K133464

JAN 17 2014

510(k) Summary

Trade Name:	Modified Trevo ProVue Retriever
Common Name:	Catheter, Thrombus Retriever
Classification Name:	Thrombus Retriever, 21CFR 870.1250 Class II
Product Code:	NRY

Submitter:	Concentric Medical, Inc. 301 E. Evelyn Avenue Mountain View, CA 94041 Tel 510-413-2681 Fax 510-413-2558 Facility Registration #2954917
Contact:	Sarah Meyer Senior Regulatory Affairs Specialist

Date Prepared:	December 13, 2013
Predicate Device:	Concentric Trevo ProVue Retriever (K122478)

Device Description

The Modified Trevo ProVue 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 allows fluoroscopic visualization. The shaped section is also radiopaque. 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 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.

Technological Characteristics and Product Feature Comparison

The Modified Trevo ProVue Retriever with a modified platinum wire weave is substantially equivalent to the predicate device in terms of design, materials used, and function. A comparison of the subject device with predicate device is summarized in the below table.

Comparison of Cleared Trevo ProVue Retriever to the Modified Trevo ProVue Retriever

Feature	**Cleared Trevo ProVue Retriever (K122478)**	**Modified Trevo ProVue Retriever**
Indications for Use	The Trevo ProVue 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.	Same as cleared device
Device Description	The Retriever consists of a flexible, tapered core wire with a shaped section at the distal end. A platinum coil allows fluoroscopic visualization. In addition, the shaped section is also radiopaque. The Retriever has a hydrophilic coating to reduce friction. The Retriever has a shaft marker to indicate proximity of Retriever tip relative to Microcatheter tip. A torque device and insertion tool are provided with the Retriever.	Same as cleared device
Target Population	Patients with symptoms of an ischemic stroke	Same as cleared device
Anatomical Sites	Neurovasculature	Same as cleared device
Accessory Devices Provided (not in direct contact with patient)	Insertion tool and torque device provided in product package	Same as cleared device
Regulatory Status		
Regulation Number	21CFR 870.1250	Same as cleared device
Regulation Name	Catheter, Thrombus Retriever	Same as cleared device
Regulatory Class	II	Same as cleared device
Product Code	NRY	Same as cleared device
Materials		
Core Wire Material	Nitinol (nickel titanium alloy)	Same as cleared device
Distal Shaped Section Material	Nitinol	Same as cleared device

Feature	Cleared Trevo ProVue Retriever (K122478)	Modified Trevo ProVue Retriever
Coil Material Distal to Distal Shaped Section	Platinum/Tungsten	Same as cleared device
Shaped Section Radiopaque Wire	Platinum/Tungsten	Same as cleared device
Coil Material Proximal to Shaped Section	304 Stainless Steel	Same as cleared device
Solder	Gold/Tin	Same as cleared device
Hydrophilic Coating	Sodium hyaluronate mixture	Same as cleared device
Nominal Design Attributes		
Overall Length	180 cm	Same as cleared device
Total Shaped Section Length (nominal)	37 mm	Same as cleared device
Active Shaped Section Length (nominal)	20 mm	Same as cleared device
Distal Tip Length (nominal)	4 mm	Same as cleared device
Proximal Core Wire Diameter	0.0180"	Same as cleared device
Shaped Section Diameter (nominal)	4 mm	Same as cleared device
Distal Taper Length (nominal)	10 mm	Same as cleared device
Packaging		
Materials and Configuration	Polyethylene Hoop, polycarbonate mounting card, Tyvek/Film Pouch, HDPE Tubing Clips, Chipboard carton	Same as cleared device
Sterilization Method	100% EtO	Same as cleared device
How Supplied	Sterile/Single Use	Same as cleared device

Risk Assessment

Risk assessment of the modifications has been conducted in accordance with EN ISO 14971:2012. Concentric Medical, Inc. has determined the modifications to the predicate device raise no new questions of safety or effectiveness.

Results of testing have demonstrated the Modified Trevo ProVue Retriever is substantially equivalent to the predicate device. Furthermore, the modifications did not result in any new failure modes nor were there any changes to existing failure modes.

Testing Summary

The results of testing conducted on the Modified Trevo ProVue 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:

Test	Test Method Summary	Results
Simulated Use -- Deliverability, Deployment, and Reloadability	Simulated use testing used a silicone neurovascular model cast from actual human neurovascular arteries. This bench testing model replicates the tortuosity, diameter and location of the arteries in the neurovasculature including the internal carotid artery (ICA) siphon. The model ends at the mid carotid arteries and proximal support is provided by a guide catheter. The model incorporates a re-circulating water bath at 37°C pressurized between 2 – 2.5 psi (100 – 126 mm Hg) to simulate the human arterial circulation. All testing follows the procedural instructions outlined in the Instructions for Use. Simulated thrombus is used to assess the devices ability to retrieve clot.	All samples passed the acceptance criteria. Device continues to meet same design requirements as predicate device K122478.

In summary, the results of simulated testing for deliverability, deployment, and reloadability that were conducted on the Modified Trevo ProVue Retriever demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.

Summary of Substantial Equivalence

The Modified Trevo ProVue Retriever is substantially equivalent to the predicate device with regard to device design, materials, intended use, and patient population. The conclusions drawn from risk assessments and the testing conducted using the Modified Trevo ProVue Retriever demonstrate that the device 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 Center – WO66-G609
Silver Spring, MD 20993-0002

January 17, 2014

Concentric Medical
% Ms. Sarah Meyer
Senior Regulatory Affairs Specialist
301 East Evelyn Ave.
Mountain View, CA 94041

Re: K133464
Trade/Device Name: Trevo ProVue Retriever
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: December 18, 2013
Received: December 19, 2013

Dear Ms. Meyer:

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 contact 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. 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,

Joyce M. Whang -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133464

Device Name: Trevo ProVue Retriever

Indications For Use:

The 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 ✓ (Part 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 Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S