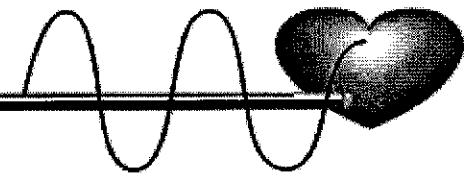
FLOWCARDIA, INC.



5) 510(k) Summary

JUL 25 2008

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

510(k) Number K08 0849

Applicant Information

Date Prepared: **March 25, 2008**

Name and Address: **FlowCardia, Inc.**
745 N. Pastoria Avenue
Sunnyvale, CA 94085
Ph: (408) 617-0352

Contact Person: **Dustin Michaels, Vice President of CR/QA/RA**
Ph: (408) 617-0352 x302
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Device Information

Classification:	DQY
Trade Name:	MicroSheath LP 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)

Device Description

The FlowCardia MicroSheath LP a single lumen catheter, 123 cm in length, with a standard luer fitting at the proximal end. The catheter is available in two tip shapes, straight and angled. The distal tip is atraumatic to help facilitate vessel navigation. A single radiopaque marker on the straight version of the MicroSheath LP and five radiopaque markers on the angled version aid in fluoroscopic visualization. The MicroSheath LP is 6F Sheath/7Fr Guide compatible.

Intended Use:

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

Technological Characteristics

The MicroSheath LP is equivalent to the VP Sheath with respect to materials, manufacturing methods and sterilization. It is also substantially equivalent to the predicate in terms of catheter stiffness, tensile strength, and torque strength. The MicroSheath LP and predicate device have the same 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 LP 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 LP is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Flowcardia, Inc.
c/o Mr. Dustin Michaels
Vice President of CR/QA/RA
745 N. Pastoria Avenue
Sunnyvale, CA 94085

JUL 25 2008

Re: K080849
MicroSheath LP Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Percutaneous
Regulatory Class: Class II
Product Code: DQY
Dated: July 17, 2008
Received: July 18, 2008

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. Lichner

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): K080849

Device Name: **MicroSheath LP Catheters**

Indications for Use:

The MicroSheath LP is a single lumen catheter intended to create a pathway for other devices in the coronary or 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. Vechman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080849