



August 9, 2019

Vascular Solutions LLC
Ms. Beka Vite
Principal Regulatory Product Specialist
6464 Sycamore Court North
Minneapolis, Minnesota 55369

Re: K191560

Trade/Device Name: Turnpike Catheter; Turnpike Spiral Catheter; Turnpike Gold Catheter; Turnpike LP Catheter

Regulation Number: 21 CFR 870.1250

Regulation Name: Percutaneous Catheter

Regulatory Class: Class II

Product Code: DQY

Dated: June 11, 2019

Received: June 13, 2019

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. 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,

for Kenneth J. Cavanaugh, Ph.D.
Director (Acting)
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K191560

Device Name

Turnpike Catheter; Turnpike Spiral Catheter; Turnpike Gold Catheter; Turnpike LP Catheter

Indications for Use (Describe)

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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: June 11, 2019

510(k) Number: K191560

Submitter's Name / Contact Person

Manufacturer

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

Contact Person

Beka Vite
Principal Regulatory Product Specialist
Tel: 763-656-4300
Fax: 763-251-0363

General Information

Trade Name

Turnpike Catheter
Turnpike Spiral Catheter
Turnpike Gold Catheter
Turnpike LP Catheter

Common / Usual Name

Catheter

Classification Name

21 CFR 870.1250, DQY, Percutaneous catheter, Class II

Predicate Device

K151981, Turnpike catheter (Vascular Solutions, Inc.)
K142065, Turnpike catheter (Vascular Solutions, Inc.)

Device Description

The Turnpike catheters are single lumen catheters designed for use in the coronary and peripheral vasculature. The catheter's 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. The distal 60cm of each catheter has a hydrophilic coating. The Turnpike catheters are available in 135 cm or 150 cm working lengths and are compatible with 0.014" guidewires and 5F guide catheters.

Intended 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.

Technological Characteristics Comparison

The key technological differences between the Turnpike catheters and the predicate device are a change to the working length and hub configuration and the addition of a low-profile version.

Substantial Equivalence and Summary of Studies

The technological differences between the subject and predicate devices have been evaluated through performance and biocompatibility tests to provide evidence of substantial equivalence for the Turnpike catheters.

The device performance was verified through the following tests:

- Deliverability
- Hydrophilic Coating Evaluation
- Tensile Strength
- Torque Strength
- Strain Relief Markings
- ISO 10555-1 Verification
- ISO 594 Hub Verification

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 Turnpike catheters are substantially equivalent to the predicate device.