K090357 /p1/2

510(k) Summary

APR 10 2009

Trade Name: HydroFrame - HydroCoil Embolic System (HES)

Generic Name: Neurovascular Embolization Device

Classification: Class II, 21 CFR 882.5950

Submitter Name and Address

MicroVention, Inc
75 Columbia
Aliso Viejo, California U.S.A.

Contact Name:

Florin Truuvert
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Predicate Device:

510(k)	Description	Clearance Date
K082461	MicroVention, Bare Platinum Framing Coils	Oct 2, 2008
K080666	MicroVention, HydroSoft (HES)	July 11, 2008

Device Description

The HydroFrame coils consist of implant coil made of platinum alloy with inner hydrogel core. The coils are designed in 3D spherical structure in various loop sizes and lengths. The coil is attached to a V-*Trak*™ MCS 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.

Indication 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 artiovenous 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.

Verification and Test Summary Table

Bench Testing	Result
Visual Inspection	Met established criteria
Dimensional Measurement	Met established criteria
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
Gel Expansion	Met established criteria

Summary of Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and equivalency of the HydroFrame coils when compared with the predicate device MicroVention Inc., Bare Platinum Framing Coils (K082461) and the HydroSoft coils (K08066).

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 HydroFrame 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

MicroVention, Inc.
c/o Florin Truuvert
Senior Director, Worldwide Regulatory Affairs
75 Columbia, Suite A
Aliso Viejo, CA 92656

APR 10 2009

Re: K090357
Trade/Device Name: HydroFrame Hydrocoil Embolic System (HES)
Regulation Number: 21 CFR 882.5950
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: February 10, 2009
Received: February 12, 2009

Dear Ms. Truuvert:

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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090357

Indications for Use

510(k) Number (if known): K090357

Device Name: HydroFrame Hydrocoil Embolic System (HES)

Indications For Use:

The HydroFrame HydroCoil Embolic System (HES) is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and artiovenous 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.

Prescription Use ___X___ 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 CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K090357