June 30, 2026

MicroVention, Inc. d/b/a Terumo Neuro
Miranda Beach
Senior Regulatory Affairs Specialist
35 Enterprise
Aliso Viejo, California 92656

Re: K261808
Trade/Device Name: ISAAC Neurovascular Navigation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: May 28, 2026
Received: June 1, 2026

Dear Miranda Beach:

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
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)*
K261808

Device Name
ISAAC Neurovascular Navigation Catheter

Indications for Use *(Describe)*
The ISAAC Neurovascular Navigation Catheter is indicated for use in facilitating advancement of catheters through the neuro and peripheral vasculature and introduction of diagnostic agents. The ISAAC Neurovascular Navigation Catheter is not intended for use in the coronary vasculature.

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

K261808

510(k) Owner Information:

510(k) Owner: MicroVention, Inc. d/b/a Terumo Neuro

Address: 35 Enterprise, Aliso Viejo, California 92656, USA

Phone Number: (714)-247-8000

Contact Person: Miranda Beach

Phone number: (949)-989-0580

Date Prepared:	June 26, 2026
Device Trade Name:	ISAAC™ Neurovascular Navigation Catheter
Common Name:	Percutaneous Catheter
Device Class:	Class II
Classification Name:	Percutaneous Catheter
Product Codes:	QJP, DQY
CFR Classification:	21 CFR 870.1250
Predicate Device:	ISAAC™ Neurovascular Navigation Catheter (K222115)

Indications for Use

The ISAAC™ Neurovascular Navigation Catheter is indicated for use in facilitating advancement of catheters through the neuro and peripheral vasculature and introduction of diagnostic agents. The ISAAC™ Neurovascular Navigation Catheter is not intended for use in the coronary vasculature.

Device Description

The ISAAC™ Neurovascular Navigation Catheter (ISAAC Catheter) is designed to facilitate the advancement of guiding catheters through the vasculature. The ISAAC Catheter is a braid-reinforced variable stiffness catheter with a pre-shaped distal segment. The distal end of the catheter is coated with hydrophilic coating around the curve on the pre-shaped section of the Simmons (SIM) configurations. It is a single lumen catheter with a radiopaque distal coiled section and a luer hub on the proximal end. The ISAAC Catheter is sterile, non-pyrogenic and intended for single use only.

TERUMO
NEURO

Comparison of Indications for Use and Technological Characteristics

The subject and predicate devices have the same intended use and fundamental technological characteristics. The changes to the polymer jackets and inner coil of the distal portion do not alter device dimensions, materials composition, or operating principle.

Feature	Predicate Device	Subject device
	ISAAC Neurovascular Navigation Catheter K222115	ISAAC Neurovascular Navigation Catheter K261808
FDA Classification	Class II	Same
Product Code(s)	DQY, QJP	Same
Regulation Number	21 CFR 870.1250	Same
Regulation Name	Percutaneous Catheter	Same
Indications for Use	The ISAAC Neurovascular Navigation Catheter is indicated for use in facilitating advancement of catheters through the neuro and peripheral vasculature and introduction of diagnostic agents. The ISAAC Neurovascular Navigation Catheter is not intended for use in the coronary vasculature.	Same
Catheter Body	Braid: Stainless Steel Catheter: Polytetrafluoroethylene (PTFE) Coiling: Tungsten Outer: Polymer	Same
Marker	Radiopaque coil	Same
Hub	Nylon	Same
Strain Relief	Polyurethane	Same
Inner Diameter	6F: 1.02 mm (0.040”)	Same
Outer Diameter	6F: 2.11 mm (0.083”)	Same
Effective Length	SIM2-3D: 150 cm SIM3-3D: 150 cm TIP45: 140 cm	Same
Coating	Hydrophilic	Same
Tip Configuration	Variable Tip Shape & Size	Same
Guidewire Compatibility	0.035” and 0.038”	Same
Accessories	Not Applicable	Same
Method of Supply	Sterile and Single Use	Same
Sterilization Method	Sterilized using 100% Ethylene Oxide	Same
Packaging Configuration	Placed on a mounting card, Tyvek pouch, shipping carton	Same

Summary of Performance Testing

Bench testing was conducted to demonstrate the subject device performs as intended and to support substantial equivalence to the predicate device. All testing met previously established acceptance criteria. Testing included the following:

- Simulated Use
- Physical Attribute (Dimensions)
- Kink Resistance
- Catheter Stiffness
- Tip Flexibility
- Catheter Flexural Fatigue
- Static Burst
- Liquid Leakage
- Leakage and Damage Under High Static Pressure Conditions
- Air Leakage
- Dynamic Burst Pressure
- Force at Break (Distal)
- Catheter Torque Strength

Animal Testing:

An animal study was not deemed necessary to support the substantial equivalence of the subject device to the predicate device.

Clinical Study:

A clinical study was not deemed necessary to support the substantial equivalence of the subject device.

Sterilization and Shelf Life

The ISAAC Catheter is sold sterile and for single use only. The ISAAC Catheter is sterilized using a validated 100% Ethylene Oxide sterilization process to ensure sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11135. The modifications described in this submission do not impact sterilization as compared to the predicate device.

The subject device's shelf-life and packaging configuration remain identical to that of the predicate device. Therefore, no additional shelf life or packaging validation testing was required to demonstrate substantial equivalence between the subject and predicate device.

Biocompatibility

The biological safety of the ISAAC Catheter was established in accordance with the ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a Risk Management Process." The ISAAC Catheter is classified as an externally communicating device, circulating blood, limited contact (≤24 hrs.).

The subject device does not introduce new or change patient contacting materials, primary packaging, or manufacturing processing aids. The patient contacting materials of construction, processing aids, design requirements, and clinical indication remain unchanged from the predicate device (K222115). Accordingly, no additional biocompatibility testing was deemed necessary, and the previously established biocompatibility data remain applicable to the subject device.

Conclusion

The subject ISAAC Neurovascular Navigation Catheter has the same intended use and similar technological characteristics as the predicate device ISAAC Neurovascular Navigation Catheter (K222115). The differences between the subject device and the predicate device do not raise new questions of safety and effectiveness. The nonclinical bench performance testing demonstrates that the subject device performs as intended and is substantially equivalent to the predicate device.