November 22, 2019

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

Re: K192207
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: October 22, 2019
Received: October 23, 2019

Dear Rhoda 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/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 -S

Xiaolin Zheng, Ph.D., M.S.
Director (*Acting*)
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)*
K192207

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 arte1y (ICA) or middle cerebral arte1y (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.

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510(k) Summary
K192207

Trade 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
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:	**October 22, 2019**
Primary Predicate Device:	Trevo XP ProVue Retriever (K190779, cleared June 25, 2019)
Reference Predicate Device:	AXS Catalyst Distal Access Catheter (K173841 cleared March 18, 2018) AXS Catalyst 7 Distal Access Catheter, *(*K183464 cleared March 13, 2019)

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.

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. Refer to table below for comparison of technological characteristics associated with Subject Device and Primary Predicate Device.

Feature	**Primary Predicate Device** **Trevo XP ProVue Retriever (K190779)**	**Subject Device** **Trevo NXT ProVue Retriever (K192207)**	**Subject Device Substantially Equivalent to Predicate Device(s)?**
Intended Use	Neurovascular mechanical thrombectomy device for acute ischemic stroke treatment used in the treatment of acute ischemic stroke to improve clinical outcomes.	Same	NA
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.	Same	NA

Feature	**Primary Predicate Device** **Trevo XP ProVue Retriever (K190779)**	**Subject Device** **Trevo NXT ProVue Retriever (K192207)**	**Subject Device Substantially Equivalent to Predicate Device(s)?**
	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.		
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	NA
Target Population	Patients experiencing acute ischemic stroke	Same	NA
Anatomical Sites	Neurovasculature	Same	NA

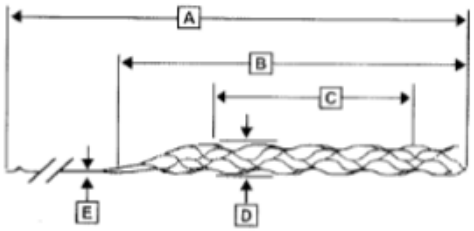
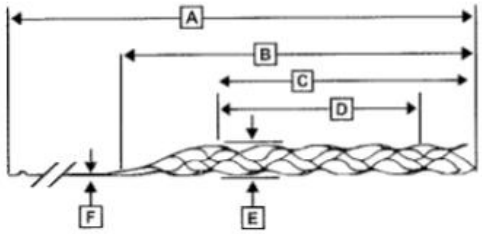
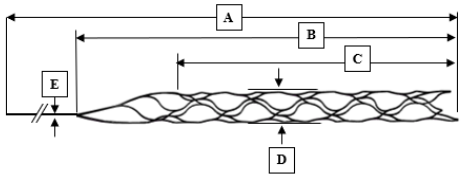
Feature	**Primary Predicate Device** **Trevo XP ProVue Retriever (K190779)**	**Subject Device** **Trevo NXT ProVue Retriever (K192207)**	**Subject Device Substantially Equivalent to Predicate Device(s)?**
Device Description	The Retriever consists of a flexible, tapered core wire with a shaped section 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 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 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.	Yes. Revised for clarity and brevity for description of torque device usage. Also identifies length of hydrophilic coating. Reference to Abbott Vascular DOC Guide Wire Extension (REF 22260) has been deleted as this feature has been removed as part of the modifications for the Trevo NXT ProVue Retriever.

Feature	**Primary Predicate Device** **Trevo XP ProVue Retriever (K190779)**	**Subject Device** **Trevo NXT ProVue Retriever (K192207)**	**Subject Device Substantially Equivalent to Predicate Device(s)?**
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	NA
Procedural Steps Aspiration Source	Syringe, Aspiration pump	Same	NA
Sizes	3x20mm 4x20mm 4x30mm 6x25mm	3x25mm 4x21mm 4x35mm 6x30mm	Yes. Modification based on customer preference. As there are no changes to the actual design of the shaped section, safety and effectiveness of the device is unaffected.
Accessory Devices	Insertion tool and torque device provided within product package	Same	NA

<table>
<tr><th>Feature</th><th><u>Primary Predicate Device</u>
Trevo XP ProVue Retriever (K190779)</th><th><u>Subject Device</u>
Trevo NXT ProVue Retriever (K192207)</th><th>Subject Device Substantially Equivalent to Predicate Device(s)?</th></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 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>
<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 3x25</td><td>√</td><td>√</td><td>√</td><td>√</td><td rowspan="4">2.5</td></tr>
<tr><td>Trevo NXT 4x21</td><td></td><td>√</td><td>√</td><td>√</td></tr>
<tr><td>Trevo NXT 4x35</td><td></td><td>√</td><td>√</td><td>√</td></tr>
<tr><td>Trevo NXT 6x30</td><td></td><td>√</td><td>√</td><td>√</td></tr>
</table>
</td><td>Yes.

