510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

NOV 1 8 2010

K102368

Trade Name: MicroPlex Coil System – Cosmos 18

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.

Contact: Laraine Pangelina

Predicate Device: MicroPlex Coil System (MCS) - Cosmos 18 (K093358, K090891)

Device Description:

The Cosmos coils consist of an implant coil made of platinum alloy. The coils are designed in 3D spherical structure in various loop sizes and lengths. The coil is attached to a V-*Trak*™ delivery pusher via a polymer filament. The delivery pusher contains radiopaque positioning markers at the distal end. The proximal end is inserted into a hand held battery powered V-*Grip*™ Detachment Controller (sold separately). The implant segment detaches upon activation of the Detachment Controller.

Indications for Use:

The MicroPlex Coil System is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The MCS 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.

Bench Test Summary:

Test	Result
Visual Inspection	Met same specifications as predicate
Dimensional Measurement	Met same specifications as predicate
Simulated Use: *Introduction, Tracking, Deployment, Frame tumbling, Microcatheter movement, Microcatheter manipulation, Compartmentalization, Periphery fill, Basket formation, Shape retention, Overall performance*	Met same specifications as predicate
Detachment Zone Tensile	Met same specifications as predicate
Advancement/Retraction Force	Met same specifications as predicate
Coil to Coupler Weld Tensile	Met same specifications as predicate
Spring Constant	Met same specifications as predicate

Technological comparison, subject and predicate device:

Feature	Predicate Device	510(k) Subject Device
Design Attributes		
Coil Shape	3D- spherical	Same
Coil OD	6-13 mm	14-24 mm
Coil Length	17-47 cm	51-68 cm
Pusher length	185 cm	Same
Materials		
Main Coil Wire	Platinum/Tungsten (92/8%) alloy	Same
Coil to Pusher Coupler	Platinum (90%)/ iridium (10%)	Same
Adhesive	Ultraviolet curing adhesive (DYMAX 1128-AM-VT)	Same
Implant to Pusher Attachment	Polyolefin elastomer	Same
General		
MRI compatibility	Yes	Same
Method of Supply	Sterile, single use	Same
Package Configuration	Placed in dispenser coil, pouch, and shipping carton	Same

Summary of Substantial Equivalence:

The MCS Cosmos Coils 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

MicroVention, Inc.
c/o Ms. Laraine Pangelina
Regulatory Affairs Project Manager
1311 Valencia Avenue
Tustin, California 92780

NOV 18 2010

Re: K102365
Trade/Device Name: MicroPlex Coil System – Cosmos 18
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular-Embolization-Device
Regulatory Class: Class II
Product Code: KRD, HCG
Dated: August 19, 2010
Received: August 20, 2010

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.

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,

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 (if known): K102365 NOV 18 2010

Device Name: MicroPlex Coil System (MCS) – Cosmos

Indications for Use: *The MicroPlex Coil System is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The MCS 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_ (Per 21 CFR 801.109) AND/OR Over-The-Counter Use_____ (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vuchnich
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102365