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# Section 2 - Summary of Safety and Effectiveness

## (1) Company Information

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JUN 15 2007

## (2) Contact Information

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## (3) Device Name

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

## (4) Device Description

The Hydro*Coil*® Embolic System (HES) is based on electrical coil detachment. The HES consist of an implantable coil attached to a delivery system called a V-TRAK™ Delivery Pusher. The Delivery Pusher is a variable stiffness, stainless steel and tapered mandrel. Two silver electrical leads run along the outside of the mandrel from the proximal to the distal end. Platinum and stainless steel wires are wound around the distal end of the mandrel to form the electrical heater and provide kink-resistance. Two outer layers of PET tubing cover the distal end of the pusher assembly. A layer of polyimide tubing covers the proximal end. The proximal end of the HES coils incorporates a platinum coupler for attachment to the Delivery Pusher. A polyolefin elastomer filament is attached to the proximal end of the coil. This filament runs through the inner lumen of the coil coupler and is attached to the distal end of the Delivery Pusher.

The Delivery Pusher is powered by a hand-held, battery-powered V-GRIP™ Detachment Controller designed specifically for the HES. A gold-plated stainless steel connector at the proximal end of the Delivery Pusher is used to connect it to the Detachment Controller. The Detachment Controller is provided separately. The coil is delivered to treatment site on the Delivery Pusher through standard neuro-interventional micro-catheters. A removable introducer sheath on the outside of the Delivery Pusher assists in the placement of the HES into the micro-catheter. Once the coil is deployed, the proximal end of the Delivery Pusher is connected to the Detachment Controller. When the Detachment Controller is turned on, the flow of current melts the polyolefin elastomer filament at the coupler/pusher junction resulting in coil detachment.

## (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 Hydro*Coil*® Embolic System (HES) with the HES-HC-HS (10) coils is substantially equivalent to the Hydro*Coil*® Embolic System (HES) with the HES-HC-S (10) coils that was determined to be substantially equivalent on December 30, 2003 (reference K033836) and the 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).

## (7) Technological Characteristics and Substantial Equivalence

The Hydro*Coil*® Embolic System (HES) with the HES-HC-HS (10) 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-HS (10) 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

MicroVention, Inc
% Mr. Vincent Cutarelli
Vice President, Regulatory Affairs
and Quality Assurance
75 Columbia, Suite A
Aliso Viejo, California 92677

JUN 15 2007

Re: K070656
Trade/Device Name: Hydro*Coil*® Embolic System with (HES) with the HES-HC-HS (10) coils
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular embolization device
Regulatory Class: II
Product Code: HCG, KRD
Dated: May 30, 2007
Received: May 31, 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.

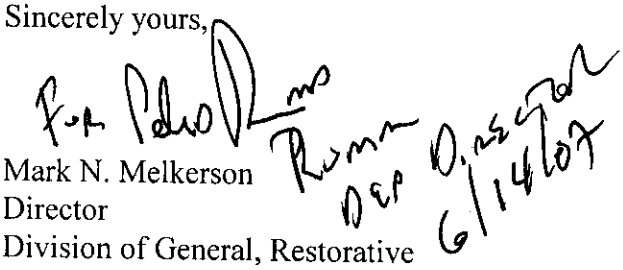
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Office of Compliance at (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications For Use

510(k) Number: _____

Device Name: Hydro*Coil*® Embolic System (HES) with the HES-HC-HS (10) coils

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.

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

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

510(k) Number L070651

Prescription Use: _X_
(Per 21 CFR 801.109)