K090001
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510(k) Summary

MAR - 5 2009

Trade Name: V-Grip Plus Detachment Controller

Generic Name: Neurovascular Embolization Device, accessory

Classification: Class II, 21 CFR 882.5950

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

Contact: Naomi Gong

Predicate Device:

Number	Description	Clearance Date
K050954	MicroPlex Coil and HydroCoil Embolization System (V-Grip Detachment Controller)	June 28, 2005

Device Description

The V-Grip *Plus* Detachment Controller is a hand held, battery operated device designed specifically to detach the MicroVention MicroPlex and HydroCoil family of coils. When the coil is delivered to the treatment site, the proximal end of the delivery pusher (of coil) is inserted into the Detachment Controller. When the Detachment Controller is activated, coil detachment occurs.

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Indication For Use

The V-Grip *Plus* Detachment Controller is used to detach the MicroVention MicroPlex Coil System and the HydroCoil Embolization System. As an accessory to the coils, the indications for use for the Detachment Controller remain the same as the coils and is as follows:
The MicroPlex Coil System and Hydrocoil Embolization System are intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. 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 embolizations in the peripheral vasculature.

Verification and Test Summary Table

Bench Testing	**Result**
Electrical output verification	Met established criteria
Functional testing	Met established criteria
Detachment testing	Met established criteria
Software validation	Met established criteria
Electrical safety testing	Met established criteria
Electromagnetic compatibility testing	Met established criteria

Summary of Substantial Equivalence

The data presented in this submission demonstrates the similarity and equivalency of the V-Grip *Plus* Detachment Controller when compared with the predicate device MicroVention V-Grip Detachment Controller (K050954).

The devices,

- Have the same intended use,
- Use the same operating principle,
- Incorporate the same basic design,
- Use similar construction and material,
- Are packaged and sterilized using same material and processes.

In summary, the V-Grip *Plus* Detachment Controller described in this submission is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 2009

MicroVention, Inc.
% Ms. Naomi Gong
Regulatory Affairs Project Manager
75 Columbia, Suite A
Aliso Viejo, California 92656

Re: K090001
Trade/Device Name: V-Grip *Plus* Detachment Controller
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular embolization device
Regulatory Class: II
Product Code: HCG
Dated: February 5, 2009
Received: February 6, 2009

Dear Ms. Gong:

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

K090001

Indications for Use

510(k) Number (if known):_____

Device Name: V-Grip *Plus* Detachment Controller

Indications For Use:

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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)

David Krause for MKM 3/4/2009

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

510(k) Number K090001