March 20, 2020

MicroVention Inc.
Ganesh Balachander
Regulatory Affairs Specialist
35 Enterprise
Aliso Viejo, California 92656

Re: K191680
Trade/Device Name: AZUR Vascular Plug
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: June 21, 2019
Received: June 24, 2019

Dear Ganesh Balachander:

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 Malone
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191680

Device Name
AZUR Vascular Plug

Indications for Use *(Describe)*
The AZUR Vascular Plug is indicated for use to reduce or block the rate of blood flow in arteries 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

SUBMITTER

MicroVention Inc.
35 Enterprise, Aliso Viejo, CA, 92656
Phone:714-847-8000
Contact Person: Ganesh Balachandar
Date Prepared: March 19, 2020

DEVICE

Name of the Device: AZUR Vascular Plug
Common Name: Vascular Embolization Device
Classification Name: Device, Embolization, arterial
Regulatory Class: Class II, 21 CFR 870.3300
Product Code: KRD

PREDICATE DEVICE

Medtronic Micro Vascular Plug (K150108)

REFERENCE DEVICE

MicroVention AZUR CX D35 Peripheral Coil System (K151358)

DEVICE DESCRIPTON

The AZUR Vascular Plug consists of an AZUR vascular occlusion plug implant that is attached to a delivery wire which is intended to be delivered to the treatment site through a microcatheter.

The AZUR Vascular Plug implant is an embolization device consisting of a conformable, self-expanding nitinol braided wire frame surrounding a flexible, occlusive membrane. The implant comes in three sizes, small (5 mm), medium (8 mm) and large (10 mm). The implant is deployed in an appropriately sized vessel to reduce or block the flow of blood. The implant has radiopaque markers to provide visual confirmation of deployment location during the interventional treatment. The implant is delivered through a microcatheter on a detachable delivery system.

The delivery wire attached to the AZUR Vascular Plug implant is 185cm in length and an outer diameter suitable for delivery through a 0.027” ID microcatheter.

A detachment controller powers the delivery pusher to detach the implant. The microcatheter and the detachment controller are provided separately.

INDICATIONS FOR USE

The AZUR Vascular Plug is indicated for use to reduce or block the rate of blood flow in arteries of the peripheral vasculature.

COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The subject device, AZUR Vascular Plug has the following similarities to the predicate device, Micro Vascular Plug (K150108), same device classification, same indications for use, same principle of operation, same device design, similar materials and same sterility assurance level and method of sterilization and hence the subject device is substantially equivalent to the predicate device (Table 1).

Table 1: Comparison of Technological Characteristics with Predicate Device

Device Attributes	**MicroVention AZUR Vascular Plug (Subject Device)**	**Medtronic Micro Vascular Plug (Predicate Device)**	**Rationale for Difference (If Present)**
FDA Medical Device Classification			
Device Classification	Class II, KRD, 21 CFR 870.3300	Class II, KRD, 21 CFR 870.3300	No difference. Identical device classification
Indications for Use			
Intended Use Statement	Indicated for use to reduce or block the rate of blood flow in arteries of the peripheral vasculature.	Intended to reduce or block the rate of blood flow in vessels of the peripheral vasculature.	No difference. Identical Intended use statement.
Principle of Operation/Fundamental Scientific Technology			
Function	Allows the device to obstruct or reduce the rate of blood flow	Allows the device to obstruct or reduce the rate of blood flow	No difference. Identical function.
Anatomical Location	Peripheral Vasculature	Peripheral Vasculature	No difference. Identical anatomical vessels.
Device Design			
Plug (implant description)	Self-expandable nitinol frame with a PTFE and PET cover over the internal wire frame	Self-expandable nitinol frame with a PTFE cover over the proximal section	Similar device design. The results of comparative bench testing, physician usability study and animal study establish the substantial equivalency of the subject device, AZUR Vascular Plug
Plug Diameter, Unconstrained	Small: 5 mm Medium: 8 mm Large: 10 mm	MVP-5Q: 6.5 mm MVP-7Q: 9.2 mm MVP-9Q: 13.0 mm	

