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 19, 2014

Mr. Steven R. Bruun
Regulatory Affairs Associate
W.L. Gore and Associates, Inc.
3250 W. Kiltie Lane
Flagstaff, AZ 86005

Re: P040037/S060
GORE VIABAHN Endoprosthesis and GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface
Filed: December 2, 2013
Amended: December 23, 2013 and August 12, 2014
Procode: NIP

Dear Mr. Bruun:

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 VIABAHN Endoprosthesis and GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface. These devices are indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery de novo and restenotic lesions up to 270 mm in length with reference vessel diameters ranging from 4.0 – 7.5 mm. These devices are also indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery in-stent restenotic lesions up to 270 mm in length with reference vessel diameters ranging from 4.0 – 6.5 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 this restriction on sale and distribution is 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 three 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.

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.

In addition to the Annual Report requirements, you must provide the following data in a separate post-approval study (PAS) report. As a condition of approval, you have agreed to conduct the following post-approval studies:

1. *RELINE Extended Follow-Up Study:* This study will be conducted as per the protocol dated August 7, 2014, Version FMRP-100107 included in P040037/S060/A002.

   This will be a continued follow-up of patients enrolled in the prospective, randomized, multicenter, GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface versus Plain Old Balloon Angioplasty (POBA) in the treatment of in-stent restenosis of the Superficial Femoral Artery (SFA) or RELINE Trial. All 88 remaining patients at 12 months, from the original 100 randomized patients, will be followed out to 24 months post-implant.

   The primary endpoint of primary patency [defined as no evidence of restenosis or occlusion within the originally treated lesion based on color-flow duplex ultrasound (CFDU) measuring a peak systolic velocity ratio (PSVR) of ≤ 2.5 without target lesion revascularization (TLR)] at 24 months will be estimated using Kaplan-Meier time-to-event analysis. The secondary endpoints to be assessed through Kaplan-Meier time-to-event analysis are primary assisted patency, secondary patency, and freedom from TLR at 24 months. Clinical success at 24 months will be tested for treatment differences using the Fisher's exact test. Serious adverse events at 24 months will be categorized and presented as frequency and proportions.

2. *New Enrollment Study*: You have agreed to a study outline in P040037/S060/A002 (dated August 11, 2014) to assess the incidence of stent fracture and evaluate the long-term performance of the GORE VIABAHN Endoprosthesis and GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface. This will be a prospective, multicenter single-arm study of newly enrolled patients treated with the GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface device for in-stent restenosis of the SFA. Patients will be followed at 30 days and annually through 36 months.

   A sample size of 108 new enrollment patients, with a minimum of 81 US and a maximum of 27 outside of the US (OUS) patients, will be enrolled across a minimum of 15 US sites and up to 5 OUS sites. Patients in Rutherford categories 2 to 5 will be enrolled to provide evidence at various clinical stages of the disease.

   The primary effectiveness endpoint is primary patency at 12 months. The primary safety endpoint is device- and procedure-related serious adverse events within 30 days of the procedure. All primary endpoints will be descriptively reported.

   The secondary endpoints of primary patency, primary assisted patency, secondary patency, freedom from TLR, and freedom from major amputation will be assessed at 12, 24 and 36 months and estimated by Kaplan Meier methods. Adverse events will be presented as counts and proportions at 30 days, 12 months, 24 months, and 36 months. In addition, the occurrence of stent fracture will be assessed annually post-implant through 36 months by a Core Lab, classified according to stent integrity grading scale (Class 0 to V) as performed for the RELINE Trial, except angiography will not be performed for additional categorization.

   The total of 108 subjects is expected to provide an evaluable sample size of 86 subjects at 1-year after 20% lost to follow-up. With 71% assumed patency for the VIABAHN device, this sample size will provide a 95% confidence interval of 60.2% to 80.3% yielding a precision of 20.1%.

Please be advised that the results from these studies 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 for the "New Enrollment Study" every six months during the first two years and annually thereafter, and the final report for the "RELINE Extended Follow-Up Study" within 30 days of your receipt of

this letter. The reports should clearly be identified as Post-Approval Study Report. Two copies for each PAS study, 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 a complete protocol of your "New Enrollment Study" 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.

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
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If you have any questions concerning this approval order, please contact Carla Wiese at 301-796-0627.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

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