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DEC 1 8 2007

510(k) Summary

General Information

Trade Name	Modified Merci® Retriever
Common Name	Endovascular Retriever
Classification	Class II, Catheter, thrombus Retriever per 21 CFR § 870.1250

and

Trade Name	Merci® Microcatheter
Common Name	Intravascular Diagnostic Catheter
Classification	Class II, Catheter, thrombus Retriever per 21 CFR § 870.1200

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

Intended Use

Merci® Retriever

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.

Concentric Microcatheter

The Concentric Microcatheter is indicated for use in the selected placement of fluids and/or other devices or agents into the peripheral, coronary and neuro vasculature during diagnostic and/or therapeutic procedures.

Predicate Device

Merci Retriever
Merci Microcatheter

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Device Description

Like the predicate device, the Merci® Retriever consists of a flexible, Nitinol core wire with shaped loops at the distal end. A radiopaque coil covers the tip allowing visualization under fluoroscopy.

The shaped loops of the Retriever are deployed distal to the thrombus or foreign body through the Microcatheter. The Retriever and Microcatheter are pulled back to engage the thrombus or foreign body in the loops of the Retriever. The Retriever, the thrombus or foreign body, and the Microcatheter are then removed from the body.

Materials

All materials used in the manufacture of the various Retrievers and Microcatheters are suitable for the intended use of the device.

Testing Summary

All devices met the required specifications for the completed tests.

Summary of Substantial Equivalence

The Merci® Retrievers and the Concentric Microcatheters are substantially equivalent to their respective predicate devices. In each case the indications for use, function, and materials used are equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2007

Concentric Medical, Inc.
% Ms. Kirsten Valley
Sr. VP, Operations & Regulatory
Affairs
301 East Evelyn Avenue
Mountain View, California 94041

Re: K072796
Trade/Device Name: Merci Retriever and Merci Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: NRY, DQO
Dated: November 19, 2007
Received: November 20, 2007

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 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K072796

Indications for Use

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

Device Name:	Merci Retriever
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.
Device Name:	Merci Microcatheter
Indications for Use:	The Merci Microcatheter is indicated for use in the selected 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_ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(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 K072796