DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 27, 2017

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

Re: K162999
Trade/Device Name: MicroPlex Coil System, HydroCoil Embolic System, AZUR Peripheral Coil System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: February 21, 2017
Received: February 22, 2017

Dear Ms. 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162999

Device Name
MicroPlex Coil System, HydroCoil Embolic System, AZUR Peripheral Coil System

Indications for Use *(Describe)*

MicroPlex Coil System and HydroCoil Embolic System:
The MicroPlex Coil System and HydroCoil Embolic System are intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The MicroPlex Coil System and HydroCoil Embolic System are also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature.

AZUR Peripheral Coil System:
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.

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510(K) SUMMARY

(Prepared October 24, 2016)

The primary purpose of the subject 50(k) is a modification to the V-Grip Detachment Controller and the AZUR Detachment Controller. The V-Grip Detachment Controller is an accessory for use with the MicroVention MicroPlex Coil System (MCS) and HydroCoil Embolic System (HES). The AZUR Detachment Controller is for use with the MicroVention AZUR Peripheral Coil System (AZUR)

Trade Name:	1. MicroPlex Coil System and HydroCoil Embolic System 2. AZUR Peripheral Coil System
Generic Name:	1. Neurovascular Embolization Device (MicroPlex Coil System and HydroCoil Embolic System) 2. Vascular Embolization Device (AZUR Peripheral Coil System)
CFR Classification:	Class II, 21 CFR 882.5950 (MicroPlex Coil System and HydroCoil Embolic System) Class II, 21 CFR 870.3300 (AZUR Peripheral Coil System)
Product Code:	HCG (MicroPlex Coil System and HydroCoil Embolic System) KRD (AZUR Peripheral Coil System)
Submitted By:	MicroVention, Inc 1311 Valencia Avenue Tustin, California 92780 U.S.A.
Contact:	Laraine Pangelina Sr. Regulatory Affairs Manager MicroVention, Inc.
Predicate Device:	1. V-Grip Detachment Controller (for use with MicroPlex Coil System and HydroCoil Embolic System), K050954 2. AZUR Detachment Controller (for use with AZUR Peripheral Coil System), K050954
Indications for Use:	*NOTE: The V-Grip Detachment Controller is an accessory for use with the MicroVention MicroPlex Coil System (MCS) and HydroCoil Embolic System (HES). The AZUR Detachment Controller is for use with the MicroVention AZUR Peripheral Coil System (AZUR). As an accessory to the coil systems, the indications for use for the Detachment Controller are the same as that for the coil systems with which they are used:* <u>MicroPlex Coil System and HydroCoil Embolic System:</u> The MicroPlex Coil System and HydroCoil Embolic System are intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous

malformations and arteriovenous fistulae. The MicroPlex Coil System and HydroCoil Embolic System are also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature.

AZUR Peripheral Coil System:

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 V-Grip Detachment Controller is an accessory for use with the MicroVention MicroPlex Coil System (MCS) and HydroCoil Embolic System (HES). The AZUR Detachment Controller is for use with the MicroVention AZUR Peripheral Coil System (AZUR).

The MCS and AZUR devices consist of an implantable coil made of a platinum alloy (Platinum/Tungsten). The HES and AZUR metal/gel devices consist of an implantable coil made of the same platinum alloy with a hydrogel inner core.

The implantable coil is attached to a delivery pusher via a polyolefin elastomer material. The proximal end of the delivery pusher is inserted into a hand held, battery powered Detachment Controller. When the Detachment Controller is activated, the flow of electrical current heats the polyolefin elastomer filament, resulting in detachment of the implantable coil. The Detachment Controller is packaged and sold separately.

The primary purpose of the subject submission is a modification to the V-Grip/AZUR Detachment Controller to facilitate battery removal and disposal after use of the device. The table below provides a summary of the differences between the current and modified Detachment Controller.

