K070707

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Summary of Safety and Effectiveness

APR - 6 2007

Submitter Name and Address:	Micrus Endovascular Corp. 821 Fox Lane San Jose, CA 95131
Contact Name:	Patrick Lee, Regulatory Affairs Specialist Phone: 408-433-1428 Fax: 408-433-1515 Email: plee@micruscorp.com
Preparation Date:	March 12, 2007
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 Cashmere, 510(k) K063653 Micrus Microcoil Delivery System, 510(k) K062036 Micrus Modified Microcoil System, 510(k) K053160 Micrus Microcoil Delivery System, 510(k) K033813 Micrus Microcoil Delivery System, 510(k) K032872
Device Description:	The Micrus MicroCoil System consists of an embolic coil ("MicroCoil") attached to a Device Positioning Unit (DPU) (single use, sterile). An "introducer sheath" covers the microcoil and DPU and is attached to a re-sheathing tool
Device Intended Use	The Micrus MicroCoil Delivery System is intended for endovascular embolization of intracranial aneurysms.

Comparison to Predicate Devices:
The Micrus Microcoil Systems with the new "introducer sheath and re-sheathing tool" have shown substantial equivalence to the FDA-cleared and marketed Micrus Microcoil Systems in terms of intended use, design, material and method of construction, and dimensions. The modification has not altered the fundamental technology of the sponsor's predicate device

Conclusion:
Based upon the design, materials, 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 a new sheath and re-sheathing tool is substantially equivalent to the predicate devices in safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

APR - 6 2007

Re: K070707
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: March 12, 2007
Received: March 14, 2007

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.

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

K070707

Indications for Use

510(k) Number (if known): _____

Device Name: Micrus Microcoil Delivery System

Indications For Use:

The Micrus MicroCoil Delivery System is intended for endovascular embolization of intracranial aneurysms.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices
510(k) Number K070707