JUN 18 2009

2 510(k) Summary

Date Prepared: March 31, 2009

Submitter's Name / Contact Person

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

Contact Person
Charmaine Sutton, RAC
Acting VP of Regulatory
Tel: 763.656.4349 (direct); Fax: 763.656.4253
Email: csutton@vascularsolutions.com

General Information

Trade Name	PiggyBack™ wire converter
Common / Usual Name	Percutaneous catheter
Classification Name	870.1250 Catheter, percutaneous
Predicate Device	K083784 Skyway OTW support catheter (Vascular Solutions, Inc.)

Device Description

The PiggyBack wire converter is a 0.035" outer-diameter support catheter that is compatible with standard 0.014" guide wires. The shaft has a hydrophilic coating to facilitate ease of advancement into the vasculature. The distal tip of the PiggyBack has a radiopaque marker band. The proximal end of the catheter, which remains outside of the patient, has a locking mechanism that secures the PiggyBack onto the 0.014" guide wire. The PiggyBack is provided in three working lengths: 80 cm, 120 cm, and 145 cm.

Intended Use / Indications

The PiggyBack wire converter is intended to be used with guide wires to access the peripheral vasculature and to facilitate placement of interventional devices.

Substantial Equivalence and Summary of Studies

The PiggyBack wire converter is substantially equivalent in intended use and indications to the predicate device. Technological differences in design and materials have been qualified through biomaterial assessments and verification testing, the results of which did not raise any new safety or performance questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 2009

Vascular Solutions, Inc.
c/o Ms. Charmaine Sutton
6464 Sycamore Ct.
Minneapolis, MN 55369

Re: K090977
Trade/Device Name: PiggyBack Wire Converter
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Percutaneous
Regulatory Class: Class II (two)
Product Code: DQY
Dated: April 2, 2009
Received: April 6, 2009

Dear Ms. Sutton:

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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Volkmer

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

Enclosure

Indications for Use

510(k) Number (if known): K090977

Device Name: PiggyBack™ wire converter

Indications for Use:

The PIGGYBACK wire converter is intended to be used with guide wires to access the peripheral vasculature and to facilitate placement of 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)

Susana R. Cruzen

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090977

(Posted November 13, 2003)