June 25, 2019

Stryker Neurovascular
Rhoda M. Santos
Senior Principal Regulatory Affairs Specialist
47900 Bayside Parkway
Fremont, California 94538

Re: K190779
Trade/Device Name: Trevo XP 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: March 26, 2019
Received: March 27, 2019

Dear Rhoda M. 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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.
Assistant 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190779

Device Name
Trevo XP 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 (0-50 cc for age < 80 years, 0-20 cc 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

Trade Name:	Trevo XP ProVue Retriever
Common Name:	Trevo Retrievers
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
Submitter:	**Stryker Neurovascular** 47900 Bayside Parkway Fremont, CA 94538 Tel 510-413-2269 Fax 510-413-2724 Facility Registration #3008853977
Contact:	**Rhoda M. Santos** Senior Principal Regulatory Affairs Specialist
Date Prepared:	**March 26, 2019**
Primary Predicate Device:	**Trevo XP ProVue Retriever (K173352)**
Reference Predicate Device:	**Trevo Retriever (K120961)**

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 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 and retrieval. An insertion tool is provided to introduce the Retriever into a Microcatheter. The Insertion Tool is a sheath in which the Retriever comes preloaded. Once half the retriever's length is inserted into the microcatheter, the insertion tool is removed. Retrievers have a modified proximal end that permits attachment of the Abbott Vascular DOC Guide Wire Extension (REF 22260). Joining the Guide Wire Extension to the Retriever facilitates removal or exchange of a catheter while maintaining the Retriever position in anatomy. After the exchange has been completed, the extension can be detached.

Accessories

The Retriever is provided with two accessories: a torque device which facilitates manipulation of the Retriever, and an insertion tool that is used to introduce the Retriever into a Microcatheter.

Indications for Use

The Indications for Use are as follows:

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 (0-50 cc for age < 80 years, 0-20 cc 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

The Trevo XP ProVue Retriever subject devices are identical to the Primary Predicate and Reference Predicate devices and differ only by the modifications to the Instructions for Use (IFU). The technological characteristics and principles of operation remain unchanged except for the alternate use of an aspiration catheter with an aspiration pump. There are no changes in the device design, materials, manufacturing, packaging and sterilization methods; therefore, biocompatibility, bench-top data, sterilization and stability data from the Primary Predicate device (**K173352**) and Reference Predicate device (**K120961**) are directly applicable.

Table 1 below provides a comparison between the Subject, the Primary Predicate and Reference Predicate devices.

Table 1: Product Feature Comparison of Subject Device to Primary Predicate Device and Reference Predicate Device

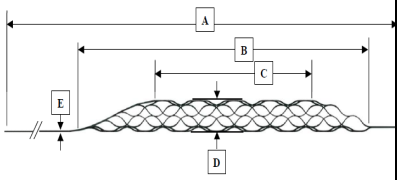
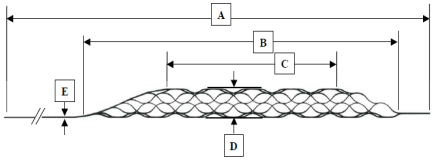
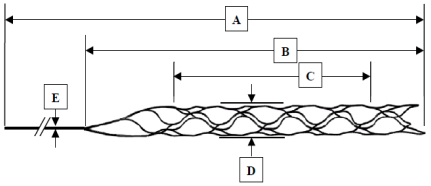
Feature	Reference Predicate Device Trevo ProVue Retriever (K120961)	Primary Predicate Device Trevo ProVue Retriever and Trevo XP ProVue Retriever (K173352)	Subject Device Trevo XP ProVue Retriever with Modified DFU	Rationale for Modification (if applicable)
Intended Use	The Trevo Retriever is intended 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-tPA) or who fail IV t-PA therapy are candidates for treatment.	Neurovascular mechanical thrombectomy device for acute ischemic stroke treatment used in the treatment of acute ischemic stroke to improve clinical outcomes.	Same as predicate K173352.	Not applicable.
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-tPA) or who fail IV t-PA therapy are candidates for treatment.	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	Same as predicate K173352.	Not applicable.

