May 16, 2024

MicroVention, Inc.
Alick Tan, Ph.D.
Associate Principal, Regulatory Affairs
35 Enterprise
Aliso Viejo, California 92656

Re: K232542
Trade/Device Name: Wedge XL Delivery Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP
Dated: April 15, 2024
Received: April 15, 2024

Dear Alick Tan:

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.

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, Ph.D.
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)*
K232542

Device Name
Wedge XL Delivery Catheter

Indications for Use *(Describe)*
The Wedge XL Delivery Catheter is intended to assist in the delivery of interventional devices, such as distal access catheters, in the neurovasculature.

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 – K232542

510(k) Owner	MicroVention, Inc. 35 Enterprise Aliso Viejo, CA 92656 Establishment Registration No: 3013556777
Contact Person	Alick Tan, PhD Associate Principal, Regulatory Affairs Telephone: 949-615-2603 Email: alick.tan@microvention.com
Date Summary Prepared	May 14, 2024
Trade Name	Wedge XL Delivery Catheter
Common Name	Percutaneous Catheter
Classification	Class II, QJP
Predicate Device	Wedge Microcatheter (K172014)
Reference Device	Delivery Catheter of the Route 92 Medical 088 Access System (K200121)

Device Description

The Wedge XL Delivery Catheter is a single lumen catheter designed to be introduced over a steerable guidewire to access small, tortuous vasculature. The semi-rigid proximal section transitions to a flexible distal tip to facilitate advancement through vessels. Radiopaque markers at the distal end facilitate fluoroscopic visualization. A larger diameter distal segment helps provide stability for navigation. The distal 110 cm outer surface of the Wedge XL Delivery Catheter is coated with a hydrophilic polymer to increase lubricity. A luer fitting on the Wedge XL Delivery Catheter hub is used for the attachment of accessories.

Indications for Use

The Wedge XL Delivery Catheter is intended to assist in the delivery of interventional devices, such as distal access catheters, in the neurovasculature.

Comparison to the Predicate Device

Substantial equivalence of the Wedge XL Delivery Catheter to the predicate device Wedge Microcatheter and to the reference device Delivery Catheter of the Route 92 Medical 088 Access System was established through an evaluation of the intended use, indications for use, principles of operation, device design, materials of construction, and an assessment of usability, safety, and effectiveness via bench and animal studies.

The Wedge XL Delivery Catheter and the predicate device Wedge Microcatheter (K172014)

- have similar intended use,
- use the same principle of operation,
- incorporate the same basic design,
- use similar construction and materials, and
- are ethylene oxide (EtO)-sterilized and packaged using the same processes.

Device Comparison Table

	Delivery Catheter of the Route 92 Medical 088 Access System (K200121)	**Wedge Microcatheter (K172014)**	**Wedge XL Delivery Catheter (K232542)**
	Reference Device	**Predicate Device**	**Subject Device**
Indications for Use	The Route 92 Medical 088 Access System, 110 cm, is indicated for use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovascular system.	The Wedge Microcatheter is intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and to assist in the delivery of interventional devices, such as the SOFIA 6F Catheter, in the neurovasculature.	The Wedge XL Delivery Catheter is intended to assist in the delivery of interventional devices, such as distal access catheters, in the neurovasculature.
Device Classification	Class II QJP 21 CFR 870.1250	Class II DQY 21 CFR 870.1250	Class II QJP 21 CFR 870.1250
Inner Diameter (ID)	0.019 in.	0.021 in.	Same as predicate (K172014)
Outer Diameter (OD)	Distal 0.080 in. Proximal 0.062 in.	0.028 – 0.034 in.	Distal Tip 0.056 in. Proximal 0.065 in.

	Delivery Catheter of the Route 92 Medical 088 Access System (K200121)	**Wedge Microcatheter (K172014)**	**Wedge XL Delivery Catheter (K232542)**
	Reference Device	**Predicate Device**	**Subject Device**
Shapeable Tip	No	Shapeable	No
Distal Segment/Bulb	Yes	Yes	Yes
Bulb OD	0.080 in.	0.064 – 0.068 in.	0.083 in.
Effective/Working Length	151 cm	158 – 160 cm	160 cm
Coating	Hydrophilic coating	Hydrophilic coating	Same
Method of Supply	Sterile and single use	Sterile and single use	Same
Method of Sterilization	Ethylene oxide	Ethylene oxide	Same

Performance Testing - Bench

The following bench performance testing was performed to support the design of the Wedge XL Delivery Catheter and demonstrate that it performs as intended. All tests passed the pre-determined acceptance criteria.

