K091961

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

JUL 30 2009

General Information

Trade Name	Concentric Microcatheter
Common Name	Diagnostic Intravascular Catheter
Classification	Diagnostic Intravascular Catheter, 21CFR 870.1200 – Class II
Submitter	Concentric® Medical, Inc. 301 E. Evelyn Avenue Mountain View, CA 94041 Tel 650-938-2100 Fax 650-237-5230
Contact	Kirsten Valley Senior Vice President, Technology & Regulatory Affairs

Intended Use

The Modified Concentric Microcatheter is indicated for use in the selective placement of fluids and/or other devices or agents into the peripheral, coronary and neuro vasculature during diagnostic and/or therapeutic procedures.

Predicate Device

Concentric Microcatheter, K003086

Device Description

The Modified Concentric Microcatheter consists of a single lumen, braided, variable stiffness shaft with a radiopaque marker on the distal end and a luer hub on the proximal end. The catheter shaft has a hydrophilic coating to reduce friction during use.

Materials

All materials used in the manufacture of the Modified Concentric Microcatheter are suitable for the intended use of the device and have been used in numerous previously cleared products.

Testing Summary

The results of verification and validation conducted on the Modified Concentric Microcatheter demonstrate that it performs as designed, is suitable for its intended use and is substantially equivalent to the predicate device.

Summary of Substantial Equivalence

The Modified Concentric Microcatheter is substantially equivalent to the predicate device with regard to device design, intended use, patient population and anatomical site. Any differences in technological characteristics between the Modified Concentric Microcatheter and the predicate device do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2009

Concentric Medical
% Ms. Kirsten Valley
301 East Evelyn Avenue
Mountain View, California 94041

Re: K091961
Trade/Device Name: Modified Concentric Microcatheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: June 29, 2009
Received: July 1, 2009

Dear Ms. Valley:

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 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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):	This application - K091961
Device Name:	Modified Concentric Microcatheter
Indications for Use:	The Modified Concentric Microcatheter is indicated for use in the selective placement of fluids and/or other devices or agents into the peripheral, coronary and neuro vasculature during diagnostic and/or therapeutic procedures.

Prescription Use _X_ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(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 K091961