K060747



# 510(k) Summary

APR 24 2007

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|---|---|
| **Trade Name:** | FX Detachable Coil System |
| **Generic Name:** | Neurovascular Embolization Device |
| **Classification:** | Class II, 21 CFR 882.5950 |
| **Submitted By:** | Micro Therapeutics, Inc.<br>DBA ev3 Neurovascular<br>2 Goodyear<br>Irvine, California 92618 |
| **Contact:** | Florin Truuvert |

**Predicate Device:**

| Number | Description | Predicate For | Clearance Date |
|---|---|---|---|
| K041649 | Sapphire NXT Detachable Coil System | FX Detachable Coil System | July 16, 2004 |
| K050543<br>K051425<br>K051560 | Nexus Detachable Coil System | FX Detachable Coil System | April 27, 2005<br>June 22, 2005<br>June 28, 2005 |

**Device Description**

The FX Detachable Coil System consists of a platinum embolization coil attached to a composite implant delivery pusher with a radiopaque positioning marker and a hand-held mechanical FX detachment actuator which facilities the release of the coil from the delivery pusher tip. The Nexus version of the FX Detachable coil is enlaced with absorbable polymer microfilaments. The FX Detachment Actuator is sold separately.

**Indication For Use**

The FX Detachable Coils are intended for embolization of those intracranial aneurysms. The FX Detachable Coils are also intended for the embolization of other neurovascular abnormalities, such as, arteriovenous malformations and arteriovenous fistulae.

K060747

2/2

## Verification and Test Summary Table

| Bench Testing | Result |
|---|---|
| Dimensional & Visual Analysis | Met established criteria |
| Force Transfer | Met established criteria |
| Ease of Delivery/Coil Frictional Characteristics | Met established criteria |
| Reliability After Fatigue & Premature Detachment | Met established criteria |
| Tensile Strength of Delivery Pusher | Met established criteria |
| Tensile Strength at Detachment Zone | Met established criteria |
| Particulate Generation – Adjusted Particles / 1 mL | Met established criteria |
| Delivery Pusher Distal Tip Buckling | Met established criteria |
| Delivery Pusher Distal Stiffness Profile | Met established criteria |
| Packaging Integrity | Met established criteria |
| Detachment Actuator Life Cycle and Reliability | Met established criteria |
| Time and Reliability of Detachment | Met established criteria |
| Radiopacity | Met established criteria |

## Summary of Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and equivalency of the FX detachable coil system compared with the predicate device NXT and Nexus detachable coil system.

The devices,

- Have the same intended use,
- Use the same operating principle,
- Incorporate the same basic design,
- Use similar construction and material,
- Are packaged and sterilized using same processes.

In summary, the FX Detachable Coil System described in this submission is, 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

Micro Therapeutics, Inc., DBA
ev3 Neurovascular
% Mr. Tom Daughters
Director, Regulatory Affairs
9775 Toledo Way
Irvine, California 92618

APR 24 2007

Re: K060747
Trade/Device Name: FX Detachable Coil System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular embolization device
Regulatory Class: II
Product Code: HCG
Dated: March 30, 2007
Received: April 2, 2007

Dear Mr. Daughters:

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" (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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Peter D Rumm MD DEP DIR 4/24/07

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

Enclosure

K060747

# Indications for Use

510(k) Number (if known):

Device Name: FX Detachable Coil System

Indications For Use:

The FX Detachable Coils are intended for the endovascular embolization of intracranial aneurysms. The FX 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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



**510(k) Number** K060747