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2 510(k) Summary

Date Prepared: August 16, 2010

JAN 24 2011

Submitter's Name / Contact Person

Manufacturer
Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369 USA
Establishment Registration # 2134812

Contact Person
Jennifer Ruether
Sr. Regulatory Affairs Associate
Tel: 763-656-4300; Fax: 763-656-4253

General Information

Trade Name	VSI Micro-Introducer Set
Common / Usual Name	Catheter introducer
Classification Name	870.1340; DYB; Catheter introducer; Class II
Predicate Devices	K990705 Coaxial Micro-Introducer Set – Standard (Greatbatch Medical) K071574 Coaxial Micro-Introducer Set – Stiffen (Greatbatch Medical)

Device Description

The VSI micro-introducer sets consist of a sheath and a dilator and are available in lengths of 10 cm to 30 cm. The sheath is available with either a 4 F or 5 F outer diameter (O.D.), and the dilator is available with regular flexibility or in a 'stiffen' version.

The sheath and dilator consist of a high-density polyethylene shaft and hub; the sheath shaft has a tapered distal tip that provides a smooth transition to the distal tip of the dilator. A rotating luer lock on the distal end of the dilator hub can be locked on to the sheath hub. The stiffen dilator shafts contains a stainless steel hypotube.

Intended Use / Indications

The VSI Micro-Introducer Set is used for percutaneous introduction of up to an 0.038 inch guidewire or catheter into the vascular system following a small gauge needle stick.

Technological Characteristics

The VSI Micro-Introducer Sets are similar in design components, dimensions, and materials to the predicate devices. The subject and predicate devices consist of a sheath and a dilator, are available in the same O.D.s, and utilize similar materials of construction. The VSI Micro-Introducer is available in a longer length than the predicate devices. Like the predicate devices, the VSI Micro-Introducer Sets have radiopaque components and are compatible with guidewires and catheters with a maximum O.D. of 0.038". Both the VSI Micro-Introducer Sets and Greatbatch Coaxial Micro-Introducer Sets are sterilized in an ethylene oxide process, and have similar sterile barrier packaging materials.

Substantial Equivalence and Summary of Studies

The VSI Micro-Introducer Set is substantially equivalent to the specified predicate devices based on comparisons of the device functionality, technological characteristics, and Indications for Use. The device design has been qualified through the following tests:

- Ink Adhesion
- Dimensional Verification
- Visual Inspection
- Radiopacity
- Guidewire Compatibility and Insertion Force
- Corrosion Resistance
- Kink
- Liquid Leak
- Aspiration
- Tensile Strength

Biocompatibility testing per ISO 10993-1 was performed, consisting of the following tests:

- Cytotoxicity
- Sensitization
- Irritation/intracutaneous reactivity
- Acute systemic toxicity
- Hemocompatibility

Results of design verification testing did not raise new safety or performance questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Vascular Solutions, Inc.
c/o Ms. Jennifer Ruether
Sr. Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, MN 55369

JAN 24 2011

Re: K101604
Trade/Device Name: VSI Micro-Introducer Set
Regulation Number: 21 CFR 870.1340
Regulatory Class: II
Product Code: DYB
Dated: December 22, 2010
Received: December 23, 2010

Dear Ms. Ruether:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

510(k) Number (if known): K101604

Device Name: VSI Micro-Introducer Set

Indications for Use:

The VSI Micro-Introducer Set is used for percutaneous introduction of up to an 0.038 inch guidewire or catheter into the vascular system following a small gauge needle stick.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101604