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1.4 Summary of Safety and Effectiveness

JAN 17 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: 408-433-1401 Email: plee@micruscorp.com
Preparation Date:	December 5, 2006
Device Name and Classification:	Micrus Microcoil System "Cashmere" Common Name: Micrus Microcoil System "Cashmere" Classification Name: Device, Artificial Embolization Regulatory Class II
Predicate Devices:	Micrus Stretch-Resistant Microcoil, 510(k) no.K022420 Micrus Microcoil Delivery System, 510(k) no. K002056 Boston Scientific GDC 360 Soft SR, 510(k) no. K042539 Cordis Trufill DCS Orbit Detachable Coil, 510(k) no.K032553
Device Description:	The Micrus Cashmere-14 MicroCoil System consists of an embolic coil ("MicroCoil") attached to a Device Positioning Unit (DPU) (single use, sterile).
Device Intended Use	The Micrus MicroCoil Delivery System is intended for endovascular embolization of intracranial aneurysms.

Comparison to Predicate Devices:

The Micrus Cashmere-14 Microcoil Systems have shown substantial equivalence to the Micrus SR Helical-18 Microcoil System in terms of intended use, design, material of construction, implant dimensions including wire diameter, primary wind diameter, pitch, coil stiffness, coil diameter, and coil length. The Cashmere-14 Microcoil system uses the same method and material of construction, packaging, and sterilization method as its predicate. The modification has not altered the fundamental technology of the sponsor's predicate device

The Micrus Cashmere-14 Microcoil System have also shown substantial equivalence to the Boston Scientific GDC 360 and Cordis Orbit microcoil predicates in terms of

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intended use and design, material of construction, implant dimensions including wire diameter, primary wind diameter, pitch, coil stiffness, coil diameter, and coil length.

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 Cashmere-14 Microcoil System 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 Corp.
% Mr. Patrick Lee
Regulatory Affairs Specialist
821 Fox Lane
San Jose, California 95131

JAN 17 2007

Re: K063653
Trade/Device Name: Cashmere-14 MicroCoil System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular embolization device
Regulatory Class: Class II
Product Code: HCG
Dated: December 6, 2006
Received: December 8, 2006

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

K063653

Indications for Use

510(k) Number (if known): _____

Device Name: Micrus Microcoil System , "Cashmere"

Model #: SRC140512-20, SRC140615-20, SRC140717-20, SRC140820-20, SRC140922-20, SRC141025-20, SRC141127-20, SRC141230-20

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 K063653