K091644

JUN 30 2009

510(k) Summary

Trade Name:	HydroCoil Embolic System – HydroSoft MicroPlex Coil System - HyperSoft
Generic Name:	Neurovascular Embolization Device
Classification:	Class II, 21 CFR 882.5950
Submitted By:	MicroVention, Inc 75 Columbia Aliso Viejo, California U.S.A.
Contact:	Naomi Gong

Predicate Devices:

Number	Description	Clearance Date
K070656	HydroCoil Embolic System with the HES-HC-HS (10) [marketed under the HydroSoft name]	June 15, 2007
K0509054	MicroPlex Coil System and HydroCoil Embolic System	June 28, 2005

Device Description

The HydroSoft coils consist of an implant made of plantinum alloy with an inner hydrogel core. The coils are designed in helical structure in various loop sizes and lengths. The coil is attached to a V-*Trak*™ delivery pusher via a polymer filament. 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. The implant segment detaches upon activation of the Detachment Controller.

The HyperSoft coils consist of an implant coil made of platinum alloy. The coils are designed in helical structure in various loop sizes and lengths. The coil is attached to a V-*Trak*™ delivery pusher via a polymer filament. 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. The implant segment detaches upon activation of the Detachment Controller.

Indications For Use

The HydroSoft and HyperSoft coils are members of the HydroCoil Embolic System (HES) and MicroPlex Coil System (MCS). The intended use as stated in the product labeling is as follows:

The HydroCoil Embolic System and MicroPlex Coil System is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The HES/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.

Verification and Test Summary Table

Bench Testing	Result
Simulated Use	Met established criteria
Detachment Test	Met established criteria
Detachment Zone Tensile	Met established criteria
Advancement/Retraction Force	Met established criteria
Coil to Coupler Weld Tensile	Met established criteria
Spring Constant	Met established criteria

Summary of Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and equivalency of the HydroSoft and HyperSoft coils when compared with the predicate devices (K070656 and K050954)

The devices,

- Have the same intended use,
- Use the same operating principle,
- Incorporate the same basic design,
- Use similar construction and material,
- Are packaged and sterilized using same material and processes.

In summary, the HydroSoft and HyperSoft coils described in this submission is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 2009

MicroVention, Inc.
c/o Naomi Gong
Regulatory Affairs Project Manager
75 Columbia
Suite A
Aliso Viejo, CA 92656

Re: K091641
Trade/Device Name: MicroVention HydroCoil® Embolic System (HES) – HydroSoft Coils and MicroPlex® Coil System (MCS) – HyperSoft Coils
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: II
Product Code: HCG
Dated: June 3, 2009
Received: June 4, 2009

Dear Ms. Gong:

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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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): K091641

Device Name: HydroSoft Embolic System (HES) – HydroSoft Coils
MicroPlex Coil System (MCS) – HyperSoft Coils

Indications For Use:

The HydroCoil Embolic System and MicroPlex Coil System is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The HES/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 _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jeff Toy

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

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