December 21, 2022

MicroVention Inc.
Riddhi Pandya
Sr. Regulatory Affairs Specialist
35 Enterprise
Aliso Viejo, California 92656

Re: K223050
Trade/Device Name: AZUR HydroPack 18 Peripheral Coil System (Detachable)
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular embolization device
Regulatory Class: Class II
Product Code: KRD
Dated: September 26, 2022
Received: November 29, 2022

Dear Riddhi Pandya:

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,

Misti L. Malone -S

Misti Malone, PhD
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223050

Device Name
AZUR HydroPack 18 Peripheral Coil System (Detachable)

Indications for Use *(Describe)*
The AZUR system is intended to reduce or block the rate of blood flow in vessels of the peripheral vasculature. It is intended for use in the interventional radiologic management of arteriovenous malformations, arteriovenous fistulae, aneurysms, and other lesions of the peripheral 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

I. SUBMITTER

MicroVention, Inc.
35 Enterprise
Aliso Viejo, CA 92656

Establishment Registration No: 3013556777

Contact Person:

Riddhi Pandya
Sr. Regulatory Affairs Specialist

Email: Riddhi.Pandya@microvention.com
Telephone: (646)-724-8792
Date Prepared: September 26, 2022

II. DEVICE

Trade Names: AZUR™ HydroPack 18 Peripheral Coil System (Detachable)

Classification Name: 21 CFR 870.3300

Regulation Name: Vascular Embolization Device

Regulatory Class: II

Product Code: KRD

III. PREDICATE DEVICE

AZUR CX Detachable 18 Peripheral Coil System (K162524, K123384)

IV. DEVICE DESCRIPTION

The Detachable AZUR HydroPack 18 Peripheral Coil System with a controlled detachable delivery method consists of an implantable coil, a delivery pusher, and a Detachment Controller (sold separately). The implantable coils are made of platinum alloy with a hydrogel inner core. The coil is attached to the delivery pusher via a polyolefin elastomer filament. The coil implant is delivered to the target treatment site through a microcatheter which has an inner dimension that is compatible with the selected AZUR HydroPack 18 Peripheral Coil System. The proximal end of the delivery pusher is inserted into the hand-held battery powered AZUR Detachment

Controller. When the implantable coil has been successfully placed in the desired location, the AZUR Detachment Controller is activated and a flow of electrical current heats the polyolefin elastomer filament, resulting in detachment of the implantable coil. The AZUR Detachment Controller is packaged and sold separately.

V. INDICATIONS FOR USE

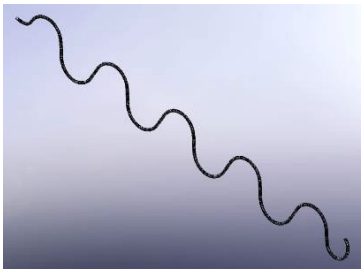
The AZUR system is intended to reduce or block the rate of blood flow in vessels of the peripheral vasculature. It is intended for use in the interventional radiologic management of arteriovenous malformations, arteriovenous fistulae, aneurysms, and other lesions of the peripheral vasculature.

VI. COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The substantial equivalence of the subject device, AZUR HydroPack 18 Peripheral Coil System (AZUR HydroPack), to the predicate device, AZUR CX 18 Peripheral Coil System (AZUR CX: K123384 cleared November 28, 2012, and K162524 cleared March 3, 2017), was established through an evaluation of the indications for use, principle of operation, materials of construction, method of placement, detachment system, sterilization and method of supply.

Device Comparison Table:

FEATURE	AZUR CX (Predicate)	AZUR HydroPack (Subject)
Indications for Use	The AZUR system is intended to reduce or block the rate of blood flow in vessels of the peripheral vasculature. It is intended for use in the interventional radiologic management of arteriovenous malformations, arteriovenous fistulae, aneurysms, and other lesions of the peripheral vasculature.	Same
DESIGN FEATURES		
Coil Shape	Spherical (3D)	Wave
Coil Restrained Length	2 - 40 cm	5 - 60 cm
Coil Construction	Pt/Tungsten alloy coil & Hydrogel core	Same
Effective Pusher Length	175 cm	185 cm

Representative Illustration		
MATERIALS		
Main Coil	Platinum (92%)/Tungsten (8%)	Same
Hydrogel Core	Hydrophilic acrylic polymer (cross linked copolymer of acrylamide and acrylic acid)	Same
Marker Band	Platinum (90%)/Iridium (10%)	Same
Detachment Element	Polyolefin elastomer filament	Same
Stretch Resistant Filament	Polyolefin Elastomer	Same
Adhesive	UV cure adhesive (DYMAX 1128A-M-VT)	Same
Delivery Pusher	Core wire: Stainless Steel Heater coil: Platinum and Stainless Steel Connector: Gold plated Stainless Steel Outer jacket: Polyethylene Terephthalate (PET) and Polyimide Electrical leads: Silver with Polyimide insulation	Same
OTHER		
Catheter Compatibility	Compatible with microcatheters having an ID of 0.019" to 0.027" (0.48 mm to 0.69 mm)	Compatible with microcatheters having an ID of 0.021" to 0.027" (0.53 mm to 0.69 mm)
Method of Sterilization	E-beam	Same
How Supplied	Sterile, for single use	Same
Packaging Material	Introducer, dispenser coil, pouch & shipping carton	Same

VII. PERFORMANCE DATA

To ensure that the modified device continues to meet the established design and performance specifications, applicable verification and validation testing was repeated on baseline and aged

devices, including the following:

- Visual and Dimensional Inspection
- Advance/Retract Force Testing
- Simulated Use Testing
- Implant/Detachment Zone Tensile

VIII. CONCLUSION

The data presented in this submission demonstrates the substantial equivalence of the subject device to the predicate device, the AZUR CX Detachable 18 Peripheral Coil System (K162524, K123384) with regard to intended use, principal of operation, materials, manufacturing processes, packaging configuration, and sterilization method. Based on the supportive data provided in this 510(k), it can be concluded that any differences in technological characteristics do not raise new concerns of safety or effectiveness. Therefore, it is our conclusion that the subject device is substantially equivalent to the predicate device.