December 15, 2017

Vascular Solutions, Inc.
% Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K173532
Trade/Device Name: Raider Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: November 13, 2017
Received: November 15, 2017

Dear Mark Job:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173532

Device Name
Raider guidewire

Indications for Use *(Describe)*
The Raider guidewire is intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and 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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510(K) SUMMARY

[As required by 21 CFR 807.92]

Date Prepared: October 20, 2017

510(k) Number: K173532

Submitter'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
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General Information

Trade Name	Raider guidewire
Common / Usual Name	Guidewire
Classification Name	21 CFR 870.1330
Predicate Device	Spectre Guidewire (K163444 – Vascular Solutions, Inc.; January 6, 2017)
Reference Device	Hi-Torque Pilot 200 (K101116 – Abbott Vascular; June 23, 2010) R350 Guidewire (K151234 – Vascular Solutions, Inc.; November 18, 2015)

Device Description

The Raider guidewire is a stainless steel core guidewire with a maximum outer diameter of 0.014" and a straight, shapeable tip. It is available in 190 cm and 300 cm lengths. The 190 cm length is compatible with a guidewire extension. The distal portion of the guidewire includes a radiopaque coil and is covered with a polymer jacket and hydrophilic coating. The proximal portion has a PTFE coating.

Intended Use

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

Technological Characteristics Comparison

The table below compares the technological characteristics of the Raider guidewire and the predicate device.

Characteristic	Raider Guidewire	Predicate Device
Maximum Diameter	0.014"	Same
Lengths	190 cm, 300 cm	Same
Core Wire Material	Stainless Steel with Distal Polymer Jacket	Nitinol and Stainless Steel
Distal Tip	Radiopaque Coil	Same

Characteristic	Raider Guidewire	Predicate Device
Lubricious Coatings	Hydrophilic (Distal) PTFE (Proximal)	Same

The technological differences between the subject and predicate devices have been evaluated through biocompatibility and bench tests to provide evidence of substantial equivalence for the Raider guidewire. The device design has been verified through the following tests:

- Tensile Strength
- Torque Strength
- Torqueability
- Tip Flexibility
- Coating Adherence/Integrity
- Catheter Compatibility
- Dimensional Analysis
- Radiopacity
- Corrosion

Device samples passed the following biocompatibility tests performed in accordance with ISO 10993-1:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemolysis
- Complement Activation
- Thrombogenicity

The Raider guidewire is substantially equivalent to the specified predicate device based on comparisons of the device functionality, technological characteristics, and indications for use. The minor technological and material differences between the Raider guidewire and the predicate device raise no new questions of safety or effectiveness. Performance data demonstrate that the Raider guidewire is as safe, as effective, and performs as well as the predicate device. Therefore, it can be concluded that the Raider guidewire is substantially equivalent to the predicate device.