July 20, 2018

Vascular Solutions, Inc.
Ms. Becky Astrup
Regulatory Product Specialist
6464 Sycamore Court North
Minneapolis, Minnesota 55369

Re: K181647
Trade/Device Name: Bandit Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: June 21, 2018
Received: June 22, 2018

Dear Ms. Astrup:

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 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,

Lydia S. Glaw -S
2018.07.20 15:51:10 -04'00'

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)*

K181647

Device Name
Bandit guidewire

Indications for Use *(Describe)*
The Bandit 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: K181647

SUBMITTER AND DEVICE

Submitter:
Vascular Solutions, Inc.
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: June 21st, 2018

Name of Device: Bandit guidewire

Common or Usual Name: Guidewire

Classification Name: Catheter Guidewire (21 CFR 870.1330)

Regulatory Class: II

Product Code: DQX

PREDICATE DEVICE

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

Vascular Solutions Inc., Raider guidewire, K173532 cleared December 15, 2017.

The Asahi Intecc Co., LTD Fielder XT guidewire, K072431 cleared September 26, 2007 is included as a reference device for this submission.

DEVICE DESCRIPTION

The Bandit guidewire is a 0.014" diameter stainless steel core guidewire with a 0.008" diameter tapered distal tip. It is available in 200 cm and 300 cm lengths. The 200 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.

INDICATIONS FOR USE

The Bandit 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 Bandit guidewire and the Raider guidewire predicate device.

Characteristic	Subject Device: Bandit	Predicate Device: Raider
Maximum Diameter	0.014”	**Identical**
Lengths	200 cm, 300 cm	**Similar** 190cm, 300cm
Core Wire Material	Stainless Steel with Distal Polymer Jacket	**Identical**
Distal Tip	Radiopaque Coil	**Identical**
Lubricious Coatings	Distal: Hydrophilic Proximal: PTFE	**Identical**

PERFORMANCE DATA

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

Performance Testing - Bench
The technological differences between the subject and predicate device have been evaluated through bench tests to provide evidence that the Bandit guidewire is substantially equivalent to the predicate device. The device design was verified through the following tests:

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

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

Biocompatibility Testing

The biocompatibility evaluation for the Bandit 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 Bandit 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
- Thrombogenicity

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

CONCLUSION

The subject Bandit guidewire is substantially equivalent to the Raider guidewire predicate device based on comparisons of the device functionality, technological characteristics, and indications for use. The results of design verification tests do not raise new or different questions of safety and effectiveness; therefore, the Bandit guidewire is substantially equivalent to the predicate device.