DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Neeta Sharma
Principal Regulatory Affairs Specialist
Medtronic Vascular
3576 Unocal Place
Santa Rosa, CA 95403

APR 13 2011

Re: P100040
Device: Valiant® Thoracic Stent Graft with the Captivia Delivery System

Dear Ms. Sharma:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) completed its evaluation of your premarket approval application (PMA) and issued an approval order on April 1, 2011. We inadvertently made an error in the follow-up requirements listed in condition of approval #2. The correct condition is listed below:

2. In addition to the Annual Report requirements outlined above, you will provide the following data in a separate post-approval study report. You will perform a post-approval study to evaluate the longer-term safety and effectiveness of the Valiant Thoracic Stent Graft with the Captivia Delivery System through five years of implantation. The primary endpoint for this study is freedom from aneurysm-related mortality at 5 years. Aneurysm-related mortality is defined as:

   > Death from rupture of the fusiform aneurysm or saccular aneurysm/penetrating ulcer or from any procedure intended to treat the fusiform aneurysm or saccular aneurysm/penetrating ulcer. If a death occurred within 30 days of any procedure intended to treat the fusiform aneurysm or saccular aneurysm/penetrating ulcer, then it is presumed to be aneurysm related.

   This study is expected to include the 160 patients enrolled in the VALOR II clinical study. At 1 month, 12 months, and, at each annual visit to five (5) years, a chest x-ray, CT scan with and without contrast, and physical examination have been or will be conducted. All data will be entered into a database, analyzed, and submitted in post-approval reports to the FDA, and a final report will be submitted after completion of the follow-up and analysis. This follow-up plan will allow 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 a supplement with revised labeling that reflects the study findings.

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.

Sincerely yours,

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

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APR 1 2011

Re: P100040
Device: Valiant® Thoracic Stent Graft with the Captivia Delivery System
Filed: October 8, 2010
Amended: October 18, 2010 and January 7, 2011
Procode: MIH

Dear Ms. Sharma:

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 Valiant® Thoracic Stent Graft with the Captivia Delivery System. This device is indicated for the endovascular repair of fusiform aneurysms and saccular aneurysms/penetrating ulcers of the descending thoracic aorta in patients having appropriate anatomy, including:

- iliac/femoral access vessel morphology that is compatible with vascular access techniques, devices, and/or accessories;
- non-aneurysmal aortic diameter in the range of 18–42 mm; and
- non-aneurysmal aortic proximal and distal neck lengths ≥ 20 mm.

We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions 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 2 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 have agreed to provide the following data in post-approval study reports (PAS). Two copies, identified as "PMA Post-Approval Study Report" and bearing the applicable PMA reference number, should be submitted to the address below.

1. You will provide a clinical update to physician users at least annually. At a minimum, this update will include, for your post-approval study cohort, a summary of the number of patients for whom data are available, with the rates of aneurysm rupture, secondary endovascular procedures, conversion to surgical repair, aneurysm-related mortality, major adverse events, endoleak, aneurysm enlargement, prosthesis migration, and patency. 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 in the ODE annual report.

2. In addition to the Annual Report requirements outlined above, you will provide the following data in a separate post-approval study report. You will perform a post-approval study to evaluate the longer-term safety and effectiveness of the Valiant Thoracic Stent

Graft with the Captivia Delivery System through five years of implantation. The primary endpoint for this study is freedom from aneurysm-related mortality at 5 years. Aneurysm-related mortality is defined as:

> Death from rupture of the fusiform aneurysm or saccular aneurysm/penetrating ulcer or from any procedure intended to treat the fusiform aneurysm or saccular aneurysm/penetrating ulcer. If a death occurred within 30 days of any procedure intended to treat the fusiform aneurysm or saccular aneurysm/penetrating ulcer, then it is presumed to be aneurysm related.

This study is expected to include the 160 patients enrolled in the VALOR II clinical study. At 1 month, 12 months, and, at each annual visit, an abdominal x-ray, CT scan with and without contrast, and physical examination have been or will be conducted. All data will be entered into a database, analyzed, and submitted in post-approval reports to the FDA, and a final report will be submitted after completion of the follow-up and analysis. This follow-up plan will allow 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 a supplement with revised labeling that reflects the study findings.

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.

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. 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. If there are multiple protocols being finalized after PMA approval, please submit each protocol as a separate 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" (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 triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing. One of those three copies may be an electronic copy (eCopy), in an electronic format that FDA can process, review and archive (general information: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm; clinical and statistical data: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm136377.htm)

U.S. Food and Drug Administration
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If you have any questions concerning this approval order, please contact Dorothy Abel at (301) 796-6366.

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