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510(k) Summary

Trade Name:	Modified Concentric Microcatheter
Common Name:	Diagnostic Intravascular Catheter
Classification Name:	Diagnostic Intravascular Catheter, 21CFR 870.1200 – Class II
Product Code:	DQO

Submitter: Concentric® Medical, Inc.
301 E. Evelyn Avenue
Mountain View, CA 94041
Tel 650-938-2100
Fax 650-237-5230
Facility Registration #2954917

Contact: Kirsten Valley

Predicate Device: Concentric Microcatheter (K111619)

Device Description

The Modified Concentric Microcatheter is a single lumen, braided, variable stiffness catheter designed 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. A luer hub on the proximal end of the shaft enables connection to the rotating hemostasis valve included in the package. The radiopaque shaft and distal marker facilitate fluoroscopic visualization. The catheter shaft is coated with a hydrophilic coating to reduce friction during use.

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.

Technological Characteristics

The Modified Concentric Microcatheter has the same technological characteristics as the predicate device (K111619). Both have braided shafts with varying durometers of polymer along the length for optimal flexibility.

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. The same test methods were applied as those previously submitted for the predicate Concentric Microcatheter. Specifically, the following tests were performed on the proposed device:

- Kink Resistance – the device's ability to withstand kinking when flexed was successfully evaluated.

- Leak Resistance – the device's leak resistance when subjected to both high pressure and vacuum was successfully evaluated.
- Flexibility Testing – the device's ability to navigate tight bends was successfully evaluated.
- Tensile Testing – the device's mechanical integrity under tensile loads was successfully evaluated.
- Torque Testing – the device's mechanical integrity when subjected to torsion was successfully evaluated.
- Coating Testing – the durability and lubricity of the device coating was successfully evaluated.
- Radiopacity – the visibility of the device under fluoroscopy was successfully evaluated.
- Particulate Testing – the amount and size of particles that are released from the device during simulated clinical use were successfully evaluated.

The following biocompatibility tests were performed on the device; results for all tests met the pre-determined acceptance criteria.

- Sensitization/Maximization
- Cytotoxicity
- Intracutaneous Reactivity
- Systemic Toxicity/Systemic Injection Test
- Systemic Toxicity/Rabbit Pyrogen Test
- Hemocompatibility/Hemolysis
- Hemocompatibility/Complement Activation
- Hemocompatibility/*in vivo* Thrombogenicity

Summary of Substantial Equivalence

The Modified Concentric Microcatheter is substantially equivalent to the predicate device with regard to device design, intended use, and patient population. 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.

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

MAR - 9 2012

Concentric® Medical, Inc.
c/o Ms. Kirsten Valley
Vice President, Technology & Regulatory Affairs
301 East Evelyn Avenue
Mountain View, CA 94041

Re: K113260
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: March 1, 2012
Received: March 5, 2012

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,

M. J. Hillebrenner

for 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

INDICATIONS FOR USE

510(k) Number (if known):	K113260
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_ (Per 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)

M.A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113260