

Section 1.4: Cerecyte-18, 510(k) Summary

1.4.1 Contact Information:

Name: Margaret Webber, Director, Regulatory & Clinical Affairs
Address: Micrus Endovascular Corporation
610 Palomar Ave.
Sunnyvale, CA 94085
Telephone: 408-830-5900, ext. 108
Date: Nov. 28, 2005

1.4.2 Device Information

Device Name: Micrus Modified MicroCoil, "Cerecyte" 18-System
Common Name: Device, Artificial Embolization
Classification: Class II

1.4.3 Predicate Devices Identification

K033813, Micrus Modified Microcoil 10-System "Cerecyte"
K002056, Micrus Microcoil Delivery System (10 and 18 sizes)

1.4.4 Device Description

The Micrus Modified MicroCoil 18-System (Cerecyte) consists of an embolic coil ("MicroCoil") attached to a Device Positioning Unit (DPU) (single use, sterile).

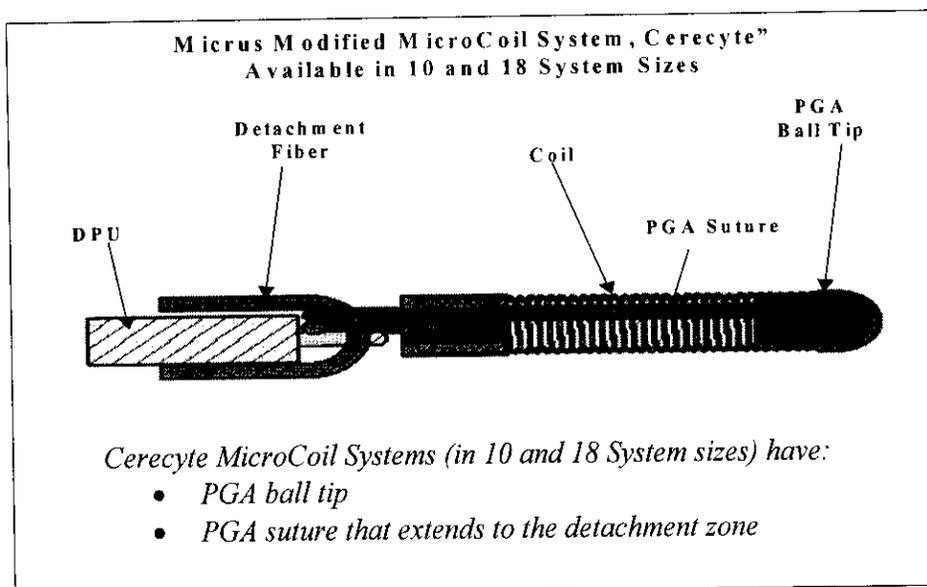
The predicate Cerecyte MicroCoil Systems in the 10-system size received FDA Clearance in February 2004. This application is for the 18-sized Cerecyte Microcoil System. The Cerecyte 18-System is compatible with commercially available 2-tip marker microcatheters which have internal lumen diameters between 0.017" and 0.021." The coils are available in helical and spherical shapes and are available in various diameters/lengths:

- Coil lengths range from 4 to 30 centimeters.
- Coil diameters range from 2 to 20 millimeters.

Micrus Cerecyte MicroCoils are fabricated from a platinum alloy wire, which is first wound into a primary coil (containing an absorbable polymer suture inside the wind) and then formed into a secondary helical or spherical shape. The only difference between the Cerecyte 18 System and 10 System is size. Both contain PGA suture as their stretch resistant member. Both contain exactly the same PGA strand, i.e., the amount of PGA suture material is identical. Micrus does not insert a larger strand of suture in the 18 system coils.

The 18 System Cerecyte MicroCoils maintain the same design features as all the current Micrus MicroCoil Systems. Compared with the current design, size 18 Cerecyte MicroCoil Systems have:

- The same intended use
- Connect to the same connecting cables
- Detach using the same Detachment Control Box.



Cerecyte 18-System coils size ranges are:

- Helical Cerecyte (CHE) ranges from 2 – 20 mm in diameter and from 4 - 30 cm in length.
- Spherical Cerecyte (CSP) ranges from 2 – 20 mm in diameter and 2.7 - 30 cm in length.

1.4.5 Indications for Use

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

Contraindications

None.

Required Accessory Products

The Micrus MicroCoil Systems require two other components for the Micrus MicroCoil Delivery System to operate:

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

Accessories, which are an Integral Part of the Sales Unit:

The Micrus MicroCoil System is packaged with an introducer in place. This introducer allows introduction of the MicroCoil into the microcatheter used by the clinician.

