

K080739

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Summary of Safety and Effectiveness

Submitter Name and Address: Micrus Endovascular Corp.
821 Fox Lane
San Jose, CA 95131

OCT 17 2008

Contact Name: Patrick Lee, Manager of Regulatory Affairs
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Preparation Date: September 16, 2008

Device Name and Classification: Micrus Microcoil Delivery System
Common Name: Micrus Microcoil System
Classification Name: Device, Artificial Embolization
Product Code HCG
Regulatory Class II

Predicate Devices: Micrus Microcoil System, 510(k) K080379
Micrus Microcoil System, 510(k) K080437
Micrus Microcoil System, 510(k) K073442
Micrus Microcoil Delivery System, 510(k) K072173
Micrus Microcoil Delivery System, 510(k) K070707

Device Description: The Micrus Microcoil System consists of an embolic coil ("Microcoil") attached to a Device Positioning Unit ("DPU")

Device Intended Use The Micrus Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and are also intended for arterial and venous embolizations in the peripheral vasculature.

Comparison to Predicate Devices:

The Micrus Microcoil Systems with a new "Device Positioning Unit" have shown substantial equivalence to FDA-cleared and marketed Micrus Microcoil Systems in terms of intended use, design, material, method of construction, and dimensions. The modification has not altered the fundamental technology of the predicate devices.

Conclusion:

Based upon the design, material, function, intended use comparison with currently marketed devices and the non-clinical testing performed by Micrus Endovascular Corporation, it is concluded that the Micrus Microcoil System with new device positioning unit is substantially equivalent to the predicate devices in safety and effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Micrus Endovascular Corporation
% Mr. Patrick Lee
Regulatory Affairs Specialist
821 Fox Lane
San Jose, California 95131

OCT 17 2008

Re: K082739

Trade/Device Name: Micrus Microcoil Delivery System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular embolization device
Regulatory Class: II
Product Code: HCG
Dated: September 16, 2008
Received: September 18, 2008

Dear Mr. Lee:

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.

Page 2 – Mr. Patrick Lee

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

K082739

Indications for Use

510(k) Number (if known): K082739

Device Name: Micrus Microcoil Delivery System

Indications For Use:

The Micrus Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and are also intended for arterial and venous embolizations in the peripheral vasculature.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Dyer, M.D.

(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K082739

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