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

February 1, 2017

Vascular Solutions, Inc.
Ms. Lisa Gallatin
Director of Regulatory
6464 Sycamore Court North
Minneapolis, Minnesota 55369

Re: K162467
Trade/Device Name: Twin-Pass Torque
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 27, 2016
Received: December 28, 2016

Dear Ms. Gallatin:

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.

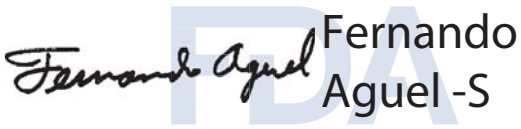
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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)*
K162467

Device Name
Twin-Pass Torque

Indications for Use *(Describe)*
The Twin-Pass catheter is intended to access discrete regions of the coronary and/or peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and to subselectively infuse/deliver diagnostic and 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: December 21, 2016

510(k) Number: __K162467_____

Submitter's Name / Contact Person

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

Contact Person
Lisa Gallatin, RAC
Director of Regulatory
Tel: 763-656-4300
Fax: 763-656-4253

General Information

Trade Name	Twin-Pass Torque
Common / Usual Name	Dual access catheter
Classification Name	Catheter, percutaneous
Predicate Device	K083784, Twin-Pass dual access catheter, Vascular Solutions, Inc.
Reference Device	K142065 and K151981, Turnpike catheter

Device Description

The Twin-Pass Torque is a dual lumen catheter consisting of an over-the-wire (OTW) lumen that runs the full length of the catheter, exiting just proximal to the distal tip, and a rapid exchange (RX) delivery lumen on the distal segment. The two exit ports are each marked by a radiopaque platinum-iridium marker band and the device shaft has two positioning marks located at 95cm (single mark) and 105cm (double marks) from the distal tip, which are not visible under fluoroscopy.

Intended Use

The Twin-Pass Torque catheter is intended to access discrete regions of the coronary and/or peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and to subselectively infuse/deliver diagnostic and therapeutic agents.

Technological Characteristics Comparison

Twin-Pass Torque is similar in design to the predicate device and both are dual lumen, percutaneous catheters intended to access discrete regions of the coronary and peripheral vasculature, facilitate placement and exchange of guidewires and subselectively infuse agents. With the exception of dimensional, material and package configuration differences, the Twin-Pass Torque is similar in design and technological characteristics to the predicate device. The dimensional, material and package configuration differences were successfully evaluated in performance tests.

Substantial Equivalence and Summary of Studies

The technological differences between the subject and predicate devices have been evaluated through performance and biocompatibility tests and results did not raise new questions of safety or effectiveness. The Twin-Pass dual access 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:

- Kink resistance
- Guidewire insertion
- Tip flexibility
- Distal shaft flexibility
- Proximal shaft support
- Coating lubricity/Durability
- Radiopacity
- Guidewire deflection
- Distal tip length
- Torque control
- Torque transmission
- Tensile strength
- Torque strength
- Torque robustness
- Hub luer tests (air leak, burst, compatibility)
- Hydrophilic coating particulate
- Package integrity

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

- Cytotoxicity
- Sensitization
- Irritation
- 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 Twin-Pass Torque dual access catheter is substantially equivalent to the predicate device.