August 27, 2021

Stryker Neurovascular
Rebecca Rosman
Senior Staff Regulatory Affairs Specialist
47900 Bayside Parkway
Fremont, California 94538

Re: K210502
Trade/Device Name: Trevo NXT ProVue Retriever
Regulation Number: 21 CFR 882.5600
Regulation Name: Neurovascular Mechanical Thrombectomy Device for Acute Ischemic Stroke Treatment
Regulatory Class: Class II
Product Code: POL, NRY
Dated: July 22, 2021
Received: July 26, 2021

Dear Rebecca Rosman:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Xiaolin Zheng, Ph.D.
Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210502

Device Name
Trevo NXT™ ProVue Retriever

Indications for Use *(Describe)*

1. The Trevo Retriever is 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.

2. 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.

3. The Trevo Retriever is 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 of the internal carotid artery (ICA) or middle cerebral artery (MCA)-M1 segments with smaller core infarcts (0-50cc for age <80 years, 0-20cc for age ≥80 years). Endovascular therapy with the device should start within 6-24 hours of time last seen well in patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy.

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
K210502

Introduction:

According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for a determination of substantial equivalence.

Submitter Name, Address and Content:

Submitter: Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538-6515
(FDA Registration Number: 3008853977)

Contact: **Ashley Twitty**
Manager, Regulatory Affairs
Phone: 602-621-3089
Fax: 510-413-2588
Email: ashley.twitty@stryker.com

Date Prepared: August 23, 2021

Device Name and Classification:

Trade/Proprietary Name: Trevo NXT™ ProVue Retriever

Common Name: Trevo Retriever

Classification Name: Neurovascular Mechanical Thrombectomy Device for Acute Ischemic Stroke Treatment, 21 CFR 882.5600, Class II
Percutaneous Catheter, 21CFR 870.1250 – Class II

Product Code: POL, NRY

Legally Marketed Predicate Device

Name of Predicate Device	Name of Manufacturer	510(k) Number
Trevo NXT™ ProVue Retriever	Stryker Neurovascular	**K203219**

Device Description

The Trevo 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. The Retriever delivery wire has a hydrophilic coating on the distal 101cm length 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 and retrieval. The Retriever comes preloaded in an insertion tool to introduce the Retriever into a Microcatheter.

Indications for Use

1. The Trevo Retriever is 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.

2. 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.

3. The Trevo Retriever is 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 of the internal carotid artery (ICA) or middle cerebral artery (MCA)-M1 segments with smaller core infarcts (0-50cc for age <80 years, 0-20cc for age ≥80 years). Endovascular therapy with the device

should start within 6-24 hours of time last seen well in patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy.

Technological Characteristics and Product Feature Comparison

Stryker Neurovascular has demonstrated the Trevo NXT ProVue Retriever with the modified IFU is substantially equivalent to the Predicate device, Trevo NXT ProVue Retriever (**K203219**) based on the same indications for use, device design, materials, manufacturing, packaging and sterilization methods. A comparison of the Subject device with the Predicate device is summarized in **Table 1** below.

Table 1. Product Feature Comparison of Subject Device to Predicate Device

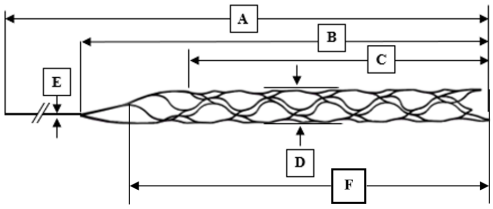
Feature	**Predicate Device** **Trevo NXT ProVue Retriever**	**Subject Device** **Trevo NXT ProVue Retriever**
Regulation Number	• 21 CFR 882.5600 • 21 CFR 870.1250	Same
Regulation Name	• Neurovascular Mechanical Thrombectomy Device for Acute Ischemic Stroke Treatment • Percutaneous Catheter	Same
Classification	Class II	Same
Product Code	• POL • NRY	Same
Intended Use	Neurovascular mechanical thrombectomy device for acute ischemic stroke treatment used in the treatment of acute ischemic stroke to improve clinical outcomes.	Same
Indications for Use	1. The Trevo Retriever is 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. 2. 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	Same

