K101625

2 510(k) Summary

JUL 19 2010

Date Prepared: June 8, 2010

Submitter's Name / Contact Person

Manufacturer
Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369 USA
Tel: 763-656-4300; Fax: 763-656-4250
Establishment Registration # 2134812

Contact Person
Jennifer Ruether
Sr. Regulatory Affairs Associate

General Information

Trade Name	Cohen Crossover Catheter
Common / Usual Name	Diagnostic intravascular catheter
Classification Name	870.1200; DQO; Diagnostic intravascular catheter; Class II
Predicate Devices	K000659 Performa Angiographic Catheters (Merit Medical) K091329 Pinnacle Destination Peripheral Guiding Sheath/Dilator (Terumo Interventional Systems)

Device Description

The Cohen Crossover Catheters are angiographic catheters used to aid in percutaneous peripheral procedures. The catheters guide an introducer sheath across the iliac bifurcation and perform a standard angiogram. The catheters are available in three sizes (6 F, 7 F, and 8 F) and taper to a radiopaque, 5 F modified hook configuration on the distal end. Side holes are located at the distal end of the catheters for contrast media injections. The catheters are compatible with 0.035" guidewires.

Intended Use / Indications

The Cohen Crossover Catheter is intended to be used to deliver radiopaque media to selected sites in the vascular system, including the lower extremities using a contralateral approach.

Technological Characteristics

The Cohen Crossover Catheter is similar in device design and performance to the predicate devices. The Cohen Crossover Catheter and the Performa Angiographic Catheter utilize similar materials of construction, the distal tips share the same shape (modified hook), have side holes, and are used for contrast delivery at a rate of up to 1200 psi. The Cohen Crossover Catheter and the Pinnacle Destination dilator have similar diameters and wall thickness. The three devices are available in similar lengths and sizes, and are compatible with similar guidewire sizes.

Substantial Equivalence and Summary of Studies

The Cohen Crossover Catheter 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:

- Simulated anatomy/concomitant device use
- Straightener removal force
- Flow rate
- Liquid leak
- Dynamic/static high pressure rating
- Aspiration
- Tensile
- Torque
- Dimensional Verification
- Biocompatibility

Results of the verification testing and biomaterial assessments 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

JUL 19 2010

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

Re: K101625
Cohen Crossover Catheter
Regulation Number: 21 CFR§ 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II (Two)
Product Code: DQO
Dated: June 8, 2010
Received: June 10, 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
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101625

Device Name: Cohen Crossover Catheter

Indications for Use:

The Cohen Crossover Catheter is intended to be used to deliver radiopaque media to selected sites in the vascular system, including the lower extremities using a contralateral approach.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

Donna R. Mitchell
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101625