with thoracic endovascular grafts. This sample size will provide sufficiently narrow 95% confidence intervals to estimate a 5 year primary endpoint rate of 5% (1.98 - 8.02) to 40% (33.21 - 46.79). A minimum of 60 patients with acute dissections and 60 patients with chronic dissections treated with the TAG device will be included in the study.

Data will be analyzed and presented separately for the acute and chronic study arms. These data will be provided in post-approval study reports that are separate from the ODE annual reports.

Please be advised that the results from this 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.

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.

FDA would like to remind you that you are required to submit PAS Progress Reports every six months during the first year and annually thereafter. The PAS Progress Reports should be submitted separately from the Annual Reports. Two copies, identified as "PMA Post-Approval Study Report" and bearing the applicable PMA reference number, should be submitted to the address below. 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

Within 30 days of your receipt of this letter, you must submit a PMA supplement that includes the complete protocol of your post-approval study. Your PMA supplement should be clearly labeled as a "Post-Approval Study Protocol" and submitted in triplicate to the address below. Please reference the PMA number above to facilitate processing. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order" (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm#2

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" (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 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 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

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 six 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 Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have questions concerning this approval order, please contact Dorothy Abel at (301) 796-6366.

Sincerely yours,

Christy L. Foreman -S

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