DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 25, 2015

MicroVention, Inc.
Cynthia Valenzuela
Project Manager, Regulatory Affairs
1311 Valencia Avenue
Tustin, California 92780

Re: K151358
Trade/Device Name: AZUR CX Peripheral Coil System - Detachable 35
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: August 18, 2015
Received: August 20, 2015

Dear Cynthia Valenzuela:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151358

Device Name
AZUR CX Peripheral Coil System - Detachable 35

Indications for Use *(Describe)*
The AZUR Peripheral Coil 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 of Safety and Effectiveness

Date Prepared: 11SEP2015

510(K) Summary

Trade Name: AZUR CX Peripheral Coil System - Detachable 35

Generic Name: Vascular Embolization Device

Classification: Class II, 21 CFR 870.3300

Submitted By: MicroVention, Inc.
1311 Valencia Avenue
Tustin, California U.S.A.

Contact: Cynthia Valenzuela
Project Manager, Regulatory Affairs
MicroVention, Inc.
Direct: 714-247-8053
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Predicate Device:

Number	Description	Clearance Date
K123384	AZUR Peripheral HydroCoil Endovascular Embolization System – Detachable 18	28NOV2015
K130577	AZUR Peripheral HydroCoil Endovascular Embolization System – Pushable 18 & 35	17JUN2013

Device Description

The AZUR CX Coils consist of implant coil made of platinum alloy with inner hydrogel core. The coils are designed in 3D spherical structure in various loop sizes and lengths. The AZUR CX Coil System (Detachable) consists of an implantable coil attached to a delivery pusher. The coil system is delivered to the treatment site through the microcatheter. The proximal end of the delivery pusher is inserted to the AZUR detachment controller. The detachment controller is activated by the user and this detaches the coil. The AZUR coils are designed for use with the AZUR Detachment Controller (Also known as AZUR Detachment Controller), specifically designed for coil detachment and is sold separately.

Indication For Use

The intended use as stated in the product labeling is as follows:

The AZUR Peripheral Coil 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.

Technological Comparison Chart

Features	**Cleared AZUR Pushable 18 & 35 (K130577)**	**Cleared AZUR CX (D18) (K123384)**	**AZUR CX (D35) Proposed device**
Design Attributes			
Coil Shape	Helical	3D - Spherical	3D - Spherical
Coil Filar OD (inch)	0.00275 – 0.0050	0.00250 – 0.00400	0.0035 – 0.0050
Primary Coil Wind OD (inch)	**18:** 0.0120 **35:** 0.0220	0.0140 – 0.0150	0.0290
3D Coil OD (mm)	18: 2 – 10mm 35: 4 – 16mm	4 – 20*****	4 – 20*****
Restrained Coil Length (cm)	18: 2 – 20mm 35: 4 – 20mm	13 - 40*****	7 – 39
Pusher Length	18: 2 – 10mm 35: 4 – 16mm	175cm	162cm
Materials			
Main Coil Wire	**18:** Platinum (92%)/ Tungsten (8%) **35:** Platinum alloy-clad tantalum [Platinum (90%)/Iridium (10%)] **35** (4 mm)**:** Platinum (92%)/ Tungsten (8%)	Platinum/Tungsten alloy (92/8)	4mm – 8mm: Platinum/Tungsten alloy (92/8) 10mm -20mm: Platinum alloy-clad tantalum [Platinum (90%)/Iridium (10%)]
Coil-to-Pusher Coupler	-	Platinum / Iridium (90/10)	No coupler
Adhesive	UV cure adhesive (DYMAX 1128-AM-VT)	UV cure adhesive (DYMAX 1128-AM-VT)	UV cure adhesive (DYMAX 1128-AM-VT)
Implant to the pusher	-	Polyolefin Elastomer	Polyolefin Elastomer
Stretch Resistant Filament	-	Polyolefin Elastomer	Polyolefin Elastomer
Hydrogel	Hydrophilic acrylic copolymer (cross-linked copolymer of polyethylene glycol diacrylamide and acrylic acid)	Hydrophilic acrylic copolymer (cross-linked copolymer of polyethylene glycol diacrylamide and acrylic acid)	Hydrophilic acrylic copolymer (cross-linked copolymer of polyethylene glycol diacrylamide and acrylic acid)
General			
Catheter Compatibility	**18:** 0.021” – 0.022” ID **35:** 0.041” – 0.047” ID	Compatible with microcatheters having an ID of $\geq$ .019”	Compatible with catheters having an ID of 0.041”-0.047”
Method of Supply	Sterile, single use	Sterile, single use	Sterile, single use
Package Configuration	Sealed in a poly (ethylene terephthalate) pouch coated with silica or aluminum oxide and placed in a shipping carton	Dispenser coil, pouch & shipping carton	Dispenser coil, pouch & shipping carton

Verification of Test Summary

Bench Testing	Result
Simulated use	Passed
Advance/Retract	Passed
Gel Expansion	Passed
Appendix Strength	Passed
Spring Constant	Passed
Pusher Sleeve Retention	Passed

Biocompatibility
Coil Implant Segment - Biocompatibility Summary

Test Method	Standard
Cytotoxicity	
MEM Elution Test	ISO 10993-5
ISO Cell Culture Agar Overlay	ISO 10993-5
Sensitization	
Sensitization-Guinea Pig Maximization Test	ISO 10993-10
Irritation	
ISO Intracutaneous Reactivity Evaluation Test	ISO 10993-10

Coil Implant Segment - Biocompatibility Summary

Test Method	Standard
Hemocompatibility	
Hemolysis	ISO 10993-4
Prothrombin Time Assay - ISO	ISO 10993-4
Systemic Toxicity	
Systemic toxicity (IV injection)	ISO 10993-11
Rabbit Pyrogen Test (material mediated)	ISO 10993-11

Test Method	Standard
Genetic Toxicology	
Bacteria Reverse Mutation Assay (Ames Test)	ISO 10993-3
Intramuscular Implantation	
7-day Muscle Implantation	ISO 10993-6
13-week Intramuscular Implantation Test	ISO 10993-6
26-week Intramuscular Implantation Test	ISO 10993-6

Biocompatibility Summary for Delivery Pusher Segment

Test Method	Standard
Cytotoxicity	
MEM Elution Test	ISO 10993-5
ISO Cell Culture Agar Overlay	ISO 10993-5
Sensitization	
Sensitization-Guinea Pig Maximization Test	ISO 10993-10
Irritation	
ISO Intracutaneous Reactivity Evaluation Test	ISO 10993-10
Hemocompatibility	
Blood compatibility Evaluation (Hemolysis)	ISO 10993-4
Prothrombin Time Assay - ISO	ISO 10993-4
Systemic Toxicity	
Systemic toxicity (IV injection)	ISO 10993-11
Rabbit Pyrogen Test (material mediated)	ISO 10993-11

Summary of Substantial Equivalence:

The data presented in this submission demonstrates the technological similarity and equivalency of the AZUR Peripheral Coils System – CX Detachable 35 Coils when compared with the predicate devices, MicroVention, Inc. AZUR CX Detachable 18 (K1223384) and AZUR Pushable 18 & 35 (K130577).

- The device,
- Has the same intended use,
- Uses the same operating principle,
- Incorporates the same basic design,
- Uses similar construction and material,
- Are packaged and sterilized using the same material and processes.

In summary, the AZUR Peripheral Coil System – CX Detachable 35 Coils described in this submission is, in our opinion equivalent to the predicate devices.