II. Safety and Effectiveness Summary

A. Contact Information

Margaret Webber
Director, Regulatory and Clinical Affairs
Micrus Corporation
495 Clyde Avenue
Mountain View, CA 94043

B. Device Name

Micrus Stretch-Resistant MicroCoil System, MSR01

Device, Artificial Embolization

Regulation Number: 882.5950

Product Code: HCG

Device Class: III

C. Predicate Device(s)

Number	Description	Clearance Date
K9993415	GDC-10 and GDC-10 (2D) Stretch Resistant Detachable Coils and GDC-18 and GDC-18 (2D) Stretch Resistant Detachable Coils	01/21/2000
K002056	Micrus MicroCoil Delivery System	01/11/2001

D. Device Description

The Micrus Stretch Resistant MicroCoil System consists of a platinum embolic coil ("MicroCoil") attached to a Device Positioning Unit (DPU) (single use, sterile),

The Micrus Stretch Resistant MicroCoil System connects to a Micrus Connecting Cable (single use, sterile) which traverses the sterile field to connect to a Micrus Detachment Control Box (DCB) (reusable, non-sterile). The Connecting Cable and Detachment Control Box are sold separately.

The Micrus Stretch-Resistant MicroCoils are available in a 10-System size, compatible with 10 and 14 sized microcatheters. They are helically shaped and are available in various diameters/dimensions. Coil lengths range from 1 to 15 centimeters and diameters range from 2 to 10 millimeters. The Stretch Resistant MicroCoils are available in two levels of softness:

1. The Micrus Soft, Stretch-Resistant MicroCoil (catalog # FSR) corresponds to the 10-System GDC Ultra Soft Stretch Resistant Coil, using a primary wind of 0.0015" to create softness.
2. The Standard Micrus Stretch-Resistant MicroCoil (catalog # HSR) corresponds to the 10-System GDC Soft, Stretch Resistant coil, using a primary wind of 0.00175".

Micrus Stretch Resistant MicroCoils are fabricated from a platinum alloy wire, which is first wound into a primary coil (containing a non absorbable polypropylene suture inside the wind) and then formed into a secondary helical

shape. The Micrus Stretch-Resistant MicroCoil System is identical to the FDA-cleared Micrus MicroCoil System with the 4 following exceptions:

1. The coil's primary wind wire diameter has been reduced from 0.00175" to 0.0015" to create softness in the Micrus Soft Stretch-Resistant MicroCoil. (The Standard Micrus Stretch-Resistant MicroCoil uses the same 0.00175" diameter primary wind as is used in the Micrus 10-System Helical MicroCoil.)
2. A non absorbable polypropylene suture has been inserted inside the primary wind coil to create stretch-resistance.
3. The polypropylene suture is connected to the distal coil end to make a non-traumatic distal ball tip.
4. A loop of polypropylene suture has been added to the socket/ring connection at the coil to Device Positioning Unit junction to secure the polypropylene suture to the Device Positioning Unit. A diagram of the socket/ring connection is provided below.

Diagram of Predicate Micrus MicroCoil Socket/Ring Connection

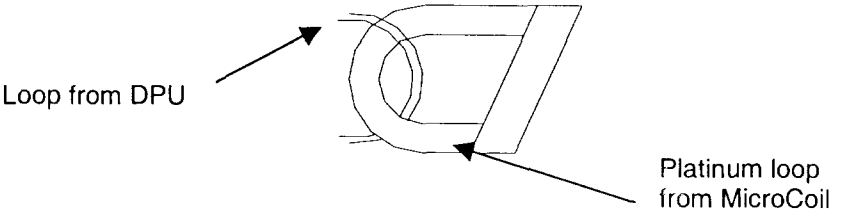
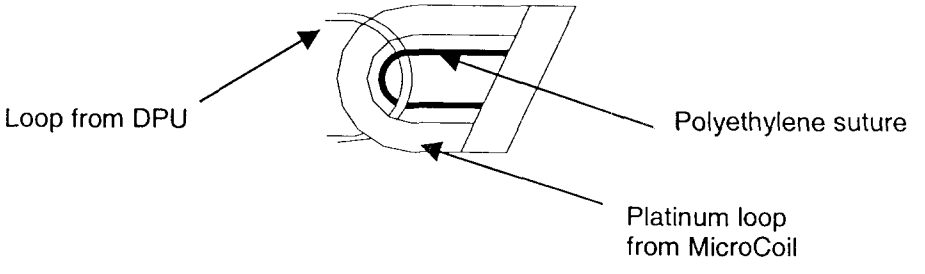