Target Vessel Diameter	Small: 2.5-4.5mm Medium:4.5mm-6.5mm Large: 6.5mm-8.0mm	MVP-5Q: 3-5mm MVP-7Q: 5-7mm MVP-9Q: 7-9mm	and the predicate device, Micro Vascular Plug.
Radiopaque Markers	Platinum marker bands at each end of the plug	Platinum marker bands at each end of the plug	Identical marker bands
Method of placement	Delivery wire through a 0.027" ID Microcatheter	Delivery wire through a 0.027" to 0.043" ID Percutaneous catheter	The AZUR Vascular Plug is designed to be delivered through a smaller ID (0.027" inner diameter) microcatheter.
Detachment System	Thermoelectric Detachment	Mechanical Detachment	The results of bench testing, and physician usability study establish the substantial equivalency of the subject device, AZUR Vascular Plug and the predicate device, Micro Vascular Plug.
Device Material			
Materials of Construction	Nitinol, ePTFE, PET, Platinum, Dymax 1128 and Polyolefin	Nitinol, PTFE, Platinum, SS301, Solder, Polypropylene sheath, Urethane and Cyanoacrylate	Similar device material. The materials used for the AZUR Vascular Plug was shown to be biocompatible per ISO 10993 testing.
Other Attributes			
Sterilization Process	EtO (Ethylene Oxide)	EtO (Ethylene Oxide)	No difference. Identical sterilization process.
Method of Supply	Sterile, single use	Sterile, single use	No difference. Identical method of supply.
Accessories	No accessories	Torquer	AZUR Vascular Plug does not use a torque device.

COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH REFERENCE DEVICE

The subject device, AZUR Vascular Plug has the following similarities to the reference device AZUR CX D35 Peripheral Coil System (K151358) :same principle of operation, same delivery wire length,

same delivery wire materials, same detachment mechanism and similar delivery wire catheter compatibility and hence the subject device is substantially equivalent to the reference device.

PERFORMANCE DATA

Biocompatibility testing

The biocompatibility evaluation for the AZUR Vascular Plug device was conducted in accordance with ISO 10993-1 Biological Evaluation of Medical Devices-Part 1: Guidance on Selection of Tests. The implant is considered a permanent implant blood contacting device, and the pusher is considered an external communicating device, limited (<24hour) circulating blood contacting device.

The battery of testing for the device included the following tests:

Implant

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Acute Systemic Toxicity
- Subacute/Subchronic Toxicity
- Genotoxicity
- Material Mediated Pyrogenicity
- Implantation
- Hemocompatibility
- Carcinogenicity

Pusher

- Cytotoxicity
- Hemocompatibility
- Subacute/Subchronic toxicity

HDPE Introducer sheath

- Cytotoxicity

Mechanical, Visual, and Material Characterization testing

Bench testing conducted for the AZUR Vascular Plug device included the following:

- Visual/Dimensional Inspection
- Electrical Resistance
- Exhaustive Extraction Study
- Simulated Use
    - Preparation/Flush
    - Introduction
    - Tracking
    - Advancement
    - Kink Resistance
    - Flexibility
    - Catheter Compatibility
    - Deployment
    - Retraction
    - Detachment
    - Wall Apposition

    - Migration Resistance
    - Overall performance
- Radial force
- Attachment strength
- Implant joint Tensile Strength
- Pusher Sleeve Retention
- Particulate
- Nickel Ion Release
- Corrosion
- Magnetic Resonance (MR) Testing
- Radiopacity
- Occlusion Time
- Shelf Life

Animal Study
The AZUR Vascular Plug was evaluated in a number of animal studies including multiple animal species and implantation sites. This analysis included the following studies:
• Porcine large animal study
• Intramuscular implant rabbit study

CONCLUSION
The AZUR Vascular Plug is substantially equivalent to the identified predicate device based on the same intended use, design, materials, principle of operation and overall technological characteristics. The nonclinical data support the substantial equivalence of the subject device and the verification and validation testing demonstrate that the subject device should perform as intended when used as instructed in the instructions for use.