Trevo Trak 21 Microcatheter is currently pending FDA review under K192122.</td></tr>
<tr><td colspan="4">Materials</td></tr>
<tr><td>Core Wire</td><td>Nitinol (nickel titanium alloy)</td><td>Same</td><td>NA</td></tr>
<tr><td>Shaped Section</td><td>Nitinol</td><td>Same</td><td>NA</td></tr>
<tr><td>Distal Coil</td><td>Platinum/Tungsten</td><td>Same</td><td>NA</td></tr>
<tr><td>Shaped Section Radiopaque Wire</td><td>Platinum/Tungsten</td><td>Same</td><td>NA</td></tr>
<tr><td>Mid Coil</td><td>304 Stainless Steel</td><td>Same</td><td>NA</td></tr>
</table>

Feature	**Primary Predicate Device** **Trevo XP ProVue Retriever (K190779)**	**Subject Device** **Trevo NXT ProVue Retriever (K192207)**	**Subject Device Substantially Equivalent to Predicate Device(s)?**
Proximal Coil / Proximal Support / Length	304 Stainless Steel	Pebax	Yes. Biocompatibility and bench testing has demonstrated that the change in the proximal coil material does not affect the safety and performance of the device.
Solder	Gold/Tin	Same	NA
Hydrophilic Coating	Sodium hyaluronate mixture	Same except with updated formulation	Yes. Biocompatibility and bench testing has demonstrated that the change in the hydrophilic coating formulation does not affect the safety and performance of the device.

Feature	**Primary Predicate Device** **Trevo XP ProVue Retriever (K190779)**	**Subject Device** **Trevo NXT ProVue Retriever (K192207)**	**Subject Device Substantially Equivalent to Predicate Device(s)?**
Dimensional Drawing	3x20, 4x20mm Retriever sizes:  4x30, 6x25mm Retriever sizes:  	All Retriever sizes:  	Yes. Modification based on customer preference. As there are no changes to the actual design of the shaped section, safety and effectiveness of the device is unaffected.

Feature	**Primary Predicate Device** **Trevo XP ProVue Retriever (K190779)**	**Subject Device** **Trevo NXT ProVue Retriever (K192207)**	**Subject Device Substantially Equivalent to Predicate Device(s)?**
Overall Length	180, 190cm	200cm	Yes. Increased length of the delivery core wire allows for compatibility with longer devices. Bench testing has demonstrated that the change in the delivery core wire length does not affect the safety and effectiveness of the device.
Total Shaped Section Length (nominal)	32, 36, 40, 44mm	Same	NA
Active Shaped Section Length	20, 25, 30mm	Same	NA

<table>
<tr><th>Feature</th><th><u>Primary Predicate Device</u>
Trevo XP ProVue Retriever (K190779)</th><th><u>Subject Device</u>
Trevo NXT ProVue Retriever (K192207)</th><th>Subject Device Substantially Equivalent to Predicate Device(s)?</th></tr>
<tr><td>Full Diameter Length (nominal)</td><td>4x30, 6x25mm Retriever sizes:

<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>All Retriever sizes:

<table><tr><th>Retriever Size (mm)</th><th>Dimension C (mm)</th></tr><tr><td>3x25</td><td>25</td></tr><tr><td>4x21</td><td>21</td></tr><tr><td>4x35</td><td>Same</td></tr><tr><td>6x30</td><td>Same</td></tr></table></td><td>Yes.

Labeling changes to replace the Active Shaped Section Length with Full Diameter Length is based on customer preference.

As there are no changes to the actual design of the shaped section, safety and effectiveness of the device is unaffected.</td></tr>
<tr><td>Shaped Section Diameter (nominal)</td><td>3, 4, 6mm</td><td>Same</td><td>NA</td></tr>
<tr><td>Proximal Core Wire Diameter</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><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>0.019</td></tr><tr><td>4x30</td><td>0.019</td></tr><tr><td>6x25</td><td>0.019</td></tr></table></td><td>Yes.

Modification accommodates SNV procedures.

As there are no actual changes to the delivery core wire outer diameter, the safety and effectiveness of the device is unaffected.</td></tr>
</table>

Feature	**Primary Predicate Device** **Trevo XP ProVue Retriever (K190779)**	**Subject Device** **Trevo NXT ProVue Retriever (K192207)**	**Subject Device Substantially Equivalent to Predicate Device(s)?**
Materials and Configuration	Polyethylene Hoop, polycarbonate mounting card, Tyvek/Film Pouch, HDPE Tubing Clips, Chipboard carton	Longer Polyethylene Hoop, polycarbonate mounting card, Tyvek/Film Pouch, Chipboard carton	Yes. Hoop was modified to accommodate longer device length, and sterilization validation has been completed.
Sterilization Method	100% EtO	Same	NA
How Supplied	Sterile/Single Use	Same	NA

Performance Data – Non-Clinical
The following performance data were provided in support of the substantial equivalence determination.

