DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 7, 2017

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

Re: K171335
Trade/Device Name: Venture 038 catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: May 5, 2017
Received: May 8, 2017

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.

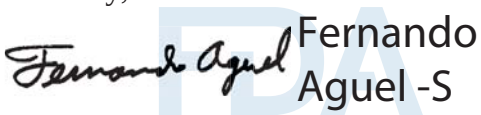
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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" (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)*

K171335

Device Name
Venture 038 catheter

Indications for Use *(Describe)*
The Venture 038 catheter is indicated for directing, steering, controlling, and supporting a guidewire to access discrete regions of the peripheral vasculature. It may also be used for manual delivery of saline solution or diagnostic contrast agents.

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.

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510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: May 5, 2017

510(k) Number: K171335

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	Venture 038 catheter
Common / Usual Name	Catheter, Percutaneous
Classification Name	Class II
Predicate Device	K040922 and K042910 - 0.014" Venture Wire Control Catheter, Velocimed, Inc.
Reference Device	K142065 – Turnpike Catheter, Vascular Solutions, Inc.

Device Description

The Venture 038 catheter is an over-the-wire single lumen catheter with a radiopaque deflectable distal tip. The deflectable distal tip is actuated by rotating a knob on the control handle of the proximal end of the catheter. The Venture 038 catheter has a working length of 120 cm or 70 cm and has a hydrophilic coating on the distal 45 cm of the catheter. The Venture 038 catheter provides support to 0.035" and 0.038" guidewires and is compatible with 6F introducer sheaths and 8F guide catheters.

Indications for Use

The Venture 038 catheter is indicated for directing, steering, controlling, and supporting a guidewire to access discrete regions of the peripheral vasculature. It may also be used for manual delivery of saline solution or diagnostic contrast agents.

Technological Characteristics Comparison

A comparison of technological differences between the subject and predicate device is provided below.

Characteristic	**Subject Device**	**Predicate Device**
	Venture 038 Catheter	**Venture Wire Control Catheter**
Intended Use	Directing, steering, controlling, and supporting a guidewire to access discrete regions of the vasculature	
Anatomical Location	Peripheral vasculature	Coronary and peripheral vasculature

Characteristic	Subject Device	Predicate Device
	Venture 038 Catheter	**Venture Wire Control Catheter**
Working Length	120 cm and 70 cm	140 cm and 70 cm
Guidewire Compatibility	0.035" or 0.038"	0.014"
Lubricous Coating	Hydrophilic coating	
Sterility	Ethylene Oxide (EO) – Sterility Assurance Level (SAL) 10^{-6}	

Substantial Equivalence and Summary of Studies

The technological differences between the subject and predicate devices have been evaluated through biocompatibility and bench tests to provide evidence that the Venture 038 catheter is substantially equivalent to the predicate device. The Venture 038 catheter is substantially equivalent to the specified predicate device based on comparisons of the device functionality, technological characteristics, and indications for use. The device design has been verified through the following tests:

- Simulated Use
- Kink Radius
- Visual Inspection
- Tip Deflection
- Tip Rotation
- Tensile Strength
- Liquid Leak
- Liquid Leak Under Pressure
- Injection Pressure
- Aspiration
- Corrosion
- Particulate Count

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

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Hemolysis
- Complement Activation
- In Vitro Hemocompatibility
- Coagulation
- Thrombogenicty

The results of the verification tests met the specified acceptance criteria and did not raise new safety or performance issues. Therefore, the Venture 038 catheter is substantially equivalent to the predicate device.