K112226

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

SEP 2 9 2011

Trade Name: HydroCoil Embolic System (HES)

Generic Name: Neurovascular Embolization Device, accessory

Classification: Class II, 21 CFR 882.5950

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

Contact: Laraine Pangelina

Predicate Device: HydroCoil Embolic System (K070656, K080666, K091641)

Device Description: The HES consists of implantable coil made of platinum alloy with inner hydrogel core. The helical-shaped implantable coil is available in various outer dimensions and lengths. The coil is attached to a V-Trak delivery pusher. 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.

The RD11-006 HES is a line extension which is substantially the same as the predicate devices (K070656, K080666, K091641). The implantable coil portion of both the predicate and the subject device is constructed from platinum alloy wire. The RD11-006 implantable coil is constructed of an oval-shaped platinum alloy wire, whereas the predicate devices are constructed of a round platinum alloy wire. All other materials and design features are the same for both the predicate and subject devices.

Indications for Use: The HES is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistula. The HES 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.

Bench Test Summary:

Test	Result
Visual Inspection	Met same criteria as predicate
Dimensional Measurement	Met same criteria as predicate
Simulated Use • Introduction • Tracking • Reposition / Deployment • Detachment • Overall Performance	Met same criteria as predicate
Spring Constant	Met same criteria as predicate
Gel Expansion	Met same criteria as predicate
Weld Tensile	Met same criteria as predicate
Advancement / Retraction Force	Met same criteria as predicate

Predicate / Subject Device Comparison:

Feature	Predicate Device	Subject Device
Coil shape	Helical	Same
Implant diameter	2 mm – 10 mm	2 mm – 7 mm
Implant restrained length	1 cm – 30 cm	2 cm – 10 cm
Deliver pusher length	185 cm	Same
Main coil wire material	Platinum/Tungsten (92/8 %) alloy	Same
Coupler material	Platinum (90%) / iridium (10%)	Same
Adhesive material	Dymax 1128-AM-VT	Same
Implant to pusher material	Polyolefin Elastomer	Same
Stretch resistant filar material	Polyolefin Elastomer	Same
Gel material	Hydrophilic Copolymer	Same
MRI compatibility	Yes	Yes
Method of supply	Sterile, single use	Same
Packaging configuration	Dispenser, pouch, carton	Same

Summary of Substantial Equivalence:

The HES coils 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 Room –WO66-G609
Silver Spring, MD 20993-0002

Microvention, Inc.
c/o Ms. Loraine Pangelina
Regulatory Affairs Project Manager
1311 Valencia Avenue
Tustin, CA 92780

SEP 29 2011

Re: K112226
Trade/Device Name: HydroCoil Embolic System (HES)
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: II
Product Code: HCG
Dated: August 02, 2011
Received: August 03, 2011

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 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 Kevin Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K112226

Device Name: HydroCoil Embolic System (HES)

Indications for Use: The HES is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The HES 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_ (Per 21 CFR 801.109) AND/OR Over-The-Counter Use_____ (Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

ALEX BAILEY

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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