K101659

2 510(k) Summary

DEC 16 2010

[As required by 21 CFR 807.92]

510(k) Number: K101659 **Date Prepared: December 13, 2010**

Submitter's Information / Contact Person

Manufacturer

Vascular Solutions, Inc.
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Minneapolis, MN 55369 USA
Establishment Registration # 2134812

Contact Person

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General Information

Trade Name	SuperCross™ microcatheter
Common / Usual Name	microcatheter
Classification Name	21 CFR 870.1250, Catheter, Percutaneous
Predicate Device	Gopher™ Gold catheter (K091345 - Vascular Solutions, Inc.)

Device Description

The SuperCross™ microcatheter (SuperCross) is a single-lumen catheter designed for use in the coronary and peripheral vasculature. The SuperCross tubing consists of a braided shaft that tapers distally to create a low profile. SuperCross is compatible with a 0.014 inch diameter guidewire with a minimum length of 180 cm. The SuperCross has a single gold marker band located 0.035 inch (0.89 mm) from the distal tip of the catheter. The distal 40 cm of the SuperCross has a hydrophilic coating to enhance deliverability to the target vasculature. The device has positioning marks located at 95 cm and 105 cm from the distal tip, respectively. The proximal end of the catheter incorporates a strain relief and a luer-lock adapter for flushing, wire insertion, and accessory attachment.

Intended Use / Indications

The SuperCross microcatheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary and/or peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and to subselectively infuse/deliver diagnostic and therapeutic agents.

Technological Characteristics

The SuperCross microcatheter is substantially equivalent in device design and performance to the predicate device. The SuperCross and predicate Gopher Gold devices have the following characteristics in common:

- Compatibility with 0.014 inch guidewires
- Shaft configuration - The shafts of the SuperCross and Gopher Gold are both constructed from a braided stainless steel backbone and several thermoplastics bonded together that taper from larger, proximal inner and outer diameters to smaller, distal inner and outer diameters.
- Radiopaque distal tips
- Positioning marks
- Similar inner and outer diameters
- Tapered distal tips - The SuperCross and predicate Gopher Gold are both designed with tapered distal tips to aid in navigating small, tortuous anatomy.
- Hub configuration - Both the predicate and subject device have proximal hubs (with strain reliefs) that are compatible with ISO 594-1 and ISO 594-2 compliant luer fittings.
- Rated to 300 psi injection pressure
- Sterilized by ethylene oxide
- Packaged in identical sterile pouch and retail box

The SuperCross and Gopher Gold devices differ in the following:

- Specific catheter shaft and hub materials and construction
- Hydrophilic coating - SuperCross has a hydrophilic coating and the predicate Gopher Gold does not.
- Torque device and threaded tip - The predicate Gopher Gold device features a threaded distal tip and is supplied with a torque device while the SuperCross does not contain these features

Substantial Equivalence and Summary of Studies

The SuperCross microcatheter is substantially equivalent to the specified predicate device based on comparisons of the device functionality, technological characteristics, and indications for use. The device design was qualified through the following tests:

- Simulated anatomy/concomitant device use
- Hydrophilic coating integrity and particulates
- Liquid leak
- Kink
- Static pressure
- Air aspiration
- Tensile
- Torque
- Dimensional verification
- Radiopacity
- Biocompatibility
    - Cytotoxicity
    - Sensitization
    - Irritation/intracutaneous reactivity
    - Acute systemic toxicity
    - Material mediated pyrogens
    - Hemocompatibility
        - Hemolysis
        - Coagulation
        - Prothrombin time
        - Hemotological parameters
        - Complement activation
        - Thrombogenicity

Results of the verification testing and biomaterial assessments met the specified acceptance criteria and 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

DEC 16 2010

Vascular Solutions, Inc.
c/o Mr. Matt Nienstedt
Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, MN 55369

Re: K101659
Trade/Device Name: SuperCross™ Microcatheter
Common Name: Catheter, Percutaneous
Regulation Number: 21 CFR 870.1250
Regulatory Class: II
Product Code: DQY
Dated: December 3, 2010
Received: December 6, 2010

Dear Mr. Nienstedt:

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

DEC 16 2010

510(k) Number (if known): K101659

Device Name: SuperCross microcatheter

Indications for Use:

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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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101659