JAN - 9 2004

K033372

Micro Therapeutics, Inc.
Premarket Notification (510(k) for Sapphire Detachable Fibered Coil System

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	Clearance Date
K031852	MTI Sapphire Detachable Fibered Coil System	August 20, 2003
K030392	MTI Sapphire Detachable Coil System	July 21, 2003
K901337	Cook, Inc. Hilal Embolization Microcoil	November 13, 1990

Device Description

The Sapphire Detachable Fibered Coil System 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 Fibered 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 Sapphire Detachable Fibered Coils are also intended for the embolization of other neuro vascular abnormalities, such as, arteriovenous malformations and arteriovenous fistulae.

Purpose Of the Submission

This Premarket Notification is submitted to obtain marketing clearance for a change in the indication for use of the Sapphire Detachable Fibered Coil System. The Sapphire fibered coils have originally received 510(k) clearance (K031852) on August 20, 2003 for embolization of neurovascular abnormalities such as arteriovenous malformations (AVMs) and arteriovenous fistulae as well as arterial and venous embolization in the peripheral vasculature.

The proposed change in indication is to expand the use of the fibered coils in aneurysm. This is supported by in-vivo, in-vitro studies as well as technological comparison to the predicate device, Cook, Inc. Hilal embolization Microcoil.

Comparison To the Predicate Device

Characteristics	**Cook, Hilal Embolization Microcoil**	**Sapphire Fibered Coils**
Microcoil system supplied as	Sterile, single use	Same
Coils shapes	Straight and Curled	Helix and Cyclone
Coil length and diameter	Various	Same
Catheter compatibility	18"	10" and 18"
Radiopacity	Radiopaque from Pt alloy wire.	Same
MRI Compatibility	Yes	Same
Material		
Main Coil	Platinum alloy	Same
Fiber Material	Synthetic fiber	Nylon 6-6
Detachment Element	Stainless Steel	Same

Summary of Substantial Equivalence

The above comparison table demonstrates the technological similarity and equivalency of the Sapphire fibered coils compared with the predicate device, Cook, Inc. Hilal embolization Microcoil. The two devices have the same intended use and incorporate the same basic technological design.

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

JAN - 9 2004

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

Re: K033372
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: October 20, 2003
Received: October 29, 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,

Miriam C. Provost

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

Indications for Use

510(k) Number (if known): K033372

Device Name: Sapphire Detachable Fiber Coil System

Indications For Use:

The Sapphire Detachable Fibered 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 Sapphire Detachable Fibered Coils are also intended for the embolization of other neuro vascular abnormalities, such as, arteriovenous malformations and arteriovenous fistulae.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K033372