Diagram of Micrus Stretch Resistant MicroCoil Socket/Ring Connection



The Stretch-Resistant MicroCoils are provided attached to a Device Positioning Unit (DPU). The Device Positioning Unit is unchanged from the original FDA cleared Micrus product. The Device Positioning Unit is designed with variable stiffness: It is most stiff at the proximal end for pushability, transitions to increased flexibility in the mid-section, and becomes most flexible at the distal end for successfully navigating the tortuosity of the cerebral vasculature. The Device Positioning Unit is fabricated from various materials including stainless steel, nitinol, platinum and polymer sheathing. It contains 2 copper conductor wires down the center, which carry the electrical energy to a platinum resistive heating coil on the distal tip of the device. The Device Positioning Unit is self-grounded, requiring no external grounding through the patient, a grounding pad, etc.

The Stretch-Resistant MicroCoil is detached from the Device Positioning Unit through a heat initiated shearing of a highly oriented, high tensile strength polyethylene (PE) fiber upon the clinician's command, once the coil is deployed into the aneurysm as desired. The Device Positioning Unit is then removed from the microcatheter and discarded. The detachment process and design is identical to the original FDA cleared Micrus products except the detachment time is reduced from 10 seconds to 5 seconds. The 5-second detachment time applies to all Micrus MicroCoil Systems.

The Detachment Control Box (DCB) is a self-contained, battery-operated device, which provides the controlled electrical energy for detachment of the MicroCoil from the Device Positioning Unit. The Detachment Control Box is unchanged from the original FDA cleared device. During aneurysm embolization, the Detachment Control Box remains outside of the sterile field (as is the case with the predicate system). The Detachment Control Box has no user adjustments for output voltage, output current or detachment cycle time. It has an on/off button, and a detach cycle start button, as well as voltage and current displays and fault and low battery indicators. When the clinician depresses the detach button, the Detachment Control Box outputs a constant voltage of 6.5 VDC at a nominal current of 125mA for 5 seconds. The delivered electrical energy serves to heat a platinum resistive heating coil at the distal end of the DPU, thereby initiating a heat shearing of the PE fiber which holds the MicroCoil to the Device Positioning Unit. Once the fiber shears, the MicroCoil is free from the Device Positioning Unit ("detached"), and the Device Positioning Unit is withdrawn and discarded.

The Connecting Cable (CCB) is used to connect the MicroCoil System to the Detachment Control Box. The Connecting Cable is unchanged from the original FDA cleared Micrus device. It utilizes proprietary connectors to prevent accidental or inappropriate connections to other devices. It traverses from the MicroCoil System (which is within the sterile field) to the Detachment Control Box (which is outside the sterile field). The Connecting Cable is provided sterile, and discarded after a single patient treatment.

E. Intended Use

The Micrus Stretch-Resistant MicroCoil Delivery System is intended for endovascular embolization of intracranial aneurysms that – because of their morphology, their location or the patient's general medical condition – are considered by the treating neurosurgical team to be a) very high risk for management by traditional operative techniques or b) inoperable.

F. *Intended Use Predicate Devices*

The predicate Micrus MicroCoil Delivery System is intended for endovascular embolization of intracranial aneurysms that – because of their morphology, their location or the patient's general medical condition – are considered by the treating neurosurgical team to be

a) very high risk for management by traditional operative techniques, or
b) inoperable.

The predicate Guglielmi Detachable Coil is intended for embolization ~~of those~~ intracranial aneurysms that – because of their morphology, their location, or the patient's general medical condition – are considered by the treating neurosurgical team to be

a) very high risk for management by traditional operative techniques, or
b) inoperable,

and for embolizing other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neuro vasculature. The GDC is also intended for arterial and venous embolizations in the peripheral vasculature.

