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Section 2 - Summary of Safety and Effectiveness

(1) Company Information

MicroVention, Inc.
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Aliso Viejo, CA 92656
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(2) Contact Information

Vincent Cutarelli
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(3) Device Name

Trade/Proprietary Name:	MicroPlex™ Coil System (MCS) with the MCS-HC-SX Helical Coil
Common/Usual Name:	Embolization Coil
Classification Name:	Device, Artificial Embolization

(4) Device Description

The MicroVention MicroPlex Coil System (MCS) consists of an implantable coil attached to a fluid injection delivery system called a Delivery Pusher. The Delivery Pusher consists of a variable stiffness tube with a retention sleeve that attaches the pusher to the implantable coil. A peel-away introducer sheath assists in the delivery of the implantable coil into the microcatheter.

The MicroPlex Coil System (MCS) is provided in two basic coil configurations, complex and helical. The MCS-CC-2D and MCS-CC-1D are platinum complex coils that establish the initial framework in the treatment of vascular abnormalities (e.g., intracranial aneurysms). The MCS-HC-R, MCS-HC-S and MCS-HC-SX are platinum helical coils that provide additional filling once the initial framework has been established by one or more complex coils. The complex and helical coils are provided in a number of diameters and lengths.

The complex and helical coils are available in 18- and 10-compatible systems. The 18-compatible systems may be delivered through 14- and 18-type micro-catheters. The 10-compatible systems may be delivered through 10- and 14-type micro-catheters.

(5) Indications for Use

The MicroPlex Coil System (MCS) is intended for embolization of those intracranial aneurysms that – because of their morphology, their location, or the patient's general medical condition – are considered by the treating neurosurgical team to be very high risk for management by traditional operative techniques or inoperable.

(6) Name of Predicate or Legally Marketed Device

The MicroPlex Coil System (MCS) with the MCS-HC-SX helical coil is substantially equivalent to the MicroPlex Coil System (MCS) that was determined to be substantially equivalent on October 29, 2001 (reference K012145).

(7) Technological Characteristics and Substantial Equivalence

The MicroPlex Coil System (MCS) with the MCS-HC-SX helical coil is substantially equivalent in operating principle, method of application, indications for use, design, packaging and sterilization to the predicate device.

(8) Performance Data Summary

Performance testing including tensile strength, coil detachment and simulated use demonstrated that the MicroPlex Coil System (MCS) with the MCS-HC-SX helical coil has equivalent performance to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Vincent Cutarelli
Vice President, Regulatory Affairs
Quality Assurance and Clinical Affairs
MicroVention, Inc.
72 Argonaut
Aliso Viejo, California 92656

Re: K021914
Trade/Device Name: MicroPlex™ Coil System (MCS)
Regulation Number: 882.5950
Regulation Name: Artificial Embolization Device
Regulatory Class: III
Product Code: HCG
Dated: June 7, 2002
Received: June 11, 2002

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Dear Mr. Cutarelli:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number: K021914

Device Name: MicroPlex™ Coil System (MCS)

Indications for Use: The MicroPlex Coil System (MCS) is intended for embolization of those intracranial aneurysms that – because of their morphology, their location, or the patient's general medical condition – are considered by the treating neurosurgical team to be very high risk for management by traditional operative techniques or inoperable

Concurrence of CDRH, Office of Device Evaluation (ODE):

NKO for CMW

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

510(k) Number K021914

Prescription Use: X
(Per 21 CFR 801.109)