April 5, 2018

MicroVention, Inc.
Marina Emond
Manager, Regulatory Affairs
1311 Valencia Avenue
Tustin, California 92780

Re: K172014
Trade/Device Name: Wedge Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: March 1, 2018
Received: March 5, 2018

Dear Marina Emond:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K172014

Device Name
Wedge Microcatheter

Indications for Use *(Describe)*
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.

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 - K172014**

| | |
|---|---|
| **Trade Name:** | Wedge Microcatheter |
| **Generic Name:** | Percutaneous Catheter |
| **Classification:** | II, 21 CFR 870.1250, DQY |
| **Submitted By:** | MicroVention, Inc.<br>1311 Valencia Ave<br>Tustin, California, USA |
| **Contact:** | Marina Emond<br>Manager, Regulatory Affairs<br>Marina.Emond@Microvention.com<br>(714) 247-8296 |
| **Date:** | April 1, 2018 |
| **Predicate Device:** | Headway 21 Microcatheter (K093160)<br>Headway 17 Microcatheter (K083343)<br>AXS Offset Delivery Assist Catheter (K163259) |

**Device Description:**

The Wedge Microcatheter is a single lumen catheter designed to be introduced over a steerable guidewire to access small, tortuous vasculature. The microcatheter has a semi-rigid proximal section with an outer shaft made of Grilamid nylon. The catheter shaft transitions to progressively softer durometers and different lengths of Polyether block amide (Pebax). The distal-most length of the microcatheter, beyond the enlarged segment, consists of a softer, atraumatic polyurethane.

The enlarged segment on the distal end of the Wedge is designed to reduce the gap between the OD of the guidewire and ID of the Sofia 6F. The tapered bulb section, approximately 1 cm length and located approximately 1.5 cm from the distal tip, can be identified on fluoroscopy between the two radiopaque

proximal marker bands of the Wedge Microcatheter. The bulb OD (0.068") is sized specifically to work with the lumen ID (0.070") of the Sofia 6F allowing for continuous flush of saline through the Sofia.

Three radiopaque markers at the distal end facilitate fluoroscopic visualization. The outer surface of the microcatheter is coated with a hydrophilic polymer coating to reduce friction during navigation in the vasculature. The lubricious inner liner is made from polytetrafluoroethylene (PTFE). A luer fitting on the Microcatheter hub is used for the attachment of accessories. The hub/strain relief provides for the kink resistance at the proximal end. The microcatheter has a straight tip that is designed to be steam shaped by the physicians at the time of the use. A steam shaping mandrel and introducer sheath (accessories) are packaged with the catheter.

**Indications for Use:**

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.

**Technological Characteristics and Product Feature Comparison:**

The subject device, Wedge Microcatheter is substantially equivalent to the predicate devices in terms of:

- Intended use
- Scientific technology
- Fundamental design
- Materials and processes for packaging and sterilization of devices

A tabular comparison of the technological characteristics between the predicate devices and subject device is provided below.

**Product Feature Comparison of Subject Device with Predicate Devices (K083343, K093160, K163259)**

| **Device** Characteristics | **Headway 17 Microcatheter (K083343)** | **Headway 21 Microcatheter (K093160)** | **AXS Offset Delivery Assist Catheter (K163259)** | **Wedge Microcatheter (Proposed)** |
|---|---|---|---|---|
| Device Classification/ Product Code | Class II/ DQY (Percutaneous catheters) | Class II/ DQY (Percutaneous catheters) | Class II/ DQY (Percutaneous catheters) | Class II/ DQY (Percutaneous catheters) |
| Intended Use | The Headway 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 therapeutic agents, such as occlusion coils. | Intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils. | The AXS Offset Delivery Assist Catheter is intended to assist in the delivery of interventional devices, such as distal access catheters, in the neurovasculature. | 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. |
| Catheter OD | .025" -.031" | .028" - .034" | .050” | .028" - .034" Equivalent to predicates |
| Catheter ID | .017" | .021" | .021” | .021" Equivalent to predicates |
| Tip | Shapeable 15 cm | Shapeable 15 cm | Straight 2 cm | Shapeable, same as predicates Headway 17 and Headway 21 |

| **Device** Characteristics | **Headway 17 Microcatheter (K083343)** | **Headway 21 Microcatheter (K093160)** | **AXS Offset Delivery Assist Catheter (K163259)** | **Wedge Microcatheter (Proposed)** |
|---|---|---|---|---|
| Distal segment/bulb | N/A | N/A | The distal outer diameter (OD) of the AXS Offset Catheter gradually increases from 0.036in at the RO Marker to 0.050in, 2 cm proximal to the RO marker. The bulb section with a 0.050in OD is maintained for 28 cm, then gradually decreases towards the proximal section. The overall distal profile of the AXS Offset catheter acts as a smooth transition and reduces the gap between the outer diameter of a steerable guidewire and inner diameter of a DAC while allowing for continuous saline flush through the DAC. | Using the same principle as the predicate AXS Offset, the slightly enlarged segment (bulb) of the Wedge reduces the gap between the outside diameter of the guidewire and the inside lumen of the Sofia allowing for continuous flush of saline through the Sofia. |
| Effective Length | 150 cm ± 2 | 150 cm ± 2 | 150 cm | 158-160 cm<br>Equivalent to predicates |
| Coating | Hydrophilic Coating | Hydrophilic Coating | Hydrophilic Coating | Hydrophilic coating of the same composition as predicates Headway 17 and Headway 21 to reduce friction during use. |
| Hydrophilic Coating Length | 100-105 cm | 100-105 cm | 80 cm | 110-115 cm<br>Equivalent to predicates |

