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

February 3, 2017

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

Re: K161901
Trade/Device Name: TrapLiner Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: January 4, 2017
Received: January 5, 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.

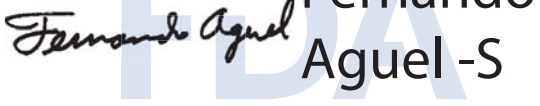
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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 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,



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)*
K161901

Device Name
TrapLiner catheter

Indications for Use *(Describe)*
The TrapLiner catheter is intended for use in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, to facilitate placement of interventional devices, and to facilitate the exchange of an interventional device while maintaining the position of a guidewire within the 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: December 30, 2016

510(k) Number: K161901

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
Tel: 763-656-4300
Fax: 763-656-4253

General Information

Trade Name	TrapLiner catheter
Common / Usual Name	Catheter
Classification Name	21 CFR 870.1250 – percutaneous catheter
Predicate Device	K112082 – GuideLiner V2 catheter (Vascular Solutions, Inc.); P860019/S040 – SCIMED Trapper exchange device (SCIMED Life Systems, Inc.)

Device Description

The TrapLiner catheter is a rapid-exchange guide extension catheter with a trapping balloon on the distal end of the pushrod. The stainless steel pushrod is covered on the distal end by a semi-circular polymer ('half-pipe') and transitions to a hydrophilic coated full-round polymer guide extension section. There are two radiopaque marker bands on the guide extension segment, one on the distal tip and one on the collar. The trapping balloon is located proximal to the half-pipe and has a single radiopaque gold marker under the proximal end of the balloon.

Intended Use

The TrapLiner catheter is intended for use in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, to facilitate placement of interventional devices, and to facilitate the exchange of an interventional device while maintaining the position of a guidewire within the vasculature.

Technological Characteristics Comparison

The TrapLiner catheter is similar in design and intended use to the primary predicate device as it is rapid-exchange guide extension catheter intended to access discrete regions of the coronary and peripheral vasculature and to facilitate the placement of guidewires and other interventional devices. Like the secondary predicate device, a trapping balloon is present on the TrapLiner catheter to maintain guidewire

position during interventional device exchange. In addition to similar dimensions and guide catheter compatibility (6F, 7F, and 8F), the subject and predicate devices are made from similar materials and both have a lubricious coating.

Substantial Equivalence and Summary of Studies

The technological differences between the subject and predicate devices have been evaluated through biocompatibility and mechanical tests to provide evidence of TrapLiner catheter substantial equivalence. The TrapLiner 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 Resistance
- Distal Shaft Flexibility
- Distal Tip Compression Force
- Collar Crush Force
- Interventional Device Passage Track Force
- Guidewire Holding Force
- Fluoroscopy Visualization
- Guide Catheter Backup Support
- TrapLiner Balloon Deflation, Device Passage
- TrapLiner Balloon Fatigue
- TrapLiner Balloon Burst
- Balloon-to-Shaft Tensile Strength
- Pushwire-to-Shaft Tensile Strength
- Distal Tensile Strength
- Friction Force
- Hydrophilic Coating Particulate in a Simulated Anatomy
- Shaft O.D.
- Shaft Length
- Effective I.D.
- Hub Luer Compatibility
- *In Vivo* Efficacy

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

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity

- Systemic Toxicity
- Pyrogenicity
- Hemocompatibility

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