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

November 18, 2015

Vascular Solutions, Inc.
Beka Vite
Regulatory Product Specialist
6464 Sycamore Court North
Minneapolis, MN 55639

Re: K151234
Trade/Device Name: R350 Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: October 16, 2015
Received: October 19, 2015

Dear Ms. 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" (21CFR 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 yours,

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)*
K151234

Device Name
R350 Guidewire

Indications for Use *(Describe)*
The R350 guidewire is indicated 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.

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

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510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: May 06, 2015

510(k) Number: K151234

Submitter's Name / Contact Person

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

Contact Person
Beka Vite
Regulatory Product Specialist
Tel: 763-657-5732
Fax: 763-656-4253

General Information

Trade Name	R350 guidewire
Common / Usual Name	Guidewire
Classification Name	21 CFR 870.1330, DQX – catheter guidewire
Predicate Devices	K021990 – R350 guidewire (Galt Medical Corp.) K141339 – Asahi RG3 guidewire (Asahi Intecc Co., Ltd.)

Device Description

The R350 guidewire is 350 cm in length with a 0.013" maximum outer diameter (O.D) (0.012" nominal O.D.). It is composed of a nitinol alloy mandrel with a straight, radiopaque 5 cm gold-coated tungsten coil distal tip. The proximal 150 cm of the R350 guidewire has a PTFE coating, while the distal 200 cm has a hydrophilic coating.

Indications for Use

The R350 guidewire is indicated 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 R350 guidewire is similar in design and intended use to the predicate devices as they are all guidewires intended for use in percutaneous procedures. The R350 guidewire and predicate devices are similar in size, and all have a radiopaque tip and lubricous coating.

Substantial Equivalence and Summary of Studies

The technological differences between the R350 guidewire and predicate devices were evaluated through biocompatibility and mechanical tests, and results did not raise new questions of safety or effectiveness.

The R350 guidewire is substantially equivalent to the specified predicate devices based on comparisons of the device functionality, technological characteristics, and indications for use. The R350 guidewire design has been verified through the following tests and inspections:

- Hydrophilic Coating Particulate
- Hydrophilic Coating Delamination Inspection (after Fracture Test)
- Fluoroscopy Visualization
- Guidewire O.D.
- Guidewire Length
- Component Alignment
- Interface with Other Devices
- Torqueability
- Torque
- Flex
- Fracture
- Tip Deflection Force
- Tip Load
- Distal Solder Joint Tensile
- Proximal Solder Joint Tensile
- Corrosion

Device samples passed the following biocompatibility tests per ISO 10993-1:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- ASTM Hemolysis
- Complement Activation
- ASTM Platelet and Leukocyte Count Assay
- Partial Thromboplastin Time
- In Vivo Thrombogenicity

The results of the design verification and validation tests met the specified acceptance criteria and did not raise new questions of safety and effectiveness. Therefore, the R350 guidewire is substantially equivalent to the predicate devices.