| **Device** Characteristics | **Headway 17 Microcatheter (K083343)** | | **Headway 21 Microcatheter (K093160)** | **AXS Offset Delivery Assist Catheter (K163259)** | **Wedge Microcatheter (Proposed)** |
|---|---|---|---|---|---|
| Packaging | Material | Dispenser hoop: Polyethylene<br>Mounting card: Polyethylene<br>Pouch: Tyvek<br>Carton Box: Bleached Sulfate | Same as Headway 17 | Catheter is placed in a dispenser coil, then inserted into a pouch and placed inside a carton box. | Same as predicates Headway 17 and Headway 21; equivalent to AXS Offset. |
| | Package Config. | Microcatheter is placed in a dispenser hoop and accessories on a mounting card that is then inserted into the pouch. The pouch is then placed inside a carton box. | | | |
| Method of Supplying | Sterile and single use | | Sterile and single use | Sterile and single use | Same |
| Method of Sterilization | Ethylene oxide | | Ethylene oxide | Ethylene oxide | Same |

**Verification Test Summary:**

The results of verification and validation testing conducted on the subject device demonstrate that it performs as intended and are summarized as follows:

| Test Description | Result |
|---|---|
| Surface Contamination | Pass |
| Physical Attributes | Pass |
| Force at Break (Catheter Distal Section) | Pass |
| Force at Break (Catheter Hub Junction) | Pass |
| Freedom from Leakage (Low Pressure, Long Duration) | Pass |
| Freedom from Leakage (High Pressure, Short duration) | Pass |
| Freedom from Leakage - Air | Pass |
| Static Burst Pressure | Pass |
| Dynamic Burst Pressure | Pass |
| Coating Durability/Lubricity | Pass |
| Tip Shape and Tip Retention | Pass |
| Simulated Use | Pass |
| Flow Rate | Pass |
| Kink Resistance | Reference Only |
| Catheter Stiffness | Pass |
| Catheter Flexural Fatigue | Pass |
| Catheter Particle Testing | Pass |
| Dead Space | Reference Only |
| Torque Strength | Pass |
| Corrosion Resistance* | Pass |
| Gauging Test* | Pass |
| Separation Force* | Pass |
| Unscrewing Torque* | Pass |
| Resistance to Overriding* | Pass |

| Test Description | Result |
|---|---|
| Stress Cracking* | Pass |
| Radiopacity* (Visibility under fluoroscopy) | Pass |
| Pyrogenicity* | Pass |
| Ship Testing* | Pass |
| Shelf Life Testing | Pass |

* Testing was previously conducted on test article that was equivalent to the Wedge Microcatheter in all aspects relevant to the testing performed, therefore it was deemed unnecessary to repeat the testing for the Wedge Microcatheter.

**Animal Testing Summary:**

The acute performance/efficacy and safety parameters analyzed (insertion of introducer sheath into RHV, peel away introducer sheath from catheter, track test with guidewire, track test with guidewire/SOFIA 6F and overall performance) were comparable between the Wedge Microcatheter and predicate Headway 21 with no dissection, perforation, luminal narrowing, thrombus formation or distal emboli were noted for both test articles.

Histopathology Results: Morphometric measurements showed no neointimal growth or stenosis in both, the Wedge Microcatheter and predicate Headway 21, with largely identical endothelial loss and no incidence of vessel wall thinning or aneurysmal dilatation. There were no disruptions of the internal elastic lamina or medial layers in any vessel regardless of treatment device. Injury was limited to minimal to occasionally marked endothelial cell denudation without remarkable thrombus deposition in any treated vessel segment. Overall, the results of the study demonstrated substantial equivalence of the Wedge Microcatheter to the predicate.

**Biocompatibility Evaluation:**

The in vitro and in vivo biocompatibility safety studies performed on the Wedge Microcatheter have demonstrated the biocompatibility of the Wedge Microcatheter and support compliance with the ISO 10993-1:2009 and FDA guidelines. The device was determined to be non-cytotoxic, non-sensitizing, intracutaneously non-irritating, systemically non-toxic, non-pyrogenic (material-mediated), non-hemolytic, have no effect on clotting, non-complement activating, and non-thrombogenic. The results of biocompatibility evaluation are summarized as follows:

| Test | Test Summary | Conclusions |
|---|---|---|
| Cytotoxicity - Medium Eluate Method | The test article extract exhibited between no cell lysis (grade 0) to slight reactivity (grade 1). | Non-cytotoxic |
| Sensitization: Maximization Test in Guinea Pigs | No irritation was present on any of the test or negative control (0% sensitized) guinea pigs. | Non-sensitizer |
| Intracutaneous Reactivity | No evidence of irritation (score 0.0). | Non-irritating |
| Systemic Injection Test in Mice | No weight loss, mortality, or evidence of systemic toxicity from the extract exposure to the mice was observed. | Systemically non-toxic |
| Rabbit Pyrogen Test | The rise of rabbit temperatures during the tree hours of observation did not exceed 0.5ºC. | Nonpyrogenic |
| ASTM Blood Compatibility - Direct and Indirect Contact Hemolysis | The test article demonstrated 0.59% hemolysis in direct contact and 1.25% hemolysis in indirect contact. | Non-hemolytic |
| Unactivated Partial Thromboplastion Time Test | An average clotting time of the test article showed no significant difference from the control. | No effect on clotting |
| Complement Activation | The plasma exposed to the test article for 90 minutes was found to exhibit no statistically significant increase in C3a. | Non-activated |
| Thrombogenicity | Both animals exhibited no signs of toxicity during the study (score 0) | Non-thrombogenic |

**Summary of Substantial Equivalence:**

The information presented in this 510(k) demonstrates the substantial equivalence between the predicates Headway 21 Microcatheter (K093160), Headway 17 (K083343), AXS Offset (K163259), and the Wedge Microcatheter in regard to the design, construction materials, operating principle, and intended use.