Accessories (Not Part of the Sales Unit, not supplied by Micrus Endovascular Corporation)

- Guiding Catheter (generally, 5-7F)
- Infusion microcatheter with 2 tip markers located 3cm apart
- Guide wire compatible with the microcatheter
- Continuous Saline Flush Set-Ups with pressure bags, one of which is a flush for the guiding catheter and one the other a flush for the microcatheter.
- Rotating Haemostatic Valves (2)
- 3-Way Stopcock
- 1-Way Valve
- IV Pole
- Femoral Sheath

1.4.5 Comparison to Predicate

Intracranial aneurysms can form for a variety of reasons, and the consequences of aneurysm formation and/or rupture can be dire for the patient. Treatment of intracranial aneurysms involves the segregation of the sac from the blood supply of the parent artery. This prevents the aneurysm from growing in size, from rupturing or from re-rupturing. Treatments currently include the application of an aneurysm clip to the base of the aneurysm using open surgical procedures (craniotomy). Alternatively, the aneurysm may be embolically closed or occluded using minimally invasive delivery of embolic coils. Embolic coils are generally made of a biocompatible metal, such as stainless steel, tungsten or platinum. Dacron, nylon, or silk fibers may be incorporated into the design to enhance thrombosis. The coils come in a variety of widths, lengths, softness, and shapes and are delivered by small catheters ("microcatheters"). Multiple coils are placed into the aneurysm to completely fill the sac and prevent continued inflow of blood. The embolic coils cause stagnation of blood within the aneurysm resulting in platelet aggregation, which leads to the development of scar tissue. This prevents the continuing enlargement of the aneurysm and the potential for rupture or re-rupture.

The intent of endovascular treatment of intracranial aneurysms using embolic coils is to pack the lumen of the aneurysm with the coils, thereby eliminating the influx of fresh blood into the lumen. The existing blood and soft clot trapped within the lumen of the aneurysm begins to solidify, ultimately becoming hardened clot and scar tissue. With treatment of the aneurysm lumen (from aneurysm dome to neck) a blood flow pathway is re-established down the lumen of the parent artery, and the weakened wall of the aneurysm is totally isolated from arterial pressures. Re-endothelialization occurs on the surface of the scar tissue, and the pre-treatment vortical flow is changed back to normal, laminar flow within the parent artery.

K053160

4/8

Micrus MicroCoil Systems have been used to treat intracranial aneurysms since May 2000. Micrus MicroCoils are available in both bare platinum implants and stretch resistant implants containing either absorbable suture (PGA) or non-absorbable suture (polypropylene). Micrus MicroCoils are also available in both 10 and 18 sizes and in spherical and helical shapes in a variety of lengths and diameters.

Clinical data regarding Micrus MicroCoils (and other intracranial coil implants) have been presented in previous 510k submissions to FDA as each new coil family member was introduced. The Cerecyte MicroCoil 18-System is an addition to the Cerecyte 10-System coil line. Below are comparison tables to demonstrate the equivalence of Cerecyte-18 to the predicate Cerecyte-10 and predicate Micrus (10 & 18 sized bare platinum helical and spherical) MicroCoil Systems.

The Design Comparison Table and Functional Comparison Table show the Cerecyte-18 Modified MicroCoils are designed in an identical manner as the current family of CE Marked Micrus MicroCoil Systems and function in an identical manner.

Design Comparison-Table

<i>Design Feature</i>	<i>Micrus Platinum 18-System Predicate</i>	<i>Micrus Cerecyte-10 System Predicate</i>	<i>Micrus Cerecyte-18 System</i>
Implant Material	Platinum Tungsten Alloy Wire. No suture.	Platinum Tungsten Alloy Wire. Absorbable PGA suture.	Same as Cerecyte 10 System predicate
Composition			
Diameter	Implant available in up to 20 mm diameter	Implant available in up to 10 mm diameter	Same as Platinum 18 System predicate
Implant length	Implant available in up to 30 cm lengths	Implant available in up to 15 cm lengths	Same as Platinum 18 System predicate
Device Positioning Unit (DPU)	Stainless steel hypotube (proximal), stainless steel braid (mid), and polymer (distal) sheathing for 2 conduction wires and distal resistive heating coil.	Stainless steel hypotube (proximal), stainless steel braid (mid), and polymer (distal) sheathing for 2 conduction wires and distal resistive heating coil.	Same as predicates.
Connecting Cable compatibility	Single cable with proprietary connectors to fit only the Micrus Detachment Control Box and the Micrus MicroCoil System.	Single cable with proprietary connectors to fit only the Micrus Detachment Control Box and the Micrus MicroCoil System.	Same as predicates.
Detachment technique	Shear polyethylene fiber with a loop of resistively heated coil.	Shear polyethylene fiber with a loop of resistively heated coil.	Same as predicates.
Packaging	Packaged in plastic loop, enclosed in pouch	Packaged in plastic loop, enclosed in foil pouch	Packaged in plastic loop, enclosed in foil pouch
Instructions for Use	Uses a single IFU for the entire MicroCoil family	Uses a single IFU for the entire MicroCoil family	Same as predicates
Microcatheter compatibility	Compatible with 2-tip marker microcatheters: <ul style="list-style-type: none"> • 10 system uses 10 & 14 catheters • 18 system uses 14 & 18 catheters 	Compatible with 2-tip marker microcatheters: <ul style="list-style-type: none"> • 10 system uses 10 & 14 catheters 	Compatible with 2-tip marker microcatheters: <ul style="list-style-type: none"> • 18 system uses 14 & 18 catheters
Sterilization	E-Beam	E-Beam	E-Beam

