K132317

510(K) SUMMARY

Trade Name: MicroPlex Coil System (MCS), VFC

Generic Name: Neurovascular Embolization Device

Classification: Class II, 21 CFR 882.5950

Date Submitted August 22, 2013

SEP 2 0 2013

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

Contact: Laraine Pangelina

Predicate Device: MicroPlex Coil System (MCS) (K111451)

Indications for Use: The MicroPlex Coil System is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The MCS is 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.

Device Description: The MCS VFC consists of an implantable coil made of bare platinum alloy. The MCS VFC implantable coils has a 3D shape in various loop sizes and lengths. The coil is attached to a V-Trak delivery pusher. The proximal end is inserted into a hand held battery powered V-Grip Detachment Controller (sold separately). The implant segment detaches upon activation of the Detachment Controller.

Bench Test Summary:

Test	Results
Visual/Dimensional Inspection Perform visual inspection and measurments using device drawing	PASS, acceptance criteria met
Simulate Use Introduction, Tracking, Deployment, Compartmentalizing, Frame Movement, Microcatheter movement, Detachment, Overall Performance	PASS, acceptance criteria met
Detachment Test Confirm successful detachment according using V-Grip Detachment Controller during simulated use testing	PASS, acceptance criteria met
Coil-to-Coupler Weld Test Test the tensile strength of the coil/coupler weld	PASS, acceptance criteria met
Spring Constant Measure the spring constant force of the coil	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.	

Predicate / Subject Technological Comparison:

Feature	Predicate Devices	Subject Device
Coil shape	3D	Same
Coil OD (mm)	3 - 15	1
Restrained coil length (cm)	6 - 45	3
Main coil wire material	Platinum/Tungsten (92/8%) alloy	Same
Coupler Material	Platinum (90%)/ iridium (10%)	Same
Adhesive Material	DYMAX 1128-AM-VT UV Adhesive	Same
Stretch resistance filar material	Polyolefin Elastomer or PET	Same
Implant-to-pusher material	Polyolefin elastomer	Same
Delivery method	V-Trak delivery pusher	Same
MRI compatibility	Yes	Yes
Method of supply	Sterile, single use	Same
Packaging configuration	Dispenser coil, pouch, shipping carton	Same

Summary of Substantial Equivalence:

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

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

September 20, 2013

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

Re: K132317
Trade/Device Name: MicroPlex Coil System (MCS), VFC
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG
Dated: August 22, 2013
Received: August 23, 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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132317

Device Name: MicroPlex Coil System (MCS), VFC

Indications For Use: The MicroPlex Coil System is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The MCS is 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 embolization in 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 Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

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