Feature	Reference Predicate Device Trevo ProVue Retriever (K120961)	Primary Predicate Device Trevo ProVue Retriever and Trevo XP ProVue Retriever (K173352)	Subject Device Trevo XP ProVue Retriever with Modified DFU	Rationale for Modification (if applicable)
		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 (0-50 cc for age < 80 years, 0-20 cc 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.		
REGULATORY INFORMATION				
Regulation Number/ Name/ Class/ Product Code	21 CFR 870.1250, Percutaneous Catheter, Class II, NRY	21 CFR 882.5600 / Neurovascular Mechanical Thrombectomy Device for Acute Ischemic Stroke Treatment, Class II, POL 21 CFR 870.1250, Percutaneous Catheter, Class II, NRY	Same as predicate K173352.	Not applicable.
Target Population	Patients experiencing acute ischemic stroke		Same as predicate K173352 and K120961.	Not applicable.
Anatomical Sites	Neurovasculature		Same as predicate K173352 and K120961.	Not applicable.
TECHNOLOGICAL CHARACTERISTICS				

Feature	Reference Predicate Device Trevo ProVue Retriever (K120961)	Primary Predicate Device Trevo ProVue Retriever and Trevo XP ProVue Retriever (K173352)	Subject Device Trevo XP ProVue Retriever with Modified DFU	Rationale for Modification (if applicable)
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. 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.	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 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. 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 Insertion Tool is a sheath in which the Retriever comes preloaded. Once half the retriever's length is inserted into the microcatheter, the insertion tool is removed. Retrievers have a modified proximal end that permits attachment of the Abbott Vascular DOC Guide Wire Extension (REF 22260). Joining Guide Wire Extension to Retriever facilitates removal or exchange of a catheter while maintaining Retriever position in anatomy. After exchange has been completed, the extension can be detached.	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 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 and retrieval. An insertion tool is provided to introduce the Retriever into a Microcatheter. The Insertion Tool is a sheath in which the Retriever comes preloaded. Once half the retriever's length is inserted into the microcatheter, the insertion tool is removed. Retrievers have a modified proximal end that permits attachment of the Abbott Vascular DOC Guide Wire Extension (REF 22260). Joining Guide Wire Extension to Retriever facilitates removal or exchange of a catheter while maintaining Retriever position in anatomy. After exchange has been completed, the extension can be detached.	Clarification for use of Retriever.

Feature	**Reference Predicate Device** **Trevo ProVue Retriever (K120961)**	**Primary Predicate Device** **Trevo ProVue Retriever and Trevo XP ProVue Retriever (K173352)**	**Subject Device** **Trevo XP ProVue Retriever with Modified DFU**	**Rationale for Modification (if applicable)**
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. The Retriever and Microcatheter are pulled back to capture the thrombus. The Retriever, thrombus and Microcatheter are then removed from the body.		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 pulled back to capture the thrombus. The Retriever, thrombus, and Microcatheter or Aspiration Catheter are removed as a unit from the body.	Revised to reflect alternative use of Aspiration Catheter with an aspiration pump. Bench testing, clinical data, and a review of relevant clinical literature demonstrates the alternative aspiration source does not raise new issues of safety or effectiveness.
Procedural Steps Aspiration Source	Syringe		Aspiration pump	Bench testing, clinical data, and a review of relevant clinical literature demonstrates the alternative aspiration source does not raise new issues of safety or effectiveness.
Sizes	4x20mm	3x20mm, 4x20mm, 4x30mm, 6x25mm	Same as predicate K173352.	Not applicable.
Accessory Devices	Insertion tool and torque device provided within product package		Same as predicate K173352 and K120961.	Not applicable.

