MicroVention, Inc.
Stephanie Onstot
Senior Regulatory Affairs Specialist
1311 Valencia Avenue
Tustin, CA 92780

July 21, 2020

Re: K193607
Trade/Device Name: BOBBY Balloon Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, QJP
Dated: June 25, 2020
Received: June 26, 2020

Dear Stephanie Onstot:

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 (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193607

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.

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510(K) SUMMARY

510(k) Owner Information:

510(k) Owner:	MicroVention, Inc.
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	Tustin, California, USA
Telephone:	714-247-8000
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Contact Person	Stephanie Onstot
Telephone	714-247-8000 x 8317

Date Prepared: June 25, 2020

Device Trade Name: BOBBY™ Balloon Guide Catheter

Classification: Class II

Classification Name: Percutaneous Catheter

Product Code(s): DQY, QJP

Regulation Number(s) 870.1250

Predicate Devices: Concentric Medical, FlowGate^{2}™ (K153729)

Indication 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.

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.

Performance Testing Summary:

The BOBBY Balloon Guide Catheter has successfully completed the following relevant performance testing demonstrating that the device is suitable for its intended use.

Performance Test Summary			
Study Name	Description	Reference Standard	Results
Conditioning, Distribution, and Shelf Life Aging Verification	To demonstrate that the product meets the packaging strength and packaging integrity following accelerated aging to a 1-year shelf life equivalent	ASTM F88 Seal Strength of Flexible Barrier materials ASTM F2096 Standard Test Method for Detecting Gross Leaks in Medical Packaging	Pass All samples met the pre-determined acceptance criteria
Packaging Visual Inspection	To demonstrate that the product meets the packaging visual inspection requirements given	N/A	Pass All samples met the pre-determined acceptance criteria
Visual Surface Requirements	To demonstrate the product satisfies the visual surface requirements	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria
Dimensional/Physical Attributes Inspection	To demonstrate that the product meets the dimensional specifications	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria
Inflation Volume vs Balloon Diameter	To demonstrate that the product meets the inflation volume vs balloon diameter specifications	In consideration of ISO 10555-4:2013 Intravascular Catheters - Sterile and Single-Use Catheters - Part 4: Balloon Dilation Catheters	Pass All samples met the pre-determined acceptance criteria
Balloon Burst Volume	To demonstrate that the Balloon is capable of withstanding an injection volume above the maximum fill volume.	In consideration of ISO 10555-4:2013 Intravascular Catheters - Sterile and Single-Use Catheters - Part 4: Balloon Dilation Catheters	Pass All samples met the pre-determined acceptance criteria
Tip Stiffness	To demonstrate that the stiffness of the distal end of the product is similar to other marketed devices.	N/A	Pass All samples met the pre-determined acceptance criteria
Torque Testing	To demonstrate that the product is capable of 720 degrees of rotation about the central lumen axis without failure.	N/A	Pass All samples met the pre-determined acceptance criteria

Performance Test Summary			
Study Name	Description	Reference Standard	Results
Force at Break	To demonstrate the product satisfies the force at break requirements	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria
Small Bore Connector Compliance with Standard	To demonstrate that the product meets the requirements	ISO 80369-7 2016, Small-bore connectors for liquids and gases in healthcare applications — Part 7, Connectors for intravascular or hypodermic applications.	Pass All samples met the pre-determined acceptance criteria
Radiopacity	To determine the radiopaque characteristics of the device.	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements ASTM F640-12 Standard Test Methods for Determining Radiopacity for Medical Use	Pass All samples met the pre-determined acceptance criteria
Particulate, Coating Integrity	This study was conducted to determine the quantity and size of particles generated during simulated use	USP <788> Particulate Matter in Injections	Pass All samples met the pre-determined acceptance criteria
Freedom from Liquid Leakage	To demonstrate that the product meets the liquid leakage requirements given in ISO 10555- 1.	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria
Hub Aspiration Air Leakage	To demonstrate that the product meets the hub aspiration air leakage requirements given in ISO 10555-1.	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria
Balloon Fatigue Test	To demonstrate that there is no degradation of the Balloon after repetitive inflation cycles.	In consideration of ISO 10555-4:2013 Intravascular Catheters - Sterile and Single-Use Catheters - Part 4: Balloon Dilation Catheters	Pass All samples met the pre-determined acceptance criteria
Simulated Use	Simulated use under in vitro conditions in a cerebral vascular model	In consideration of ISO 10555-4:2013 Intravascular Catheters - Sterile and Single-Use Catheters - Part 4: Balloon Dilation Catheters	Pass All samples met the pre-determined acceptance criteria