15053160

6/8

Functional Testing Comparison-Table

The physician will expect the same level of softness, lack of friction, and detachment reliability as other Micrus MicroCoil family members.

The following studies were performed specifically on the Cerecyte-18 Microcoil System to ensure the design change did not affect safety or function.

Functional Comparison Table

Test	Micrus Modified MicroCoil System Test Result	Substantial Equivalence
Coil Stiffness/Softness for Cerecyte-18 MicroCoils V0544	Characteristic: Stiffness limits for the Cerecyte-18 MicroCoil Systems. Test data: The Cerecyte-18 MicroCoils met the stiffness specifications.	Substantially equivalent.
Friction in the Microcatheter (Delivery Force) V0542	Characteristic: Average push force must be substantially equivalent to predicates. Test data: The Modified MicroCoil had average push forces that are comparable to those of the predicate.	Substantially equivalent.
Tensile Strength V0547	Characteristic: Pre-detachment tensile strength of the suture ball tip and MicroCoil to DPU must be substantially equivalent to the stretch resistant Cerecyte-10 predicate. Test data: Tensile strength meets desired strength criteria.	Substantially equivalent to the stretch resistant predicate
Durability (Reliability after Fatigue) V0543	Characteristic: Withstand deployment and retraction 6 times in a tortuous anatomy. Test data: No knotting, no breakage, no stretching occurred. Durability meets desired durability criteria.	Substantially equivalent

The following studies were performed on the Cerecyte-10 Microcoil System and are listed here as a reference because the test results also apply to the Cerecyte 18 Microcoil System. All results are on file with FDA in 510k #K033813.

Test	Micrus Modified MicroCoil System Test Result	Substantial Equivalence
Sterilization Validation V0394 for Cerecyte 10-System	<p>Characteristic: Minimum Sterility Assurance Level of 10^{-6}.</p> <p>Test data: Cerecyte-10 was validated under V0394. Due to the significant similarities (in materials used, manufacturing processes, product weight & density, and packaging) between the 10 & 18 Systems, V0394 will serve as validation for the 18-system Cerecyte.</p>	Substantially equivalent.
MRI Compatibility of Implant	No change was made which would impact MRI compatibility.	Substantially equivalent
Package Integrity V0399 for Cerecyte 10 System	<p>Characteristic: Demonstrate package integrity per ISO 11607</p> <p>Test: No change was made to packaging. Reference Cerecyte 10 test result V0399.</p>	Substantially equivalent
Ship/Transit V0400 for Cerecyte 10 System	<p>Characteristic: Successfully withstand domestic and international distribution environment</p> <p>Test: Does successfully withstand domestic and international distribution environment. No change was made to packaging or product materials. Reference Cerecyte 10 test result.</p>	Substantially equivalent

This functional testing demonstrates the substantially equivalent performance of the Micrus Cerecyte-18 MicroCoil System with the 2 predicate devices: (1) Micrus MicroCoil Delivery System, and (2) Micrus Cerecyte-10 MicroCoil System. All test results are included in "Section 2.2, Verification/Validation."

K053160

7/18

K053160

8/9

Summary of Safety and Effectiveness

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 Modified MicroCoil, "Cerecyte" 18-System is substantially equivalent to the Micrus Modified MicroCoil "Cerecyte" 10-System in safety and effectiveness.

Margaret Webber
Director, Regulatory and Clinical Affairs
Micrus Endovascular Corporation
November 28, 2005



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 7 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Margaret Webber
Director, Regulatory & Clinical Affairs
Micrus Endovascular Corporation
610 Palomar Avenue
Sunnyvale, California 94085

Re: K053160
Trade/Device Name: Micrus Modified Microcoil 18-System,
"Cerecyte" Model #s CSP and CHE
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular embolization device
Regulatory Class: II
Product Code: HCG
Dated: November 8, 2005
Received: November 14, 2005

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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a small "M" and "N" at the end.

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K053160
9/9

Indications for Use

510(k) Number (if known): K053160

Device Name: Micrus Modified Microcoil 18-System, Cerecyte" Model #s CSP and CHE

Indications For Use:

The Micrus Modified Microcoil System, "Cerecyte-18" is intended for endovascular embolization of intracranial aneurysms.

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)

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

510(k) Number K053160