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

March 3, 2017

MicroVention, Inc
Laraine Pangelina
Sr. Regulatory Affairs Manager
1311 Valencia Avenue
Tustin, California 92780

Re: K162524
Trade/Device Name: AZUR CX Detachable 18 Peripheral Coil System
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: January 30, 2017
Received: February 1, 2017

Dear Ms. Laraine Pangelina:

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,

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)*
K162524

Device Name
AZUR CX Detachable 18 Peripheral Coil System

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

Trade Name: AZUR CX Detachable 18 Peripheral Coil System

Generic Name: Vascular Embolization Device

Classification: Class II, 21 CFR 870.3300

Date Submitted: September 1, 2016

Submitted By:
MicroVention, Inc
1311 Valencia Avenue
Tustin, California 92780 U.S.A.

Contact:
Laraine Pangelina
Sr. Regulatory Affairs Manager
MicroVention, Inc.
PH: 714-247-8150

Predicate Device: AZUR CX Detachable 18 Peripheral Coil System (K123384)

Reference Device: K120630, AZUR Peripheral Coil System – Detachable 18

Indications for Use: 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.

Device Description: The AZUR CX Detachable 18 Peripheral Coil System consists of an implantable coil attached to a delivery pusher.

The implantable coil is made of platinum alloy with an inner hydrogel core. The implantable coils are designed in 3D spherical structure in various loop sizes and lengths. They are delivered to the treatment site through the microcatheter. The proximal end of the delivery pusher is inserted to the AZUR Detachment Controller, which is activated by the user and this detaches the coil. The AZUR Detachment Controller is packaged and sold separately.

Predicate / Subject Technological Comparison:

Design Feature	Cleared Device (K123384)	Line Extension (subject device)
Coil shape	3D spherical	Same
Coil OD (mm)	4 – 20	2 - 3
Coil Length, restrained (cm)	13 - 40	2 - 8
Method of Coil Delivery	Coil attached to a delivery pusher. The proximal end of the delivery pusher is inserted to the AZUR Detachment Controller, which is activated to detach and deliver the coil. The AZUR Detachment Controller is packaged and sold separately.	Same
Catheter Compatibility	Compatible with microcatheters having an ID of ≥ 0.021"	Compatible with microcatheters having an ID of 0.019" - 0.027"
Method of Supply	Sterile, single use	Same
Package Configuration	Dispenser coil, pouch & shipping carton	Same

Pre-Clinical Testing: Microvention developed a design verification and validation program for the AZUR CX Detachable 18 Peripheral Coil System Line Extension with reference to the FDA Guidance for Vascular and Neurovascular Embolization Devices. Bench testing was undertaken to demonstrate the substantial equivalence of the subject device to the AZUR CX Detachable 18 Peripheral Coil System when used according to the Instructions for Use. The design verification and validation program included the evaluations listed below:

- Visual Inspection
- Simulated Use Testing
- Advance/Retract force testing

Summary of Substantial Equivalence:

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 (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.