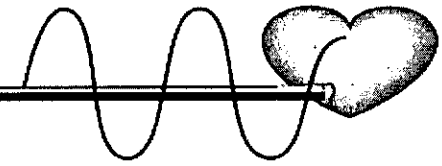
MAY 29 2009

FLOWCARDIA, INC.



4) 510(k) Summary

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

510(k) Number K091254

Applicant Information

Date Prepared: **April 28, 2009**

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
Fax: (408) 617-9198

Device Information

Classification:	DQY
Trade Name:	The CROSSER System
Common Name:	Percutaneous Catheter
Classification Name:	Percutaneous Catheter, 74 DQY / 21 CFR 870.1250

Predicate Device

The CROSSER System manufactured by FlowCardia, Inc. (K062868)

Device Description

The CROSSER® System consists of a re-usable electronic Generator, Foot Switch, high-frequency Transducer, and single-use CROSSER 14 Over the Wire Catheter.

The CROSSER Catheter is connected to the electronic Generator through the Transducer. The Foot Switch is used to activate the system. The Generator and Transducer convert AC power into high frequency mechanical vibrations which are propagated through a Nitinol core wire to the Stainless steel tip of the CROSSER Catheter. The main body of the catheter is constructed from Pebax and a hydrophilic coating which covers the distal end of the catheter.

Technological Characteristics

The FlowCardia CROSSER 14 Over the Wire Catheter is substantially equivalent to the predicate CROSSER 14 Catheter. The predicate CROSSER 14 Catheter and CROSSER 14 Over the Wire Catheter are identical with respect to indications for use, design, construction and performance. The main difference is a rapid-exchange (RX) guidewire rail system in the predicate versus a conventional over-the-wire (OTW) guidewire rail system.

Physical Test Data

Design analysis, bench, and biocompatibility testing were conducted according to the relevant guidance documents to demonstrate that the FlowCardia CROSSER 14 Over the Wire Catheter met the acceptance criteria and performed similarly to the predicate device. In addition to dimensional verification, the following functional tests were performed: Tensile Strength, Torque Strength, Torqueability, Tip Flexibility, Coating Adherence/Integrity, Bench top Simulated Efficiency, Catheter Fatigue Testing, Biocompatibility, and Shelf Life Testing.

Conclusion

Based upon the aforementioned comparison testing the CROSSER 14 Over the Wire Catheter 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

MAY 29 2009

Flow Cardia, Inc.
c/o Mr. Dustin Michaels
Vice President, CR/QA/RA
745 North Pastoria Avenue
Sunnyvale, CA 94085-2918

Re: K091254
Trade/Device Name: The CROSSER 14 Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: April 28, 2009
Received: April 29, 2009

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 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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

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

Enclosure

3). **Statement of Indications for Use**

510(k) Number (if known): K091254

Device Name: **The CROSSER® System**

Indications for Use:

The CROSSER® System is indicated in coronary arteries to facilitate the intra-luminal placement of conventional guidewires beyond chronic total occlusions.

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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K091254