Feature	Predicate Device Trevo NXT ProVue Retriever	Subject Device Trevo NXT ProVue Retriever
	(IV t-PA) or who fail IV t-PA therapy are candidates for treatment. 3. The Trevo Retriever is 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 of the internal carotid artery (ICA) or middle cerebral artery (MCA)-M1 segments with smaller core infarcts (0-50cc for age <80 years, 0-20cc for age ≥80 years). Endovascular therapy with the device should start within 6-24 hours of time last seen well in patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy.	
Target Population	Patients experiencing acute ischemic stroke	Same
Anatomical Sites	Neurovasculature	Same
TECHNOLOGICAL CHARACTERISTICS		
Device Description	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. The Retriever delivery wire has a hydrophilic coating on the distal 101cm 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 and retrieval. The Retriever comes preloaded in an insertion tool to introduce the Retriever into a Microcatheter.	Same
Principle of Operation	The Trevo Retriever is delivered to the thrombus using a microcatheter. The Microcatheter is then retracted to deploy the shaped section of the Retriever. If using an Aspiration Catheter, remove Microcatheter. Advance Aspiration Catheter over proximal section of Retriever while applying aspiration using a 60 mL syringe or an aspiration pump. The Retriever with Microcatheter or Aspiration Catheter are	Same

<table>
<tr><th>Feature</th><th><u>Predicate Device</u>
Trevo NXT ProVue Retriever</th><th><u>Subject Device</u>
Trevo NXT ProVue Retriever</th></tr>
<tr><td></td><td>pulled back to capture the thrombus. The Retriever, thrombus, and Microcatheter or Aspiration Catheter are removed as a unit from the body.</td><td></td></tr>
<tr><td>Procedural Steps Aspiration Source</td><td>Syringe, Aspiration pump</td><td>Same</td></tr>
<tr><td>Accessory Devices</td><td>Insertion tool and torque device provided within product package</td><td>Same</td></tr>
<tr><td>Sizes</td><td>3x32mm
4x28mm
4x41mm
6x37mm</td><td>Same</td></tr>
<tr><td>Compatibility</td><td>
<table>
<tr><th>Retriever Size</th><th>Trevo Pro14 Microcatheter Inner Diameter 0.017 inches (0.43 mm)</th><th>Trevo Trak 21 Microcatheter Inner Diameter 0.021 inches (0.53 mm)</th><th>Trevo Pro18 Microcatheter Inner Diameter 0.021 inches (0.53 mm)</th><th>Excelsior® XT-27® Microcatheter (REF XT275081) Inner diameter 0.027 inches (0.69 mm)</th><th>Recommended Minimum Vessel ID (mm)</th></tr>
<tr><td>Trevo NXT 3x32</td><td>✓</td><td>✓</td><td>✓</td><td>✓</td><td rowspan="4">2.5</td></tr>
<tr><td>Trevo NXT 4x28</td><td></td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>Trevo NXT 4x41</td><td></td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>Trevo NXT 6x37</td><td></td><td>✓</td><td>✓</td><td>✓</td></tr>
</table>
Compatibility of the Retriever with other microcatheters has not been established. Performance of the Retriever device may be impacted if a different microcatheter is used.

