K052257

Appendix E: Summary of Safety and Effectiveness

NOV 23 2005

Common/Usual Name: Intravascular Catheter

Product Trade Name: Twin-Pass™ Dual Access Catheter

Classification Name: Unclassified
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 Twin-Pass Dual Access Catheter is a 3F O.D. catheter that has two lumens—a short distal lumen and a second full length lumen—each of which are compatible with a 0.014" standard guide wire. The Twin-Pass catheter has a working length of 135cm and contains positioning markers at 95 and 105cm which provide a visual indication of the relative positions of Twin Pass and the end of a standard 105cm guide catheter. Two radiopaque marker bands at the end of each wire lumen provide for a radiographic means of locating the position of each lumen. 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. A 126cm stiffening mandrel is included which provides support and pushability to the Twin-Pass.

Intended Use:
The Twin-Pass Dual Access Catheter is to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement of guidewires and other interventional devices, and for use during two guidewire procedures.

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

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

Predicate Device:
The Twin-Pass Dual Access Catheter is similar in intended use and function to the Lumend Percutaneous Catheter, the Quick-Cross Catheter, and the Dual Lumen Catheter.

Conclusions:
The Twin-Pass Dual Access Catheter is substantially equivalent to the Lumend Percutaneous Catheter, the Quick-Cross Catheter, and the Dual Lumen Catheter. The testing performed confirms that the Twin-Pass Dual Access Catheter will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 23 2005

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

Re: K052257
Twin-Pass™ Dual Access Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: DQY
Dated: September 30, 2005
Received: October 3, 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,

Donna R. Volkmer

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: K052257

Device Name: Vascular Solutions Twin-Pass Dual Access Catheter

Indications for Use:

The Twin-Pass Dual Access Catheter is to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement of guidewires and other interventional devices, and for use during two guidewire procedures.

Prescription Use ✓ 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)

Donna R. Kochner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052257