

**510(k) Summary**

APR 20 2006

**Trade Name:** Nexus Morpheus 3D CSR**Generic Name:** Neurovascular Embolization Device**Classification:** Class II, 21 CFR 882.5950**Submitted By:** Micro Therapeutics, Inc.

DBA ev3 Neurovascular

2 Goodyear

Irvine, California 92618

**Contact:** Florin Truuvert**Predicate  
Device:**

Number	Description	Predicate For	Clearance Date
K050543	Nexus Detachable Coils, Tetris 3D	Nexus Detachable Coil, Morpheus 3D	April 27, 2005

**Device Description**

The Nexus coils are platinum alloy coils, enlaced with absorbable polymer fibers, and attached to a stainless steel guiding system with a radiopaque positioning coil. Nexus coils are designed for use with the NXT Detachment System specifically designed for coil detachment. The NXT Detachment System is sold separately.

**Indication For Use**

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

**Verification and Test Summary Table**

<b>Bench Testing</b>	<b>Result</b>
Coil Deformation	Met established criteria
Dimensional & Visual Analysis	Met established criteria
Ease of Delivery/Coil Frictional Characteristics	Met established criteria
In Vitro Aneurysm Fills and Reliability After Fatigue	Met established criteria
Microfilament Pull-Out	Met established criteria
Tensile Strength	Met established criteria

**Summary of Substantial Equivalence**

The data presented in this submission demonstrates the technological similarity and equivalency of the Nexus Morpheus 3D CSR coils compared with the predicate device Nexus Tetrus 3D CSR.

The two 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 Nexus coils described in this submission are, in our opinion, substantially equivalent to the predicate device.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 20 2006

Micro Therapeutics, Inc.  
dba ev3 Neurovascular  
c/o Ms. Florin Truuvert  
Regulatory Affairs Manager  
2 Goodyear  
Irvine, California 92618

Re: K060625

Trade/Device Name: Nexus Detachable Coil, Morpheus 3D CSR  
Regulation Number: 21 CFR 882.5950  
Regulation Name: Neurovascular embolization device  
Regulatory Class: II  
Product Code: HCG  
Dated: March 21, 2006  
Received: March 22, 2006

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 (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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "M. Melkerson". To the left of the signature is a small, stylized initial or mark.

Mark N. Melkerson  
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: Nexus Detachable Coil, Morpheus 3D CSR

Indications For Use:

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

Prescription Use   X    
(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)



\_\_\_\_\_  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

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510(k) Number   K060625