APR - 4 2011

K110483

510(k) Summary

Name of Device:	Trade Name:	Modified HD Guide Catheter
	Common Name:	Percutaneous Catheter
	Classification Name:	Percutaneous Catheter, 21CFR 870.1250 – Class II
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	HD Guide Catheter (K090335)	
Date	March 23, 2011	

Device Description

The Modified HD Guide Catheter consists of a single lumen, braided, variable stiffness shaft designed for use in facilitating the insertion and guidance of an occlusion catheter, infusion catheter or other appropriate microcatheter into a selected blood vessel in the peripheral, coronary or neurovascular system. A radiopaque marker is included on the distal end for angiographic visualization. The catheter shaft has a hydrophilic coating to reduce friction during use. A luer hub on the proximal end allows attachments for flushing, insertion of catheters and aspiration. A rotating hemostatic valve with side-arm adapter is provided with each catheter for flushing, catheter insertion and aspiration. Modified HD Guide Catheter dimensions are indicated on product label. The Modified HD Guide catheter family is being extended to include a 6.3 F size.

Intended Use

The Modified HD Guide Catheter is indicated for use in facilitating the insertion and guidance of an occlusion catheter, infusion catheter or other appropriate microcatheter into a selected blood vessel in the peripheral, coronary and neuro vascular systems. It may also be used as a diagnostic angiographic catheter.

Technological Characteristics

The Modified HD Guide Catheter has the same technological characteristics as the K080583 and K090335 predicate devices. The device design, materials used, function, physical properties and composition have not been changed.

Testing Summary

The results of verification and validation conducted on the Modified HD Guide Catheter demonstrate that it performs as designed, is suitable for its intended use and is substantially equivalent to the predicate device. The same performance standards, test methods and specifications were applied as those previously submitted in the predicate HD Guide Catheter 510(k) submissions. Specifically, kink resistance, flow rate, coating lubricity, leak resistance, tensile strength and flexibility testing were performed.

Summary of Substantial Equivalence

The Modified HD Guide Catheter 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 HD Guide Catheter 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

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

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Re: K110483
Trade/Device Name: Modified HD Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: March 23, 2011
Received: March 24, 2011

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 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): ~~This application~~ K110483

Device Name: Modified HD Guide Catheter

Indications for Use: The Modified HD Guide Catheter is indicated for use in facilitating the insertion and guidance of an occlusion catheter, infusion catheter or other appropriate microcatheter into a selected blood vessel in the peripheral, coronary and neuro vascular systems. It may also be used as a diagnostic angiographic catheter.

Prescription Use _X_ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_X_ (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. Kelman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110483