510(k) Summary

JAN 2 8 2009

510(k) Number: K081846

Date Prepared September 8, 2008

Submitter Information

Submitter's Name: Vascular Solutions, Inc.
Address: 6464 Sycamore Court
Minneapolis, MN 55369

Establishment Registration 2134812

Contact Person: Julie Tapper, Senior Regulatory Affairs Associate
jtapper@vascularsolutions.com
763-656-4300

Device Information

Trade Name: GrebSet micro-introducer kit
Classification Name: Diagnostic Intravascular Catheter
Product Code: DQO
Regulation: 21 CFR 870.1200

Predicate Devices

Vascular Solutions; InnerChange Micro-Introducer Catheter (K073585)
Boston Scientific; AccuStick II (K unknown)
Cook Medical; Neff Percutaneous Access Set (K unknown)

Device Description

The GrebSet micro-introducer kit is designed to be used to gain access and deliver contrast media to selected vascular sites. The GrebSet catheter is compatible with ≤0.038"/.965mm guidewires. Each GrebSet kit consists of the following components:

- Access needle (21G echogenic percutaneous entry needle OR 20G echogenic Trocar needle)
- 0.018" guidewire
- Dilator
- Catheter with radiopaque marker band located on distal tip

Intended Use/Indications for Use

The GrebSet micro-introducer kit is intended to facilitate the percutaneous placement of guidewires in the vascular system and for delivery of contrast media to vascular sites.

Summary of Non-Clinical Testing

Testing conducted included assessments of the design verification of the GrebSet catheter along with biocompatibility assessments and shelf life testing to ensure that the device would

perform as intended. The results of this testing confirmed the suitability of the GrebSet Catheter for its intended use. Each bench test that was conducted is listed, as follows:

Aspiration Testing	Corrosion Resistance
Catheter Liquid Leakage Under Pressure	GrebSet Catheter Curve Retention
Static & Dynamic High Pressure Catheter Testing	GrebSet Catheter Tortuosity
Catheter Kink Testing	Hydrophilic Coating Performance
Fluoroscopic Visualization Test	Catheter Torque Test
Catheter Flow Rate Test	Force At Break

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

Statement of Equivalence
The GrebSet micro-introducer kit has similar intended for use and functions as the predicate device.

Conclusion
Through the data and information presented, Vascular Solutions considers the GrebSet micro-introducer kit to be substantially equivalent to the predicate device. The testing performed confirms that the GrebSet Catheter will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JAN 28 2009

Re: K081846
Trade/Device Name: GrebSet™ Micro-introducer Kit
Common Name: Diagnostic Intravascular Catheter
Regulation Number: 21 CFR 870.1200
Regulatory Class: II
Product Code: DQO
Dated: December 23, 2008
Received: December 24, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0210. 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 Biometrics' (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,

for 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: K081846

Device Name:
GrebSet™ Micro-introducer Kit

Indications for Use:
The GrebSet micro-introducer kit is intended to facilitate the percutaneous placement of guidewires in the vascular system and for delivery of contrast media to vascular sites.

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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K081846