510(K) SUMMARY

K133626

DEC 2 0 2013

Trade Name: AZUR PURE Peripheral Coil System, Pushable 18

Generic Name: Vascular Embolization Device, accessory

Classification and Product Code: Class II, 21 CFR 870.3300
Product Code KRD

Date Submitted: November 22, 2013

Submitted By:
MicroVention, Inc
1311 Valencia Avenue
Tustin, California 92780
U.S.A
Phone: 714-247-8000

Contact:
Laraine Pangelina
Sr. Regulatory Affairs Project Manager
MicroVention, Inc.

Predicate Device: AZUR PURE Peripheral Coil System, Pushable 18 (K122543)

Indications for Use: The AZUR PURE 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 PURE Peripheral Coil System, Pushable 18, consists of an implantable coil housed in an introducer. A stainless steel stylet is used to deploy the coil from the introducer into a delivery catheter. The coil is delivered to the treatment site through the delivery catheter using a standard guidewire.

The subject of this Special 510(k) is the addition of a platinum overcoil to the AZUR PURE Pushable 18 device. The purpose is to improve tracking performance of the coil implant during delivery.

With the exception of the modification to add the platinum overcoil, the modified devices are identical to the cleared predicate devices with regard to intended use, principal of operation, materials, manufacturing processes, packaging configuration, and sterilization method.

Pre-Clinical Testing:

Design Verification and Validation Bench Test Summary			
Test / Test Description	**Acceptance Criteria**	**Test & Acceptance Criteria same as predicate device? Y/N**	**Result**
Simulate Use Introduction, Tracking, Deployment, Compartmentalizing, Frame Movement, Microcatheter movement, Detachment, Overall Performance	All performance ratings shall be ≥ 3	Y	PASS, acceptance criteria met
Advancement Force Measure the force required to advance the coil into the microcatheter	< 0.3 lbf	Y	PASS, acceptance criteria met
Tensile Strength at Glue Joint Test the tensile strength platinum coil glue joint	0.05 lbf minimum	Y	PASS, acceptance criteria met
Expansion Characteristics Determine the expansion over time	Fully hydrated (≥ 20 min.) ≤ 0.026"	Y	PASS, acceptance criteria met
CONCLUSION: The results of the bench testing demonstrate that the subject device is safe and effective when used according to the instructions for use and performs equivalent to the predicate device. The testing was used in support of the risk analysis documentation for the subject device.			

Note: The biological safety of the subject device has previously been verified in accordance with the ISO10993-1, Biological Evaluation of Medical Devices, using similar 510(k) cleared devices.

Predicate / Subject Technological Comparison:

Feature	Azur PURE 18 Predicate Devices	Subject Devices
Indications for Use	The AZUR PURE 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
Device Overview	The AZUR PURE Peripheral Coil System, Pushable 18, consists of an implantable coil housed in an introducer. A stainless steel stylet is used to deploy the coil from the introducer into a delivery catheter. The coil is delivered to the treatment site through the delivery catheter using a standard guidewire.	Same
Coil shape	Helical	Same
Coil OD (mm)	3 - 16	Same
Coil Length (cm)	6 - 14	Same
Hydrogel Implant Material	Hydrophilic copolymer	Same
Overcoil	None	Platinum[1]
Delivery Method	Coil housed in an introducer with proximal hub. Pushable delivery using guidewire.	Same
[1] With the exception of the modification to add the platinum overcoil, the modified devices are identical to the cleared predicate devices with regard to intended use, principal of operation, materials, manufacturing processes, packaging configuration, and sterilization method. Any differences in technological characteristics do not introduce any new issues of safety or effectiveness. Therefore, it is our conclusion that the subject device is substantially equivalent to the predicate device.		

Summary of Substantial Equivalence:

With the exception of the modification to add the platinum overcoil, the modified devices are identical to the cleared predicate devices with regard to intended use, principal of operation, materials, manufacturing processes, packaging configuration, and sterilization method. Any differences in technological characteristics do not introduce any new issues of safety or effectiveness. Therefore, it is our conclusion that the subject device is substantially equivalent to the predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 20, 2013

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

Re: K133626
Trade/Device Name: AZUR PURE Peripheral Coil System, Pushable 18
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: November 22, 2013
Received: November 26, 2013

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K133626

Device Name: AZUR PURE Peripheral Coil System, Pushable 18

Indications for Use: The AZUR PURE 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.

Prescription Use X (Per 21 CFR 801.109) AND/OR Over-The-Counter Use____ (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)