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

January 6, 2017

Vascular Solutions, Inc.
Beka Vite
Sr. Regulatory Product Specialist
6464 Sycamore Court North
Minneapolis, Minnesota 55369

Re: K163444
Trade/Device Name: Spectre Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: December 7, 2016
Received: December 9, 2016

Dear Beka Vite:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

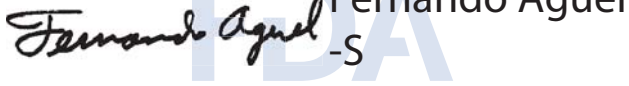
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,




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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K163444

Device Name
Spectre guidewire

Indications for Use *(Describe)*
The Spectre guidewire is intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and/or peripheral vasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 2 510(k) Summary

[As required by 21 CFR 807.92]

**Date Prepared:** December 7, 2016

**510(k) Number:** K163444

**Submit t er's Name / Contact Person**

**Manufacturer**
Vascular Solutions, Inc.
6464 Sycamore Court North
Minneapolis, MN 55369 USA
Establishment Registration # 2134812

**Contact Person**
Beka Vite
Sr. Regulatory Product Specialist
Tel: 763-656-4300
Fax: 763-656-4253

**General Information**

| | |
|---|---|
| **Trade Name** | Spectre guidewire |
| **Common / Usual Name** | Guidewire |
| **Classification Name** | 21 CFR 870.1330, Catheter Guidewire (DQX) |
| **Predicate Device** | K161702 – Endura guidewire (VSI) |

**Device Description**

The Spectre guidewire is a straight tip guidewire with a maximum outer diameter of 0.014" available in 190 cm and 300 cm lengths. The Spectre guidewire consists of a bi-metal stainless steel and nitinol core wire covered on the distal end by a radiopaque coil at the distal tip. The distal end of the Spectre guidewire has a hydrophilic coating (HPC) and the proximal end is coated with polytetrafluoroethylene (PTFE). The 190 cm length model is compatible with a guidewire extension.

**Intended Use**

The Spectre guidewire is intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and/or peripheral vasculature.

**Technological Characteristics Comparison**

The table below compares the technological characteristics of the Spectre guidewire.

| Characteristic | Subject Device<br>Spectre Guidewire | Predicate Device<br>Endura Guidewire<br>(K161702, VSI) |
|---|---|---|
| **Indications for Use** | Intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and/or peripheral vasculature. | Same |
| **Anatomical Location** | Coronary and peripheral vasculature | Same |
| **Dimensions** | Maximum O.D.: 0.014”<br>Length: 190 cm and 300 cm | Same |
| **Core Wire** | Nitinol and Stainless Steel | Same |
| **Distal Tip** | 3 cm radiopaque coil | Same |
| **Lubricious Coatings** | Hydrophilic (distal end) and PTFE (proximal end) | Same |
| **Sterility** | Ethylene Oxide (EO) – Sterility Assurance Level (SAL) $10^{-6}$ | Same |

**Substantial Equivalence and Summary of Studies**

The technological differences between the subject and predicate devices have been evaluated through bench tests to provide evidence that the Spectre guidewire is substantially equivalent to the predicate device. The Spectre guidewire is substantially equivalent to the specified predicate device based on comparisons of the device functionality, technological characteristics, and indications for use. The device design has been verified through the following tests:

- Track Force
- Guidewire Support Profile

The results of the verification tests met the specified acceptance criteria and did not raise new safety or performance issues. Therefore, the modified Spectre guidewire is substantially equivalent to the predicate device.