June 29, 2020

Vascular Solutions LLC
Iroquois Ledbeter
Regulatory Product Specialist
6464 Sycamore Court North
Minneapolis, Minnesota 55369

Re: K193119
Trade/Device Name: Twin-Pass Dual Access Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: May 28, 2020
Received: May 29, 2020

Dear Iroquois Ledbeter:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Interventional Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K193119

Device Name
Twin-Pass Dual Access Catheter

Indications for Use *(Describe)*
The Twin-Pass catheter is intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement and exchange of guidewires and other interventional devices, for use during two guidewire procedures and to subselectively infuse/deliver diagnostic or therapeutic 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: January 03, 2020

510(k) Number: K193119

Submitter's Name / Contact Person

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

Contact Person
Iroquois Ledbeter
Regulatory Product Specialist
Tel: 763-656-4300
Fax: 763-251-0363

General Information

Trade Name	Twin-Pass Dual Access Catheter
Common / Usual Name	Catheter
Classification Name	21 CFR 870.1250, DQY, Percutaneous catheter, Class II
Predicate Device	K060327, Twin-Pass dual access catheter (Vascular Solutions, Inc.)
Reference Device	K162467, Twin-Pass Torque dual access catheter (Vascular Solutions, Inc.)

Device Description

The Twin-Pass dual access catheter is a dual lumen catheter designed for use in the peripheral and coronary vasculature. The Twin-Pass catheter consists of an over-the-wire (OTW) lumen that runs the length of the catheter and a rapid exchange (RX) delivery lumen on the distal segment. The Twin-Pass catheter has a hydrophilic coating on the distal 18cm of the catheter. The Twin-Pass catheter has a working length of 135cm and have white positioning marks located at 95cm (single mark) and 105cm (double marks) from the distal tip, respectively. The Twin-Pass catheter has a platinum-iridium marker band located 1mm from the distal tip and a second platinum-iridium marker band located 11mm from the distal tip, identifying the distal end of the OTW lumen.

Intended Use

The Twin-Pass catheter is intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement and exchange of guidewires and other interventional devices, for use during two guidewire procedures and to subselectively infuse/deliver diagnostic or therapeutic agents.

Technological Characteristics Comparison

The key technological differences between the Twin-Pass catheter and the predicate and reference devices are a change to distance between distal tip wire exit ports, device outer diameter, shaft materials, lubricious coat length, and hub and strain relief process and materials.

Substantial Equivalence and Summary of Studies

The technological differences between the subject and predicate/reference devices have been evaluated through performance and biocompatibility tests to provide evidence of substantial equivalence for the Twin-pass catheter.

The device performance was verified through the following tests:

- Deliverability
  - Track Force
  - Kink Resistance
  - Guide Catheter Compatibility
  - Guidewire Movement
- Hydrophilic Coating Evaluation
  - Particulate
  - Coating Lubricity/Durability
  - Drops of Fluid
- Tensile Strength
  - Shaft
  - Tip
  - Hub
- Torque Robustness
- Hub Markings
- ISO 10555-1 Verification
  - Working Length
  - Crossing Profile
  - Radiopacity
  - Aspiration
  - Liquid Leak
  - Static Pressure
  - Dynamic Pressure
  - Surface Defects
- ISO 594 Hub Verification
  - Luer Gage
  - Air Leakage During Aspiration
  - Liquid Leakage Under Pressure
  - Separation Force of Luer Fitting
  - Unscrewing Torque
  - Ease of Luer Fitting Assembly
  - Resistance to Overriding
  - Stress Cracking

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

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemolysis
- Complement Activation
- Thrombogenicity

The results of the verification tests met the specified acceptance criteria and did not raise new questions of safety or effectiveness; therefore, the Twin-Pass catheter is substantially equivalent to the predicate and reference devices.