K132952

DEC 19 2013

510(K) SUMMARY

(Prepared November 12, 2013)

Trade Name: MicroPlex Coil System (MCS), HydroCoil Embolic System (HES)

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.

Contact: Laraine Pangelina, Sr. Regulatory Affairs Project Manager

Predicate Devices: MicroPlex Coil System (MCS)
(K103758, K091641, K111451, K103758, K08241, K093919, K090891, K093358, K102365)
HydroCoil Embolic System (HES)
(K091641, K103758, K113457, K112226, K120908, K090357, K100454, K091641, K080666)

Indications for Use: Intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. 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: Treatment of cerebral aneurysms can be performed either by surgical clipping or endovascular techniques (e.g., embolization coils). Endovascular methods to embolize intracranial aneurysms with implantable platinum embolization coils were developed in the 1970s. Embolization coils including the MicroVention MCS and HES products are now widely used to treat all aneurysms.

The MCS consists of an implantable coil made of bare platinum alloy (Platinum/Tungsten), and the HES consists of an implantable coil made of the same platinum alloy with a hydrogel inner core. The coil is attached to a delivery pusher via a polyolefin elastomer material. The delivery pusher contains radiopaque positioning markers at the distal end. The proximal end is inserted into a hand held battery powered V-Grip™ Detachment Controller. When the Detachment Controller is activated, the flow of electrical current heats the polyolefin elastomer filament, resulting in detachment of the implant segment. The V-Grip is packaged and sold separately.

The modified MCS and HES devices are substantially equivalent to the cleared predicate devices with regard to intended use, principal of operation, materials, manufacturing processes, packaging configuration, and sterilization method.

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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**
Visual Inspection Perform visual inspection and measurements using device drawing	Per product drawing	Y	Pass Met established criteria
Simulated Use The test simulates a neurointerventional embolization procedure to assess deployment, repositioning, and detachment in an aneurysm.	All performance ratings shall be ≥ 3	Y	Pass Met established criteria
Pusher Resistance Using a digital multimeter, measure the resistance through a microcatheter.	36.7-53.0Ω	Y	Pass Met established criteria
Detachment Zone Tensile Using an Instron tester, measure the breakforce at the detachment zone.	≥0.08 lbf	Y	Pass Met established criteria
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.			

Biocompatibility Test Summary – HES Coil Implant		
Test	**Requirement**	**Result**
MEM Elution	ISO 10993-5	Passed
ISO Cell Culture Agar Overlay	ISO 10993-5	Passed
Sensitization-Guinea Pig Maximization	ISO 10993-10	Passed
ISO Intracutaneous Reactivity Evaluation	ISO 10993-10	Passed
Hemolysis	ISO 10993-4	Passed
Prothrombin Time Assay - ISO	ISO 10993-4	Passed
Systemic toxicity (IV injection)	ISO 10993-11	Passed
Rabbit Pyrogen Test (material mediated)	ISO 10993-11	Passed
Bacteria Reverse Mutation Assay (Ames)	ISO 10993-3	Passed
7-day Muscle Implantation	ISO 10993-6	Passed
13-week Intramuscular Implantation Test	ISO 10993-6	Passed
26-week Intramuscular Implantation Test	ISO 10993-6	Passed

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Biocompatibility Test Summary – MCS Coil Implant		
Test	**Requirement**	**Result**
MEM Elution	ISO 10993-5	Passed
ISO Cell Culture Agar Overlay	ISO 10993-5	Passed
Sensitization-Guinea Pig Maximization	ISO 10993-10	Passed
ISO Intracutaneous Reactivity Evaluation	ISO 10993-10	Passed
Hemolysis	ISO 10993-4	Passed
Prothrombin Time Assay - ISO	ISO 10993-4	Passed
Systemic toxicity (IV injection)	ISO 10993-11	Passed
Rabbit Pyrogen Test (material mediated)	ISO 10993-11	Passed
Bacteria Reverse Mutation Assay (Ames)	ISO 10993-3	Passed
7-day Muscle Implantation	ISO 10993-6	Passed
90-day Intramuscular Implantation Test	ISO 10993-6	Passed
100-day Intramuscular Implantation Test	ISO 10993-6	Passed
Biocompatibility Test Summary – Delivery Pusher		
Test	**Requirement**	**Result**
MEM Elution	ISO 10993-5	Passed
ISO Cell Culture Agar Overlay	ISO 10993-5	Passed
Sensitization-Guinea Pig Maximization	ISO 10993-10	Passed
ISO Intracutaneous Reactivity Evaluation	ISO 10993-10	Passed
Hemolysis	ISO 10993-4	Passed
Prothrombin Time Assay - ISO	ISO 10993-4	Passed
Systemic toxicity (IV injection)	ISO 10993-11	Passed
Rabbit Pyrogen Test (material mediated)	ISO 10993-11	Passed

Predicate / Subject Technological Comparison:

Feature	MCS Predicate Devices	HES Predicate Devices	Subject Devices
Indications for Use	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.	Same	Same
Device Overview	An implantable coil attached to a delivery pusher via a polyolefin elastomer material. The delivery pusher contains radiopaque	Same	Same

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	positioning markers at the distal end. The proximal end is inserted into a hand held battery powered Detachment Controller. When the Detachment Controller is activated, the flow of electrical current heats the polyolefin elastomer filament, resulting in detachment of the implant segment. The Detachment Controller is packaged and sold separately.		
Coil shape	Helical, 3D	Same	Same
Coil OD (mm)	1-24	1-24	Same
Restrained coil length (cm)	1-68	1-50	Same
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	Polyolefin Elastomer or PET	PET	Same
Implant-to-pusher material	Polyolefin elastomer	Same	Same
Delivery method	V-Trak delivery pusher	V-Trak delivery pusher	V-Trak Advanced delivery pusher[1]

[1] The subject device is the same as the predicate devices with the exception of the modified V-Trak Advanced deliver pusher. Other than the colorant in the PET connector tube, the V-Trak Advanced delivery pusher is essentially the same as the cleared V-Trak delivery pusher. The MCS and HES devices with the V-Trak Advanced delivery pusher are the same with regard to intended use and principal of operation. Any differences in technological characteristics do not introduce any new issues of safety or effectiveness. Therefore, it is our conclusion that the MCS and HES devices with the V-Trak Advanced delivery pusher is substantially equivalent to the predicate devices.

Summary of Substantial Equivalence:

The subject devices are the same as the predicate devices with regard to intended use and principal of operation. Any differences in technological characteristics do not introduce any new issues of safety or effectiveness. Therefore, it is our conclusion that the MCS and HES devices with the V-Trak Advanced delivery pusher is substantially equivalent to the 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

December 19, 2013

MicroVention Terumo
c/o Ms. Laraine Pangelina
Sr. Regulatory Affairs Project Manager
MicroVention, Incorporated
1311 Valencia Avenue
Tustin, CA 92780

Re: K132952
Trade/Device Name: Microplex Coil System (MCS), Hydrocoil Embolic System (HES)
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: November 18, 2013
Received: November 21, 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 Carlos Peña, Ph.D.
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): K132952

Device Name: MicroPlex Coil System (MCS), HydroCoil Embolic System (HES)

Indications For Use:

Intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. 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 ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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