K052258

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Summary of Safety and Effectiveness

Date Prepared: October 28, 2005

Common/Usual Name: Intravascular Catheter

Product Trade Name: Skyway™ Support Catheter

Classification Name: Percutaneous Catheter
Product Code: DQY

Manufacturer: Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, Minnesota 55369
USA

Establishment Registration: 2134812

Contact: Sara L. Coon
Senior Regulatory Affairs Associate
(763) 656-4300 phone
(763) 656-4200 fax

Performance Standards: No performance standards have been developed under section 514 for this device.

Device Description:
The Skyway Support Catheters are 3F O.D. catheters that taper to a 1.9F tip and are compatible with a 0.014" standard guide wires. The Skyway catheters have a working length of 130-135cm and contains positioning markers at 95 and 105cm which provide a visual indication of the relative positions of Skyway and the end of a standard 105cm guide catheter. A single radiopaque markerband at tip of the catheter provide for a radiographic means of locating the tip position. The softer, distal end of the catheter is coated with a hydrophilic coating to assist passage through the guide catheter and vessels while the proximal end of the catheter contains a strain relief and a standard luer hub. The catheters are provided in both an over-the-wire (OTW) and rapid exchange (RX) versions. The RX version has a uniquely designed RX port to facilitate exchange of short guidewires. A 120cm stiffening mandrel is included with the Skyway RX version to provide support and pushability.

Intended Use:
The Skyway Support Catheter is to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral

arterial vasculature and to facilitate placement of guidewires and other interventional devices.

Summary of Non-Clinical Testing:
Testing conducted included assessments of the design verification of the Skyway Support Catheter along with biocompatibility assessments. The results of this battery of tests confirmed the suitability of the Skyway Support Catheter for its intended use.

Summary of Clinical Testing:
No clinical evaluations of this product have been conducted.

Predicate Device:
The Skyway Support Catheter is similar in intended use and function to the Lumend Percutaneous Catheter and the Quick-Cross Catheter.

Technological Characteristics compared to Predicates:
The Skyway Support Catheter is similar to the Lumend Percutaneous Catheter (K011562) and the Quick-Cross Catheter)K033678) in shape, size, indications, materials and catheter type.

Conclusions:
The Skyway Support Catheter is substantially equivalent to the Lumend Percutaneous Catheter and the Quick-Cross Catheter. The testing performed confirms that the Skyway Support Catheter will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2005

Vascular Solutions, Inc.
c/o Ms. Sara L. Coon
Senior Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, MN 55369

Re: K052258
Skyway™ Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: II
Product Code: DQY
Dated: November 28, 2005
Received: November 29, 2005

Dear Ms. Coon:

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

II. Indications For Use Statement

510(k) Number: K052258

Device Name: Vascular Solutions Skyway™ Support Catheter

Indications for Use:

The Skyway Support Catheter is to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature and to facilitate placement of guidewires and other interventional devices.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052258