G. *Technological Comparison*

MicroCoil System

Characteristic	Micrus MicroCoil Predicate	GDC Stretch Resistant Predicate	Micrus Stretch Resistant
How Supplied	Sterile, Single Use	Sterile, Single Use	Same as predicates
	MicroCoil attached to DPU.	Coil attached to pusher wire.	Same as Micrus predicate
	Polyethylene introducer over coil.	Polyethylene introducer over coil.	Same as predicates
	In plastic packaging hoop.	In plastic packaging hoop.	Same as predicates

Implantable Embolic Coil

Characteristic	Micrus MicroCoil Predicate	GDC Stretch Resistant Predicate	Micrus Stretch Resistant
Materials of Construction	Platinum/Tungsten alloy wire & Au/Sn solder.	Platinum/Tungsten alloy wire & Au/Sn solder. Polypropylene suture.	Same as predicates Same as GDC predicate
Shape	2 mm – 30 mm	2 mm – 30 mm	1 mm – 15 mm
Dimensions	Various diameters and lengths to treat a variety of aneurysm sizes.	Various diameters and lengths to treat a variety of aneurysm sizes.	Same as predicates
Radiopacity	Radiopaque from Pt alloy wire.	Radiopaque from Pt alloy wire.	Same as predicates
MRI Compatibility	Yes	Yes	Same as predicates
Method of Attachment to Device Positioning Unit	High tensile strength, highly oriented polyethylene fiber.	Welded or soldered to wire.	Same as Micrus predicate
Method of Detachment from DPU	Shear polyethylene fiber with a loop of resistively heated coil.	Electrolytic corrosion of positioning wire near junction of implantable coil.	Same as Micrus predicate
Provided:	Sterile, single use	Sterile, single use	Same as predicates

Device Positioning Unit

Characteristic	Micrus MicroCoil Predicate	GDC Stretch Resistant Predicate	Micrus Stretch Resistant
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. Guide wire introducer. Most flexible distally, medium flexibility in mid-section and stiffest proximally to allow pushing of the embolic coil through the tortuous cerebral vasculature.	Same as predicates Same as Micrus predicate Same as predicates
Construction	Stainless steel hypotube (proximal), stainless steel braid (mid) and polymer (distal) sheathing for 2 conduction wires and distal RH coil.	Variably ground stainless steel wire, with polymer coverings in the distal section to facilitate electrochemical corrosion of wire to release coil.	Same as Micrus predicate
Working Length	175 cm	175 cm	Same as predicates
Package Configuration	In plastic packaging hoop. Introducer in place (for introduction of MicroCoil into the microcatheter).	In plastic packaging hoop. Introducer in place (for introduction of coil into the microcatheter).	Same as predicates Same as predicates
Compatible with:	Microcatheters with minimum 0.14" i.d. ("10" sized systems), or 0.16" i.d. ("18" sized systems). 2 radiopaque tip markers 3 cm apart (examples: Tracker 10, Tracker 18, Excel 14, Prowler 10, Prowler 14).	Microcatheters with minimum 0.14" i.d. ("10" sized systems), or 0.16" i.d. ("18" sized systems). 2 radiopaque tip markers 3 cm apart (examples: Tracker 10, Tracker 18, Excel 14, Prowler 10, Prowler 14).	Same as predicates "10" sized systems Same as predicates

Connecting Cables (Unchanged for Micrus Stretch Resistant MicroCoil)

Characteristic	Micrus MicroCoil Predicate	GDC Stretch Resistant Predicate	Micrus Stretch Resistant
How supplied	Sterile, single use	Sterile, single use	Same as predicates
Physical	Single cable with proprietary connectors to fit only the Micrus Detachment Control Box and the Micrus MicroCoil System	Two separate cables with proprietary connectors at one end to fit the GDC Power Supply, "Test Lead Clip" type connector to grasp pusher wire and patient grounding electrode	Same as Micrus predicate
Length	262 cm.	152 and 274 cm.	Same as Micrus predicate

Detachment Control Box (Unchanged for Micrus Stretch Resistant MicroCoil)

