

AUG 11 2004

510(k) Summary

General Information

Classification	Class II, Percutaneous Catheter per 21 CFR § 870.1250
Trade Name	Concentric Merci® Retriever Models X5 and X6
Submitter	Concentric Medical, Inc. 1380 Shorebird Way Mountain View, CA 94043 Tel: 650-938-2100 Fax: 650-938-2700
Contact	Kevin F. MacDonald Vice President, Clinical and Regulatory Affairs

Intended Use

The Merci Retriever is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke. Patients who are ineligible for treatment with intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. The Merci Retriever is also indicated for use in the retrieval of foreign bodies misplaced during interventional radiological procedures in the neuro, peripheral and coronary vasculature.

Predicate Devices

Concentric Retriever K030476
Manufactured by Concentric Medical, Inc.

Device Description

The Merci Retriever consists of a Nitinol tapered wire with a helical shaped distal tip. A platinum coil is attached over the helical distal tip. A radiopaque distal coil facilitates fluoroscopic visualization.

Materials

All materials used in the manufacture of the Merci Retriever are suitable for this use and have been used in numerous previously cleared products.

Testing Summary

The Merci Retriever was tested in the same manner as the predicate Concentric Retriever (K030476). All components, subassemblies, and/or full devices met the required specifications for the completed tests. The Merci Retriever was designed under the Concentric Quality System that is in compliance with 21CFR§820.30.

Summary of Clinical Testing

The MERCI Clinical Study established that no new issues of safety and effectiveness exist when the Merci Retriever is used for thrombus removal versus foreign body removal from the neurovasculature.

Summary of Substantial Equivalence

The Merci Retriever is equivalent to the predicate device, the Concentric Retriever. The indications for use, function, methods of manufacturing, and materials used are substantially equivalent. Concentric Medical, Inc. believes the Merci Retriever is substantially equivalent to existing legally marketed device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 2004

Mr. Kevin F. MacDonald
Vice President, Clinical and Regulatory Affairs
Concentric Medical, Inc.
1380 Shorebird Way
Mountain View, California 94043

Re: K033736
Trade/Device Name: Concentric Merci[®] Retriever
Models X5 and X6
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, thrombus retriever
Regulatory Class: II
Product Code: NRY
Dated: May 28, 2004
Received: June 2, 2004

Dear Mr. MacDonald:

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.

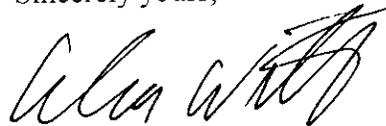
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 - Mr. Kevin F. MacDonald

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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033736

Device Name: Concentric Merci® Retriever
Models X5 and X6

Indications for Use: The Merci Retriever is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke. Patients who are ineligible for treatment with intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. The Merci Retriever is also indicated for use in the retrieval of foreign bodies misplaced during interventional radiological procedures in the neuro, peripheral and coronary vasculature.

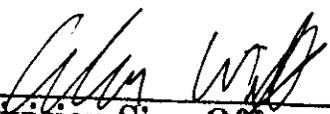
Prescription Use X
(Per 21 CFR 801 Subpart D)

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)



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K033736