APR 2 8 2011

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

K103758

Trade Name: MicroPlex Coil System – Cosmos 10
HydroCoil Embolic System - HydroFrame 10

Generic Name: Neurovascular Embolization Device, accessory

Classification: Class II, 21 CFR 882.5950

Submitted By: MicroVention, Inc
1311 Valencia Avenue
Tustin, California 92780 U.S.A.
714-247-8000

Contact: Laraine Pangelina

Date Prepared: April 20, 2011

Predicate Device: MicroPlex Coil System, Cosmos 10 (K093919)
HydroCoil Embolic System, HydroFrame 10 (K090357)

Indications for Use: Intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and artiovenous fistula. The MCS and HES are 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.

Device Description: The MCS Cosmos 10 consists of an implantable coil made of bare platinum alloy. The HES HydroFrame 10 consists of implantable coil made of platinum alloy with a biologically inert and stable inner hydrogel core. Both the Cosmos 10 and the HydroFrame 10 coils are available in various loop sizes and lengths. The coil is attached to a V-Trak delivery pusher. The proximal end of the delivery pusher is inserted into a hand held battery powered V-Grip Detachment Controller (sold separately). The implantable coil detaches upon activation of the Detachment Controller.

Both the Cosmos 10 and the HydroFrame 10 coil implants have a PET member within the primary coil to provide stretch resistance properties. Both feature a 3-dimensional shape that creates a frame when placed within an aneurysm.

The HydroFrame 10 also has a hydrogel core member that runs parallel with the stretch resistant member within the coil. The expansion properties of the hydrogel allow for improved filling properties of the implanted coil.

The table below provides information about the physical properties of the Cosmos 10 and HydroFrame 10, with a comparison to their respective predicate devices.

MCS Cosmos 10		
Feature	**Predicate Device**	**Subject Device**
Coil shape	3D - spherical	Same
Coil implant diameter	3-12mm	2.0-2.5mm
Coil restrained length	6-45cm	2-4cm
Deliver pusher length	185cm	Same
Main coil wire material	Platinum/Tungsten alloy	Same
Coupler material	Platinum/Iridium	Same
Adhesive material	Utraviolet cure	Same
Implant to pusher material	Polyolefin elastomer	Same
Stretch resistant filar material	Polyolefin elastomer	PET
MRI compatibility	Yes	Same
Method of supply	Sterile, single use	Same
Packaging configuration	Dispenser coil, pouch, carton	Same

HES HydroFrame 10		
Feature	**Predicate Device**	**Subject Device**
Coil shape	3D - spherical	Same
Coil implant diameter	3-12mm	2.0-2.5mm
Coil restrained length	6-43cm	2.4cm
Deliver pusher length	185cm	Same
Main coil wire material	Platinum/Tungsten alloy	Same
Coupler material	Platinum/Iridium	Same
Adhesive material	Utraviolet cure	Same
Implant to pusher material	Polyolefin elastomer	Same
Stretch resistant filar material	Polyolefin elastomer	PET
Gel	Hydrophilic acrylic copolymer	Same
MRI compatibility	Yes	Same
Method of supply	Sterile, single use	Same
Packaging configuration	Dispenser coil, pouch, carton	Same

Bench Test Summary:

Test	Result
Visual Inspection	Met same criteria as predicate
Dimensional Measurement	Met same criteria as predicate
Simulated Use: Introduction, Tracking, Deployment, Frame tumbling, Microcatheter movement, Microcatheter manipulation, Compartmentalization, Periphery fill, Basket formation, Shape retention, Overall performance	Met same criteria as predicate
Spring Constant	Met same criteria as predicate
Gel Expansion (HES only)	Met same criteria as predicate
Weld Tensile	Met same criteria as predicate

Summary of Substantial Equivalence:

The Cosmos 10 and HydroFrame 10 coils that are the subject of this submission are substantially equivalent to the predicate device with regard to intended use, patient population, device design, materials, processes, and operating principal.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Microention, Inc.
Laraine Pangelina
Regulatory Affairs Project Manager
1311 Valencia Avenue
Tustin, CA 92780

APR 2 8 2011

Re: K103758
Trade/Device Name: Microplex Coil System–Cosmos 10 and, Hydrocoil System–Hydroframe 10
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular embolization device
Regulatory Class: Class II
Product Code: HCG
Dated: March 25, 2011
Received: March 29, 2011

Dear Ms. Pangelina

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 note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103758

Device Name: MicroPlex Coil System (MCS) – Cosmos 10
HydroCoil Embolic System (HES) – HydroFrame 10

Indications For Use:

Intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The MCS and 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)

JEFFREY TOY

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

510(k) Number K103758