Characteristic	Micrus MicroCoil Predicate	GDC Stretch Resistant Predicate	Micrus Stretch Resistant
How supplied	Non-Sterile, reusable. Used outside the sterile field.	Non-Sterile, reusable. Used outside the sterile field.	Same as predicates Same as predicates
Power Source	Alkaline batteries.	Alkaline batteries.	Same as predicates
Displays	Voltage, Current, Low Battery, Fault, Detach Cycle	Voltage, Current, Low Battery, Fault (Check), Detach Time	Same as Micrus predicate
Detachment Cycle Duration	5 seconds	Variable (could be more than 60 minutes)	Same as Micrus predicate
Output Voltage	6.5 VDC	Variable (up to 7.4 VDC) to achieve 1 mA current through device and patient ground	Same as Micrus predicate
Output Current	125 mA nominal, 200 mA max.	Variable: Attempts to achieve 1 mA through device and patient ground.	Same as Micrus predicate

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Detachment Control Box Continued (Unchanged for Micrus Stretch Resistant MicroCoil)

Characteristic	Micrus MicroCoil Predicate	GDC Stretch Resistant Predicate	Micrus Stretch Resistant
"Detach" feedback	"Detach Cycle" light goes from illuminated to off. Also, a beep sounds once a second for 5 seconds to provide an audible countdown of the 5 second detachment time. Clinician verifies detachment fluoroscopically per device labeling.	Tone sounds and "Detach" light goes on. Based upon voltages seen during detachment cycle, clinician may re-initiate detachment cycle, or verifies detachment fluoroscopically per device labeling.	Same as Micrus predicate
Method to attach Connecting Cable to Detachment Box	Proprietary connector; fits only one-way to assure proper polarity.	Banana plugs, one male, one female to assure proper polarity.	Same as Micrus predicate
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 connecting cable lead, through stainless steel pusher wire, through patient's circulatory system to needle placed in patient's blood vessel or a grounding pad, through negative connecting cable lead, back to negative terminal of GDC Power Supply box.	Same as Micrus predicate

Accessories

Characteristic	Micrus MicroCoil Predicate	GDC Stretch Resistant Predicate	Micrus Stretch Resistant
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	Sterile Connecting Cables for GDC	Same as Micrus predicate
	Micrus Detachment Control Box	GDC Power Supply	Same as Micrus predicate
	5-7F Guide Catheter*	5-7F Guide Catheter*	Same as predicates
	Microcatheter (see above)*	Microcatheter (see above)*	Same as predicates
	Guide wire compatible with microcatheter*	Guide wire compatible with microcatheter*	Same as predicates
	Continuous saline/heparin saline flush*	Continuous saline/heparin saline flush*	Same as predicates
	Rotating haemostatic valves*	Rotating haemostatic valves*	Same as predicates
	3-Way stopcock*	3-Way stopcock*	Same as predicates
	1-Way valve*	1-Way valve*	Same as predicates
	IV pole*	IV pole*	Same as predicates
	Femoral Sheath*	Femoral Sheath*	Same as predicates
	Alkaline Batteries*	Alkaline Batteries*	Same as predicates

This technological comparison demonstrates the substantially equivalent technologies used in the Micrus Stretch-Resistant MicroCoil Delivery System as compared with the 2 predicate devices: (1) Boston Scientific/Target Therapeutics GDC System, Soft and UltraSoft Stretch Resistant GDC Coil System, and (2) the Micrus MicroCoil Delivery System.

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

The non-clinical tests performed on the Micrus MicroCoil System were based upon the intended use of the device, the performance of the predicate devices (GDC Soft and Ultra Soft Stretch-Resistant System and the Micrus 10 System Helical MicroCoil System) and an analysis of the failures of the predicate device (as based upon a review of applicable MDR reports).

