December 29, 2020

Stryker Neurovascular
Kathy Nguyen
Staff Regulatory Affairs Specialist
47900 Bayside Parkway
Fremont, California 94538

Re: K203219
Trade/Device Name: Trevo XP ProVue Retriever, 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: October 30, 2020
Received: November 2, 2020

Dear Kathy Nguyen:

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,

for Naira Muradyan, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203219

Device Name
Trevo XP ProVue Retriever and 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)-Ml 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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: **Kathy Nguyen**
Staff Regulatory Affairs Specialist
Phone: 510-413-2366
Fax: 510-413-2588
Email: Kathy.Nguyen@stryker.com

Date Prepared: December 22, 2020

Device Name and Classification:

Trade/Proprietary Name: Trevo XP ProVue Retriever and 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, 21 CFR 870.1250 – Class II

Product Code: POL, NRY

Legally Marketed Predicate Device

Name of Predicate Device	Name of Manufacturer	510(k) Number
Trevo XP ProVue Retriever	Stryker Neurovascular	**K190779**
Trevo NXT™ ProVue Retriever	Stryker Neurovascular	**K200117**

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 (0-50 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

Stryker Neurovascular has demonstrated the Trevo XP ProVue Retriever and Trevo NXT ProVue Retriever is substantially equivalent to the Predicate device, Trevo XP Provue Retriever **(K190779)** and Trevo NXT ProVue Retriever (**K20117**) based on the same indications for use, device design, materials, manufacturing, packaging and sterilization methods.

Comparison of Technological Characteristics with the Primary Predicate Device:

The intended use remains as a neurovascular mechanical thrombectomy device for acute ischemic stroke treatment used in the treatment of acute ischemic stroke to improve clinical outcomes. The technological characteristics and principles of operation remain unchanged.

The Subject device is substantially equivalent to the Predicate device cleared under **K190779 & K200117** based on the following:

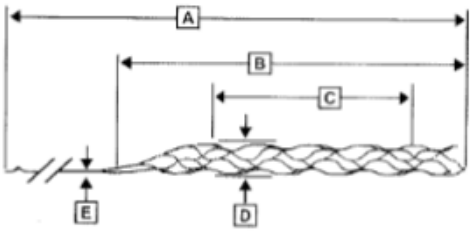
- Same indications for use
- Same materials and manufacturing processes
- Same device design and technology
- Same biocompatibility information
- Same materials and processes for packaging
- Same sterilization method and process for devices

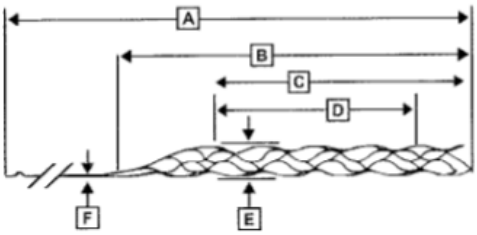
A comparison of the Subject device with the Predicate device is summarized in **Table 1** (Trevo XP ProVue Retriever) and **Table 2** (Trevo NXT ProVue Retriever) below.

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

Feature	Predicate Device Trevo XP ProVue Retriever (K190779)	Subject Device Trevo XP ProVue Retriever
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 (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.	Same
Regulation Number/ Name/ Class/ Product Code	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
Target Population	Patients experiencing acute ischemic stroke	Same
Anatomical Sites	Neurovasculature	Same

<table>
<tr><th>Feature</th><th><u>Predicate Device</u>
Trevo XP ProVue Retriever (K190779)</th><th><u>Subject Device</u>
Trevo XP ProVue Retriever</th></tr>
<tr><td>Device Description</td><td>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.</td><td>Same</td></tr>
<tr><td>Principle of Operation</td><td>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.</td><td>Same</td></tr>
<tr><td>Procedural Steps
Aspiration Source</td><td>Syringe, Aspiration pump</td><td>Same</td></tr>
<tr><td>Sizes</td><td>3x20mm
4x20mm
4x30mm
6x25mm</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>Compatibility</td><td>
<table>
<tr><th>Retriever Size</th><th>Trevo Pro14 Microcatheter</th><th>Trevo Pro18 Microcatheter</th><th>Excelsior® XT-27® Microcatheters (150cm x 6cm straight REF XT275081</th><th>Recommended Minimum Vessel ID (mm)</th></tr>
<tr><td>Trevo XP ProVue</td><td>√</td><td>√</td><td></td><td rowspan="5">2.5</td></tr>
<tr><td>Trevo XP ProVue</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</td></tr>
<tr><td>Core Wire</td><td>Nitinol (nickel titanium alloy)</td><td>Same</td></tr>
</table>

