



Food and Drug Administration
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June 12, 2015

Concentric Medical, Inc.
Ms. Rhoda M. Santos
Principal Regulatory Affairs Specialist
301 East Evelyn Avenue
Mountain View, California 94041

Re: K150616

Trade/Device Name: Trevo XP ProVue Retriever (4x30mm)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: May 8, 2015
Received: May 11, 2015

Dear Ms. Santos:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Carlos L. Pena -S 

Carlos L. Peña, PhD, MS
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)

K150616

Device Name

Trevo XP ProVue Retriever (4x30mm)

Indications for Use (Describe)

The Trevo XP ProVue Retriever (4x30mm) 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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Trade Name: Trevo XP ProVue Retriever (4x30mm)
Common Name: Catheter, Thrombus Retriever
Classification Name: Thrombus Retriever, 21CFR 870.1250 Class II
Product Code: NRY

Submitter: **Concentric Medical, Inc.**
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Contact: **Rhoda M. Santos**
Principal Regulatory Affairs Specialist

Date Prepared: **May 8, 2015**
Predicate Device: **Trevo XP ProVue Retriever (4x20mm) (K132641)**

Device Description

The Trevo XP ProVue Retriever (4x30mm) 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 radiopaque markers on the 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 is provided with the Retriever to facilitate manipulation. The torque device is used to lock the core wire to the microcatheter during the procedure. Locking of the torque device to the wire allows the microcatheter and Retriever to be retracted as a system during clot retrieval. An insertion tool is provided to introduce the Retriever into a microcatheter. 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 XP ProVue Retriever (4x30mm) 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 Trevo XP ProVue Retriever (4x30mm) is substantially equivalent to the primary predicate device in terms of basic design, materials used, and function. A comparison of the subject device with Primary Predicate Trevo XP ProVue Retriever (4x20mm) is summarized in the below table. Additionally, shaped section measurements are also compared to the reference predicate device [Solitaire FR Revascularization Device SFR2-4-40 (4x40mm) (K141491)].

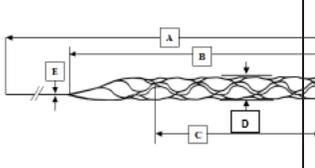
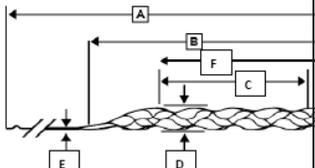
**Product Feature Comparison of Subject Device with Primary Predicate Device
Trevo XP ProVue Retriever (4x20mm) (K132641)**

Feature	<u>Primary Predicate</u> Cleared Trevo XP ProVue Retriever (4x20mm) (K132641)	<u>Subject Device</u> Trevo XP ProVue Retriever (4x30mm)	<u>Rationale for difference</u> (if applicable)
Indications for Use	The Trevo XP 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	N/A

Trevo XP ProVue Retriever (4x30mm)

Feature	<u>Primary Predicate</u> Cleared Trevo XP ProVue Retriever (4x20mm) (K132641)	<u>Subject Device</u> Trevo XP ProVue Retriever (4x30mm)	<u>Rationale for difference</u> (if applicable)
Device Description	<p>The Retriever consists of a flexible, tapered core wire with a shaped section at the distal end. Platinum markers at the distal end allow fluoroscopic visualization. In addition, the shaped section is also radiopaque. Retriever dimensions are indicated on product label.</p> <p>The Retriever has a hydrophilic coating to reduce friction during use. The Retriever has a shaft marker to indicate proximity of Retriever tip relative to Microcatheter tip. A torque device is provided with the Retriever to facilitate manipulation. An insertion tool is provided to introduce the Retriever into a Trevo[®] Microcatheter.</p>	Same with the exception that the subject Retriever is introduced via an Excelsior XT-27 Microcatheter (whereas the predicate device is introduced via a Trevo [®] Microcatheter)	<p>The Excelsior XT-27 and Trevo Pro18 Microcatheters are compatible with the 4x30mm device and will be indicated as such in the IFU.</p> <p>Bench testing has demonstrated that the compatibility of Excelsior XT-27 with the 4x30mm device does not affect the safety and effectiveness of the device.</p>
Target Population	Patients with symptoms of an ischemic stroke	Same	N/A
Anatomical Sites	Neurovasculature	Same	N/A
Accessory Devices Provided (not in direct contact with patient)	Insertion tool and torque device provided in product package	Same	N/A

