DEC - 1 2011

510(k) Summary

[As required by 21 CFR 807.92]

510(k) Number: K112082 **Date Prepared: November 16, 2011**

Submitter's Information / Contact Person

Manufacturer

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

Contact Person

Matt Nienstedt
Regulatory Product Specialist
Tel: 763.656.4317 (direct)
Fax: 763.656.4253
Email: mnienstedt@vasc.com

Alternate Contact Person

Stacy Ouellette
Senior Regulatory Operations Associate
Tel: 763.656.4217 (direct)
Fax: 763.656.4253
Email: souellette@vascularsolutions.com

General Information

Trade Name	GuideLiner® V2 catheter
Common / Usual Name	catheter
Classification Name	21 CFR 870.1250, percutaneous catheter
Predicate Device	GuideLiner catheter (K091750 - Vascular Solutions, Inc.)

Device Description

The GuideLiner V2 is a single-lumen catheter offered in four sizes (5.5F, 6F, 7F, and 8F) and is compatible with 6F, 7F, and 8F guide catheters. GuideLiner V2 has a working length of 150 cm and may be placed over either an exchange length or 180 cm guidewire. The larger sizes of GuideLiner catheters are intended to be used within the proximal portions of the coronary vasculature to provide support and/or facilitate use of multiple interventional devices. The distal portion of the device is a 25 cm, single-lumen catheter constructed with a PTFE liner, stainless steel coil, various durometers of Pebax (polyether block amide) resin, and a silicone wipe on the outside diameter of the lumen. The catheter lumen is reflowed to the distal end of a stainless steel push wire. A Pebax paddle-style hub is over molded onto the proximal end of the push wire.

GuideLiner V2 catheters have two radiopaque platinum-iridium marker bands – one located 2 mm from the distal tip and one located 1 cm distal from the proximal shaft lumen opening. The devices have two non-radiopaque positioning marks located at 95cm (single mark) and 105cm (double mark) from the distal tip, respectively.

Intended Use / Indications

GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement and exchange of guidewires and other interventional devices.

Technological Characteristics

The GuideLiner V2 and predicate GuideLiner devices have the following characteristics in common:

- Catheter shaft lumen consists of various durometers of Pebax resin reflowed together.
- Radiopaque marker bands
- Positioning marks
- Silicone wipe
- Identical inner and outer catheter lumen diameters for 6F, 7F, 8F devices
- Sterilized by ethylene oxide
- Packaged in identical sterile pouch and retail box

The GuideLiner 2.0 and predicate GuideLiner devices differ in the following:

- Shaft materials, construction, and length
- Dimensional differences

Substantial Equivalence and Summary of Studies

GuideLiner V2 catheters are substantially equivalent to the predicate device based on comparisons of the device functionality, technological characteristics, and indications for use. The device design was qualified through the following tests:

- Simulated anatomy/concomitant device use
- Kink resistance
- Tensile
- Torque
- Dimensional verifications and visual inspections
- Biocompatibility
    - Cytotoxicity
    - Sensitization
    - Irritation/intracutaneous reactivity
    - Acute systemic toxicity
    - Material-mediated pyrogens
    - Hemocompatibility
        - Hemolysis
        - Coagulation
        - Prothrombin time
        - Hemotological parameters
        - Complement activation
        - Thrombogenicity

Results of the verification testing and biomaterial assessments met the specified acceptance criteria and did not raise new safety or performance questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 1 2011

Vascular Solutions, Inc.
c/o Mr. Matt Nienstedt
Regulatory Product Specialist
6464 Sycamore Court
Minneapolis, MN 55369

Re: K112082
Trade/Device Name: GuideLiner® V2 Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 16, 2011
Received: November 17, 2011

Dear Mr. Nienstedt:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 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

Enclosure

Indications for Use

510(k) Number: K112082

Device Name: GuideLiner V2 catheter

Indications for Use:

GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement and exchange of guidewires and other interventional devices.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112082