<table>
<tr><th>Feature</th><th><u>Predicate Device</u>
Trevo XP ProVue Retriever (K190779)</th><th><u>Subject Device</u>
Trevo XP ProVue Retriever</th></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>Outer Jacket</td><td>Not applicable.</td><td>Not applicable.</td></tr>
<tr><td>Mid Coil</td><td>304 Stainless Steel</td><td>Same</td></tr>
<tr><td>Proximal Coil / Proximal Support / Length</td><td>304 Stainless Steel</td><td>Same</td></tr>
<tr><td>Solder</td><td>Gold/Tin</td><td>Same</td></tr>
<tr><td>Hydrophilic Coating</td><td>Sodium hyaluronate mixture, L578 formulation</td><td>Same</td></tr>
<tr><td>Dimensional Drawing</td><td>3x20, 4x20mm Retriever sizes:
 

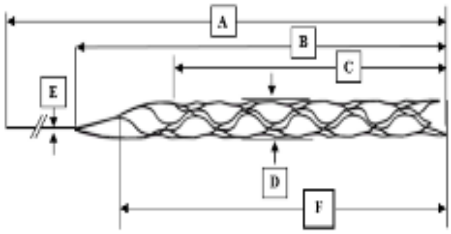
4x30, 6x25mm Retriever sizes:
 
</td><td>Same</td></tr>
<tr><td>Core Wire Dimension</td><td>Flatten Thickness
0.0030" +/- 0.0003"</td><td>Flatten Thickness
0.0040" +/- 0.0003"</td></tr>
<tr><td>Overall Length (A)</td><td>180, 190cm</td><td>Same</td></tr>
<tr><td>Total Shaped Section Length (nominal) (B)</td><td>32, 36, 40, 44mm</td><td>Same</td></tr>
<tr><td>Full Diameter Length
(C) 4x30 & 6x25</td><td>20, 25, 30mm</td><td>Same</td></tr>
<tr><td>Active Shaped Section Length
(C) 3x20 & 4x20
(D) 4x30 & 6x25</td><td><table><tr><th>Retriever Size (mm)</th><th>Dimension C (mm)</th></tr><tr><td>3x20</td><td>NA</td></tr><tr><td>4x20</td><td>NA</td></tr><tr><td>4x30</td><td>35</td></tr><tr><td>6x25</td><td>30</td></tr></table></td><td>Same</td></tr>
<tr><td>Shaped Section Diameter (nominal)
(D) 3x20 & 4x20
(E) 4x30 & 6x25</td><td>3, 4, 6mm</td><td>Same</td></tr>
</table>

<table>
<tr><th>Feature</th><th><u>Predicate Device</u>
Trevo XP ProVue Retriever (K190779)</th><th><u>Subject Device</u>
Trevo XP ProVue Retriever</th></tr>
<tr><td>Proximal Core Wire Diameter
(E) 3x20 & 4x20
(F) 4x30 & 6x25</td><td><table><tr><th>Retriever Size (mm)</th><th>Dimension E (inches)</th></tr><tr><td>3x20</td><td>0.015</td></tr><tr><td>4x20</td><td>0.018</td></tr></table><table><tr><th>Retriever Size (mm)</th><th>Dimension F (inches)</th></tr><tr><td>4x30</td><td>0.018</td></tr><tr><td>6x25</td><td>0.018</td></tr></table></td><td>Same</td></tr>
<tr><td>Materials and Configuration</td><td>Polyethylene Hoop, polycarbonate mounting card, Tyvek/Film Pouch, HDPE Tubing Clips, Chipboard carton</td><td>Same</td></tr>
<tr><td>Sterilization Method</td><td>100% EtO</td><td>Same</td></tr>
<tr><td>How Supplied</td><td>Sterile/Single Use</td><td>Same</td></tr>
</table>

Table 2. Product Feature Comparison of Subject Device to Predicate Device

Feature	<u>Predicate Device</u> Trevo NXT ProVue Retriever (K200117)	<u>Subject Device</u> 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 (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	Same

Feature	**Predicate Device** **Trevo NXT ProVue Retriever (K200117)**	**Subject Device** **Trevo NXT ProVue Retriever**
	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.	
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 pulled back to capture the thrombus. The Retriever, thrombus, and Microcatheter or Aspiration Catheter are removed as a unit from the body.	Same
Procedural Steps Aspiration Source	Syringe, Aspiration pump	Same
Accessory Devices	Insertion tool and torque device provided within product package	Same
Sizes	3x32mm 4x28mm 4x41mm 6x37mm	Same

