November 22, 2019

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

Re: K192122
Trade/Device Name: Trevo Trak™ 21 Microcatheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO, DQY
Dated: November 7, 2019
Received: November 8, 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, 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)*
K192122

Device Name
Trevo Trak 21 Microcatheter

Indications for Use *(Describe)*
The Microcatheter is indicated for use in the selective placement of devices and/or fluids, such as contrast media, into the peripheral, coronary, and neuro vasculature during diagnostic and/or therapeutic procedures.

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
K192122

Trade/Proprietary Name:	Trevo Trak™ 21 Microcatheter
Common Name:	Catheter, intravascular, diagnostic
Regulation Name:	Catheter, intravascular, diagnostic, 21 CFR 870.1200 – Class II
Product Code:	DQO
Trade/Proprietary Name:	Trevo Trak™ 21 Microcatheter
Common Name:	Percutaneous Catheter
Regulation Name:	Percutaneous Catheter, 21CFR 870.1250 – Class II
Product Code:	DQY

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

Contact: **Rhoda M. Santos**
Senior Principal Regulatory Affairs Specialist
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Date Prepared: November 20, 2019

Legally Marketed Predicate Devices

Name of Predicate Device	Name of Manufacturer	510(k) Number
Trevo® Pro 18 Microcatheter	Stryker Neurovascular	**K113260**

Device Description

The Trevo Trak 21 Microcatheter is a single-lumen, braided shaft, variable stiffness catheter with radiopaque marker(s) on the distal end and a luer hub on the proximal end. The catheter shaft has a hydrophilic coating to reduce friction during use. The radiopaque shaft and distal marker(s) facilitate fluoroscopic visualization.

Indications for Use

The Microcatheter is indicated for use in the selective placement of devices and/or fluids, such as contrast media, into the peripheral, coronary, and neuro vasculature during diagnostic and/or therapeutic procedures.

Technological Characteristics and Product Feature Comparison

Stryker Neurovascular has demonstrated the Trevo Trak™ 21 Microcatheter is substantially equivalent to the Predicate device, Trevo Pro18 Microcatheter (**K113260**) based on the same or similar materials, similar design, and the same fundamental operating principles. A comparison of the Subject device with the Predicate device is summarized in

Table 1 below.

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

Detail	Subject Device (K192122)	Predicate Device (K113260)
Manufacturer	Stryker Neurovascular	Stryker Neurovascular
510(k) Number	**K192122**	**K113260**
Device Trade Name	**Trevo Trak™ 21 Microcatheter**	**Trevo® Pro 18 Microcatheter**
Regulation Number	21 CFR 870.1250	Same
Regulation Name	Percutaneous Catheter	Same
Classification	II	Same
Product Code	DQY	Same
Intended Use/Indication for Use	The Microcatheter is indicated for use in the selective placement of devices and/or fluids, such as contrast media, into the peripheral, coronary, and neuro vasculature during diagnostic and/or therapeutic procedures.	The Microcatheter is indicated for use in the selective placement of fluids and/or other devices or agents into the peripheral, coronary, and neuro vasculature during diagnostic and/or therapeutic procedures.
Device Description	The Microcatheter is a single-lumen, braided shaft, variable stiffness catheter with radiopaque marker(s) on the distal end and a luer hub on the proximal end. The catheter shaft has a hydrophilic coating to reduce friction during use. The	The Microcatheter is a single-lumen, braided shaft, variable stiffness catheter with radiopaque marker(s) on the distal end and a luer hub on the proximal end. The catheter shaft has a hydrophilic coating on the distal 100cm to reduce friction during

Detail	Subject Device (K192122)	Predicate Device (K113260)
	radiopaque shaft and distal marker(s) facilitate fluoroscopic visualization. Device dimensions and configuration are shown on the product label. A rotating hemostasis valve with side-arm adapter is provided with each microcatheter.	use. The radiopaque shaft and distal marker(s) facilitate fluoroscopic visualization. Device dimensions and configuration are shown on the product label. A rotating hemostasis valve with side-arm adapter is provided with each microcatheter.
Accessory Devices Provided (not in direct contact with patient)	Rotating Hemostasis Valve (RHV) packaged within device	Same
Outer Jacket	Polymeric microcatheter	Same
Shaft Braid	Stainless Steel	Same
Strain Relief	Polyolefin	Same
Inner Layer	PTFE	Same
Catheter Hub	Polyurethane	Same
Marker Band	Platinum/Iridium	Same
Adhesive	Acrylic (Acrylated Urethane)	Same
Outer Jacket Coating	Hydrophilic Coating	Same
Labeled Shaft Outer Diameter	2.4F/2.0F	Same
Labeled Shaft Inner Diameter	.021”	Same
Effective Length	162 cm	150 cm
Packaging Materials and Configuration	HDPE Packaging Hoop, Tyvek/Film Pouch, SBS Carton	HDPE Packaging Hoop, HDPE mounting card, Tyvek/Film Pouch, HDPE Tubing Clips, SBS Carton
Sterilization Method	EO Sterilization	Same
How Supplied	Single Use/Sterile	Same

Detail	Subject Device (K192122)	Predicate Device (K113260)
Principles of Operation	The device is advanced into the vasculature over an appropriately sized guide wire. Once the microcatheter is inserted, the catheter can be advance through the vasculature to the desired location.	Same

Testing Summary

Performance Data – Bench Testing

The results of design verification and design validation testing conducted on the Trevo Trak 21 Microcatheter demonstrates that it performs as designed, is suitable for the indication for use, and is substantially equivalent to the legally marketed Predicate device. The design verification and design validation bench testing are summarized in **Table 2** below.

