5 510(k) Summary

This summary of the 510(k) premarket notification for the Concentric Balloon Guide Catheter is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

5.1 Manufacturer

Concentric Medical Inc.
2585 Leghorn Street
Mountain View, CA. 94043
Telephone: (650) 938-2100
Registration #: 2954917

5.2 Contact Person

Kevin MacDonald
Vice President, Clinical and Regulatory Affairs

5.3 Date Prepared

June 7, 2002

5.4 Classification

Percutaneous Catheter, 21CFR 870.1250 – Class II
Balloon Type Catheter, 21CFR 878.4200 – Class II

5.5 Trade Name

Concentric Balloon Guide Catheter

5.6 Generic/Common Name

Percutaneous Catheter or Balloon Type Catheter

5.7 Predicate Devices

Concentric Balloon Guide Catheter (K010954)

5.8 Intended Use

The Concentric Balloon Guide Catheter is indicated for use in facilitating and guidance of intravascular catheters into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures.

5.9 Product Description

The Concentric Balloon Guide Catheter device, cleared under K010954, is a 9F coaxial lumen braided shaft, variable stiffness catheter with a radiopaque marker on the distal end. The balloon is flush mounted on the distal end of the catheter. The inner diameter of the balloon guide catheter is 0.085". The maximum inflation diameter is 10 mm, and the maximum inflation length is 10 mm.

The design of the modified Concentric Balloon Guide Catheter differs in dimension and includes a new material, Cristamid. All other characteristics remain the same as compared to the original device. The outer and inner diameters have been downsized to 7F and 0.059" respectively. Biocompatibility of Cristamid has been established and results provided in the Concentric HD Guide Catheter Premarket Notification (K003880).

5.10 Substantial Equivalence

The Concentric 7F Balloon Guide Catheter is intended for use in interventional radiological procedures. The Concentric 7F Balloon Guide Catheter is equivalent to the Concentric 9FBalloon Guide Catheter (K010954). The Concentric 7F Balloon Guide Catheter is substantially equivalent to the predicate device with regards to device design, intended use, patient population and anatomical site.

5.11 Testing in Support of Substantial Equivalence

Performance testing has been conducted and the results of the testing verified that the Concentric Balloon Guide Catheter performs as designed and is suitable for its intended use.

5.12 Conclusion

As contained in this 510(k) summary, the Concentric Balloon Guide Catheter is substantially equivalent to the predicate devices identified in regards to device design, intended use, patient population and anatomical site.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 0 2002

Concentric Medical, Inc.
c/o Mr. Kevin MacDonald
Vice President, Clinical and Regulatory Affairs
2585 Leghorn Street
Mountain View, CA 94043

Re: K021899
Trade Name: Concentric Balloon Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: June 7, 2002
Received: June 10, 2002

Dear Mr. Mac Donald:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Statement of Indications for Use

INDICATIONS FOR USE

510(k) Number (if known): K021899

Device Name: Concentric Balloon Guide Catheter

Indications for Use:

The Concentric Balloon Guide Catheter is indicated for use in facilitating and guidance of intravascular catheters into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices
510(k) Number K021899