<table>
<tr><th>Feature</th><th><u>Predicate Device</u>
Trevo NXT ProVue Retriever (K200117)</th><th><u>Subject Device</u>
Trevo NXT ProVue Retriever</th></tr>
<tr><td>Compatibility</td><td>
<table>
<tr><th>Retriever Size</th><th>Trevo Pro14 Microcatheter</th><th>Trevo Trak 21 Microcatheter*</th><th>Trevo Pro18 Microcatheter</th><th>Excelsior® XT-27 Microcatheter (REF XT275081)</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>
</td><td>Same</td></tr>
<tr><td></td><td>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>Same</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>
<tr><td>Hydrophilic Coating</td><td>Sodium hyaluronate mixture, T070 formulation</td><td>Same</td></tr>
<tr><td colspan="3">DIMENSIONS</td></tr>
<tr><td>Dimensional Drawing</td><td>All Retriever sizes:
 
</td><td>Same</td></tr>
<tr><td>Core Wire Dimensions</td><td>Flatten Thickness
0.0030" +/- 0.0003"</td><td>Flatten Thickness
0.0040" +/- 0.0003"</td></tr>
<tr><td>Overall Length (A)</td><td>200cm</td><td>Same</td></tr>
<tr><td>Total Shaped Section Length (B)</td><td>32, 36, 40, 44mm</td><td>Same</td></tr>
</table>

Feature	**Predicate Device** **Trevo NXT ProVue Retriever (K200117)**	**Subject Device** **Trevo NXT ProVue Retriever**
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

Risk Assessment

Risk assessment of the modifications has been conducted in accordance with EN ISO 14971. Stryker Neurovascular has determined the modifications to the Predicate device raise no new questions of safety or effectiveness.

Results of verification testing are appropriate for use in determining that the Trevo Retriever devices are substantially equivalent to the Predicate device. Furthermore, the modifications associated with the Subject device 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

There are no changes to the device intended use or indications for use statement. Other than the modification of the core wire dimension, there are no changes in the device materials, manufacturing, packaging and sterilization methods; therefore, biocompatibility data, bench performance data, sterilization and stability data from the Predicate device (**K10779 & K200117**) are directly applicable. Relevant testing data supporting the Subject device are summarized as follows.

Performance Data – Bench Testing

Testing on the Subject device was conducted for core wire dimension change. The results of design verification testing conducted on the Trevo XP ProVue Retriever and Trevo NXT ProVue Retriever demonstrates that it is substantially equivalent to the legally marketed Predicate device. The design verification bench testing are summarized in **Table 3** below.

Table 3- Performance Data – Bench Testing

Test	Test Method Summary	Conclusions
Insertion Tool Use, Dimensions	Purpose: Evaluate device integrity after use of insertion tool Method: Device is prepared per IFU and inspected prior to use. The device is subjected to 3 runs of simulated use in a clinically relevant vasculature model and inspected after each run.	Device integrity met acceptance criteria.
Retriever / Microcatheter Deliverability (Track Test- First Push)	Purpose: To determine the trackability of retriever Method: Measure the force required to track a retriever through a microcatheter placed in a clinically relevant vasculature model.	Deliverability force met acceptance criteria.
Retriever In-Vivo Resheathability	Purpose: Evaluate device integrity after re-sheathing into microcatheter Method: Device is prepared per IFU and inspected prior to use. The device is subjected to 3 runs of simulated use in a clinically relevant vasculature model and inspected after each run.	Device integrity met acceptance criteria.
Retractability of Retriever into Balloon Guide Catheter	Purpose: Evaluate device integrity after retracting retriever into Balloon Guide Catheter Method: Device is prepared per IFU and inspected prior to use. The device is subjected to 3 runs of simulated use in a clinically relevant vasculature model and inspected after each run.	Device integrity met acceptance criteria.
Retriever Shaft Kink Resistance	Purpose: Evaluate device integrity after tracking through a tortuous anatomy Method: Device is prepared per IFU and inspected prior to use. The device is subjected to 3 runs of simulated use in a clinically relevant vasculature model and inspected after each run.	Device integrity met acceptance criteria.