<table>
<tr><th>Feature</th><th><u>Reference Predicate Device</u>
Trevo ProVue Retriever (K120961)</th><th><u>Primary Predicate Device</u>
Trevo ProVue Retriever and Trevo XP ProVue Retriever (K173352)</th><th><u>Subject Device</u>
Trevo XP ProVue Retriever with Modified DFU</th><th>Rationale for Modification (if applicable)</th></tr>
<tr><td>Compatibility</td><td><table><tr><td>Retriever size</td><td>Trevo 18 MC</td></tr><tr><td>Trevo ProVue 4X20mm</td><td>✓</td></tr></table></td><td><table><tr><td>Retriever size</td><td>Trevo Pro14 MC</td><td>Trevo Pro18 MC</td><td>Excelsior ® XT-27® Microcatheters (150cm x 6cm straight REF 275081)</td><td>Recommended Vessel Minimum ID (mm)</td></tr><tr><td>Trevo XP ProVue 3X20mm</td><td>✓</td><td>✓</td><td></td><td rowspan="5">2.5</td></tr><tr><td>Trevo XP ProVue 4X20mm</td><td></td><td>✓</td><td></td></tr><tr><td>Trevo ProVue 4X20mm</td><td></td><td>✓</td><td></td></tr><tr><td>Trevo XP ProVue 4X30mm</td><td></td><td>✓</td><td>✓</td></tr><tr><td>Trevo XP ProVue 6X25mm</td><td></td><td></td><td>✓</td></tr></table></td><td>Same as predicate K173352.</td><td>Not applicable.</td></tr>
<tr><td colspan="5">Materials</td></tr>
<tr><td>Core Wire</td><td colspan="2">Nitinol (nickel titanium alloy)</td><td>Same as predicate K173352 and K120961.</td><td>Not applicable.</td></tr>
<tr><td>Shaped Section</td><td colspan="2">Nitinol</td><td>Same as predicate K173352 and K120961.</td><td>Not applicable.</td></tr>
<tr><td>Distal Coil</td><td colspan="2">Platinum/Tungsten</td><td>Same as predicate K173352 and K120961.</td><td>Not applicable.</td></tr>
<tr><td>Shaped Section Radiopaque Wire</td><td>Not applicable.</td><td>Platinum/Tungsten</td><td>Same as predicate K173352.</td><td>Not applicable.</td></tr>
<tr><td>Proximal Coil</td><td colspan="2">304 Stainless Steel</td><td>Same as predicate K173352 and K120961.</td><td>Not applicable.</td></tr>
<tr><td>Solder</td><td colspan="2">Gold/Tin</td><td>Same as predicate K173352 and K120961.</td><td>Not applicable.</td></tr>
<tr><td>Hydrophilic Coating</td><td colspan="2">Sodium hyaluronate mixture</td><td>Same as predicate K173352 and K120961.</td><td>Not applicable.</td></tr>
<tr><td colspan="5">Dimensions</td></tr>
</table>

Feature	Reference Predicate Device Trevo ProVue Retriever (K120961)	Primary Predicate Device Trevo ProVue Retriever and Trevo XP ProVue Retriever (K173352)	Subject Device Trevo XP ProVue Retriever with Modified DFU	Rationale for Modification (if applicable)
Dimensional Drawing	Trevo ProVue Retriever: 	Trevo ProVue Retriever:  Trevo XP ProVue Retriever: 	Same as predicate K173352.	Not applicable.
Overall Length (A)	180cm	180, 190cm	Same as predicate K173352.	Not applicable.
Total Shaped Section Length (nominal) (B)	37mm	32, 36, 37, 40, 44mm	Same as predicate K173352.	Not applicable.
Active Shaped Section Length (nominal) (C)	20mm	20, 25, 30mm	Same as predicate K173352.	Not applicable.
Shaped Section Diameter (nominal) (D)	4mm	3, 4, 6mm	Same as predicate K173352.	Not applicable.
Proximal Core Wire Diameter (E)	0.018 inches	0.015, 0.018 inches	Same as predicate K173352.	Not applicable.
Packaging				
Materials and Configuration	Polyethylene Hoop, polycarbonate mounting card, Tyvek/Film Pouch, HDPE Tubing Clips, Chipboard carton		Same as predicate K173352 and K120961.	Not applicable.
Sterilization Method	100% EtO		Same as predicate K173352 and K120961.	Not applicable.
How Supplied	Sterile/Single Use		Same as predicate K173352 and K120961.	Not applicable.

Performance Data - Non-Clinical

Stryker Neurovascular performed the following non-clinical bench test to assess the usability of the Trevo Retriever with the AXS Catalyst Distal Access Catheter (DAC) as part of the AXS Universal Aspiration System.

Test	Test Method Summary	Conclusions
Simulated Use	Simulated Use testing utilized a neurovascular model with a re-circulating water bath at 37ºC to simulate the human arterial circulation and to assess the device's ability to retrieve the clot and achieve recanalization.	Simulated Use met acceptance criteria.

Performance Data - Clinical

To support the labeling modifications, Stryker Neurovascular conducted an analysis of Real World Data (RWD) from the Trevo Retriever Registry to assess safety or effectiveness on the combination use of Trevo Retriever and intermediate catheter aspiration approach in the clinical study. Additionally, a comprehensive review of relevant clinical literature supports the broad usage of various commercially available aspiration catheters and stent retrievers.

Conclusion

Based on the successful completion of the Simulated Use study, additional bench testing, and clinical data from the Trevo Registry and clinical literature review, the combination neurothrombectomy approach of using the Trevo® Retriever and the AXS Catalyst® Distal Access Catheter) with the AXS Universal™ Aspiration System as an alternative aspiration source for removal of thrombus in the neurovasculature is substantially equivalent to the Primary Predicate device (**K173352**) and Reference Predicate device (**K120961**).