II. Safety and Effectiveness Summary

A. Contact Information

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Director, Regulatory & Clinical Affairs
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610 Palomar Avenue
Sunnyvale, CA 94085
Tel: 408-830-5900, ext. 108
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B. Device Name

Long Spherical MicroCoil System (member of Micrus MicroCoil Delivery System)

Device, Artificial Embolization

Regulation Number: 882.5950

Product Code: HCG

Device Class: III

C. Predicate Device

510k# K002056: Micrus MicroCoil Delivery System, cleared on Jan 11, 2001.

D. Device Description

The current Micrus Spherical MicroCoil System (510k # K002056) is available in 10 and 18 system sizes.

- The 10 System Spherical MicroCoils are available in diameters ranging from 2 mm to 10 mm and in lengths ranging from 2 cm to 20 cm.
- The 18 System Spherical MicroCoils are available in diameters ranging from 2 mm to 19 mm and in lengths ranging from 2 cm to 30 cm.

The proposed longer Spherical MicroCoil, which is the focus of this submission, is designed to provide move aneurysm-framing loops to provide better aneurysm wall and aneurysm neck coverage in aneurysms ranging from 6 to 10 mm in size:

- The "Long 10 System Spherical" MicroCoils will be available in diameters ranging from 6 mm to 10 mm and in lengths ranging from 20 cm to 30 cm.

These long Spherical MicroCoils are a line extension of the current regular length Micrus Spherical MicroCoils. The table below shows the lengths of both the regular and proposed long Spherical MicroCoils.

Comparison Table: Long Spherical MicroCoils Vs. Current Spherical MicroCoils

Long Spherical MicroCoil Sizes	Current Spherical MicroCoil Sizes
6 mm x 20 cm	6 mm x 12cm
7 mm x 20 cm	7 mm x 14cm
8 mm x 25 cm	8 mm x 16 cm
9 mm x 25 cm	9 mm x 18.5 cm
10 mm x 30 cm	10 mm x 20.5 cm

Both the original length and long length Spherical MicroCoil Systems are "framing" coils, to be used interchangeably to frame the inner wall of the aneurysm prior to filling it with Helical MicroCoils. All Micrus MicroCoils are part of the complete Micrus MicroCoil Delivery System, which has three components (sold and provided individually):

1) Micrus Platinum MicroCoil Systems, Spherical, Helical, Straight, and Stretch Resistant configurations, consist of an embolic coil attached to a variable stiffness Device Positioning Unit (DPU). The DPU has a radiopaque marker band located three (3) centimeters from its distal end for compatibility with infusion microcatheters with 2 tip markers.

2) Detachment Control Boxes (DCB). This device provides the energy to detach the MicroCoil from the DPU at the clinician's command. The DCB is provided NON-STERILE.

3) Connecting Cable. The Connecting Cable is used to bring the energy from the DCB to the MicroCoil System, and is approximately 5-ft (1.5 m) long.

Note: The MicroCoil System and the Connecting Cable are provided sterile and non-pyrogenic, if in their unopened packages.

E. *Intended Use*

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

F. *Intended Use (Predicate)*

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

G. *Technological Comparison*

Characteristic	Micrus Current Spherical MicroCoil (10-System)	Proposed Longer Spherical MicroCoil (10-System)	Comparison
MicroCoil System			
How supplied	Sterile, single use. MicroCoil attached to the DPU, polyethylene introducer over MicroCoil, in plastic packaging hoop.	Sterile, single use. Embolic coil attached to the pusher wire, polyethylene introducer over embolic coil, in plastic packaging hoop.	Identical
Implantable Embolic Coil			
Materials of construction	Platinum/Tungsten alloy wire & Au/Sn solder.	Platinum/Tungsten alloy wire & Au/Sn solder.	Identical
Shape	3D Spherical shape with atraumatic tip.	3D Spherical shape with atraumatic tip.	Identical
Dimensions	Various diameters and lengths to treat a variety of aneurysm sizes. Diameters from 2 – 12 mm Lengths from 2.5 cm to 20.5 cm.	Various diameters and lengths to treat a variety of aneurysm sizes. Diameters from 6 –10 mm Lengths from 20 – 30 cm	Within same diameter range. Longer lengths available.
Radiopacity	Radiopaque from Pt alloy wire.	Radiopaque from Pt alloy wire.	Identical
MRI Compatibility	Yes	Yes	Identical
Method of attachment to device positioning unit	High tensile strength, highly oriented polyethylene fiber.	High tensile strength, highly oriented polyethylene fiber.	Identical
Method of detachment from device positioning unit	Shear PE fiber with a loop of a resistively heated coil.	Shear PE fiber with a loop of a resistively heated coil.	Identical
Provided:	Sterile, single use	Sterile, single use	Identical