Balloon Guide Catheters and Aspiration Catheters (commercially available aspiration catheters with minimum inner diameter 0.058 inches (1.47mm)) are recommended for use during thrombus removal procedures.</td><td>
<table>
<tr><th>Retriever Size</th><th>Trevo Pro14 Microcatheter Inner Diameter 0.017 inches (0.43 mm)</th><th>Trevo Trak 21 Microcatheter Inner Diameter 0.021 inches (0.53 mm)</th><th>Trevo Pro18 Microcatheter Inner Diameter 0.021 inches (0.53 mm)</th><th>Excelsior® XT-27® Microcatheter (REF XT275081) Inner diameter 0.027 inches (0.69 mm)</th><th>Recommended Minimum Vessel ID (mm)</th></tr>
<tr><td>Trevo NXT 3x32</td><td>✓</td><td>✓</td><td>✓</td><td>✓</td><td rowspan="4">2.5</td></tr>
<tr><td>Trevo NXT 4x28</td><td></td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>Trevo NXT 4x41</td><td></td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>Trevo NXT 6x37</td><td></td><td>✓</td><td>✓</td><td>✓</td></tr>
</table>
Compatibility of the Retriever with other microcatheters has not been established. Performance of the Retriever device may be impacted if a different microcatheter is used.

Balloon Guide Catheters and Aspiration Catheters (commercially available aspiration catheters with minimum inner diameter 0.046 inches (1.17mm)) are recommended for use during thrombus removal procedures.</td></tr>
<tr><td colspan="3">MATERIALS</td></tr>
<tr><td>Core Wire</td><td>Nitinol (nickel titanium alloy)</td><td>Same</td></tr>
<tr><td>Shaped Section</td><td>Nitinol</td><td>Same</td></tr>
<tr><td>Distal Coil</td><td>Platinum/Tungsten</td><td>Same</td></tr>
<tr><td>Shaped Section Radiopaque Wire</td><td>Platinum/Tungsten</td><td>Same</td></tr>
<tr><td>Mid Coil</td><td>304 Stainless Steel</td><td>Same</td></tr>
<tr><td>Proximal Coil</td><td>Pebax</td><td>Same</td></tr>
<tr><td>Solder</td><td>Gold/Tin</td><td>Same</td></tr>
</table>

Feature	**Predicate Device** **Trevo NXT ProVue Retriever**	**Subject Device** **Trevo NXT ProVue Retriever**
Hydrophilic Coating	Sodium hyaluronate mixture	Same
DIMENSIONAL DRAWING		
Dimensional Drawing	All Retriever sizes:  	All Retriever sizes: Same
Overall Length (A)	200cm	Same
Total Shaped Section Length (B)	32, 36, 40, 44mm	Same
Full Diameter Length (C)	21, 25, 30, 35mm	Same
Shaped Section Diameter (D)	3, 4, 6mm	Same
Delivery Core Wire Outer Diameter (E)	0.015, 0.019”	Same
Cell Coverage Length (F)	28, 32, 37, 41mm	Same
PACKAGING		
Materials and Configuration	Polyethylene Hoop, polycarbonate mounting card, Tyvek/Film Pouch, Chipboard carton	Same
Sterilization Method	100% EtO	Same
How Supplied	Sterile/Single Use	Same

The differences between the devices are not critical as demonstrated above and through the testing referenced below.

Risk Assessment

Risk assessment of the Trevo NXT ProVue Retriever has been conducted in accordance with EN ISO 14971. Stryker Neurovascular has determined that the labeling changes to the Trevo NXT ProVue Retriever raise no new questions of safety or effectiveness. Results of testing are appropriate for determining that the Trevo NXT ProVue Retriever with the modified IFU is substantially equivalent to the legally marketed Predicate device.

Testing Summary

There are no changes to the device intended use or indications for use statement. Other than the proposed labeling changes regarding compatibility, there are no changes in the device design, materials, manufacturing, packaging and sterilization methods; therefore, biocompatibility data, bench performance data, sterilization and stability data from the Predicate device (**K203219**) are directly applicable. Relevant testing data supporting the Subject device are summarized as follows.

Performance Data – Bench Testing

Stryker Neurovascular performed the following non-clinical bench test to assess the usability of the Trevo Retriever with 0.046 in. ID aspiration catheters. The additional bench testing is summarized in **Table 2** below.