Trevo XP ProVue Retriever (4x30mm)

Feature	<u>Primary Predicate</u> Cleared Trevo XP ProVue Retriever (4x20mm) (K132641)	<u>Subject Device</u> Trevo XP ProVue Retriever (4x30mm)	<u>Rationale for difference (if applicable)</u>
Microcatheter Compatibility	Trevo Pro 18 Microcatheter	Excelsior XT-27 Microcatheter and Trevo Pro 18 Microcatheter	<p>The Excelsior XT-27 and Trevo Pro18 Microcatheters are compatible with the 4x30mm device and will be indicated as such in the IFU.</p> <p>Bench testing has demonstrated that the compatibility of Excelsior XT-27 with the 4x30mm device does not affect the safety and effectiveness of the device.</p>
Materials	Core Wire Material: Nitinol (nickel titanium alloy) Distal Shaped Section Material: Nitinol Coil Material Distal to Distal Shaped Section : Platinum/Tungsten Shaped Section Radiopaque Wire: Platinum/Tungsten Coil Material Proximal to Shaped Section: 304 Stainless Steel Solder: Gold/Tin Hydrophilic Coating: Sodium hyaluronate mixture	Same	N/A
Dimensional Drawing			Additional reference (Length of the non-tapered portion of shaped section (F)) allows customers to directly compare the length of the 4x30mm retriever to the labeling of competitive stentriever.
Overall Length (A)	180cm	Same	N/A
Total Shaped Section Length (nominal) (B)	32mm	44mm	<p>Shaped section has been lengthened to meet user preferences.</p> <p>Bench and animal testing has demonstrated that the longer shaped section does not affect the safety and effectiveness of the device.</p>

Trevo XP ProVue Retriever (4x30mm)

Feature	Primary Predicate Cleared Trevo XP ProVue Retriever (4x20mm) (K132641)	Subject Device Trevo XP ProVue Retriever (4x30mm)	Rationale for difference (if applicable)
Active Shaped Section Length (nominal) (C)	20mm	30mm	Shaped section has been lengthened to meet user preferences. Bench and animal testing has demonstrated that the longer shaped section does not affect the safety and effectiveness of the device.
Shaped Section Diameter (nominal) (D)	4mm	Same	N/A
Proximal Core Wire Diameter (E)	0.0180in	Same	N/A
Length of the non-tapered portion of shaped section (F)	Not provided in labeling	35mm	Additional reference (Length of the non-tapered portion of shaped section (F)) allows customers to directly compare the length of the 4x30mm retriever to the labeling of competitive stentriever.
Shaped section	4 rows and 4 rings of cells.	4 rows and 7 rings of cells.	Shaped section has been lengthened to meet user preferences. Bench and animal testing has demonstrated that the longer shaped section does not affect the safety and effectiveness of the device.
Hydrophilic coating length	Coating extends from the proximal end of the core wire up to the proximal coil.	Coating extends from a point 80cm distal to the proximal end of the core wire up to the proximal coil to enable physician to hold the device more securely.	The lubricious coating was removed from the proximal end of the core wire so the physician can hold the device more securely. Bench testing has demonstrated that the change in coating length does not affect the safety and effectiveness of the device.

Trevo XP ProVue Retriever (4x30mm)

Feature	<u>Primary Predicate</u> Cleared Trevo XP ProVue Retriever (4x20mm) (K132641)	<u>Subject Device</u> Trevo XP ProVue Retriever (4x30mm)	<u>Rationale for difference</u> (if applicable)
Shaped section distal platinum coil markers	Platinum markers attached to 3 distal tips of the distal end of the shaped section.	Same	N/A
Core wire marker band placement and presence	Core wire marker bands at 59.53” from the proximal end of the shaped section.	Core wire marker bands at 57.56” from the proximal end of the shaped section. Location moved (~5cm more distal) to allow compatibility with the XT-27 Microcatheter.	<p>The placement of the shaft markers (Core wire marker bands) was moved to allow the Trevo XP ProVue Retriever (4x30mm) to be compatible with the Excelsior XT-27 Microcatheter.</p> <p>Bench testing has demonstrated that the difference in placement of the core wire marker bands does not affect the safety and effectiveness of the device.</p>
	6 marker bands are present on the core wire.	4 marker bands are present on the core wire.	<p>Difference in number of shaft markers (core wire marker bands) to make sizes easily identifiable in manufacturing.</p> <p>Bench testing has demonstrated that the difference in number of shaft markers (core wire marker bands) does not affect the safety and effectiveness of the device.</p>

