K062877

Section 5. 510(k) Summary

The 510(k) Summary is provided on the following page.

JAN 18 2007

510(k) Summary

(As required by 21 CFR 807.92(c))

510(k) Number: K062877

Date Prepared

September 25, 2006

Submitter Information

Submitter's Name:	Vascular Solutions, Inc.
Address:	6464 Sycamore Court Minneapolis, MN 55369
Contact Person:	Julie Tapper Regulatory Affairs Associate Phone 763-656-4228 Fax 763-656-4253

Device Information

Trade Name:	Twin-Pass™ .023" Dual Access Catheter
Common Name:	Diagnostic intravascular catheter
Class:	II
Classification Name:	Diagnostic intravascular catheter (21 CFR 870.1200, Product Code DQO)

Predicate Devices

Twin-Pass Dual Access Catheter (K052257), manufactured by Vascular Solutions, Inc.
Langston Dual Lumen Catheter (K061565), manufactured by Vascular Solutions, Inc.

Device Description

The Twin-Pass .023" catheter has a polymeric dual-lumen design. The over-the wire lumen extends from the luer hub to the catheter's distal end and accommodates ≤0.018 guidewires. The rapid-exchange lumen is on the distal 20cm of the catheter and accommodates ≤0.014 guidwires. The Twin-Pass .023" catheter is compatible with ≥6F guide catheters and has a working length of approximately 135cm. Each catheter has a single radiopaque markerband near its distal tip and printed positioning marks at 95cm and 105cm from the catheter's distal tip. Each catheter is supplied with a stiffening mandrel assembly that is inserted into the over-the-wire lumen to provide added support while placing the catheter at its desired location. The Twin Pass .023" catheter is provided sterile and intended for a single use.

Intended Use/Indications for Use

The Twin-Pass .023″ catheter is intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral vasculature, to facilitate placement and exchange of guidewires and other interventional devices, for use during two guidewire procedures and to subselectively infuse/deliver diagnostic or therapeutic agents.

Additionally, the Twin-Pass .023″ catheter is intended to be used to measure intra-arterial pressure within the peripheral and coronary vasculature.

Summary of Testing

Bench testing was conducted on the Twin-Pass .023″ catheter and included an assessment of the physical properties of the device and its ability to achieve its intended use. The results of the tests confirmed the suitability of the device for its intended use. Each bench test that was conducted is listed, below.

Tortuosity	Flow Rate
Catheter Kink Resistance	Guidewire Interface
Hub-to-proximal-shaft Bond Strength	Guide Catheter Interface
Proximal-to-distal-shaft Bond Strength	Packaging—Packaging Mandrel Removal Force
Stiffening Mandrel Assembly Bond Strength	Packaging—Pouch Visual Appearance after Distribution Testing
Stiffening Mandrel Removal Force	Packaging—Product Containment after Distribution Testing
Fluid Leak Under Pressure	Packaging—Product Visual Appearance after Distribution Testing
Air Leak During Aspiration	Packaging—Labeling Legibility after Distribution Testing
Frequency Response	

Statement of Equivalence

The Twin-Pass .023″ catheter is substantially equivalent to the currently marketed Twin-Pass and Langston catheters, based on comparisons of the device classifications, indications for use, technological characteristics, and sterilization methods.

Conclusion

The Twin-Pass .023″ catheter is substantially equivalent to the currently marketed Twin-Pass and Langston catheters, based on comparisons of the device classifications, indications for use, technological characteristics, and sterilization methods. Bench tests confirmed the suitability of the device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2007

Vascular Solutions, Inc.
c/o Ms. Julie Tapper
Regulatory Affairs Associate
6464 Sycamore Court North
Minneapolis, MN 55369

Re: K062877
Twin-Pass™ .023" Dual Access Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: II (two)
Product Code: DQO
Dated: December 20, 2006
Received: December 21, 2006

Dear Ms. Tapper:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Volmer

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

Enclosure

Indications for Use Statement

510(k) Number: K062877

Device Name:
Twin-Pass™ .023″ Dual Access Catheter

Indications for Use:
The Twin-Pass .023″ catheter is intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral vasculature, to facilitate placement and exchange of guidewires and other interventional devices, for use during two guidewire procedures and to subselectively infuse/deliver diagnostic or therapeutic agents.

The Twin-Pass .023″ catheter is additionally intended to be used to measure intra-arterial pressure within the peripheral and coronary vasculature.

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

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Kuhney

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062877