K022735

SEP 6 2002

Section 2 - Summary of Safety and Effectiveness

(1) Company Information

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(2) Contact Information

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(3) Device Name

Trade/Proprietary Name:	MicroPlex™ Coil System (MCS) and HydroCoil™ Embolic System (HES) with the HydroLink™ Syringe Kit
Common/Usual Name:	Embolization Coil
Classification Name:	Device, Artificial Embolization

(4) Device Description

The MicroVention MicroPlex Coil System (MCS) and HydroCoil Embolic System (HES) consist of an implantable coil attached to a fluid injection delivery system called a Delivery Pusher. The coil is delivered on the Delivery Pusher through standard neurointerventional microcatheters. The Delivery Pusher consists of a variable stiffness tube with a retention sleeve that attaches the pusher to the implantable coil. A peel-away introducer sheath assists in the delivery of the coil into the microcatheter. The HydroLink Syringe Kit is packaged separately and includes a 1.0-cc syringe for system de-airing and a 0.25-cc and/or 0.5-cc syringe for coil detachment. An introducer needle is also included for use with the 0.25-cc or 0.5-cc syringe to fill the hub of the Delivery Pusher with contrast agent and eliminate any air.

The MicroPlex Coil System (MCS) is marketed in two basic coil configurations, complex and helical. The MCS-CC-2D and MCS-CC-1D are platinum complex coils that are used

K022735

to establish the initial framework in the treatment of vascular abnormalities (e.g., intracranial aneurysms). The MCS-HC-R, MCS-HC-S and MCS-HC-SX are platinum helical coils that provide additional filling once the initial framework has been established by one or more complex coils. The MCS-CC-2D, MCS-CC-1D, MCS-HC-R and MCS-HC-S platinum coils were determined to be substantially equivalent on October 29, 2001 (reference K012145). The MCS-HC-SX platinum coils were determined to be substantially equivalent on July 9, 2002 (reference K021914). The complex and helical coils are provided in a number of diameters and lengths to meet the needs of the physician.

The MCS-HCP are platinum helical coils with an outer layer of a hydrophilic, acrylic polymer that also provides additional filling once the initial framework has been established by placement of one or more MCS platinum complex coils. The MCS-HCP coils were determined to be substantially equivalent on July 29, 2002 (reference K020434) and were originally included as part of the MicroPlex Coil System (MCS). In order to differentiate the platinum/polymer coils from the platinum coils, the system trade name has been changed to HydroCoil Embolic System (HES) and the coils are denoted as HES-HC-R.

(5) Indications for Use

The MicroPlex Coil System (MCS) and HydroCoil Embolic System (HES) with the HydroLink Syringe Kit are intended for embolization of those intracranial aneurysms that – because of their morphology, their location, or the patient's general medical condition – are considered by the treating neurosurgical team to be very high risk for management by traditional operative techniques or inoperable. The MCS and HES are also intended for embolization of other neuro-vascular abnormalities such as arteriovenous malformations and arteriovenous fistulae and for arterial and venous embolizations in the peripheral vasculature.

(6) Name of Predicate or Legally Marketed Device

MicroVention MicroPlex Coil System (MCS) – K012145 (October 29, 2001)
MicroVention MicroPlex Coil System (MCS) – K021914 (July 9, 2002)
MicroVention MicroPlex Coil System (MCS) – K020434 (July 29, 2002)
Merit Medical Piston Syringe – K875196 (February 11, 1988)

(7) Technological Characteristics and Substantial Equivalence

The MicroPlex Coil System (MCS) and HydroCoil Embolic System (HES) with the HydroLink Syringe Kit is substantially equivalent to the MicroPlex Coil System (MCS) that was determined to be substantially equivalent per K012145, K021914 and K020434 and the Merit Medical Piston Syringe that was determined to be substantially equivalent per K875196. The operating principles, method of application, indications for use and technological characteristics are the same as the predicate devices.

K022735

(8) Performance Data Summary

Performance testing including tensile strength, coil detachment and simulated use demonstrated that the MicroPlex Coil System (MCS) and HydroCoil Embolic System (HES) with the HydroLink Syringe Kit has equivalent performance to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 6 2002

Mr. Vincent Cutarelli
Vice President, Regulatory Affairs,
Quality Assurance and Clinical Affairs
Microvention, Inc.
72 Argonaut
Aliso Viejo, CA 92656

Re: K022735
Trade/Device Name: MicroPlex™ Coil System (MCS) and HydroCoil™ Embolic System with the HydroLink™ Syringe Kit.
Regulation Number: 882.5950
Regulation Name: Artificial Embolization Device
Regulatory Class: III
Product Code: HCG
Dated: August 14, 2002
Received: August 19, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

K022735

Indications For Use

510(k) Number: _____

Device Name: MicroPlex™ Coil System (MCS) and HydroCoil™ Embolic System with the HydroLink™ Syringe Kit

Indications for Use: The MicroPlex Coil System (MCS) and HydroCoil Embolic System (HES) with the HydroLink Syringe Kit are intended for embolization of those intracranial aneurysms that – because of their morphology, their location, or the patient's general medical condition – are considered by the treating neurosurgical team to be very high risk for management by traditional operative techniques or inoperable. The MCS and HES are also intended for embolization of other neuro-vascular abnormalities such as arteriovenous malformations and arteriovenous fistulae 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 K022735

Prescription Use: X
(Per 21 CFR 801.109)