October 20, 2017

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

Re: K172090
Trade/Device Name: GuideLiner V3 Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 21, 2017
Received: September 22, 2017

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 (DICE) 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 (DICE) 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172090

Device Name
GuideLiner V3 Catheter

Indications for Use *(Describe)*

GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices.

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: September 19, 2017

510(k) Number: K172090

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	GuideLiner V3 Catheter
Common / Usual Name	Catheter
Classification Name	21 CFR 820.1250
Predicate Device	GuideLiner V2 Catheter - K112082
Reference Device	TrapLiner Catheter – K161901

Device Description

The GuideLiner V3 catheter is a rapid-exchange guide extension catheter designed for use in the coronary and peripheral vasculature. It is available in five sizes – 5F, 5.5F, 6F, 7F, and 8F. All sizes of the GuideLiner V3 catheter have a 150 cm working length, consisting of a 125 cm long stainless steel pushwire shaft followed distally by a 25 cm long full-round, silicone-wiped guide extension segment. The distal 17 cm of the 125 cm pushwire shaft is covered with a semi-circular polymer that meets the proximal end of the full-round guide extension segment. The GuideLiner V3 catheter has two platinum-iridium marker bands; the distal marker band is located at the distal tip and the proximal marker band is located near the collar. The GuideLiner V3 catheter also has two positioning marks located 95 cm (single mark) and 105 cm (double mark) from the distal tip.

Intended Use

GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices.

Technological Characteristics Comparison

The key technological difference between the GuideLiner V3 catheter and the predicate device is the addition of the semi-circular polymer transition from the pushrod to the full-round guide extension segment. An additional 5F configuration is also included.

Substantial Equivalence and Summary of Studies

The technological differences between the subject and predicate devices have been evaluated through biocompatibility and performance tests to provide evidence of substantial equivalence for the GuideLiner V3 catheter. The GuideLiner V3 catheter is substantially equivalent to the specified predicate devices based on comparisons of the device functionality, technological characteristics, and indications for use. The device design has been verified through the following tests:

- Kink Radius
- Bend Diameter
- Extension into Anatomy
- Silicone Coating
- Radiopacity
- Contrast Delivery
- Interventional Device Delivery
- Shaft Tensile
- Hub Tensile
- Torque Strength
- Distal Shaft Length
- Half-Pipe Length
- Working Length
- Guide Catheter Compatibility

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

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Pyrogenicity
- ASTM Hemolysis
- Complement Activation
- Thrombogenicity

The results of the verification tests met the specified acceptance criteria and did not raise new safety or performance issues. Therefore, the GuideLiner V3 catheter is substantially equivalent to the predicate device.