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

August 13, 2015

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

Re: K151981
Trade/Device Name: Turnpike Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: DQY
Dated: July 16, 2015
Received: July 17, 2015

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 yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K151981

Device Name: Turnpike catheters

Indications for Use: The Turnpike catheters are intended to be used to access discrete regions of the coronary and/or peripheral vasculature. They may be used to facilitate placement and exchange of guidewires and to subselectively infuse/deliver diagnostic and therapeutic agents.

Prescription Use ___X ___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

2 510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: July 15, 2015

510(k) Number: K151981

Submitter's Name / Contact Person

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

Contact Person
Beka Vite
Regulatory Product Specialist
Tel: 763-656-4300
Fax: 763-656-4253

General Information

Trade Name	Turnpike catheter
Common / Usual Name	Catheter
Classification Name	21 CFR 870.1250, DQY, Percutaneous catheter, Class II
Predicate Device	K142065, Turnpike catheter (Vascular Solutions, Inc.)

Device Description

The Turnpike catheters are single lumen catheters designed for use in the coronary and/or peripheral vasculature. The shaft is constructed of two polymer layers that encapsulate a braid and a dual-layer coil. The Turnpike catheters have a radiopaque tip (polymer or gold-plated) and are available in various tip and shaft configurations and one of two working lengths. The Turnpike catheters are hydrophilic coated and are compatible with 0.014" guidewires and 5F guide catheters.

Intended Use / Indications

The Turnpike catheters are intended to be used to access discrete regions of the coronary and/or peripheral vasculature. They may be used to facilitate placement and exchange of guidewires and to subselectively infuse/deliver diagnostic and therapeutic agents.

Technological Characteristics Comparison

There are no technological differences between the subject and predicate devices relevant to the labeling change being effected.

Substantial Equivalence and Summary of Studies

Since there is no indication or technology change relevant to the labeling change being effected, no tests were necessary to demonstrate substantial equivalence. The addition of the contraindication and warning does not change the indications for use. Therefore, the Turnpike catheters are substantially equivalent to the predicate devices.