K131948

510(K) SUMMARY

Trade Name: MicroPlex Coil System (MCS)

Generic Name: Neurovascular Embolization Device

Classification: Class II, 21 CFR 882.5950

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

OCT 04 2013

Contact: Laraine Pangelina

Predicate Device: MicroPlex Coil System (MCS)

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 devices consist of an implantable coil made of platinum alloy (MCS) or a platinum allot with an inner hydrogel core (HES). The coil is attached to a V-Trak delivery pusher via a polymer filament. The proximal end of the pusher 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	Result
Visual Inspection	Met the same acceptance criteria as the predicate devices
Dimensional Measurement	Met the same acceptance criteria as the predicate devices
Simulated Use	Met the same acceptance criteria as the predicate devices
Detachment Test	Met the same acceptance criteria as the predicate devices
Coil to Coupler Weld Tensile	Met the same acceptance criteria as the predicate devices
Spring Constant	Met the same acceptance criteria as the predicate devices

Predicate / Subject Technological Comparison:

Design Feature	Predicate Device (K091641)	Predicate Device (K103758)	Line Extension (MCS HyperSoft 3D)
Coil shape	Helical	3D	3D
Coil Filar Size	0.00125 – 0.00150	0.00200 – 0.00225"	0.00125"
Coil Implant Diameter	1 – 8 mm	2 – 12 mm	1.0 – 1.5 mm
Coil Restrained Length	1 – 10 cm	2 – 45 cm	1.5 – 4.5 mm
Main Coil Wire Material	Platinum/Tungsten (92/8%) alloy	Same	Same
Coupler Material	Platinum (90%)/ iridium (10%)	Same	Same
Adhesive Material	DYMAX 1128-AM-VT UV Adhesive	Same	Same
Stretch Resistance Filar Material	PET	Polyolefin Elastomer (3-12mm coils) or PET (2.0-2.5mm coils)	PET
Implant-to-V-Trak Attachment Material	Confidential	Same	Same
Delivery Method	V-Trak delivery pusher	Same	Same
Package Configuration	Dispenser hoop, pouch, and carton	Same	Same
MRI Compatibility	Yes	Yes	Yes
Method of Supply	Sterile, single use	Same	Same

Summary of Substantial Equivalence:

Based on a comparison of technical specifications and device testing results, the MCS HyperSoft 3D devices are substantially equivalent to legally marketed predicate devices.

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

October 4, 2013

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

Re: K131948
Trade/Device Name: MicroPlex Coil System (MCS): MCS HyperSoft 3D
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG and KRD
Dated: July 16, 2013
Received: September 6, 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,

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): K131948

Device Name: MicroPlex Coil System (MCS)

Indications for Use: The MicroPiex 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.

Prescription Use _X_ AND/OR Over-The-Counter Use
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Victor Krauthamer -S
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(Division Sign Off)

Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number _____