November 26, 2021

Stryker Neurovascular
Shivani H. Patel
Senior Staff Regulatory Affairs Specialist
47900 Bayside Parkway
Fremont, California 94538

Re: K211594
Trade/Device Name: Trevo Trak 21 Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY, DQO
Dated: November 9, 2021
Received: November 10, 2021

Dear Shivani H. Patel:

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,

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)*
K211594

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.

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

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510(k) Summary
K211594

Trade/Proprietary Name:	Trevo Trak™ 21 Microcatheter
Common Name:	Catheter, Percutaneous, Neurovasculature
Regulation Name:	Percutaneous Catheter, 21 CFR 870.1250 – Class II
Product Code:	QJP
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, 21 CFR 870.1250 – Class II
Product Code:	DQY

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

Contact: **Shivani H. Patel**
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Date Prepared: November 18, 2021

Legally Marketed Predicate Devices

Name of Predicate Device	Name of Manufacturer	510(k) Number
Trevo Trak™ 21 Microcatheter	Stryker Neurovascular	**K192122**

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 Trak 21 Microcatheter (**K192122**), based on the same materials, same 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	Predicate Device (K192122)
Manufacturer	Stryker Neurovascular	Same
510(k) Number	K211594	K192122
Device Trade Name	**Trevo Trak™ 21 Microcatheter**	Same
Regulation Number	21 CFR 870.1250 21 CFR 870.1200	Same
Regulation Name	Percutaneous Catheter	Same
Classification	II	Same
Product Code	QJP, DQO, DQY	DQO, DQY
Indication for Use	*The Microcatheter is indicated for use in the selective placement of devices and/or fluids, such as contrast media, into the*	Same

Detail	Subject Device	Predicate Device (K192122)
	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 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.	Same
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

Detail	Subject Device	Predicate Device (K192122)
Labeled Shaft Outer Diameter	2.4F/2.0F	Same
Labeled Shaft Inner Diameter	.021”	Same
Effective Length	162 cm	Same
Packaging Materials and Configuration	HDPE Packaging Hoop, Tyvek/Film Pouch, SBS Carton	Same
Sterilization Method	EO Sterilization	Same
How Supplied	Single Use/Sterile	Same
Shelf-Life	6 months	2 years
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 advanced through the vasculature to the desired location.	Same
Recommended minimum inner diameter of guide catheter	0.046 inch inner diameter	0.058 inch inner diameter

The differences between the devices do not raise new questions of safety and effectiveness.

Risk Assessment

A risk assessment of the Trevo Trak 21 Microcatheter has been conducted in accordance with EN ISO 14971. Stryker Neurovascular has determined that the labeling changes to the Trevo Trak 21 Microcatheter raise no new questions of safety and effectiveness. The results of testing demonstrate that the Trevo Trak 21 Microcatheter with the modified labeling is substantially equivalent to the legally marketed Predicate device.

Testing Summary

Performance Data – Bench Testing

Stryker Neurovascular performed the following non-clinical bench testing to assess the compatibility of the Trevo Trak 21 Microcatheter with 0.046 inch inner diameter (ID) guide catheters. The bench testing is summarized in **Table 2** below.

Table 2. Performance Data - Bench Testing

Test	Test Method Summary	Conclusions
Simulated Use/Compatibility	User will assess Trevo Trak™ 21 Microcatheter with a worst case compatible guide catheter in the in vitro simulated use model.	Simulated Use testing met acceptance criteria.
Particulate Characterization	Use light obscuration particle counting to measure the total number of particulates generated during simulated use.	Particulate generation was acceptable and comparable to the predicate device.
Coating Integrity	Use visual inspection to identify the location, size, and number of occurrences of anomalies on the coated surface of the Trevo Trak™ 21 Microcatheter before and after simulated use.	Coating integrity was acceptable both before and after simulated use.
Track Force Testing	Use a Track Tester Model to measure the Trevo Trak™ 21 Microcatheter track force through a guide catheter during simulated use.	Track Testing results 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 six-months. Product shelf-life testing was performed on the Subject device and the results met established criteria. The packaging shelf-life and Distribution Shipping Challenge Conditioning and testing was performed on the Predicate device and test results were reviewed and cleared in K192122.

Sterilization

The sterilization evaluation previously conducted for the Trevo Trak 21 Microcatheter was used to support the subject device and can be found in **K192122**. The Trevo Trak 21 Microcatheter is 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 biocompatibility testing previously conducted for the Trevo Trak 21 Microcatheter was used to support the subject device and can be found in **K192122**. The results of biocompatibility testing and biological safety evaluation of the Trevo Trak 21 Microcatheter demonstrate that the device meets the biological safety requirements per EN ISO 10993-1, "*Biological evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process*" for an externally communicating medical device with circulating blood contact for less than 24 hours. Therefore, the Trevo Trak 21 Microcatheter, accessory, and primary packaging are considered biocompatible for their intended use.

Conclusion

Stryker Neurovascular has demonstrated the Trevo Trak 21 Microcatheter is substantially equivalent to the Predicate device (**K192122**) based on same intended use / indications for use, same materials, same fundamental design, and the same operating principles. The conclusions drawn from the 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 the device Instructions for Use. Stryker Neurovascular has demonstrated that the Trevo Trak 21 Microcatheter is substantially equivalent to the legally marketed Predicate device.