Test	Test Method Summary	Conclusions
Reloadability into Insertion Tool	Purpose: Evaluate device integrity after reloading retriever into insertion tool Method: Device is prepared per IFU and inspected prior to use. The device is subjected to 3 runs of simulated use in a clinically relevant vasculature model and inspected after each run.	Device integrity met acceptance criteria.
Retriever Shaped Section Torque/Tensile Durability	Purpose: To determine durability of shaped section after multiple torque and tensile loading cycles. Method: Apply two clockwise (CW) or counter clockwise (CCW) revolutions and load proximal 50% of exposed shaped section to 1.7 lbf five times, then pull to failure. Device shall withstand six cycles at 1.7 lbf before fracture.	Torque/tensile durability met acceptance criteria.
Retriever Proximal Curl Resistance	Purpose: To determine if curl formation is present after the required revolutions. Method: Apply 5 clockwise (CW) or 5 counter clockwise (CCW) revolutions, the core wire shall not form a curl or fracture.	Curl resistance met acceptance criteria.
Retriever Mid Joint Tensile Strength	Purpose: To determine the mid joint tensile strength of a retriever Method: Identify mid solder joint(s) and subject to tensile testing. The device shall withstand 1.7 lbf minimum before wire or solder joint failure.	Mid Joint Tensile met acceptance criteria.
Retriever platinum wire and joint durability	Purpose: To determine the durability of platinum wire weaves and solder joints of a retriever Method: Identify Mid-Joint and position tubing with Retriever inside. Wrap tubing containing shaped section around Dowel Pin in one layer until the entire shaped section is wrapped around the pin, unwrap and repeat a total of 6 times. Unsheath device and examine the platinum wire and solder joint areas of Retriever.	Platinum wire and joint met acceptance criteria.
Retriever platinum wire joint tensile strength	Purpose: To determine the platinum wire solder joint tensile strength of a retriever Method: Free Platinum wires by cutting platinum wire and then unweaving from Nitinol struts. The joint is subjected to tensile testing. The joint shall withstand 0.1 lbf minimum before wire or solder joint failure	Platinum wire solder joint met acceptance criteria.

Test	Test Method Summary	Conclusions
ISO Fracture	Purpose: For testing for fracture of endovascular retrievers (called retriever herein) based on EN ISO 11070:2014, Sterile single-use intravascular introducers, dilators and guidewires, Annex F, Test method for fracture of guidewires. Method: The retriever wire is wound around a cylindrical former for at least eight complete turns, then unwound and examined for fractures. The diameter of the cylindrical former is less than or equal to ten times the maximum outside diameter (OD) of the wire.	Fracture resistance met acceptance criteria.
ISO Flexure	Purpose: For testing for resistance of guide wires, delivery wires, or introducer wires to damage by flexing based on EN ISO 11070:2014, Annex G: Sterile, single-use intravascular catheter introducers, Test for resistance of guide wires to damage by flexing. Method: The retriever delivery wire is subjected to 20 cycles of repeated reverse bending and straightening, then examined for damage and flaking of lamination.	Flexure resistance met acceptance criteria.
Retrievability of Retriever with Intermediate Catheter	Purpose: Evaluate device integrity after retrieval of Retriever with Intermediate Catheter Method: Device is prepared per IFU and inspected prior to use. The device is subjected to 3 runs of simulated use in a clinically relevant vasculature model and inspected after each run.	Device integrity met acceptance criteria.

Performance Data – Animal, Clinical

No animal or clinical studies were conducted as there is no change to the indications for use or the fundamental scientific technology. Substantial equivalence of the Subject device has been established to the Predicate devices through the results of bench testing.

Shelf Life Testing

Shelf life testing previously conducted for the Trevo XP ProVue Retriever and Trevo NXT ProVue Retriever were leveraged to support the changes to the device and can be found in **K190779** and **K200117**. Shelf life testing was not performed on the Subject device since there was no impact to device material, or safety and efficacy as a result of the core wire design modification. As with the Predicate device, the Subject device is labeled with a 2-year shelf life.

Sterilization

Sterilization evaluation previously conducted for the Trevo XP ProVue Retriever and Trevo NXT ProVue Retriever were leveraged to support the labeling changes to the device and can be found in **K190779** and **K200117**. The Trevo XP ProVue Retrievers and 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 XP ProVue Retrievers and 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 XP ProVue Retriever and Trevo NXT ProVue Retriever was leveraged to support the core wire design modification to the device and can be found in **K190779** and **K200117**. The results of biocompatibility testing, and biological safety evaluation of the Trevo XP ProVue Retriever and 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 XP ProVue Retriever and 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 XP ProVue Retriever and 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 and the bench testing results summarized above, the Subject device demonstrates substantial equivalence to the legally marketed Predicate device (**K190779** and **K200117**).