Performance Test Summary			
Study Name	Description	Reference Standard	Results
Flexural Fatigue	To demonstrate that the product does not lose structural integrity when used in the tortuous path model.	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria
Kink Resistance	To demonstrate that the device has similar kink resistance compared to the predicate device.	N/A	Pass All samples met the pre-determined acceptance criteria
Lubricity and durability of the hydrophilic coating	To demonstrate that the hydrophilic coating is lubricious and durable.	N/A	Pass All samples met the pre-determined acceptance criteria
Guidewire lumen burst pressure (Static, dynamic)	To demonstrate that the device does not burst below rated burst pressure.	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria
Balloon Deflation Time	To demonstrate that the device has similar balloon deflation time compared to the predicate device.	ISO10555-4:2013 Intravascular catheters – Sterile and single-use catheters – Part 4: Balloon dilation catheters	Pass All samples met the pre-determined acceptance criteria
Lumen Collapse	To demonstrate that the guidewire lumen does not collapse under aspiration.	N/A	Pass All samples met the pre-determined acceptance criteria

No animal or clinical studies were required to demonstrate substantial equivalence.

Biocompatibility Testing Summary

Categorized as Externally Communicating Device, Circulating Blood, Limited Contact (≤ 24 hours), per ISO 10993-1, the following testing was conducted:

Test Name	Test Method	Results
Cytotoxicity	Tested in accordance with ISO 10993-5, Biological Evaluation of Medical Devices – Part 5: Tests for *in vitro* cytotoxicity	Pass Noncytotoxic according to the predetermined acceptance criteria
Sensitization	Tested in accordance with ISO 10993-10, Biological Evaluation of Medical Devices – Part 10 Tests for Irritation and Skin Sensitization, Kligman Maximization Test	Pass Did not elicit a sensitization response according to the predetermined acceptance criteria
Intracutaneous Irritation	Tested in accordance with ISO 10993-10, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization	Pass Test requirements for intracutaneous reactivity were met according to the predetermined acceptance criteria

Test Name	Test Method	Results
Systemic Toxicity: Systemic Injection Test	Tested in accordance with ISO 10993-11, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity	Pass Test requirements for systemic toxicity were met according to the predetermined acceptance criteria
Systemic Toxicity: Material Mediated Pyrogenicity	Tested in accordance with ISO 10993-11, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity and USP NF 36:2018 <151> Pyrogen Test	Pass Non-pyrogenic, met the predetermined acceptance criteria
Hemocompatibility: Hemolysis	Tested in accordance with ASTM F756-17, Standard Practice for Assessment of Hemolytic Properties of Materials and ISO 10993-4, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood, Tests for Hemolytic Properties, Direct and Indirect Methods	Pass Non-hemolytic, met the predetermined acceptance criteria
Hemocompatibility: Complement Activation	Tested in accordance with ISO 10993-4, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood, SC5b-9 Complement Activation	Pass Does not activate the complement system, met the predetermined acceptance criteria
Hemocompatibility: Thrombogenicity	Tested in accordance with ISO 10994-4, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood, and ASTM F2888-19, Standard Practice for Platelet Leukocyte Count-An In Vitro Measure for Hemocompatibility Assessment of Cardiovascular Materials	Pass Demonstrates similar thromboresistance characteristics as the control device, met the predetermined acceptance criteria
Hemocompatibility: *In Vitro* Hemocompatibility	Tested in accordance with ISO 10993-4, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood, Hemocompatibility, Direct Contact Method	Pass Not expected to result in adverse effects *in vivo,* met the predetermined acceptance criteria
Hemocompatibility: Partial Thromboplastin Time	Tested in accordance with ISO 10994-4, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood and ASTM F2382-18, Standard Test Method for Assessment of Intravascular Medical Device Materials on Partial Thromboplastin Time (PTT)	Pass Does not have an effect on coagulation of human plasma, met the predetermined acceptance criteria

Predicate Device Comparison

The following table provides a comparison of the key characteristics of the BOBBY Balloon Guide Catheter to the predicate device.

