

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Trade Name: 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: Vin Cutarelli
714-247-8181
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Predicate Device: HydroCoil[®] Embolic System (HES) K100454

Device Description:

The MicroVention HydroCoil[®] Embolic System (HES) consists of an implantable coil attached to a delivery system called a V-Trak[®] delivery pusher. The HES coils are platinum coils augmented with a hydrophilic polymer. The V-Trak[®] delivery pusher is powered by a V-Grip[®] detachment controller, which is provided separately.

The HES is available in several coil types based on the coil primary diameter and configuration. Each coil type must be delivered only through a wire-reinforced microcatheter with the minimum inner diameter specified. Within each coil type is a broad range of coil secondary (loop) diameters and lengths.

Indications for Use:

The HydroCoil[®] Embolic System (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.

The device should only be used by physicians who have undergone pre-clinical training in all aspects of HES procedures as prescribed by MicroVention.

Substantial Equivalence:

The purpose of this submission is to update the labeling with the additional device experience from the HydroCoil Endovascular Aneurysm Occlusion and Packing Study (HELPS) trial. The HydroCoil[®] Embolic System (HES) with the modified product labeling is substantially equivalent to the predicate device with regard to intended use, operating principle, device design, materials, manufacturing processes and patient population.



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 Mr. Vin Cutarelli
Senior Vice President, Regulatory Affairs and Quality Assurance
1311 Valencia Ave.
Tustin, CA 92780

DEC - 1 2011

Re: K112181

Trade/Device Name: HydroCoil® Embolic System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: November 3, 2011
Received: November 4, 2011

Dear Mr. Cutarelli:

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" (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 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,



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):

K112181

Device Name:

HydroCoil Embolic System

Indications for Use:

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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)

Jeffrey Toy

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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