Trevo XP ProVue Retriever (4x30mm)

Feature	Primary Predicate Cleared Trevo XP ProVue Retriever (4x20mm) (K132641)	Subject Device Trevo XP ProVue Retriever (4x30mm)	Rationale for difference (if applicable)
Radial Force	Radial Force at 1.5mm diameter: 0.70 +0.15/-0.20N	Radial Force at 1.5mm diameter: 0.95 +0.15 /-0.25N	The longer length of the 4x30mm device resulted in a higher radial force specification. Bench and animal testing has demonstrated that the higher radial force specification does not affect the safety and effectiveness of the device. No evidence of vessel dissection or perforation demonstrated in animal testing using Trevo XP ProVue retriever (6x30mm, as worst case size for 4x30mm).
	Radial Force at 3.0mm diameter: ≤0.5 N	Same	N/A
Packaging Materials and Configuration	Polyethylene Hoop, polycarbonate mounting card, Tyvek/Film Pouch, HDPE Tubing Clips, Chipboard carton	Same	N/A
Sterilization Method	100% EtO	Same	N/A
How Supplied	Sterile/Single Use	Same	N/A

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 are appropriate for use in determining that the Trevo XP ProVue Retriever (4x30mm) is substantially equivalent to the predicate device.

The modifications did not result in the identification of any new failure modes nor were there any changes to existing failure modes, including no change to severity or occurrence; and, therefore, no change to overall residual risk.

Testing Summary

Performance Data – Bench

The results of verification and validation testing conducted on the Trevo XP ProVue Retriever (4x30mm) demonstrate that it performs as designed, and is suitable for its intended use. The verification and validation test results demonstrate that the Trevo XP ProVue Retriever (4x30mm) is substantially equivalent to the predicate device. Specifically, the following tests were performed on the subject device:

Test	Test Method Summary	Conclusions
Dimensional Verification	Verified dimensions using specified measurement tool.	Dimensional verification meets acceptance criteria.
Retriever Mid Joint Tensile Strength	Identify joint and prepare sample for test. Use Instron tensile tester to determine applied peak tensile force. Record results.	Retriever Mid Joint Tensile Strength meets acceptance criteria.
Retriever Tip Tensile Strength	Load sample. Use Instron tensile tester to determine applied peak tensile force. Record results. Repeat until remaining distal cells with markers are tested. Record results.	Retriever Tip Tensile Strength meets acceptance criteria.
Retriever Shaped Section Radial Force	Constrain shaped section of retriever and release to specified diameter. Use Instron tensile tester and Blockwise RF iris fixture to determine applied force at the specified diameter. Record results.	Retriever Shaped Section Radial Force meets acceptance criteria.
Retriever / Vessel Interaction (Tip Flexibility)	Load sample so that the distal tip will be flexed. Use Instron tensile tester to determine applied peak compression/flex force. Record results.	Retriever/Vessel Interaction (Tip Flexibility) meets acceptance criteria.
Retriever Torque Tensile Durability	Grip shape section and core wire. Apply two full rotations to core wire grips to torque device. Instron pulls five tensile cycles to 1.7lbs then sixth cycle to failure. Record results.	Retriever Torque Tensile Durability meets acceptance criteria.
Retriever Platinum Wire Joint Strength	Identify joint and cut platinum wire, freeing it from the shaped section for test. Use Instron tensile tester to determine applied peak tensile force on individual platinum wire. Record results.	Retriever Platinum Wire Joint Strength meets acceptance criteria.

