

K070707

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**Summary of Safety and Effectiveness**

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

APR - 6 2007

**Contact Name:** Patrick Lee, Regulatory Affairs Specialist  
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**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.



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.

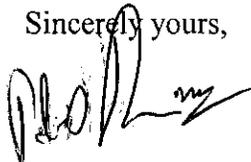
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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 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,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with a stylized flourish at the end.

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    
 (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)



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

510(k) Number 1070707