February 16, 2018

Vascular Solutions, Inc
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K180128
Trade/Device Name: Warrior 14 guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: January 14, 2018
Received: January 17, 2018

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,

for Kenneth J. Cavanaugh -S

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)*

K180128

Device Name
Warrior 14 guidewire

Indications for Use *(Describe)*

The Warrior 14 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

[As required by 21 CFR 807.92]

510(k) NUMBER: K180128

SUBMITTER

Vascular Solutions

6464 Sycamore Court North

Minneapolis, MN 55369 USA

Establishment Registration # 2134812

Phone: 763-656-4300

Fax: 763-656-4253

Contact Person: Becky Astrup, Regulatory Product Specialist

Date Prepared: December 8, 2017

DEVICE

Name of Device: Warrior 14 guidewire

Common or Usual Name: Catheter Guidewire

Classification Name: Catheter Guidewire (21 CFR 870.1330)

Regulatory Class: II

Product Code: DQX

PREDICATE/REFERENCE DEVICES

The legally marketed devices to which substantial equivalence is claimed is:

Vascular Solutions Spectre guidewire, K163444 (cleared January 6, 2017)

The Asahi Confianza Pro 12 guidewire, K041531 (cleared August 3, 2004) and the Vascular Solutions R350 guidewire, K151234 (cleared November 18, 2015) are included as reference devices for this submission.

DEVICE DESCRIPTION

The Warrior 14 guidewire is a 0.014" diameter stainless steel core guidewire with a 0.009" diameter tapered distal tip. The distal 20cm of the guidewire has a spring coil, of which the distal 2.5cm is visible under fluoroscopic methods. The guidewire has a straight shapeable tip with a tip load of 14 grams. The distal portion of the guidewire has a hydrophilic coating and the proximal portion has a PTFE coating. It is available in 190cm and 300cm lengths. The proximal end of the 190cm version has a guidewire extension feature. The Warrior 14 guidewire is intended for single use and sterilized with ethylene oxide.

INDICATIONS FOR USE

The Warrior 14 guidewire is intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The table below compares the technological characteristics of the Warrior 14 guidewire and, Spectre guidewire predicate.

Characteristic	Subject Device: Warrior 14	Predicate Device: Spectre
Maximum Diameter	0.014"	**Identical**
Lengths	190cm, 300cm	**Identical**
Tip Configuration	Straight, Shapeable	**Identical**
Lubricious Coating- Distal	Hydrophilic	**Identical**
Lubricious Coating- Proximal	PTFE	**Identical**
Core Wire Material	Stainless Steel	**Similar** Nitinol and Stainless Steel
Radiopaque Material	Platinum, Tungsten	**Identical**
Radiopaque Tip Length	2.5cm	**Equivalent** 3cm
Tip O.D.	0.009"	**Similar** 0.014"
Tip Load	14g	**Similar** ≤ 1.5g

PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the Warrior 14 guidewire was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The Warrior 14 guidewire is considered an externally communicating device in contact with circulating blood and tissue for a limited period of time (<24 hours) during use. The battery of tests included the following:

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

Passing results from biomaterial tests demonstrate that the Warrior 14 guidewire is non-cytotoxic, non-sensitizing, non-irritating, non-systemically toxic, non-pyrogenic, non-hemolytic, not an activator of the complement system, and thromboresistant.

Performance Testing- Bench

The device design was verified through the following tests:

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

The results of the verification tests met the specified acceptance criteria and did not raise different questions of safety or effectiveness.

CONCLUSIONS

In summary, the technological differences between the Warrior 14 guidewire, subject of this 510(k) and the predicate device do not raise different questions of safety and effectiveness. The Warrior 14 guidewire is identical to the predicate device in its indications for use and substantially equivalent in technology, materials, and performance to the predicate device. Performance data demonstrate that the Warrior 14 guidewire is as safe, as effective, and performs as well as the predicate device. Therefore, it can be concluded that the Warrior 14 guidewire is substantially equivalent to the predicate device.