Table 2. Performance Data - Bench Testing

Test	Test Method Summary	Conclusions
Dimensional Verification	Purpose: To describe the procedure and technique of making dimensional measurements using various measurement equipment. Method: Verify dimensions using specified measurement tool. Record measurements.	Dimensional verification met acceptance criteria.
Tensile Strength	Purpose: To determine tensile strength of catheters based on EN ISO 10555-1. Method: Identify catheter joints, including catheter to hub junction, and prepare sample for test. Use tensile tester to apply tensile load to sample and identify peak tensile force. Record results.	Tensile strength met acceptance criteria.
Air Leak Resistance	Purpose: To determine whether the device meets the freedom from leakage-air aspiration requirement of 4.7.2 of EN ISO 10555-1 and 4.2.2 of EN 1707. Method: Connect test hub sample to a partially filled syringe. With the nozzle of the syringe pointing down towards the ground, withdraw the plunger to the 10cc mark. Hold for 15 seconds	Air leak resistance of catheter met acceptance criteria.

Test	Test Method Summary	Conclusions
	and examine the water in the syringe for the formation of air bubbles. Record results.	
Liquid Leak Resistance	Purpose: To determine whether the device meets the freedom from leakage-liquid leak requirement 4.7.1 of EN ISO 10555-1 and 4.2.1 of EN 1707. Method: Connect test hub sample to fixture and flush with water to expel air. Occlude distal tip. Apply pressure of 300 kPa to 320 kPa and maintain pressure for 30s. Visually inspect catheter/hub joint and catheter shaft for leaks. Record results.	Liquid leak resistance of catheter met acceptance criteria.
Burst pressure	Purpose: To determine if the catheter can resist its rated burst pressure without causing leakage or damage to the catheter. This test is performed in accordance with EN ISO 10555-1:2013, Annex F. Method: Prepare test sample. Apply specified burst pressure (greater than the rated burst pressure) to test sample and maintain pressure for at least 2 seconds. Observe sample for any leakage or damage. Record results.	Burst pressure met acceptance criteria.
Particulate characterization	Purpose: To characterize acute phase particulate generated as a result of product specific simulated use steps. Method: 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 generation was acceptable.
Coating Integrity	Purpose: Coated surface shall be visually characterized before and after simulated use with sufficient magnification to identify any defects which could be associated with loss of coating under anticipated clinical use conditions. Method: Remove test sample from packaging and inspect for damage. Visually inspect external surface of test sample using minimum 10x magnification for surface defects. Record results.	Coating integrity was acceptable.

Test	Test Method Summary	Conclusions
Torsion Bond Strength	Purpose: To measure the strength of a catheter shaft when torque is applied. Method: Prepare test sample and insert into torsional bond strength test fixture with tortuous path model. Apply torque to proximal end of catheter while distal end is fixed. Record maximum observed number of 360-degree rotations.	Torsional Bond Strength met acceptance criteria.
Kink Resistance	Purpose: To measure the kink radius of a catheter shafts. Method: Prepare test sample. Position test sample in a loop and place within a vice ensuring loop apex is within the vice. Slowly close the vice until the test sample kinks. Measure distance between vice grips and record result.	Kink resistance met acceptance criteria.
Chemical Compatibility	Purpose: To determine visual and dimensional integrity of catheter following exposure to saline and non-ionic contrast liquids. Method: Prepare sample for test. Flush sample with water for 1 minute and then measure OD and ID of test sample. Insert mandrel and take images of test sample for initial characterization. Dip test sample and mandrel into specified chemicals and hold for 1 minute. Remove test sample, measure OD, ID and cross-sectional area. Take images of test sample for post-exposure characterization. Record results.	Chemical compatibility met acceptance criteria.
Tip Flexibility	Purpose: To measure the maximum force required to deflect test sample by 45°. Method: Prepare sample for test. Use Instron and appropriate fixtures to deflect test sample while measuring force. Record maximum force achieved.	Tip Flexibility met acceptance criteria.
Distal Tip Shape	Purpose: To verify that the catheter tip is smooth, rounded, tapered or similarly finished in order to minimize trauma to vessels during use per EN ISO 10555-1. Method: Visually inspect distal tip to verify distal tip end is smooth, rounded, tapered or similarly finished. Record results.	Distal Tip Shape met acceptance criteria.