Performance Testing:
To confirm that the performance of the Subject device, Trevo NXT ProVue Retriever, is substantially equivalent to the performance of the Primary Predicate, device verification and validation testing was conducted on those aspects of the devices that could be affected by the differences between the Primary Predicate device and the Subject device.

Validation:
In accordance with FDA's guidance, "*Pre-Clinical and Clinical Studies for Neurothrombectomy Devices*," issued June 18, 2007, an *in vitro* Simulated-use study was completed to assess the usability of the subject device, Trevo NXT ProVue Retriever. Users evaluated the device in a simulated use tortuous anatomical model under simulated clinical conditions per the proposed Directions for Use (DFU).

All Users observed that the Trevo NXT ProVue Retrievers successfully met all the design attribute evaluations defined in the Trevo NXT ProVue Retriever design validation protocol, when utilized in simulated use tortuous anatomy. There were no additional risks identified by the Users. All Trevo NXT ProVue Retrievers used in testing adequately met the customer needs defined in internal documentation.

Leveraged Non-Clinical Data:
Data supporting the performance characteristics that were not impacted by the proposed modifications were leveraged from the Primary Predicate device. Previous data remains valid as there are no changes to the design / geometry of the shaped section associated with the proposed modifications for the Trevo NXT ProVue Retrievers. As there are no changes to the design of the shaped section, the following tests and associated data were leveraged as listed below:

- Dimensional Verification
- Retriever Shape Section Radial Force
- Retriever Torque/Tensile Durability
- Retriever Mid Joint Tensile Strength
- Retriever Tip Tensile Strength
- Retriever Wire Joint Tensile Strength
- Retriever Wire and Joint Durability
- Simulated Use

Non-Clinical Data:
In accordance with FDA's guidance, "*Pre-Clinical and Clinical Studies for Neurothrombectomy Devices*," issued June 18, 2007, additional design verification and validation testing conducted on the Trevo NXT ProVue Retriever demonstrates that it performs as designed and is suitable for its intended use. The test results are appropriate to support a determination of substantial equivalence to the Primary Predicate device.

The performance bench testing performed are listed below:

Test	Test Method Summary	Conclusions
Dimensional Verification	Verified dimensions using specified measurement tool.	Dimensional verification meets acceptance criteria.
Retriever Delivery Wire Kink Resistance	Using appropriate simulated use model in 37ºC water/saline bath, complete retrieval procedure per IFU for three retrieval attempts. Remove device from the model and inspect delivery core wire for damage. Record results.	Retriever Delivery Wire Kink Resistance meets acceptance criteria.
Tip Flexibility	Load sample so that the distal tip will be flexed. Use Instron tensile tester to determine applied peak compression/flex force. Record results.	Tip Flexibility meets acceptance criteria.
Retriever Shaped Section Radial Force	Constrain shaped section of retriever and release to specified diameter. Use Instron tensile tester and Blockwise RF iris fixture to determine applied force at the specified diameters. Record results.	Retriever Shaped Section Radial Force meets acceptance criteria.
Corrosion Resistance	Immerse test sample in saline bath per EN ISO 10555-1. Remove test sample and allow to dry at room temperature. Inspect sample for signs of corrosion. Record results.	Corrosion Resistance meets acceptance criteria.
Particulate Characterization	Measure the total number of particulates generated during simulated use. Report in each of four size ranges ≥10µm, ≥25µm, ≥50µm, and ≥100µm. If >100µm are observed, complete particle count analysis of bin sizes ≥200µm, ≥500µm and ≥1000µm. Record results.	Particulate characterization was acceptable.
Coating Integrity Characterization	Inspect the device coating prior to simulated use. Run the device through a clinically relevant tortuous model. Visually inspect the device coating after simulated use. Record results.	Coating Integrity was acceptable.
ISO Fracture	Wind retriever wire around a cylindrical former for at least eight complete turns, then unwind and examine for fractures per EN ISO 11070, Annex F. Visually inspect sample for fractures. Record results.	ISO Fracture meets acceptance criteria.
ISO Flexure	The retriever delivery core wire is subjected to 20 cycles of repeated reverse bending and straightening per EN ISO 11070, Annex G. Visually inspect sample for damage and flaking of (PTFE) coating. Record results.	ISO Flexure meets acceptance criteria.
Reloadability into Insertion Tool	Using appropriate simulated use model in 37ºC water/saline bath, complete retrieval procedure per IFU for three retrieval attempts. Remove device from the model and inspect for damage. Record results.	Reloadability into Insertion Tool meets acceptance criteria.
Coating Lubricity/Durability	Prepare sample for test. Use friction tester to measure the frictional force of the device sample when pulled between two clamped pads. Record the average frictional force at 6th cycle.	Coating Lubricity/Durability meets acceptance criteria.

