July 1, 2026

Stryker Neurovascular
Jesse Nelson
Staff Regulatory Affairs Specialist
47900 Bayside Parkway
Fremont, California 94538

Re: K261889
Trade/Device Name: Trevo Trak 21 Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQO
Dated: June 5, 2026
Received: June 5, 2026

Dear Jesse Nelson:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Naira Muradyan, PhD
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DHT5A: Division of Neurosurgical,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261889

Device Name
Trevo Trak 21 Microcatheter

Indications for Use *(Describe)*
The Microcatheter is indicated to provide vascular access for selective placement of devices and/or fluids, such as contrast media, within the neurovasculature, including large intracranial vessels (e.g., internal carotid artery [ICA] and middle cerebral artery [MCA]), 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.

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

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Date Prepared: June 29, 2026

Submitter: Stryker Neurovascular
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Trade Name: Trevo Trak™ 21 Microcatheter
Common Name: Catheter, Percutaneous, Neurovasculature
Regulation Name: Percutaneous Catheter, 21 CFR 870.1250 – Class II
Product Code: QJP

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

Legally Marketed Predicate Device:

Name of Predicate Device	510(k) Number
Trevo Trak 21 Microcatheter	K211594 (Cleared 26-Nov-2021)

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 on the distal 100 cm 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.

Indications for Use

The Microcatheter is indicated to provide vascular access for selective placement of devices and/or fluids, such as contrast media, within the neurovasculature, including large intracranial vessels (e.g., internal carotid artery [ICA] and middle cerebral artery [MCA]), 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 (K211594), based on the similar intended use, 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 (K261889)	Predicate Device (K211594)
Manufacturer	Stryker Neurovascular	Same
510(k) Number	K261889	K211594
Device Trade Name	**Trevo Trak 21 Microcatheter**	Same
Regulation Number	21 CFR 870.1250 21 CFR 870.1200	Same
Regulation Name	Percutaneous Catheter Diagnostic Intravascular Catheter	Same

Classification	II	Same
Product Code	QJP, DQO	DQY, QJP, DQO
Intended Use/Indication for Use	**INTENDED USE** The Microcatheter is intended for selective placement of devices and/or fluids, such as contrast media, within the neurovasculature during diagnostic and/or therapeutic procedures. **INDICATIONS FOR USE** The Microcatheter is indicated to provide vascular access for selective placement of devices and/or fluids, such as contrast media, within the neurovasculature, including large intracranial vessels (e.g., internal carotid artery [ICA] and middle cerebral artery [MCA]), during diagnostic and/or therapeutic procedures.	**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.
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 coatings on the distal 100cm 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.	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 use. The radiopaque shaft and distal marker(s) facilitate fluoroscopic visualization. Device dimensions and configuration are shown on the product label. A rotating hemostatic

	A rotating hemostatic valve with side-arm adapter is provided with each microcatheter. The Trevo Trak 21 Microcatheter provides vascular access to the neurovascular for selective placement of devices and/or the delivery of diagnostic agents into the neurovasculature during diagnostic and/or therapeutic endovascular procedures when used as intended.	valve with side-arm adapter is provided with each microcatheter.
Accessory Devices	Rotating Hemostasis Valve (RHV) packaged with 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	0.021”	Same
Effective Length	162 cm	Same
Packaging Materials	HDPE Packaging Hoop, Tyvek/Film Pouch, SBS Carton	Same

and Configuration		
Sterilization Method	EO Sterilization	Same
How Supplied	Single Use/Sterile	Same
Principles of Operation	The device is advanced into the neurovascular vasculature over an appropriately sized guide wire. Once the microcatheter is inserted, the catheter can be advanced through the neurovasculature to the desired location.	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
Shelf life	2-year	Same

Performance Testing

The K261889 submission does not propose any modifications to the subject device design, materials, or manufacturing processes. The proposed changes to the intended use and indications for use, limiting device use to neurovasculature only, did not warrant new testing.

Shelf-Life Testing

Shelf life testing previously conducted for the Trevo Trak 21 Microcatheter in K192122 was leveraged since there are no changes to device materials, design, or manufacturing processes as a result of the intended use, indications for use and labeling changes. As with the Predicate device, the Subject device is labeled with a 2-year shelf life.

Conclusion

Stryker Neurovascular has demonstrated the Trevo Trak 21 Microcatheter is substantially equivalent to the Predicate device (**K211594**) based on similar intended use, same materials, same fundamental design, and the same operating principles. The amended intended use and indications for use described in this premarket notification limit the device use to the neurovasculature, compared to prior/predicate's use in peripheral, coronary and neurovasculature, and do not introduce any new risks and have no impact on the existing risks associated with the device use.