Test	Test Method Summary	Conclusions
Surface Condition	Purpose: To verify the external surface of the catheter is free from extraneous matter, process or surface defects along the shaft. Method: Visually inspect external surface of test sample using minimum 2.5x magnification for surface defects. Record results.	Surface condition met acceptance criteria.
Distal Shaft Trackability	Purpose: To evaluate the force required to track the catheter through a tortuous model as well as evaluate the lubricity and durability of the catheter. Method: Prepare sample for test. Use track tester to measure the track force of the test sample through a tortuous model using a tri-axial approach. Record the peak force during advance tracking at 6^{th} cycle.	Distal shaft trackability met acceptance criteria.
Luer Testing per EN 1707	Purpose: To determine if microcatheter hub and accessory meet requirements 4.1 through 4.7 of EN 1707. Method: Test methods conforms with section 5 of EN 1707.	Luer testing meets acceptance criteria.
In-vitro Simulated Use Study	Purpose: To evaluate interventional device delivery, durability and integrity of the Subject device as a general access and delivery catheter in a tortuous anatomical model with multiple physician users. Method: Perform a simulated interventional procedure by tracking the device to the target site for interventional device delivery using a neurovascular model that replicates the tortuosity, diameter and location of the arteries in the neurovasculature. Devices were visually inspected post testing.	All test samples met acceptance criteria.
Compatibility with Retrieval devices	Purpose: To ensure the microcatheter shall be able to resheath a retriever in good condition without a captured thrombus after deployment of the entire shaped section into the vessel at least 2 times without functional impact and integrity to the tip.	Compatibility with Retrieval devices met acceptance criteria.

Test	Test Method Summary	Conclusions
	Method: Entire shaped section is deployed into the vessel at least 2 times and inspected for functional impact and integrity of the tip. Integrity is defined as no missing material or tears at the tip. Functional impact is defined as inability to resheath the shaped section. A deployment is defined as the entire shaped section of the retriever is deployed into the vessel.	
Product Integrity Post Removal	Purpose: To determine damage to product following removal of the catheter and its accessories from its packaging. Method: Prepare product and remove from packaging per DFU, followed by -inspecting for kinks, stretches or crushing of the catheter shaft. Self-evident inspection: -No damage on RHV.	Product integrity post removal met acceptance criteria.

Performance Data – Animal Study, Clinical Study

No animal study or clinical study was conducted as bench testing was determined sufficient for verification and validation purposes.

Shelf Life Testing

The labeled shelf life for the Trevo Trak 21 Microcatheter is two years. Shelf life testing (product and packaging) and Distribution Shipping Challenge Conditioning and testing were performed on the Subject device, and the results met established criteria.

Sterilization

The Trevo Trak 21 Microcatheter and accessory (RHV) are sterilized with 100% Ethylene Oxide. The Trevo Trak 21 Microcatheter and accessory are provided sterile. A sterility assurance level (SAL) of 10^{-6} has been demonstrated. The Trevo Trak 21 Microcatheter and accessory meet EO residuals per EN ISO 10993-7 for a limited contact delivery system – externally communicating. The Trevo Trak 21 Microcatheter and accessory are for single use only.

Biocompatibility

The Trevo Trak 21 Microcatheter was assessed for biocompatibility in accordance with EN ISO 10993-1, "*Biological evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process*". The Subject device is considered an externally communicating medical device with circulating blood contact for less than 24 hours. The Trevo Trak 21 Microcatheter passed all recommended biocompatibility testing. An overview of the biocompatibility testing is summarized below.

Table 3. Overview of Biocompatibility Studies Performed on the Subject Device

Test			Acceptance Criteria	Conclusion
ISO 10993-4	Hemolysis	Direct Contact	Hemolysis is ≤ 5%.	Pass
		Extraction	Non-hemolytic (0.0%)	Pass
	Thrombosis	Thromboresistance	Thrombosis is acceptable for clinical application.	Pass
		Complement Activation	Potential activator ($p < 0.05$ versus negative and activated controls, ~4% of positive control, ~173% of negative control)	Pass
		Coagulation	Slight potential enhancement of coagulation system (17% faster clotting versus negative control)	Pass
ISO 10993-5	Cytotoxicity		No less than or equal to 50% cell viability.	Pass
ISO 10993-10	Sensitization		Not a sensitizer.	Pass
	Irritation		No significant irritation.	Pass
ISO 10993-11	Material Mediated Pyrogenicity		No febrile reaction greater than 0.5°C.	Pass
	Acute Systemic Toxicity		No mortality or evidence of systemic toxicity.	Pass
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	Pass
	FTIR		No unexpected readings.	Pass
	Latex (LEAP - ASTM D6499)		No detectable latex.	Pass

Conclusion

Stryker Neurovascular has demonstrated the Trevo Trak 21 Microcatheter is substantially equivalent to the Predicate device (**K113260**) based on same intended use / indications for use, same or similar materials, same fundamental design, and the same operating principles. The conclusions drawn from risk assessment and the bench testing results summarized above demonstrate that the benefits of the device outweigh any residual risks when used in accordance with device Directions for Use. Stryker Neurovascular has demonstrated that the Trevo Trak 21 Microcatheter is substantially equivalent to the legally marketed Predicate device.