Characteristic	Current V-Grip/AZUR Detachment Controller (K050954)	Modified V-Grip/AZUR Detachment Controller (Subject Device)
Power Source	Three - 12 V alkaline batteries, not removable or replaceable	One - 9 V alkaline battery, removable, not replaceable
Output Voltage	8 VDC ± 1V	9.00 VDC ± 0.50V
Output Current	170 mA nominal, 246 mA maximum	170 mA nominal, 256 mA maximum
Housing/Funnel	ABS 633 Plastic ABS Polyac 747 Funnel: Color Science #CS4B627A (V-Grip) and #CS3W768A-2 (AZUR) Housing: Color Science #CS2Y457A (V-Grip) and # CS3G257A (AZUR)	Same materials. Modified dimensions and configuration to allow battery removal

Bench Test Summary:

Test	Test Method Summary	Result
Output Voltage and Time	All 22 samples (minimum) before and after sterilization shall have a measurement rating of 9.0 ± 0.5V and 0.75 ± 0.10 seconds for a minimum of 20 cycles, to meet 90% confidence of 90% reliability for the voltage, time, and number of cycles.	PASS
Detachment	All 22 samples (minimum) before and after sterilization shall detach the implants at the 11th and 20th cycles in under three detachment attempts.	PASS
Battery Voltage Measurement	All 22 samples (minimum) before and after sterilization shall meet the acceptance criteria of > 7V.	PASS
LED and Buzzer Sequence	All 22 samples (minimum) before and after sterilization shall pass the conditional LED and buzzer sequence tests for standard operation, detachment testing, and functional testing beyond 20 cycles.	PASS
EMC Compatibility	Test samples were subjected to five EMC tests in accordance with IEC 60601-1-2:2014. Testing was conducted for MicroVention by TUV America in San Diego, CA.	PASS
Software Validation	Software validation testing was performed to demonstrate that the modified V-Grip/Azur Detachment Controller met the requirements of Design Specifications and the Software Requirements Specification.	PASS
Electrical Safety	The modified V-Grip/AZUR Detachment Controller was evaluated by TUV SUD America in accordance with IEC 60601-1:2012 Edition 3.1 and other related standards. The evaluation included the risk management file review and safety testing, which concluded that the subject device meets the selected requirements of the test specifications.	PASS
Shelf Life, Accelerated Aging 1 year	Shelf life testing was performed on 22 samples that had been subjected to the equivalent of 1-year accelerated aging. The test samples were sterilized according to the sterilization cycle that will be utilized for commercialized product, and subjected to simulated shipping hazard per ISTA 3A. Visual inspection and output performance were tested. Since there are no changes in the candidate packaging system and the change in sterilization load density is insignificant for the subject device when compared to the predicate devices. Sterilization validation has been validated for the predicate device at the Sterility Assurance Level of 10^{-6}.	PASS

Predicate / Subject Technological Comparison:

Characteristic	Current V-Grip/AZUR Detachment Controller (K050954)	Modified V-Grip/AZUR Detachment Controller
V-Grip Device General Description	A self-contained, disposable, hand held, battery powered detachment controller provides the controlled electrical energy for the detachment of the coil from the delivery pusher.	Same
Power Source	Three - 12 V alkaline batteries, not removable or replaceable	One - 9 V alkaline battery, removable, not replaceable
Output Voltage	8 VDC ± 1V	9.00 VDC ± 0.50V
Output Current	170 mA nominal, 246 mA maximum	170 mA nominal, 256 mA maximum
Printed Circuit Board	Qty.1: PD00285 - Printed Circuit Board	Qty.1: PD110285 - Printed Circuit Board
Housing/Funnel	ABS 633 Plastic ABS Polyac 747 Funnel: Color Science #CS4B627A (V-Grip) and #CS3W768A-2 (AZUR) Housing: Color Science # CS2Y457A (V-Grip) and # CS3G257A (AZUR)	Same materials. Modified dimensions and configuration to allow battery removal
Detachment cycle time	0.75 seconds	Same
Detachments per unit	20	Same
Method of Supply	Sterile and single patient use	Same
Package Configuration	Placed in sealed pouch 5 units per carton box	Same
Method of Sterilization	Ethylene oxide	Same

Summary of Substantial Equivalence:

The devices that are the subject of this submission are substantially equivalent to the predicate devices with regard to intended use, patient population, device design, materials, processes, and operating principal.