- Physical Attributes
- Surface Contamination
- Coating Lubricity and Durability
- Simulated Use
    - Preparation/Ease of Assembly
    - Introducer Sheath Insertion
    - Tracking With/Without Guidewire
    - Delivery Catheter/Guidewire Lock Up
    - Catheter Ovalization
    - Lubricity/Durability of Hydrophilic Coating
    - Guide Catheter Tracking over Wedge XL Delivery Catheter
    - Particle Testing
- Dynamic Burst Pressure
- Freedom from Air Leakage
- Freedom from Liquid Leakage
- Static Burst Pressure
- Force at Break
- Catheter Flexural Fatigue
- Catheter Particle Testing
- Kink Resistance
- Torque Strength
- Luer-Connector Dimensions and Performance Testing per ISO 80369-7

Radiopacity testing and corrosion resistance testing were previously conducted on a test article that was equivalent to the Wedge XL Delivery Catheter in all aspects relevant to the testing performed, therefore it was deemed unnecessary to repeat the testing for Wedge XL Delivery Catheter.

Biocompatibility Evaluation

Test	Test Summary	Results
Cytotoxicity (ISO MEM Elution Test)	The test article extract exhibited slight reactivity (grade 1).	Non-cytotoxic
Sensitization (ISO Guinea Pig Maximization Test)	No sensitization was observed in the tested animals.	Non-sensitizer
Irritation Reactivity (ISO Intracutaneous Reactivity Test)	No irritation was observed in the tested animals.	Non-irritant
Material Mediated Pyrogenicity (ISO/USP Material Mediated Pyrogenicity Test)	No single animal showed a temperature rise of 0.5 °C or more above its baseline temperature.	Non-pyrogenic
Systemic Toxicity (ISO Acute Systemic Toxicity Test)	No weight loss, mortality, or evidence of systemic toxicity in the tested animals.	No systemic toxicity
Hemocompatibility Hemolysis Assay – Extract and Direct Methods (ASTM Hemolysis Assay)	The test article demonstrated 1.2% hemolysis in direct contact and 0.0% hemolysis in indirect contact.	Non-hemolytic
Hemocompatibility Complement Activation Assay (ISO Hemocompatibility: Complement Activation Assay (SC5b-9))	The human serum exposed to the test article for 60 minutes was found not to activate SC5b-9.	Non-activator

Test	Test Summary	Results
Hemocompatibility Partial Thromboplastin Time (PTT) Test (ASTM Hemocompatibility: Partial Thromboplastin Time (PTT) Assay)	The average clotting time of the test article showed no significant difference from the control.	Non-activator
Hemocompatibility Heparinized Blood Platelet and Leukocyte (ASTM Hemocompatibility: Heparinized Blood Platelet and Leukocyte Count Assay)	The average leukocyte and platelet counts of the test article showed no significant difference from the control.	Non-activator
Hemocompatibility In-Vitro Blood Loop Assay (ISO In-vitro Blood Loop Assay with Comparison Article)	The worst-case sample thrombus observed on the test article showed minimal thrombus formation.	Thromboresistant

Animal Study

Acute, subacute, and chronic animal testing was conducted in accordance with Good Laboratory Practice (GLP) Regulation (21 CFR Part 58) comparing the Wedge XL Delivery Catheter to the predicate Wedge Microcatheter (K172014). The study was designed to assess the safety and performance of catheter tracking in a porcine model. The porcine model was chosen because the vessel sizes allow the insertion and navigation of standard-sized catheters used in humans. Animals were survived to subacute (3 days) and chronic (30 days) time points after procedures to evaluate the vascular response to device use. The study results demonstrated that use of the subject Wedge XL Delivery Catheter with the SOFIA 88 Catheter (K214024) and Wedge Microcatheter with the SOFIA 6F Catheter (K172014, K150366) performed equally in all animal testing. During postmortem examination there were no remarkable gross findings in any of the vessels evaluated with either test or control devices. There was a comparable histological impact of device use on arterial sections in which test and control devices were used. Artery sections subjected to the stiffest segment of the Wedge XL Delivery Catheter exhibited similar tissue responses as to control devices. Overall, the histologic findings were consistent with routine catheterization procedures, which are commonly observed after interventional procedures in porcine models. The results of the animal study did not raise any safety concerns with either the test Wedge XL Delivery Catheter or control Wedge Microcatheter. The devices are deemed equivalent.

Conclusion

MicroVention concludes based upon the comparison of the device intended use, indications for use, operating principles, technological characteristics, and the review of the performance bench testing, animal study assessments, sterility, and biocompatibility evaluation that the Wedge XL Delivery Catheter is substantially equivalent to the predicate Wedge Microcatheter and performs as intended. Any differences between the subject device and the predicate device do not raise new or different questions of safety and effectiveness.