Table 2. Performance Data - Design Verification Bench Testing

Test	Test Method Summary	Conclusions
Simulated Use	Simulated Use testing utilized a neurovascular model to assess the device's ability to retrieve the clot and achieve recanalization.	Simulated Use testing met acceptance criteria.
Particulate Characterization	Purpose: The purpose of this test was to document and assess the particulate matter generated from the delivery of neuro-interventional devices (including the Trevo NXT ProVue Retriever) through the inner lumen of the AXS Vecta 46 Intermediate Catheter. Method: Particulate testing was conducted with AXS Vecta 46 and Trevo NXT ProVue Retriever in a simulated use condition based on the device IFU and a clinically relevant tortuous model.	All test samples met the applicable user needs and acceptance criteria.

Performance Data – Animal

To support the labeling modification, Stryker Neurovascular leveraged data from an animal study that was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58) to evaluate vascular trauma, recanalization and/or distal emboli of the proposed devices for performing a combined neurothrombectomy procedure.

Performance Data – Clinical

To support the labeling modifications, Stryker Neurovascular conducted analyses of Real-World Data (RWD) from an administrative claims database, post-market registries (The Trevo Retriever Registry and The ASSIST Registry), as well as a review of relevant literature to assess safety and effectiveness of the recommended use of the Trevo with aspiration catheters with a minimum inner diameter (ID) of 0.046in (1.17mm).

Regression analysis of RWD indicated that using Trevo with smaller aspiration catheters is equivalent to using Trevo with larger aspiration catheters with similar odds of good functional outcome (0.72; 95% CI: 0.44-1.17) and similar odds for multiple safety endpoints. Further analysis of registry data confirmed equivalence of revascularization rates and clinical outcomes independent of catheter size with the 90% CI for the difference in means of the severity adjusted posterior probabilities for eTICI≥2c to be from 0.003 to 0.009 (.30% to 0.90%). For 90-day MRS, the CI was from -0.050 to 0.042 (-5.0% to 4.2%). In both cases, the upper and lower bounds of the intervals were within the equivalence margin of ±5%.

Shelf Life Testing

Shelf life testing previously conducted for the Trevo NXT ProVue Retriever was leveraged to support the changes to the device and can be found in **K192207**. Shelf life testing was not performed on the Subject device since there was no impact to device material, design, or safety and efficacy as a result of the labeling changes. As with the Predicate device, the Subject device is labeled with a 2-year shelf life.

Sterilization

Sterilization evaluation previously conducted for the Trevo NXT ProVue Retriever was leveraged to support the labeling changes to the device and can be found in **K192207**. The Trevo

NXT ProVue Retrievers are sterilized with 100% Ethylene Oxide and provided sterile. A sterility assurance level (SAL) of 10^{-6} has been demonstrated. The Trevo NXT ProVue Retrievers meet EO residuals per EN ISO 10993-7 for limited contacting, externally communicated devices. The Trevo NXT ProVue Retrievers are for single use only.

Biocompatibility

Biocompatibility testing previously conducted for the Trevo NXT ProVue Retriever was leveraged to support the labeling changes to the device and can be found in **K192207**. The results of biocompatibility testing, and biological safety evaluation of the Trevo NXT ProVue Retrievers demonstrate that the devices meet biological safety requirements per ISO 10993-1 for externally communicating medical devices with circulating blood contact for less than 24 hours. The Trevo NXT ProVue Retrievers are considered to have no residual risk of biological hazards. Also, the devices and its packaging do not contain detectable latex. Therefore, the Trevo NXT ProVue Retriever devices, accessories, and primary packaging are considered biocompatible for their intended use.

Conclusion

Based on the conclusions drawn from risk assessment, bench testing results, Real World Data from an Administrative Claims, and an analysis of relevant clinical literature summarized above, the Subject device demonstrates substantial equivalence to the legally marketed Predicate device (**K203219**).