Test	Test Method Summary	Conclusions
Retriever / Microcatheter Deliverability (Track Test- First Push)	Measure the force to push the device through a tortuous model in a 37ºC water bath. Record maximum force from the first 5cm push.	Retriever/Microcatheter Deliverability meets acceptance criteria.
Retriever In-Vivo Resheathability Into Microcatheter	Using appropriate simulated use model in 37ºC water/saline bath, complete retrieval procedure per IFU for three retrieval attempts. Remove device from the model and inspect for damage. Record results.	Retriever In-Vivo Resheathability into Microcatheter meets acceptance criteria.
Retractability of Retriever into BGC	Using appropriate simulated use model in 37ºC water/saline bath, complete retrieval procedure per IFU for three retrieval attempts. Remove device from the model and inspect for damage. Record results.	Retractability of Retriever into BGC meets acceptance criteria.
Retrievability of Retriever with Intermediate Catheter	Using appropriate simulated use model in 37ºC water/saline bath, complete retrieval procedure per IFU for three retrieval attempts. Remove device from the model and inspect for damage. Record results.	Retractability of Retriever with Intermediate Catheter meets acceptance criteria.
Product Integrity Post Removal	Remove product from packaging hoop per IFU. Visually inspect product for kinks on delivery wire or retriever. Record results.	Product Integrity Post Removal meets acceptance criteria.
Stent Containment in Insertion Tool	Remove product from packaging hoop per IFU. Visually inspect position of stent retriever within insertion tool. Record results.	Stent Containment in Insertion Tool meets acceptance criteria.
Design Validation	Design Validation testing utilized a neurovascular model with a re-circulating water bath at 37ºC to simulate the human arterial circulation and assess device performance.	Design Validation testing met acceptance criteria.

Results of verification and validation testing are appropriate for use in determining that the Trevo NXT ProVue Retriever devices are substantially equivalent to the Primary Predicate and Reference devices. Based on the successful completion of the verification and validation testing on accelerated aged devices, the Subject device has met all the pre-specified requirements and is safe for clinical use.

Biocompatibility:

The biocompatibility evaluation for the Trevo® NXT ProVue Retrievers was conducted in accordance with the FDA guidance, "Use of International Standard ISO-10993-1, 'Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process,'" and International Standard ISO 10993-1 as recognized by FDA.

A summary of the biocompatibility testing completed follows:

Test Method, Category, and Description			Acceptance Criteria	Conclusion
ISO 10993-4	Hemolysis	Direct Contact	Hemolysis is ≤ 5%.	Acceptance criteria met
		Extraction		Acceptance criteria met
	Thrombosis	Thromboresistance	Thrombosis is acceptable for clinical application.	Acceptance criteria met
		Complement Activation (sC5b-9)		Acceptance criteria met
		Coagulation (Partial Thromboplastin Time)		Acceptance criteria met
ISO 10993-5	Cytotoxicity (L929 MEM Elution)		No less than or equal to 50% cell viability.	Acceptance criteria met
ISO 10993-10	Sensitization (Guinea Pig Maximization)		Not a sensitizer.	Acceptance criteria met
	Irritation (Rabbit Intracutaneous [Intradermal])		No significant irritation.	Acceptance criteria met
ISO 10993-11	Material Mediated Pyrogenicity		No febrile reaction greater than 0.5°C.	Acceptance criteria met
	Acute Systemic Toxicity		No mortality or evidence of systemic toxicity.	Acceptance criteria met
ISO 10993-18	Physicochemical (USP <661>)		Non-volatile Residue ≤ 15 mg Residue on Ignition ≤ 5 mg Heavy Metals ≤ 1 ppm Buffering Capacity ≤ 10.0 mL	Acceptance criteria met
	FTIR		No unexpected readings.	Acceptance criteria met
	Latex (LEAP - ASTM D6499)		No detectable latex.	Acceptance criteria met

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.

Sterilization and Shelf Life:

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.

Aging studies for the Subject device demonstrate that the device packaging remains functional and maintains sterility for shelf life of 2 years. Aging studies for packaging integrity, seal strength and device functionality met all acceptance criteria.

Performance Data – Animal, Clinical

No clinical or animal testing was performed on the Subject device 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.

Conclusions:
Based on the supporting documentation provided in this submission, Stryker Neurovascular believes the Subject devices demonstrated substantial equivalence to the listed Predicate devices.