Test	Test Method Summary	Conclusions
Retriever Platinum Wire and Joint Durability	Wrap and unwrap the entire length of the shaped section of the retriever (sheathed in its insertion tool) around a 2.0 mm pin. Repeat for a total of 6 wrap-unwrap cycles. Perform visual inspection and record results. Perform 10 deploy/reload cycles into insertion tool. Perform visual inspection and record results.	Retriever Platinum Wire and Joint Durability meet acceptance criteria.
Radiopacity	Radiopacity is assessed based on visual assessment of the device being used under fluoroscopy per acceptance criteria.	Same platinum weave wires (same diameter and composition) and configuration (weave design) as the predicate device (Trevo XP ProVue 4x20), therefore previous data remains valid. Radiopacity meets acceptance criteria.
Retriever / Microcatheter Deliverability	Measure the force to push the device through a tortuous model in a 37degC water bath. Record maximum force from the first 5 cm push.	Retriever/Microcatheter Deliverability meets acceptance criteria.
Particulate Evaluation	Measured total number of particulate and size of particulate generated during the simulated delivery, deployment and resheathing of the device. Particulate counting was assessed for $\geq 10\mu\text{m}$, $\geq 25\mu\text{m}$, and $\geq 50\mu\text{m}$ size ranges	All samples meet acceptance criteria.
Coating Integrity Evaluation	An assessment of coating lubricity and durability using a test model to evaluate friction encountered from full circumferential contact of the coated core wire with pads. The hydrated core wires (hydration simulates an aqueous environment) are pulled through the rubber pads using a calibrated tensile machine so that the resistance can be measured and recorded.	All samples meet acceptance criteria.

Test	Test Method Summary	Conclusions
Simulated Use	Simulated use testing uses a neurovascular model cast from actual human neurovascular arteries. This bench testing model replicates the tortuosity, diameter and location of the arteries in the neurovasculature. The model incorporates a re-circulating water bath at 37°C pressurized between 2 – 2.5 psi (100 – 126mm Hg) to simulate the human arterial circulation. All testing follows the procedural instructions outlined in the Instructions for Use.	Simulated Use meets acceptance criteria.

Performance Data – Animal

Animal Studies (acute and chronic) were conducted to demonstrate safety of the Trevo XP ProVue Retriever using a larger diameter device (6x30mm) than the subject device (4x30mm). A Trevo XP ProVue Retriever 6x30mm test article was developed for use in animal testing. The 6x30mm Trevo XP ProVue Retriever test article is comparable in design (i.e., same materials and similar tip design, cell size and distal truncation) and coating material to the Trevo XP ProVue Retriever 4x30mm design, except for the diameter (and associated radial force) which were increased to allow for a “worst case.” The 6x30mm devices are worst case devices for assessing retriever/vessel interaction because they have a higher radial force part specification than the subject device. Animal studies were conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58). The 6x30mm devices were deployed and animals were evaluated for evidence of arterial transmural dissection or perforation. The safety and usability results from the animal studies met acceptance criteria and suggest that the subject device is safe, usable and is equivalent to the predicate device.

Performance Data – Clinical

No clinical study was performed as there is no change to the indications for use or the fundamental scientific technology for the subject device. Substantial equivalence of the subject device has been established to the predicate device through the results of bench and animal testing.

Sterilization and Shelf life

The Trevo XP ProVue Retriever (4x30mm) is sterilized by 100% Ethylene Oxide using an identical method (including sterilization chamber) to the predicate device, Trevo ProVue Retriever (K132641) and to an earlier device iteration (Trevo ProVue Retriever). The materials of construction and packaging are identical to the predicate device. Therefore, the results from the Trevo ProVue sterilization validation are applicable to the subject device (Trevo XP ProVue Retriever 4x30mm) and no additional sterilization validation testing is required.

Ethylene oxide (EO) residual testing for the Trevo XP ProVue Retriever 4x30mm was adopted from the predicate device, Trevo ProVue Retriever (K132641) and an earlier device iteration (Trevo ProVue Retriever) as the materials and packaging are identical to the predicate device.

Aging studies for the Trevo XP ProVue Retriever (4x30mm) have established the product remains functional and maintains sterility through the proposed shelf life. Since the packaging materials and configuration are identical to the predicate device, aging studies previously conducted for packaging integrity remain valid and no new packaging testing is required for the Trevo XP ProVue Retriever (4x30mm).

Biocompatibility

The Trevo XP ProVue Retriever (4x30mm) was assessed for impact to biocompatibility. Materials used in the Trevo XP ProVue Retriever (4x30mm) are all the same materials used in the cleared Trevo ProVue Retriever (K132641). Both the Trevo XP ProVue Retriever (4x30mm) 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.

Summary of Substantial Equivalence

The Trevo XP ProVue Retriever (4x30mm) 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 Trevo XP ProVue Retriever (4x30mm) demonstrate that the device performs as designed, is suitable for its intended use and is substantially equivalent to the legally marketed predicate device.