FLOWCARDIA, INC.

5) 510(k) Summary

This summary of 510(k) information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21CFR807.92.

510(k) Number ____K073289_____

Applicant Information

Date Prepared: **November 20, 2007**

Name and Address: **FlowCardia, Inc.**
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Sunnyvale, CA 94085
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Contact Person: **Dustin Michaels, Sr. Director of RA/QA/CR**
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Device Information

Classification: DQY
Trade Name: MicroSheath XL Catheters
Common Name: Percutaneous Catheter
Classification Name: Percutaneous Catheter, 74 DQY / 21 CFR 870.1250

Predicate Devices

The VP Sheath manufactured by FlowCardia, Inc. (K051580)
Viking 6Fr Guiding Catheters manufactured by Guidant (K972484)
Zuma 6Fr Guiding Catheters manufactured by Medtronic (K981198)

Device Description

The FlowCardia MicroSheath™ XL is a single lumen catheter that is available in four lengths: 53cm, 73cm, 93cm or 123cm, and three different tip configurations: vertebral, internal mammary artery, and multipurpose. All MicroSheath XL catheters have a standard luer fitting at the proximal end. A radiopaque distal tip aids in fluoroscopic visualization. The distal tip is atraumatic to help facilitate vessel navigation. The MicroSheath XL is also 7F Sheath compatible.

Intended Use:

The MicroSheath XL is a single lumen catheter intended to create a pathway for other devices in the peripheral vasculature.

Technological Characteristics

The MicroSheath XL is equivalent to the VP Sheath with respect to materials, manufacturing methods and sterilization. It is also substantially equivalent to the Viking and Zuma guiding catheters in terms of catheter stiffness, tensile strength, torque strength, and tip shapes. The MicroSheath XL is substantially equivalent to all three predicate devices when comparing intended use.

Physical Test Data

Design analysis, bench, and biocompatibility testing were conducted according to the relevant guidance documents to demonstrate that the FlowCardia MicroSheath XL Catheters met the acceptance criteria and performed similarly to the predicate devices. In addition to dimensional verification, the following functional tests were performed and compared to the predicates: Tensile Strength, Tip Flexibility, Access and Navigation Bench Modeling, Critical Bend Testing, Leak and Pressure Testing, Tensile Testing, and Torque Strength.

Conclusion

Based upon these comparisons the MicroSheath XL is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2008

FlowCardia, Inc.
c/o Mr. Dustin Michaels
Sr. Director
745 N. Pastoria Avenue
Sunnyvale, CA 94085

Re: K073289
MicroSheath XL Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: November 20, 2007
Received: November 21, 2007

Dear Mr. Michaels:

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,

Donna R. Volmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K073289

Device Name: **MicroSheath XL Catheters**

Indications for Use:

The MicroSheath XL is a single lumen catheter intended to create a pathway for other devices in the peripheral vasculature.

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. Vadney

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K073289