Characteristic	Micrus Current Spherical MicroCoil (10-System)	Proposed Longer Spherical MicroCoil (10-System)	Comparison
Device Positioning Unit			
Physical	Variable stiffness composite introducer (most flexible distally, medium flexibility in mid-section and stiffest proximally) to allow pushing of the embolic coil through the tortuous cerebral vasculature.	Variable stiffness composite introducer (most flexible distally, medium flexibility in mid-section and stiffest proximally) to allow pushing of the embolic coil through the tortuous cerebral vasculature.	Identical
Construction	Stainless steel hypotube (proximal), stainless steel braid (mid) and polymer (distal) sheathing for 2 conduction wires and distal RH coil.	Stainless steel hypotube (proximal), stainless steel braid (mid) and polymer (distal) sheathing for 2 conduction wires and distal RH coil.	Identical
Working Length	195 cm	195 cm	Identical
Package Configuration	In plastic packaging hoop, with introducer in place (for introduction of MicroCoil into the microcatheter)	In plastic packaging hoop, with introducer in place (for introduction of coil into the microcatheter)	Identical
Compatible with:	Microcatheters with minimum 0.14" i.d. ("10" sized systems) with 2 radiopaque tip markers 3 cm apart (examples: Tracker 10, Excel 14, Prowler 10, Prowler 14)	Microcatheters with minimum 0.14" i.d. ("10" sized systems) with 2 radiopaque tip markers 3 cm apart (examples: Tracker 10, Excel 14, Prowler 10, Prowler 14)	Identical
Connecting Cables			
How supplied	Sterile, single use	Sterile, single use	Identical
Physical	Single cable with proprietary connectors to fit only the Micrus DCB and the Micrus MicroCoil System	Single cable with proprietary connectors to fit only the Micrus DCB and the Micrus MicroCoil System	Identical
Length	262 cm.	262 cm.	Identical
Detachment Box			
How supplied	Non-Sterile, reusable. Used outside the sterile field.	Non-Sterile, reusable. Used outside the sterile field.	Identical
Power Source	Alkaline batteries.	Alkaline batteries.	Identical
Displays	Voltage, Current, Low Battery, Fault, Detach Cycle	Voltage, Current, Low Battery, Fault, Detach Cycle	Identical
Detachment Cycle Duration	5 seconds	5 seconds	Identical
Output Voltage	6.5 VDC	6.5 VDC	Identical
Output Current	125 mA nominal, 200 mA max.	125 mA nominal, 200 mA max.	Identical
"Detach" feedback	"Detach Cycle" light goes from illuminated to off. Clinician verifies detachment fluoroscopically per device labeling.	"Detach Cycle" light goes from illuminated to off. Clinician verifies detachment fluoroscopically per device labeling.	Identical
Method of attaching Connecting Cable to Detachment Box	Proprietary connector fits only one way to assure proper polarity.	Proprietary connector fits only one way to assure proper polarity.	Identical
Flow of Current	From positive terminal, through positive lead in connecting cable, through positive conductor of DPU, through resistance heating coil, through negative conductor of DPU, through negative lead in connecting cable, back to negative terminal of detachment control box.	From positive terminal, through positive lead in connecting cable, through positive conductor of DPU, through resistance heating coil, through negative conductor of DPU, through negative lead in connecting cable, back to negative terminal of detachment control box.	Identical

Characteristic	Micrus Current Spherical MicroCoil (10-System)	Proposed Longer Spherical MicroCoil (10-System)	Comparison
Accessory Products Required to Perform the Procedure. * - Not provided as part of the system, chosen based upon physician experience and preference.	Micrus Sterile Connecting Cable Micrus Detachment Control Box 5-7F Guide Catheter* Microcatheter (see above)* Guide wire compatible with microcatheter* Continuous saline/heparin saline flush* Rotating hemostatic valves* 3-Way stopcock* 1-Way valve* IV pole* Femoral Sheath* Alkaline Batteries*	Micrus Sterile Connecting Cable Micrus Detachment Control Box 5-7F Guide Catheter* Microcatheter (see above)* Guide wire compatible with microcatheter* Continuous saline/heparin saline flush* Rotating hemostatic valves* 3-Way stopcock* 1-Way valve* IV pole* Femoral Sheath* Alkaline Batteries*	Identical

This technological comparison demonstrates the substantially equivalent technologies used in the proposed longer Micrus Spherical MicroCoil System and the predicate Micrus MicroCoil System.

H. *Discussion of Non-Clinical Tests and Conclusions*

The non-clinical tests performed on the Micrus longer Spherical MicroCoil System were based upon the intended use of the device and the performance of the predicate Micrus regular length Spherical MicroCoil System.

The following table outlines the important device characteristics and the non-clinical test data generated:

Test	Proposed Long Spherical MicroCoil System	Substantial Equivalence to the current Micrus Spherical MicroCoil System
V0381	The 10 System long Spherical MicroCoil System demonstrates the durability to withstand 6 cycles of deployment and retraction through the tip of the microcatheter in a tortuous anatomy flow model without stretching, knotting, or breaking.	Substantially equivalent
V0384	The long Spherical MicroCoil System is able to advance, retract, frame the aneurysm, and enable packing of the framed aneurysm with helical filler coils.	Substantially equivalent
V0387	The frictional forces of the long Spherical MicroCoil System were equal or less than the currently marketed helically shaped and spherically shaped MicroCoil systems.	Substantially equivalent

This non-clinical testing has demonstrated the substantially equivalent performance of the Micrus Long Spherical MicroCoil System with the predicate Micrus Regular Length Spherical MicroCoil System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2003

Ms. Margaret Webber
Director, Regulatory and Clinical Affairs
Micrus Corporation
610 Palomar Avenue
Sunnyvale, California 94085

Re: K032872
Trade/Device Name: MicroCoil System
Regulation Number: 21 CFR 882.5950
Regulation Name: Artificial embolization device
Regulatory Class: III
Product Code: HCG
Dated: September 11, 2003
Received: September 15, 2003

Dear Ms. Webber:

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.

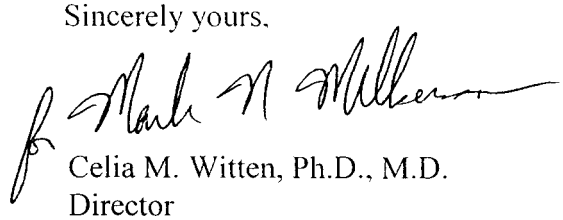
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Device Name:

510(k) Number (if known):

Indications for Use:

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

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Over the Counter Use:
or
Prescription Use: X
(Per 21 CFR 801.109)

for Mark N Milhous

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

(510(k) Number K032872