Comparison Chart			
Feature	**Subject Device**	**Predicate device**	**Comparison**
	BOBBY Balloon Guide Catheter K193607	8F FlowGate$^{2™}$ Balloon Guide Catheter K153729	
FDA Classification	Class II	Class II	Same
Product Code(s)	DQY, QJP	DQY	Same
Regulation Number	870.1250	870.1250	Same
Regulation Name	Percutaneous Catheter	Percutaneous Catheter	Same
Anatomical Locations	Peripheral and neuro vasculature	Peripheral and neuro vasculature	Same

Comparison Chart			
Feature	**Subject Device** BOBBY Balloon Guide Catheter K193607	**Predicate device** 8F FlowGate$^{2™}$ Balloon Guide Catheter K153729	**Comparison**
Material	Commonly used medical grade plastics (e.g. nylon, PTFE, polyethylene, polyolefin) and stainless steel	Commonly used medical grade plastics (e.g. nylon, PTFE, polyolefin) and stainless steel	Similar, minor differences do not raise new questions of safety and efficacy, confirmed through biocompatibility and performance testing
Reinforced Catheter Shaft	Stainless steel braid and coil reinforced shaft	Stainless steel braid reinforced shaft	Similar, minor differences do not raise new questions of safety and efficacy
Injection Port	Yes	Yes	Same
Radiopacity	Yes, shaft is visible due to distal tip Pt-Ir marker bands	Yes, shaft material contains barium sulfate, distal tip Pt-Ir marker band	Similar, minor difference does not raise new questions regarding safety and efficacy, both devices are radiopaque
Radiopaque Marker Bands	2	1	Similar, minor difference does not raise new questions regarding safety and efficacy, both devices utilize radiopaque marker bands
Compliant Balloon	Yes, polyurethane	Yes, silicone	Similar, material differences do not raise new questions of safety and efficacy, both materials are used for compliant balloons for intravascular use
Labeled Shaft Outer Diameter	0.110 in (2.8 mm) 8Fr	0.106 in (2.7 mm) 8Fr	Similar, minor differences do not raise new questions of safety and efficacy

Comparison Chart			
Feature	**Subject Device** BOBBY Balloon Guide Catheter K193607	**Predicate device** 8F FlowGate$^{2™}$ Balloon Guide Catheter K153729	**Comparison**
Labeled Shaft Inner Diameter	0.086 in (2.18 mm) 6.5Fr	0.084 in (2.1 mm) 6.4Fr	Similar, minor differences do not raise new questions of safety and efficacy
Effective length	95 cm (37.4 in)	85 cm, 95cm (33.5, 37.4 in)	Similar, minor differences do not raise new questions of safety and efficacy
Tip Shape	Straight	Straight	Same
Coating	Hydrophilic Coating – Distal portion of shaft	None	Difference does not raise new questions of safety and efficacy. Hydrophilic coatings are commonly used to lubricate vascular catheters.
Internal Construction	Coaxial lumen	Coaxial lumen	Same
Accessories Supplied	Peel Away Sheath	Dilator, Rotating Hemostasis Valve, Tuohy Borst Valve with sideport, Peel Away Sheaths, Luer-Activated Valves	Similar, minor differences do not raise new questions of safety and efficacy.
How Supplied	Sterile, single use	Sterile, single use	Same
Sterilization Method	EtO	EtO	Same
Sterility Assurance Level	10^{-6}	10^{-6}	Same

Conclusion:

MicroVention, Inc. concludes through a review of the benchtop assessments, the comparison of the device classification, indications for use, operating principle, technological characteristics, sterility, and biocompatibility that the BOBBY Balloon Guide Catheter is substantially equivalent to the predicate device, FlowGate$^{2™}$ Balloon Guide Catheter. Any differences are minor and do not raise different questions of safety and effectiveness.