March 13, 2019

Vascular Solutions, LLC
Becky Astrup
Regulatory Affairs Specialist
6464 Sycamore Court North
Minneapolis, Minnesota 55369

Re: K182570
Trade/Device Name: Venture 0.014" Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 8, 2019
Received: February 11, 2019

Dear Becky 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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

Digitally signed by Lydia S. Glaw -S
Date: 2019.03.13 15:26:36 -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)*

K182570

Device Name
Venture 0.014" Catheter

Indications for Use *(Describe)*
The Venture 0.014" catheters are indicated for directing, steering, controlling, and supporting a guidewire to access discrete regions of the coronary and peripheral vasculature. The OTW version (Model 5821) 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.

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]

510(k) Number: K182570

SUBMITTER AND DEVICE

Submitter:
Vascular Solutions, LLC
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: September 14th, 2018

Name of Device: Venture 0.014" Catheter

Common or Usual Name: Catheter

Classification Name: Catheter, Percutaneous (21 CFR 870.1250)

Regulatory Class: II

Product Code: DQY

PREDICATE DEVICES

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

Primary Predicate Device: Vascular Solutions, Venture Wire Control Catheter, K042910 - cleared November 22, 2004.

Predicate Device: Vascular Solutions, Venture Wire Control Catheter, K061843 - cleared August 1, 2006.

The Vascular Solutions Turnpike Catheter, K142065- cleared November 25, 2014 and the Vascular Solutions Venture 038 Catheter, K171335- cleared June 7, 2017 are included as reference devices for this submission.

DEVICE DESCRIPTION

The Venture 0.014" catheters are single lumen catheters with a radiopaque deflectable distal tip designed to provide guidewire support during interventional procedures in the coronary and peripheral vasculature. The Venture 0.014" catheters are compatible with 0.014" guidewires and are available in two configurations. The rapid exchange configuration consists of a hypotube shaft with a rapid exchange (RX) lumen and deflectable tip on the distal segment. The over the wire configuration consists of an over-the-wire (OTW) lumen that runs the entire length of the catheter with a deflectable tip. The Venture 0.014" catheter tips are deflectable 90° by rotating a deflection knob on the control handle of the proximal end and a hydrophilic coating on the distal end of the catheter enhances deliverability to the target vasculature. The Venture 0.014" catheters are sterilized with ethylene oxide.

INDICATIONS FOR USE

The Venture 0.014" catheters are indicated for directing, steering, controlling, and supporting a guidewire to access discrete regions of the coronary and peripheral vasculature. The OTW version (Model 5821) may also be used for manual delivery of saline solution or diagnostic contrast agents.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The Venture 0.014" catheter included in this Special 510(k) submission is a modification of the current Venture Wire Control Catheter. Modifications include a change in distal tip jacket material and, applicable to the OTW configuration only, an additional material processing step for the manufacturing of the liner component and removal of the proximal positioning marks. A comparison of technological differences between the subject and predicate devices is provided below.

Characteristic	Predicate Devices: Venture Wire Control Catheter *K042910, K061843*	Subject Device: Venture 0.014" Catheter
Principles of Operation	Deflectable tip is actuated by turning the knob on the proximal handle.	
Anatomical Location	Coronary and peripheral vasculature	
Guidewire Compatibility	0.014"	
Working Length	**K061843 (RX)** 145 cm **K042910 (OTW)** 140 cm	**Model 5820 (RX):** 144.5 cm **Model 5821 (OTW):** 139.5 cm
Proximal Markers	Markers on the shaft for 90 cm and 100 cm guides.	**Model 5820 (RX):** Markers on the shaft for 90 cm and 100 cm guides. **Model 5821 (OTW):** NA- No positioning marks
Tip Deflection	90° from catheter axis.	
Lubricious Coating	Hydrophilic Coating	
Sterility	Ethylene Oxide (EO) – Sterility Assurance Level (SAL) 10^{-6}	
Biocompatibility	Meets ISO 10993-1	

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 devices have been evaluated through bench tests to provide evidence that the Venture 0.014" catheter is substantially equivalent to the predicate devices. The device design was verified through the following tests:

- Deliver, Deflect, and Retract
- Guidewire Steerability
- Tip Deflection Angle
- Tip Rebound
- Tip Rotation
- Tip Tensile
- Surface Defects
- Guidewire Movement
- Torque Robustness
- Luer to Extension Tensile
- Extension to Back Handle Tensile
- Liquid Leakage from Fitting Assembly under Pressure
- Static Pressure
- Coating Lubricity/Durability
- Throw Length
- Particulates
- HPC Fluid Drops
- Therapeutic Agent Conditioning
- Dynamic Pressure

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 Venture 0.014" catheter 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 Venture 0.014" catheter 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 Venture 0.014" catheter 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 Venture 0.014" catheter is substantially equivalent to the Venture Wire Control Catheter predicate devices 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 Venture 0.014" catheter is substantially equivalent to the predicate devices.