510(K) SUMMARY K102657

General Information

Trade Name	Concentric Balloon Guide Catheter
Common Name	Percutaneous Catheter
Classification	Percutaneous Catheter, 21CFR 870.1250 – Class II

NOV 17 2010

Submitter	Concentric® Medical, Inc. 301 E. Evelyn Avenue Mountain View, CA 94041 Tel 650-938-2100 Fax 650-938-2700
Contact	Kirsten Valley Senior Vice President, Technology and Regulatory Affairs

Predicate Device

Concentric Balloon Guide Catheters (K010954 and K021899).

Device Description

The Concentric Balloon Guide Catheters are coaxial-lumen, braid-reinforced, variable stiffness catheters designed for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. A radiopaque marker on the distal end facilitates angiographic visualization. A compliant balloon is mounted on the distal end to provide temporary vascular occlusion during angiographic procedures. A bifurcated luer hub on the proximal end allows attachments for flushing, inflation and aspiration. Balloon Guide Catheter dimensions and maximum recommended balloon inflation volume are indicated on product label. If indicated on product label, a dilator is provided. The Balloon Guide Catheter is identical to K010954 and K021899.

Indications for Use

The Concentric Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for the Merci Retriever.

Technological Characteristics

The Concentric Balloon Guide Catheter has the same technological characteristics as the predicate device. The device design, materials used, function, physical properties and composition have not been changed. Specifically, the device is coaxial-lumen, braid-reinforced, variable stiffness catheter with a radiopaque marker on the distal end. A soft, compliant balloon is mounted on the distal end. A bifurcated luer hub on the proximal end allows attachments for flushing, inflation and aspiration.

Testing Summary

The Balloon Guide Catheter is identical to K010954 and K021899 and there were no design changes. For this 510k, Concentric Medical referenced the bench testing, biocompatibility and sterility information in K010954 and K021899. The safety and effectiveness of the Balloon Guide Catheter was also demonstrated by referencing the MERCI and Multi MERCI clinical trials in (K070521 and K082034).

Summary of Substantial Equivalence

The Concentric Balloon Guide Catheters are substantially equivalent to the predicate device with regard to device design, intended use, and patient population. As a result, the Concentric Balloon Guide Catheter is as safe and effective as 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, Inc.
c/o Ms. Kristen Valley
Senior Vice President, Technology and Regulatory Affairs
301 East Evelyn Avenue
Mountain View, CA 94041

Re: K102657
Trade/Device Name: Concentric Balloon Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 14, 2010
Received: September 15, 2010

NOV 17 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

INDICATIONS FOR USE

510(k) Number (if known): This application K102657

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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)

JEFFREY Toy

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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