510(k) Summary

Trade Name:	Sapphire Detachable Fiber Coils
Generic Name:	Artificial Embolization Coil
Classification:	Class III, 21 CFR 882.5950
Submitted By:	Micro Therapeutics, Inc. 2 Goodyear Irvine, California 92618
Contact:	Florin Truuvert

Predicate Device:

Number	Description	Predicate For	Clearance Date
K993418	Fibered GDC VortX Shape Guglielmi Detachable Coil	Sapphire Fibered Helix and Cyclone	1/21/2000

Device Description

The Sapphire Detachable Coil (SDC) is manufactured from a platinum alloy wire which is first wound into primary coil and then formed into a secondary helical shape. The coil is welded to a positioning wire, which consist of ground stainless steel core wire with a stainless steel coil laser welded at the distal end and a Teflon outer jacket. The coil is detached by the battery operated power supply (Sapphire Detachment System, SDS), which dissolves a small detachment element between the emboliozation coil and the positioning wire. The fibered coil is manufactured with nylon fibers secured into the primary coil. The fibered coils are available in two shapes (Helix and Cyclone) and different sizes.

Indication For Use

The Sapphire Detachable Coils are intended for the 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) be inoperable.

The intended uses of the Sapphire fiber coils are narrowed relative to the predicate device GDC, but still fall within the 510(k) cleared intended use.

Sapphire Detachable Fibered Coil - The Sapphire fibered coil is intended for embolization of neurovascular abnormalities such as arteriovenous malformations (AVMs) and arteriovenous fistulae. The Fibered Sapphire is also intended for arterial and venous embolizations in the peripheral vasculature.

Verification and Test Summary Table

Bench Testing	**Sapphire Fibered Coils**
Coil Strength (Coil Deformation and Softness Testing)	Meet established acceptance criteria
Ease of Delivery	Meet established acceptance criteria
Reliability After Fatigue & Premature Detachment	Meet established acceptance criteria
Tensile Strength of Coil & Detachment Zone	Meet established acceptance criteria
Tensile Strength of Delivery Wire	Meet established acceptance criteria
Delivery Wire Flexibility	Meet established acceptance criteria
Detachment Time	Meet established acceptance criteria
Radiopacity	Meet established acceptance criteria
Particulate Generation of Detachment Zone	Meet established acceptance criteria
Aging and Shelf Life (3 year)	Meet established acceptance criteria
Fiber Pull Out	Meet established acceptance criteria
Fiber Endurance	Meet established acceptance criteria
Packaging validation after 3-year accelerated aging	Meet established acceptance criteria
Animal Testing	**Comparison to the Predicate Device**
Coil Per Aneurysm (Avg./S.D.)	Comparable
Detachment Time (seconds)	Comparable
Coil Detachment Reliability (detachment attempts/coil)	The Sapphire demonstrated higher reliability
Post Embolization Angiographic Assessment	Comparable
Angiographic Assessment One-Month Follow-Up	Comparable
Angiographic Assessment Three-Month Follow-Up	Comparable
Physician Device Evaluation	**Acceptance Criteria**
Ease of Coil Preparation	Comparable
Ability to move coil within Catheter	Comparable

Access	**Acceptance Criteria**
Ability to Place catheter tip in desired location	Comparable
Trackability, Friction of coil through catheter	Comparable
Coil Visualization	**Acceptance Criteria**
Fluoroscopic visibility of Coil	Comparable
Fluoroscopic visibility of Detachment Markers	Comparable
Coil Delivery Procedure	**Acceptance Criteria**
Ability to Position Coil in Sac	Comparable
Detachment Time	Comparable
Ability to Pack Aneurysm Sac	Comparable
Ability to Reposition	Comparable
Ease of use of the SDS Detachment System	Comparable
Coil Positional Stability/Aneurysm Occlusion	Comparable
Overall	**Acceptance Criteria**
Ease of Use	Comparable
Overall performance	Comparable
MRI Compatibility	Compatible with 1.5 Tesla

Summary of Substantial Equivalence

The above comparison table demonstrates the technological similarity and equivalency of the Sapphire fibered coils compared with the predicate device, Target GDC fibered coils. The two devices have the same intended use,

- Use the same operating principle,
- Incorporate the same basic design,
- Have the same Intended Use,
- Are packaged and sterilized using similar materials and processes.

In summary, the Sapphire fibered coils described in this submission are, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2003

Ms. Florin Truuvert
Manager, Regulatory Affairs
Micro Therapeutics, Inc.
2 Goodyear
Irvine, California 92618

Re: K031852
Trade/Device Name: Sapphire Detachable Fibered Coil System
Regulation Number: 21 CFR 882.5950
Regulation Name: Artificial embolization device
Regulatory Class: III
Product Code: HCG
Dated: June 13, 2003
Received: June 24, 2003

Dear Ms. Truuvert:

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,

for 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

K031852

Indications for Use Statement

510(k) Number (if known): _____

Device Name: Sapphire Detachable Fibered Coil System

Indications for Use:

Sapphire Detachable Coils (Non-Fiber)

The Sapphire Detachable Coils are intended for the 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) be inoperable.

The intended uses of the Sapphire fiber coils are narrowed relative to the predicate device GDC, but still fall within the 510(k) cleared intended use.

Sapphire Detachable Fibered Coil - The Sapphire fibered coil is intended for embolization of neurovascular abnormalities such as arteriovenous malformations (AVMs) and arteriovenous fistulae. The Fibered Sapphire is also intended for arterial and venous embolizations in the peripheral vasculature.

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

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over the Counter Use** _____

(Per 21 CFR 801.109)

for Mark N Milhern

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

510(k) Number K031852