K122478

510(k) Summary

OCT 31 2012

Trade Name:	Modified Trevo Retriever
Common Name:	Catheter, Thrombus Retriever
Classification Name:	Catheter, Thrombus Retriever, 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 Vice President, Technology and Regulatory Affairs

Date Prepared:	October 24, 2012
Predicate Device:	Trevo Retriever (K120961)

Device Description

Like the predicate device, the Modified Trevo Retriever consists of a flexible, tapered core wire with a shaped section at the distal end. It is designed to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke. A radiopaque coil at the distal end and new radiopaque platinum wires in the shaped section allow fluoroscopic visualization. Retriever dimensions are indicated on the product label. The Retriever has a hydrophilic coating to reduce friction during use. A torque device and an insertion tool are provided with the Retriever. The proximal end of the device is compatible with the Abbott guide wire extension to facilitate removal or exchange of a catheter while maintaining the Retriever position in the vessel.

Indications for Use

The Indications for Use are identical to that of the predicate devices and are as follows:

> The Modified Trevo Retriever is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

The intended therapeutic use of the device is not impacted and no new issues of safety and effectiveness are raised by the modification.

Technological Characteristics

The Modified Trevo Retriever has the same technological characteristics as the predicate device. The basic design, materials used, and function have not been changed. Radiopaque platinum wires have been added to the shaped section to allow fluoroscopic visualization.

Testing Summary

The results of verification and validation testing conducted on the Modified Trevo Retriever demonstrate that it performs as designed, is suitable for its intended use and is substantially equivalent to the predicate device. Specifically, the following tests were performed on the proposed device:

- Simulated Use Testing: the device's ability to be used in a neurovascular model per procedural instructions outlined in the Instructions for Use was successfully evaluated.
- Tensile Testing: the device's mechanical integrity under tensile loads was successfully evaluated.
- Radial Force Testing: the resulting radial force when the device is constrained radially was successfully evaluated.
- Tip Deflection Force Testing: the force to deflect the distal tip of the device was successfully evaluated.
- Torque/Tensile Durability: the ability of the device to withstand torque and tensile load cycles without fracture was successfully evaluated.
- Kink Resistance: the ability of the device shaft to resist kinking was successfully evaluated.

Verification and Validation of modified components includes:

- Platinum Wire and Joint Durability: the platinum wire and joint integrity following loading cycles was successfully evaluated.
- Platinum Wire Attachment: the platinum wire attachment strength was successfully evaluated.
- Radiopacity: the visibility of the platinum shaped section under fluoroscopy during use was successfully evaluated.

Summary of Substantial Equivalence

The Modified Trevo Retriever is substantially equivalent to the predicate device with regard to device design, materials, intended use, and patient population. The conclusions drawn from the verification and validation testing conducted using the Modified Trevo Retriever demonstrate that it performs as designed, is suitable for its intended use and is substantially equivalent to the legally marketed 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. Kirsten Valley
Vice President, Technology and Regulatory Affairs
301 E. Evelyn Avenue
Mountain View, CA 94041

OCT 31 2012

Re: K122478
Trade/Device Name: Modified Trevo Retriever
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Thrombus Retriever
Regulatory Class: Class II
Product Code: NRY
Dated: August 13, 2012
Received: August 14, 2012

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

K122478

4. Statement of Indications for Use

INDICATIONS FOR USE

510(k) Number (if known):	This application
Device Name:	Modified Trevo Retriever
Indications for Use:	The Modified Trevo Retriever is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

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)

Samuel K. Shimp III
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

Page 1 of 1

510(k) Number K122478