K041649

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JUL 16 2004

510(k) Summary

Trade Name:	Sapphire NXT Detachable Coil System
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
K030392	Sapphire Detachable Coil System	Sapphire NXT Detachable Coil System	July 21, 2003
K033372	Sapphire Detachable Fibered Coil System	Sapphire NXT Detachable Fibered Coil System	January 9, 2004
K040694	Sapphire Tetris 3D Detachable Coil System	Sapphire NXT Tetris 3D Detachable Coil System	March 25, 2004

Device Description

The Sapphire™ NXT Detachable Coil is manufactured from a platinum alloy wire which is first wound into primary coil and then formed into a secondary three-dimensional structure, which forms helical and spherical shapes. The coil is coated with parylene polymer material. The embolization coil is laser welded to the detachment element made of stainless steel. The detachment element is then laser welded to the delivery wire assembly, which consists of a stainless steel wire and a radiopaque positioning coil that is partially covered with Teflon. The positioning coil provides visual indication under fluoroscopy for positioning of the embolization coil.

In the case of fibered coils, nylon fiber bundles are secured into the primary coil at regular intervals on the coil length.

The tension safe coil is manufactured with an inner filament made of a Nickel-Titanium.

The coil is detached by the battery operated power supply (NDS), which dissolves a small detachment element between the emboliozation coil and the positioning wire.

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

Verification and Test Summary Table

Bench Testing	Result
Coil Deformation	Passed
Ease of Delivery/Coil Frictional Characteristics	Passed
Reliability After Fatigue & Premature Detachment	Passed
Fiber Pull-Out	Passed
Coil Knotting	Passed
Tensile Testing – (Final weld of Implant to guidewire)	Passed
Tensile Testing – (Weld of core-wire to positioning segment)	Passed
Detachment Time	Passed
Particulate Generation – Adjusted Particles / 1 mL	Passed
Coil Deployment Friction Coil-on-Coil	Comparable to standard Sapphire

Summary of Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and equivalency of the Sapphire NXT coils compared with the predicate device Sapphire coils.

The two devices have the same intended use,

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

In summary, the Sapphire NXT 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

JUL 16 2004

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

Re: K041649
Trade/Device Name: Sapphire NXT Detachable Coil System
Regulation Number: 21 CFR 882.5950
Regulation Name: Artificial embolization device
Regulatory Class: III
Product Code: HCG
Dated: June 16, 2004
Received: June 17, 2004

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.

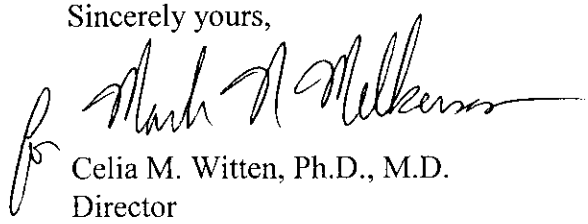
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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):

Device Name: Sapphire NXT Detachable Coil System

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

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

for Mark N Milhem

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

510(k) Number K041649