



Food and Drug Administration
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September 2, 2016

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

Re: DEN150049
Trevor ProVue and XP ProVue Retrievers
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 882.5600
Regulation Name: Neurovascular Mechanical Thrombectomy Device for Acute Ischemic
Stroke Treatment
Regulatory Classification: Class II
Product Code: POL
Dated: October 22, 2015
Received: October 26, 2015

Dear Ms. Santos:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the Trevor ProVue and XP ProVue Retrievers, prescription devices under 21 CFR Part 801.109 that are indicated “*for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion, and smaller core infarcts who have first received intravenous tissue plasminogen activator (IV t-PA). Endovascular therapy with the device should start within 6 hours of symptom onset.*” FDA concludes that this device should be classified into class II. This order, therefore, classifies the Trevor ProVue and XP ProVue Retrievers, and substantially equivalent devices of this generic type, into class II under the generic name, Neurovascular Mechanical Thrombectomy Device for Acute Ischemic Stroke Treatment.

FDA identifies this generic type of device as:

Neurovascular Mechanical Thrombectomy Device for Acute Ischemic Stroke Treatment.

A neurovascular mechanical thrombectomy device for acute ischemic stroke treatment is a prescription device used in the treatment of acute ischemic stroke to improve clinical outcomes. The device is delivered into the neurovasculature with an endovascular approach, mechanically removes thrombus from the body, and restores blood flow in the neurovasculature.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not

substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On October 26, 2015, FDA received your *de novo* requesting classification of the Trevo ProVue and XP ProVue Retrievers into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Trevo ProVue and XP ProVue Retrievers into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the Trevo ProVue and XP ProVue Retrievers indicated “*for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion, and smaller core infarcts who have first received intravenous tissue plasminogen activator (IV t-PA). Endovascular therapy with the device should start within 6 hours of symptom onset,*” can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measure
Adverse Tissue Reaction	Biocompatibility Evaluation
Infection	Sterility Testing Shelf-life Testing Labeling
Tissue or Vessel Damage: <ul style="list-style-type: none"> • Dissection • Perforation • Hemorrhage 	Non-clinical Performance Testing Clinical Performance Testing Labeling
Stroke Progression	Non-clinical Performance Testing Clinical Performance Testing Labeling
Emboli	Non-clinical Performance Testing Clinical Performance Testing Labeling

In combination with the general controls of the FD&C Act, the Neurovascular Mechanical Thrombectomy Device for Acute Ischemic Stroke Treatment is subject to the following special controls:

1. The patient contacting components of the device must be demonstrated to be biocompatible.
2. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including:
 - a. Mechanical testing to demonstrate the device can withstand anticipated tensile, torsional, and compressive forces.
 - b. Mechanical testing to evaluate the radial forces exerted by the device.
 - c. Non-clinical testing to verify the dimensions of the device.
 - d. Non-clinical testing must demonstrate the device can be delivered to the target location in the neurovasculature and retrieve simulated thrombus under simulated use conditions.
 - e. Non-clinical testing must demonstrate the device is radiopaque and can be visualized.
 - f. Non-clinical testing must evaluate the coating integrity and particulates under simulated use conditions.
 - g. Animal testing must evaluate the safety of the device, including damage to the vessels or tissue under anticipated use conditions.
3. Performance data must support the sterility and pyrogenicity of the patient contacting components of the device.
4. Performance data must support the shelf-life of the device by demonstrating continued sterility, package integrity, and device functionality over the specified shelf-life.
5. Clinical performance testing of the device must demonstrate the device performs as intended for use in the treatment of acute ischemic stroke and must capture any adverse events associated with the device and procedure.
6. The labeling must include:
 - a. Information on the specific patient population for which the device is intended for use in the treatment of acute ischemic stroke, including but not limited to, specifying time from symptom onset, vessels or location of the neurovasculature that can be accessed for treatment, and limitations on core infarct size.
 - b. Detailed instructions on proper device preparation and use for thrombus retrieval from the neurovasculature.
 - c. A summary of the clinical testing results, including a detailed summary of the device- and procedure-related complications and adverse events.
 - d. A shelf life.

In addition, this is a prescription device and must comply with 21 CFR 801.109. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Neurovascular Mechanical Thrombectomy Device for Acute Ischemic Stroke Treatment they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C 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 FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Leigh Anderson at (301) 796-6610.

Sincerely,

Jonette Foy, Ph.D.
Deputy Director
for Engineering and Science Review
Office of Device Evaluation
Center for Devices and
Radiological Health