K133310
JAN 10 2014

510(k) Summary

510(k) Owner:
Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
9775 Toledo Way
Irvine, CA 92618
Establishment Registration No. 2029214

Contact Person:
Angela Lamprey
Regulatory Affairs Specialist
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Date Summary Prepared:
09 December 2013

Trade Name of Device:
Axium™ Detachable Coil System

Common Name of Device:
Neurovascular Embolization Device

Classification of Device:
21 CFR 882.5950 – Class II

Predicate Device:
Axium™ Detachable Coil System (K081465)
Cleared 08/19/2008

Device Description:
The Axium™ Detachable Coil System consists of a platinum coil secured to a composite delivery wire and is compatible with a 2-marker band micro catheter and a mechanical detachment system. The Axium™ Detachable Coil System consists of three (3) components:

1 – Implantable Coil
2 – Implant Delivery Pusher
3 – Instant Detacher. The Instant Detacher is packaged and sold separately.

Axium™ coil configurations include bare platinum, PGLA enlaced platinum and Nylon enlaced platinum coils. Bare configuration coils are non-fiber-enlaced, whereas PGLA and Nylon are enlaced with PGLA and Nylon fibers respectively.

This submission expands the size offerings of the Axium™ Detachable Coil System by adding one (1) new model number to the Axium bare product portfolio with a new diameter and coil length combination (SKU QC-1.5-1-Helix). Currently cleared sizes for Axium™ bare under K081465 already include a coil diameter of 1.5mm and a coil length of 1cm; however, not in combination.

Intended Use:

The Axium™ Detachable Coil System is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Axium™ Detachable Coils are also indicated for arterial and venous embolizations in the peripheral vasculature.

Performance Data:

The following test(s) was performed to support the addition of the new size offering:

Non-Clinical

Bench Testing:

There were no material, design, sterilization, packaging or manufacturing process changes that resulted from the introduction of the new SKU (QC-1.5-1-Helix). The following testing was adopted from existing test data for currently cleared Axium™ coil sizes:

- Dimensions – 1st Loop Outer Diameter
- Dimensions – Length
- Coil Deformation
- Friction
- Fatigue After Knotting and Reliability Detachment
- Torque Response
- Force Transfer – Implant
- Coil Tensile – Polypropylene
- Coil Tensile – Implant/Weld (Implant Coil to Coil Shell Weld)
- Coil Tensile – Assembly
- Particulate
- Pusher Dimensions
- Marker Radiopacity
- Tip Buckling
- Detachment Zone Stiffness
- Kink Resistance
- Hypotube and Weld Tensile Strength
- Force Transfer – Pusher
- Pusher Elongation
- MRI Compatibility

In addition, no clinical or animal testing was performed as there is no change in the indications for use or the fundamental scientific technology of the device.

Conclusion:

The new Axium™ Detachable Coil System size offering (QC-1.5-1-Helix) is substantially equivalent to the currently cleared Axium™ Detachable Coil System based on the successful completion of non-clinical testing; a thorough assessment of existing test data; as well as identical principles of operation, materials of construction, dimensions, packaging, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 10, 2014

Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
c/o Ms. Angela Lamprey
Regulatory Affairs Special
9775 Toledo Way
Irvine, CA 92618

Re: K133310
Trade/Device Name: Axium™ Detachable Coil System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG and KRD
Dated: December 9, 2013
Received: December 11, 2013

Dear Ms. Lamprey:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133310

Device Name: Axium™ Detachable Coil System

Indications For Use:

The Axium Detachable Coil System is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Axium Detachable Coils are also indicated for arterial and venous embolizations in the peripheral vasculature.

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

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S