



June 9, 2026

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

Re: K261549

Trade/Device Name: BOBBY Balloon Guide Catheter  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: QJP, DQY  
Dated: May 8, 2026  
Received: May 11, 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](mailto: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  
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Physical Medicine Devices  
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Enclosure

## Indications for Use

510(k) Number (if known)  
K261549

Device Name  
BOBBY Balloon Guide Catheter

### Indications for Use (Describe)

The BOBBY Balloon Guide Catheter is intended for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for retrieval devices.

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**

**K261549**

### **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 8, 2026

**Device Trade Name:** BOBBY™ Balloon Guide Catheter

**Common Name:** Balloon Guide Catheter

**Device Class:** Class II

**Classification Name:** Percutaneous Catheter

**Product Codes:** QJP, DQY

**CFR Classification:** 21 CFR 870.1250

**Predicate Device:** BOBBY™ Balloon Guide Catheter (K193607)

### **Indications for Use:**

The BOBBY Balloon Guide Catheter is intended for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for retrieval devices.

### **Device Description:**

The BOBBY™ Balloon Guide Catheter is a co-axial, braid-reinforced, variable stiffness catheter with an external hydrophilic coating. The BOBBY Balloon Guide Catheter incorporates a compliant balloon, radiopaque markers, and a bifurcated luer hub on the proximal end. Both inflation lumen and guidewire lumen are constructed with a PTFE inner liner.

The BOBBY Balloon Guide Catheter has an inner lumen through which a guidewire and catheter can be inserted, and a co-axial outer lumen that is used to inflate and deflate the balloon with a syringe filled with contrast media. A bifurcated luer hub is attached to the proximal end of the balloon guide catheter to provide access to both the inner and outer lumens. In addition, a

hydrophilic coating is applied to the distal end of the balloon guide catheter to provide a lubricious outer surface for catheter advancement in the vasculature. A compliant balloon is mounted on the distal end to provide temporary vascular occlusion during angiographic procedures. The balloon incorporates a distal air-purging system to purge air from the inflation lumen prior to use. The balloon catheter also incorporates radiopaque markers to facilitate fluoroscopic visualization and indication of the balloon position.

**Comparison of Technological Characteristics:**

The subject and predicate devices have the same intended use and fundamental technological characteristics. The device changes do not alter device dimensions, materials composition, or operating principle.

Feature	Predicate Device	Subject device
	BOBBY Balloon Guide Catheter K193607	BOBBY Balloon Guide Catheter K261549
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 BOBBY Balloon Guide Catheter is intended for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neurovascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for retrieval devices.	Same
Anatomical Locations	Peripheral and neuro vasculature	Same
Materials	Commonly used medical grade plastics (e.g. nylon, PTFE, polyethylene, polyolefin) and stainless steel	Same
Reinforced Catheter Shaft	Stainless steel braid and coil reinforced shaft	Same
Injection Port	Yes	Same
Radiopacity	Yes, shaft is visible due to distal tip Pt-Ir marker bands	Same
Radiopaque Marker Bands	2	Same
Compliant Balloon	Yes, polyurethane	Same
Labeled Shaft Outer Diameter	0.110 in (2.8 mm) 8Fr	Same
Labeled Shaft Inner Diameter	0.086 in (2.18 mm) 6.5Fr	Same

Feature	Predicate Device	Subject device
	BOBBY Balloon Guide Catheter K193607	BOBBY Balloon Guide Catheter K261549
Effective Length	95 cm (37.4 in)	Same
Tip Shape	Straight	Same
Coating	Hydrophilic Coating – distal portion of shaft	Same
Internal Construction	Coaxial lumen	Same
Accessories Supplied	Peel Away Sheath	Same
How Supplied	Sterile, single use	Same
Sterilization Method	EtO	Same
Sterility Assurance Level	10 <sup>-6</sup>	Same

**Summary of Bench Testing:**

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

- Simulated Use
- Compatibility with Devices and Agents
- Balloon Rated Burst
- Balloon Inflation / Deflation Time
- Balloon Fatigue
- Balloon Decay
- Atraumatic Tip and Flexible Distal Tip
- Lumen Collapse During Aspiration
- Kink Resistance
- Force at Break
- Freedom from Leakage – Liquid
- Freedom from Leakage – Air
- Dynamic Burst Pressure
- Burst Pressure of Catheter
- Flexural Fatigue
- Balloon Compliance
- Catheter Particle Testing
- Torque Strength Testing

**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 subject device, as packaged with included accessories, 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 BOBBY Balloon Guide 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 balloon guide catheter is classified as an externally communicating device, circulating blood, limited contact ( $\leq 24$  hrs.).

The subject device does not introduce new materials or alter any patient-contacting surfaces. Materials of construction, sterilization method, sterility assurance level, and packaging configuration remain unchanged from the predicate device (K193607). Accordingly, no additional biocompatibility testing was conducted, and the previously established biocompatibility data remains applicable to the subject device.

**Conclusion:**

The subject BOBBY Balloon Guide Catheter has the same intended use and similar technological characteristics as the predicate device BOBBY Balloon Guide Catheter (K193607). The differences between the subject device and predicate device do not raise new questions of safety and effectiveness. The nonclinical performance testing demonstrates that the subject device performs as intended and is substantially equivalent to the predicate device.