

K091750

2 510(k) Summary

Date Prepared: June 11, 2009

Submitter's Name / Contact Person

NOV - 4 2009

Manufacturer

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

Contact Person

Loucinda Bjorklund
Senior Regulatory Affairs Associate
Tel: 763.656.4208 (direct); Fax: 763.656.4253
Email: lbjorklund@vascularsolutions.com

General Information

<u>Trade Name</u>	GuideLiner catheter
<u>Common / Usual Name</u>	Catheter
<u>Classification Name</u>	870.1250, Catheter, Percutaneous
<u>Predicate Device</u>	K082337, Minnie Support Catheter (Vascular Solutions, Inc.)

Device Description

The GuideLiner is a catheter that consists of a single lumen distal tube (with a radiopaque marker band at the distal tip) secured to a proximal shaft. GuideLiner catheters are available in three sizes for use with 6F, 7F or 8F guide catheters. The catheters are packaged in a dispenser coil inside a single sterile barrier pouch and sterilized by ethylene oxide.

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.

Substantial Equivalence and Summary of Studies

GuideLiner catheters are substantially equivalent in intended use and indications to the predicate device. Technological differences in design and materials have been qualified through biomaterial assessments and bench testing, the result of which did not raise new safety or performance questions.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vascular Solutions, Inc.
c/o Ms. Loucinda Bjorkland
Senior Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, MN 55369

NOV - 4 2009

Re: K091750
Trade/Device Name: GuideLiner Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: October 8, 2009
Received: October 9, 2009

Dear Ms. Bjorkland:

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.

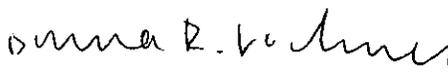
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "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 (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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 (if known): K091750

Device Name: GuideLiner 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)

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Dennis R. Volante
(Division Sign-Off)
Division of Cardiovascular Devices

(Posted November 13, 2003)

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