5. 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:	February 25, 2014
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. Radiopaque platinum wires in the shaped section and new radiopaque markers on the new truncated distal end 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. The Modified Trevo ProVue Retriever is offered in two sizes.

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 is substantially equivalent to the predicate device in terms of basic design, materials used, and function. A comparison of the subject device with predicate device is summarized in the below table.

Product Feature Comparison of Subject Device with Predicate Device

Feature	Results
Indications for Use	Same
Device Description	Same except new truncated distal end with new distal radiopaque markers.
Target Population	Same
Accessory Devices Provided	Same
Materials	Same
Overall Length	Same except 3x20 size is longer.
Total Shaped Section Length	Shorter than predicate device.
Active Shaped Section Length	Same
Distal Tip and Distal Taper Length	Not applicable to subject device, modified device distal end has been truncated.
Proximal Core Wire Diameter	Same except 3x20 size has a smaller diameter
Shaped Section Diameter	Same except 3x20 size has a smaller diameter
Packaging Materials and Configuration	Same
Sterilization Method	Same
How Supplied	Same

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 verification and validation 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 verification and validation 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	Conclusions
1.	Dimensional Verification	Verified dimensions using specified measurement tool.	Dimensional verification meets acceptance criteria.
2.	Retriever Proximal Joint Tensile Strength	Identified joint and cut sample for test. Recorded peak tensile force results.	Retriever Proximal Joint Tensile Strength meets acceptance criteria.
3.	Retriever Mid Joint Tensile Strength	Identified joint and cut sample for test. Recorded peak tensile force results.	Retriever Mid Joint Tensile Strength meets acceptance criteria.
4.	Retriever Tip Tensile Strength	Loaded sample. Recorded peak tensile force results.	Retriever Tip Tensile Strength meets acceptance criteria.
5.	Retriever Shaped Section Radial Force	Constrained shaped section of retriever to specified diameter. Recorded radial force results.	Retriever Shaped Section Radial Force meets acceptance criteria.
6.	Retriever/Vessel Interaction (Tip Flexibility)	Loaded sample so that the distal tip was flexed. Recorded peak compression/flex force results.	Retriever/Vessel Interaction (Tip Flexibility) meets acceptance criteria.
7.	Retriever Torque Tensile Durability	Gripped device and applied rotations to torque device. Pulled tensile cycles to a max load then last cycle to failure. Recorded results.	Retriever Torque Tensile Durability meets acceptance criteria.
8.	Retriever Platinum Wire Joint Strength	Identified joint and cut sample for test. Recorded peak tensile force on each individual platinum wire results.	Retriever Platinum Wire Joint Strength meets acceptance criteria.
9.	Retriever Platinum Wire and Joint Durability	Wrapped and unwrapped the entire length of the shaped section of the retriever (sheathed in insertion tool) around a pin and repeat. Performed visual inspection and recorded results. Performed deploy/reload cycles into insertion tool. Performed visual inspection and recorded results.	Retriever Platinum Wire and Joint Durability meets acceptance criteria.
10.	Radiopacity	Radiopacity was assessed based on visual assessment of the device being used under fluoroscopy.	Radiopacity meets acceptance criteria.
11.	Retriever/Microcatheter Deliverability	Measured the force to push the device through a tortuous model.	Retriever/Microcatheter Deliverability meets acceptance criteria.
12.	Proximal Curl Resistance	Applied rotations to distal end of core wire with device constrained. Recorded the number of rotations until a loop results or stop rotations at specified number if no loop results.	Proximal Curl Resistance meets acceptance criteria.
13.	Simulated Use	Simulated use testing used a silicone neurovascular model cast from actual human neurovascular arteries. This bench testing model replicates the tortuosity, diameter and location	Simulated Use meets acceptance criteria.

	Test	Test Method Summary	Conclusions
		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 37ºC 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.	

Biocompatibility

The modified Trevo ProVue Retriever was assessed for impact to biocompatibility. Materials used in the modified Trevo ProVue Retriever are all the same materials used in the cleared Trevo ProVue Retriever (K122478). Furthermore, screening testing was performed successfully, providing further assurance that any design or process changes did not adversely affect the biocompatibility of the modified Trevo ProVue Retriever. Screening testing included cytotoxicity, hemolysis, and physicochemical testing, summarized below. Both the modified Trevo ProVue Retriever and the cleared Trevo ProVue Retriever meet biological safety requirements per ISO 10993-1 for externally communicating medical devices with circulating blood contact for less than 24 hours.

Test Description	Result			Conclusion
Cytotoxicity Using the ISO Elution Method	*Dilution*	*Result Grade*	*Pass/Fail*	Non-cytotoxic. The score of "3" is not attributed to the changes made to the modified Trevo ProVue Retriever since this result is consistent with historical cytotoxicity data collected on Retriever devices (such as K122478) with hydrophilic coating.
	Undiluted	3 – Moderate reactivity	*	
	50%	0 – No reactivity	**Pass**	
	25%	0 – No reactivity	**Pass**	
	12.5%	0 – No reactivity	**Pass**	
	6.25%	0 – No reactivity	**Pass**	
	3.13%	0 – No reactivity	**Pass**	
ASTM Hemolysis (combined direct contact and extract)	**Pass.** Hemolytic index: 0.0% (direct contact) and 0.4% (extract)			Non-Hemolytic
Physicoche-mical Tests Plastics	**Pass**. Non-volatile residue: 2 mg Residue on ignition: ≤ 2 mg Heavy metal: < 1 ppm Buffering capacity: < 1.0 mL			No heavy metals or leachables.

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 verification and validation 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 13, 2014

Concentric Medical, Inc.
c/o Ms. Sarah Meyer
Senior Regulatory Affairs Specialist
301 E. Evelyn Ave.
Mountain View, CA 94041

Re: K132641
Trade/Device Name: Modified Trevo ProVue Retriever
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Thrombus Retriever
Regulatory Class: Class II
Product Code: NRY
Dated: October 14, 2013
Received: October 15, 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): K132641

Device Name: Modified 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 ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 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