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

Test		MicroCoil Stretch-Resistant Delivery System (MSR01) Test Result	Substantial Equivalence of MSR01
V0284-A	1. Aneurysm Packing Ability 2. Detachment Reliability	Characteristic: (1) Complete occlusion aneurysms. (2) Detachment Reliability. Test data (1): No filling defects evident on angio. Test data (2): No premature detachment / auto-detach caused by exposure to blood, body fluids, body temperatures or repeated manipulation. 100% first detach-cycle detachment achieved.	Substantially equivalent to Micrus predicate device.
V0284-B V0284-C	Coil Stability Aneurysm Occlusion	Characteristic: Positional stability and aneurysm occlusion. Test data: Positional stability and aneurysm occlusion maintained through 6 months of implant. No coil compaction present at 6-month angio.	Substantially equivalent to predicate devices.
V0288	GDC Bench Marking	Characteristic: Established specifications for delivery force, tensile strength, and stiffness. The Micrus Stretch Resistant MicroCoil must be substantially equivalent to predicates. Test data: Showed substantial equivalence in delivery force, tensile, and stiffness.	Substantially equivalent to GDC Benchmark.

V0289	Coil Stiffness/Softness	Characteristic: Stiffness limit desired for Finishing Stretch Resistant MicroCoil. Test data: Finishing Stretch Resistant MicroCoil and Helical Stretch Resistant MicroCoil stiffness is within desired stiffness limit.	Substantially equivalent to predicate devices.
V0290-A V0290-B	Friction in the Microcatheter (Delivery Force)	Characteristic: Average push force must be substantially equivalent to predicates. Test data: Finishing Stretch Resistant MicroCoil and Helical Stretch Resistant MicroCoil average push force exhibit comparable delivery forces.	Substantially equivalent to predicate devices.
V0295	MDR Database Review	Characteristic: MDR review for clinical risks. Test data: MSR01 risk assessment includes and addresses all risks encountered in review of predicate device MDR review.	Substantially equivalent to predicate devices.
V0298	Biocompatibility of Materials	Characteristics: Meets the requirements of ISO 10993. Test data: The only new material in the Micrus Stretch Resistant MicroCoil is polypropylene monofilament # 6523. It is identical to the pre-approved GDC stretch resistant suture.	Substantially equivalent to GDC predicate device.
V0301	Sterilization Validation	Characteristic: Minimum Sterility Assurance Level of 10^{-6}. Test data: Passed minimum sterility assurance level of 10^{-6}.	Substantially equivalent to predicate devices.

V0302	Shelf Life Test	Characteristic: No performance degradation after 1 year of shelf life aging. Test data: Minimum tensile strength after 1 year accelerated aging shows no degradation.	Substantially equivalent to predicate devices.
V0304	Tensile Strength	Characteristic: Tensile strength of suture ball tip and MicroCoil to DPU must be substantially equivalent to predicates. Test data: Tensile strength meets desired strength criteria.	Substantially equivalent to predicate devices.
V0305	Durability (Reliability after Fatigue)	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 to Micrus predicate device.
V0026	MRI Compatibility of Implant	No change was made which would impact MRI compatibility.	Substantially equivalent to predicate devices.

This non-clinical testing has demonstrated the substantially equivalent performance of the Micrus MicroCoil Stretch-Resistant MicroCoil System with the 2 predicate devices: (1) Boston Scientific/Target Therapeutics GDC Stretch Resistant System, and (2) Micrus MicroCoil System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Margaret Webber
Director, Regulatory & Clinical Affairs
Micrus Corporation
495 Clyde Avenue
Mountain View, California 94043

OCT 2 2 2002

Re: K022420
Trade/Device Name: Micrus Stretch-Resistant MicroCoil System
Regulation Number: 21 CFR 882.5950
Regulation Name: Artificial Embolization Device
Regulatory Class: Class III
Product Code: HCG
Dated: July 16, 2002
Received: July 24, 2002

Dear Ms. Weber:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Mark N Melkerson

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

K022420

Device Name: **Micrus Stretch-Resistant MicroCoil System**

510(k) Number (if known):

Indications for Use:

The Micrus Stretch-Resistant MicroCoil System is intended for endovascular embolization of intracranial aneurysms that – because of their morphology, their location or the patient's general medical condition – are considered by the treating neurosurgical team to be a) very high risk for management by traditional operative techniques or b) inoperable.

(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: ✓
(Per 21 CFR 801.109)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022420