September 8, 2025

REV Neuro LLC
Shiva Ardakani
RA/QA
7060 Koll Center Parkway, Suite 300
Pleasanton, California 94566

Re: K250960
Trade/Device Name: DUO Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQO, DQY
Dated: August 7, 2025
Received: August 8, 2025

Dear Shiva Ardakani:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250960

Device Name
DUO Microcatheter

Indications for Use *(Describe)*
The DUO Microcatheter is intended for 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 (K250960)
[As required by 21 CFR 807.92]

Submitter's Name / Contact Person

Submitter: REV Neuro LLC
7060 Koll Center Pkwy, Suite 300
Pleasanton, CA 94566

Contact Person: Shiva Ardakani
RA/QA
Phone: (925) 931-1300 ext. 209
Email: shiva.ardakani@expansemedical.com

Date Prepared: August 4, 2025

General Information

Trade/ Proprietary Name:	DUO Microcatheter
Common Name:	Catheter, Percutaneous, Neurovasculature
Regulatory Name:	Catheter, Percutaneous, 21 CFR 870.1250 - Class II
Product Code:	QJP

Trade/ Proprietary Name:	DUO Microcatheter
Common Name:	Catheter, Intravascular, Diagnostic
Regulatory Name:	Catheter, Intravascular, Diagnostic, 21 CFR 870.1200 - Class II
Product Code:	DQO

Trade/ Proprietary Name:	DUO Microcatheter
Common Name:	Catheter, Percutaneous
Regulatory Name:	Catheter, Percutaneous, 21 CFR 870.1250 - Class II
Product Code:	DQY

Predicate Device: Trevo Trak™ 21 Microcatheter (K211594)

Indications for Use

The DUO Microcatheter is intended for 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 DUO Microcatheter is a disposable, single use, sterile device. The DUO Microcatheter is a single-lumen, 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 80 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 steam shaping mandrel and a peel away introducer are provided with each microcatheter.

Technological Characteristics and Product Feature Comparison

REV Neuro has demonstrated the DUO Microcatheter is substantially equivalent to the Predicate device, Trevo Trak™ 21 Microcatheter (K211594) 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 below.

Device Attribute	**Predicate Device** Trevo Trak™ 21 Microcatheter	**Subject Device** DUO Microcatheter
510(k) Number	K211594	K250960
Product Code	QJP, DQO, DQY	QJP, DQO, DQY
Regulation Number	21 CFR 870.1250 21 CFR 870.1200	21 CFR 870.1250 21 CFR 870.1200
Classification	II	II
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.	The DUO Microcatheter is intended for 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 coating on the distal 100 cm to reduce friction during use. The radiopaque shaft and distal marker(s) facilitate fluoroscopic visualization.	The Microcatheter is a single-lumen, 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 80 cm to reduce friction during use. The radiopaque shaft and distal marker(s) facilitate fluoroscopic visualization.
Accessory Devices	Rotating Hemostasis Valve (RHV)	Peel Away Introducer, Steam Shaping Mandrel
Shaft Construction	Polymer jacket with Stainless Steel reinforcement and PTFE inner layer	Polymer jacket with Stainless Steel reinforcement and PTFE inner layer
Market Band	Platinum/ Iridium	Platinum/ Iridium
Outer Jacket Coating	Hydrophilic Coating	Hydrophilic Coating
Labeled Shaft Outer Diameters	2.4F/ 2.0F	2.8F proximal / 2.4F distal

Device Attribute	Predicate Device Trevo Trak™ 21 Microcatheter	Subject Device DUO Microcatheter
Labeled Shaft Inner Diameter	0.021”	0.021”
Effective Length	162 cm	160 cm
Packaging Materials and Configuration	HDPE Packaging Hoop, Tyvek/Film Pouch, SBS Carton	HDPE Packaging Hoop and PETG with SIL Tray, Tyvek/Film Pouch, SBS Carton
How Supplied	Single Use/Sterile	Single Use/Sterile
Sterilization	EO Sterilization	EO Sterilization
Shelf Life	2 years	3 years
Principle 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.	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.

