## 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

K093358

JAN 15 2010

**Trade Name:** MicroPlex Coil System – Cosmos

**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 (K090891)

**Device Description:** The Cosmos 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*™ MCS 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. The implant segment detaches upon activation of the Detachment Controller.

**Indications for Use:** The Cosmos is a member of the MicroPlex Coil System (MCS). The intended use as stated in the product labeling is as follows:

*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.*

**Bench Test Summary:**

| Test | Result |
|---|---|
| Visual Inspection | Met established criteria |
| Dimensional Measurement | Met established criteria |
| Simulated Use | Met established criteria |
| Detachment Test | Met established criteria |
| Detachment Zone Tensile | Met established criteria |
| Advancement/Retraction Force | Met established criteria |
| Coil to Coupler Weld Tensile | Met established criteria |
| Spring Constant | Met established criteria |

**Summary of Substantial Equivalence:**

The 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

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Laraine Pangelina
Regulatory Affairs Project Manager
MicroVention, Inc.
1311 Valencia Ave.
Tustin, CA 92780

JAN 1 5 2010

Re: K093358
Trade/Device Name: MicroPlex Coil System (MCS) – Cosmos 18
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: II
Product Code: HCG
Dated: October 27, 2009
Received: October 28, 2009

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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kesia Alexander for

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): K093358

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.*

Prescription Use X AND/OR Over-The-Counter Use____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

**510(k) Number** k093358