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K041551

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Section 2 - Summary of Safety and Effectiveness

(1) Company Information

MicroVention, Inc.
75 Columbia
Aliso Viejo, CA 92656
Telephone: (949) 461-3314
Fax: (949) 461-3329
www.microvention.com

(2) Contact Information

Vincent Cutarelli
Telephone: (949) 768-1184 ext. 105
Fax: (949) 768-0464
E-mail: vinc@microvention.com

(3) Device Name

Classification Name:	Device, Artificial Embolization
Trade/Proprietary Name:	Hydro*Coil*® Embolic System (HES)
Common/Usual Name:	Embolization Coil

(4) Device Description

The Hydro*Coil*® Embolic System (HES) consists of an implantable coil attached to a fluid injection delivery system called a delivery pusher. The delivery pusher is a variable stiffness stainless steel tube with several outer layers of PET tubing. A luer hub at the proximal end of the pusher is used for system de-airing and coil detachment. The HES coils are platinum helical coils with an outer layer of a hydrophilic polymer. The polymer material is a cross-linked copolymer of acrylamide and acrylic acid. The proximal end of the coil incorporates a coupler for attachment to the delivery pusher. PET tubing is heat-shrunk over the coupler/pusher junction in order to attach the coil to the delivery pusher. The coil is delivered to the treatment site on the delivery pusher through standard neuro-interventional micro-catheters. An introducer sheath on the outside of the delivery pusher assists in the placement of the HES into the micro-catheter. A 1.0-cc syringe is used for system de-airing and a 0.25-cc syringe is used for coil detachment.

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(5) Indications for Use

The Hydro*Coil*® 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.

(6) Name of Predicate or Legally Marketed Device

The modified Hydro*Coil*® Embolic System (HES) is substantially equivalent to the Hydro*Coil*® Embolic System (HES) that was determined to be substantially equivalent on October 22, 2003 (reference K032590) and December 30, 2003 (reference K033836), and to the Matrix™ Stretch Resistant Detachable Coils that were determined to be substantially equivalent on May 14, 2003 (reference K031168).

(7) Technological Characteristics and Substantial Equivalence

The modified Hydro*Coil*® Embolic System (HES) is equivalent in operating principle, method of application, indications for use, design, materials, packaging and sterilization to the predicate devices.

(8) Performance Data Summary

Performance testing has demonstrated that the modified Hydro*Coil*® Embolic System (HES) is equivalent in performance to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 7 2004

Mr. Vincent Cutarelli
Vice President, Regulatory Affairs,
Quality Assurance and Clinical Affairs
MicroVention, Inc.
75 Columbia, Suite A
Aliso Viejo, California 92656

Re: K041551
Trade/Device Name: HydroCoil® Embolic System (HES)
Regulation Number: 21 CFR 882.5950
Regulation Name: Embolization coil
Regulatory Class: III
Product Code: HCG
Dated: June 7, 2004
Received: June 9, 2004

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K041551

Indications For Use

510(k) Number (if known):

Device Name: Hydro*Coil*® Embolic System (HES)

Indications For Use: The Hydro*Coil*® 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.

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)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041551