Testing Summary

Performance Data – Bench Testing

The results of design verification and design validation testing conducted on the DUO Microcatheter demonstrate that it performs as designed, is suitable for the intended use, and is substantially equivalent to the legally marketed Predicate device. The design verification and design validation bench testing are summarized below.

Test	Test Method Summary	Conclusion
Dimensional Verification	The device dimensions were measured to confirm they meet design specifications.	Pass
Tensile Strength	Tensile strength was measured across material transitions based on ISO-10555-1.	Tensile strength was above acceptance criterion established by Trackability testing.
Air Leak Resistance	Air leak tested based on ISO 10555-1.	Pass
Liquid Leak Resistance	Liquid leak tested based on ISO 10555-1.	Pass
Burst Pressure	Burst pressure tested based on ISO 10555-1.	Static burst pressures were above acceptance criterion established by manual syringe delivery of contrast.
Particulate Characterization	Particulates were collected from a validated model, characterized, and compared to the predicate.	Particulate generation was comparable to the predicate device

Coating Integrity	Hydrophilic coating was inspected before and after simulated use in a tortuous model.	Pass
Torque Strength	The distal end of the catheter was constrained while the proximal end of the catheter was rotated in a model to verify that the catheter can withstand torsional load.	Pass
Kink Resistance	Kink resistance was tested for all applicable segments of the catheter.	Pass
Chemical Compatibility	Catheter was visually inspected before and after exposure to various clinically relevant chemicals.	Pass
Tip Flexibility	Tip stiffness tested per ISO 10555-1at multiple locations and compared to the predicate.	Tip flexibility was comparable to the predicate device.
Distal Tip Configuration	The distal tip was inspected to verify it is smooth and rounded.	Pass
Surface Condition	Surface was inspected to verify the external surface of the catheter is free from extraneous matter, process or surface defects along the shaft.	Pass
Trackability	To evaluate the force required to track the catheter through a tortuous model compared to the predicate.	Pass
Luer Testing	Hub luer was tested to meet the requirements of ISO 80369-7.	Pass
Compatibility and Simulated use	The device was used in simulated anatomical model to assess overall performance and interaction with ancillary devices and stent retrievers.	Pass
Corrosion	Corrosion resistance was evaluated per ISO 10555-1.	Pass
Radiopacity	Radiopacity was evaluated under fluoroscopy in an in vitro model.	Pass

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

Biocompatibility

The DUO Microcatheter was assessed for biocompatibility in accordance with 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 ≤24 hours. An overview of the biocompatibility testing is summarized below:

Test/Method/Standard	Test Result	Conclusion
Cytotoxicity (ISO 10993-5)	Non-Cytotoxic	Pass
Complement Activation (ISO10993-4)	Non-Activator	Pass
Hemolysis - Direct and Extract (ISO 10993-4)	Non-Hemolytic	Pass
Partial Thromboplastin Time (ISO 10993-4)	Comparable to Control	Pass
In Vitro Blood Flow Loop Assay (ISO 10993-4)	Non-Thrombogenic	Pass
Platelet Leukocyte Count (ISO 10993-4)	Non-Thrombogenic	Pass
Intracutaneous Reactivity (ISO 10993-23)	Non- Irritating	Pass
Sensitization /Maximization Test (ISO 10993-10)	Non-Sensitizing	Pass
Acute Systemic Toxicity (ISO 10993-11)	Non - Toxic	Pass
Material Mediated Pyrogenicity (ISO 10993-11)	Non- Pyrogenic	Pass

Conclusion

The DUO Microcatheter is deemed substantially equivalent to the predicate device (K211594) based on the same intended use/indications for use and similar design, materials, packaging, fundamental scientific technology, and operating principles. Performance testing and biocompatibility testing demonstrated that the DUO Microcatheter performs as intended. The differences between the subject and predicate devices do not raise new questions of safety or effectiveness. Therefore, the DUO Microcatheter is considered substantially equivalent to the predicate device.