APR 17 2008

Vascular SOLUTIONS

510(k) Summary

510(k) Number: K073585

Date Prepared	December 19, 2007

Submitter Information

Submitter's Name/ Address:	Vascular Solutions, Inc. 6464 Sycamore Court Minneapolis, MN 55369
Establishment Registration	2134812
Contact Person:	Alyssa Malinski 763-656-4300 amalinski@vascularsolutions.com
Alternative contact:	Doralie Poganski 763-656-4300 dpoganski@vascularsolutions.com

Device Information

Trade Name: InnerChange™ Micro-Introducer Catheter
Common Name: Diagnostic Intravascular Catheter
Classification Name: Diagnostic Intravascular Catheter
Product Code: DQO
Regulation: Class II, 21 CFR 870.1200

Predicate Device(s)

- Vascular Solutions, Inc. InnerChange Micro-Introducer Catheter (K062627)

Device Description
The INNERCHANGE micro-introducer catheter combines a micro-introducer kit for obtaining vascular access with a hydrophilically coated diagnostic catheter. The INNERCHANGE catheter is designed to be used for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures. The INNERCHANGE micro-introducer catheter is compatible with ≤0.038" / .965mm guidewires. Each INNERCHANGE micro-introducer catheter consists of the following components:

- 21G percutaneous entry needle
- 0.018" guidewire
- Dilator
- Catheter with selected tip shape and attached stopcock

Intended Use/Indications for Use
The INNERCHANGE micro-introducer catheter is intended for use in accessing the vascular system through a small gauge needle stick and for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures.

Summary of Non-Clinical Testing
Testing conducted included assessments of the design verification of the InnerChange Micro-Introducer Catheter along with biocompatibility assessments and shelf life testing. The results of this testing confirmed the suitability of the InnerChange Micro-Introducer Catheter for its intended use. Each bench test that was conducted is listed:

- Radiopacity
- Visual inspection (lubricious coating)
- Visual inspection of catheter/dilator
- Catheter Curve retention
- Dilator passage
- Dilator/catheter tapered tip assembly
- Guidewire passage
- Catheter Tortuosity test
- Hydrophilic coating inspection after tortuosity
- Flow rate with contrast
- Dynamic pressure test (catheter only)
- Kink radius
- Liquid leak test (catheter only)
- Proximal to distal shaft strength

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

Statement of Equivalence

The InnerChange Micro-Introducer Catheter has the exact intended use and function as the Vascular Solutions InnerChange Catheters (K062627).

Conclusion

Through the data and information presented, Vascular Solutions considers the InnerChange Micro-Introducer Catheter to be substantially equivalent to the Vascular Solutions InnerChange Catheters (K062627). The testing performed confirms that the InnerChange Micro-Introducer Catheter will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2008

Vascular Solutions
c/o Ms. Alyssa Malinski
6464 Sycamore Court
Minneapolis, MN 55369

Re: K073585
Trade Name: InnerChange Micro-Introducer Catheter (Models 7900, 7901, 7902, 7903, 7904, 7905)
Regulation Number 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: DQO
Dated: April 11, 2008
Received: April 14, 2008

Dear Ms. Malinski:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

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 (if known): K073585

Device Name: InnerChange™ Micro-Introducer Catheter

Indications for Use:
The INNERCHANGE micro-introducer catheter is intended for use in accessing the vascular system through a small gauge needle stick and for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Mc Namara

(Division Sign-Off)
Division of Cardiovascular Devices

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