Section 2 – 510(k) Summary

(1) Company Information

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(2) Contact Information

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(3) Device Name

Classification Name:	Device, Embolization, Arterial
Trade/Proprietary Name:	Hydro*Coil*® Embolic System (HES)
	AZUR™ Peripheral HydroCoil® Endovascular Embolization Coil System – Pushable 18 and 35
Common/Usual Name:	Embolization Coil
Classification	Class II

(4) Device Description

The Hydro*Coil*® Embolic System (HES) with the HES-HC-PP (18) and HES-HC-PP (35) coils consists of an implantable coil housed in an introducer. A stainless steel stylet is used to deploy the coil from the introducer into a delivery catheter. The coil is delivered to the treatment site through the delivery catheter using a standard guidewire. Both the delivery catheter and guidewire are not included in the system.

(5) Indications for Use

The Hydro*Coil*® Embolic System (HES) with the HES-HC-PP (18) and HES-HC-PP (35) coils is intended to reduce or block the rate of blood flow in vessels of the peripheral vasculature. It is intended for the interventional radiologic management of arteriovenous malformations, arteriovenous fistulae, aneurysms and other lesions of the peripheral vasculature.

(6) Name of Predicate or Legally Marketed Device

The Hydro*Coil*® Embolic System (HES) with the HES-HC-PP (18) and HES-HC-PP (35) coils is substantially equivalent to the Cordis Vascular Occlusion System that was determined to be substantially equivalent on March 24, 1999 (reference K983483), the MicroVention Micro*Plex*® Coil System (MCS) and Hydro*Coil*® Embolic System (HES) with a Modified Detachment System that was determined to be substantially equivalent on June 28, 2005 (reference K050954) and the MicroVention Micro*Plex*® Coil System (MCS) and Hydro*Coil*® Embolic System (HES) with the HES-HC-R (18) and HVO-HC-R (18) Coils that was determined to be substantially equivalent on October 22, 2003 (reference K032590)..

(7) Technological Characteristics and Substantial Equivalence

The Hydro*Coil*® Embolic System (HES) with the HES-HC-PP (18) and HES-HC-PP (35) coils is substantially 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 Hydro*Coil*® Embolic System (HES) with the HES-HC-PP (18) and HES-HC-PP (35) coils 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

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MicroVention Inc.
c/o Mr. Vincent Cutarelli
Vice President, Regulatory Affairs and Quality Assurance
75 Columbia, Suite A
Aliso Viejo, CA 92656

Re: K071939
HydroCoil® Embolization System (HES) with the HES-HC-PP (18) and HES-HC-PP (35) Coils
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: October 30, 2007
Received: November 2, 2007

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number: K071939

Device Name: Hydro*Coil*® Embolic System (HES) with the HES-HC-PP (18) and HES-HC-PP (35) coils

Indications for Use: The Hydro*Coil*® Embolic System (HES) with the HES-HC-PP (18) and HES-HC-PP (35) coils is intended to reduce or block the rate of blood flow in vessels of the peripheral vasculature. It is intended for the interventional radiologic management of arteriovenous malformations, arteriovenous fistulae, aneurysms and other lesions of the peripheral vasculature.

Concurrence of CDRH, Office of Device Evaluation (ODE):

Donna R Kucharczyk

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K071939

Prescription Use: X
(Per 21 CFR 801.109)