DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 22, 2016

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

Re: K153594
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
Dated: December 21, 2015
Received: December 23, 2015

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153594

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

Indications for Use *(Describe)*
The MicroPlex Coil System (MCS) and HydroCoil Embolic System (HES) are intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The MCS and HES are 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.

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

(Prepared December 01, 2015)

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 MicroVention, Inc.
Predicate Device:	MicroPlex Coil System (MCS) - K132952 HydroCoil Embolic System (HES) - K132952
Indications for Use:	The MicroPlex Coil System (MCS) and HydroCoil Embolic System (HES) are intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The MCS and HES are 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	Test Method	Results
Visual Inspection	Using a microscope, inspect per product drawings	All test samples met the acceptance criteria and passed testing.
Pusher Resistance	Measure the pusher resistance using a digital multi-meter	All test samples met the acceptance criteria and passed testing.
Simulated Use	Using cerebrovascular benchtop model, conduct the following assessments on each test sample: • Introduction • Tracking inside microcatheter • Deployment • Microcatheter Movement • Detachment	All test samples met the acceptance criteria and passed testing.
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. The results of the bench testing validated the conformance to the same design criteria and the predicate devices.		

Predicate / Subject
Technological Comparison:

Design Feature	Predicate Devices	Subject Devices
Implant Coil Shape	Helical or 3D	Same
Implant Coil Wire material	Platinum/Tungsten (92/8 %) alloy	Same
Implant Hydrogel material	MCS – None HES – Hydrophilic acrylic copolymer	Same
Implant Coil-to-Pusher Coupler material	Platinum (90%) / iridium (10%)	Same
Implant to Pusher filament / SR member material	Polyolefin elastomer or PET	Same
Adhesive material	Ultraviolet curing adhesive (DYMAX 1128-AM-VT)	Same
Delivery Pusher Overall Construction	Variable stiffness stainless steel hypotube with platinum and stainless steel coils at the distal end.	Same
Delivery Pusher Proximal Connector Construction	• 3 gold connectors (Ø.016") over mandrel • Middle gold connector is welded to mandrel • Distal gold connector is welded to hypotube • Annealed section of hypotube distal of gold connector • Polyimide tube used for insulation • 1 solder joint visible, 1 solder joint not visible (inside hypotube)	• Gold plated hypotube used for one connector (Ø.014") • 2 gold connectors (Ø.016") over hypotube • Polyimide tube used for insulation • 2 solder joints visible
Delivery Pusher Length	185 cm	195cm

Risk Analysis:

The MCS and HES products are designed, developed and tested in accordance with the MicroVention Design and Development procedure and with the MicroVention internal quality system procedure for risk management. Possible hazards and associated risk related to the device modification and clinical usage of the device were identified, examined and found to be acceptable after the implementation of the mitigation measures such as physician training program, labeling warnings and instructions for use.

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.