510(k) Summary

Trade Name: Bare Platinum Framing Coils, BPFC

Generic Name: Neurovascular Embolization Device

OCT - 2 2008

Classification: Class II, 21 CFR 882.5950

Submitted By: MicroVention, Inc
75 Columbia
Aliso Viejo, California U.S.A.

Contact: Florin Truuvert

Predicate Device:

Number	Description	Predicate For	Clearance Date
K050954	MicroVention Inc., MicroPlex Coil System (MCS)	Bare Platinum Framing Coils	June 28, 2005

Device Description

The Bare Platinum Framing Coils, BPFC, consist of 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.

Indication For Use

The BPFC as a member of the MicroPlex Coil System (MCS) 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2008

Ms. Florin Truuvert
Director, Regulatory Affairs
Microvention, Incorporated
75 Columbia, Suite A
Aliso Viejo, California 92656-1408

Re: K082461
Trade/Device Name: Bare Platinum Framing Coils (BPFC)
Regulation Number: 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: II
Product Code: HCG
Dated: August 25, 2008
Received: September 4, 2008

Dear Ms. Truuvert:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

K082461

Indications for Use

510(k) Number (if known): K082461

Device Name: Bare Platinum Framing Coils (BPFC)

Indications For Use:

The MicroPlex Coil System (MCS) 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___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
~~Division of Anesthesiology, General Hospital~~
~~Infection Control, Dental Devices~~

Neil R Ogden for mxm

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

510(k) Number: _____

Page 1 of _1_

510(k) Number K082461