K122316

MicroVention
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510(K) Summary

AUG 29 2012

Trade Name: AZUR 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

Predicate Device:

Number	Description	Clearance Date
K093002	AZUR Peripheral HydroCoil Endovascular Embolization System – Detachable 35	October 08, 2009

Device Description

The AZUR Peripheral Coil System - Detachable 35 consists of an implantable coil attached to a delivery pusher. The coil system is delivered to the treatment site through the microcatheter. The detachment controller is activated by the user and this detached the coil. The detachment controller utilizes battery power to detach the coils from the delivery pusher.

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.

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Verification and Test Summary Table

Bench Testing	Result
Dimensional Measurement	Met established criteria
Simulated Use	Met established criteria
Device Repositioning	Met established criteria
Device Detachment	Met established criteria
Advance / Retract Force	Met established criteria

Summary of Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and equivalency of the AZUR Peripheral Coil System - Detachable 35 line extension coils when compared with the predicate devices, MicroVention AZUR Detachable 35 (K093002).

The devices,

- Have the same intended use,
- Use the same operating principle,
- Incorporate the same basic design,
- Use similar construction and material,
- Are packaged and sterilized using same material and processes.

In summary, the AZUR Peripheral Coil System - Detachable 35 Coils described in this submission is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

AUG 29 2012

MicroVention, Inc.
c/o Ms. Cynthia Valenzuela
International Regulatory Affairs
1311 Valencia Avenue
Tustin, CA 92780

Re: K122316
Trade/Device Name: AZUR Peripheral Coil System – Detachable 35
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II (two)
Product Code: KRD
Dated: July 25, 2012
Received: August 1, 2012

Dear Ms. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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): K122316

Device Name: AZUR Peripheral Coil System – Detachable 35

Indications For Use:

The AZUR 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.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

M S Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122316