DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 28, 2015

Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
Ms. Patricia Casing
Regulatory Affairs Specialist
9775 Toledo Way
Irvine, California 92618

Re: K151447
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: June 30, 2015
Received: July 1, 2015

Dear Ms. Casing:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151447

Device Name
Axium Detachable Coil System

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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:	Patricia Casing Regulatory Affairs Specialist Telephone: (949) 680 - 1307 E-mail: patricia.casing@covidien.com
Date Summary Prepared:	June 30, 2015
Trade Name of Device:	Axium™ Detachable Coil System
Common Name of Device:	Neurovascular Embolization Device
Classification of Device:	21 CFR 882.5950 – Class II
Product Code	HCG and KRD
Predicate Device:	Axium™ Detachable Coil System: • K133310, cleared January 10, 2014 • K081465, cleared August 19, 2008 • K060747, cleared April 24, 2007
Performance Data:	The following bench tests were performed to support the addition of new sizes to the Axium coil line and to establish substantial equivalence to predicate Axium™ Detachable Coil System : • Dimensions – Coil, Sheath, Implant Delivery Pusher • Visual Inspections – Coil, Sheath, Implant Delivery Pusher • Friction • Force Transfer • Coil Deformation • Fatigue and Knotting • Coil Tensile – Polypropylene • Coil Tensile – Implant/Weld (Implant Coil to Coil Shell Weld) • Labeling verification The following testing was adopted from existing test data for currently cleared Axium™ coil sizes: • Torque Response • Coil Tensile – Assembly • Pusher Dimensions • Marker Radiopacity • Tip Buckling • Detachment Zone Stiffness

- Kink Resistance
- Hypotube and Weld Tensile Strength
- Pusher Elongation
- MRI Compatibility

Sterilization, biocompatibility and aging data were also adopted from the predicate device as there is no change to the manufacturing process or packaging for the addition of these new SKUs.

In addition, no clinical or animal testing was performed as the subject device has a similar safety profile and a similar effectiveness profile when compared to the predicate device.

In addition, there is no change in the indications for use or the fundamental scientific technology of the device that would require more extensive testing.

Conclusion: The thirty-five (35) new Axium™ Detachable Coil System size offerings are 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 materials of coil implant construction, principles of operation, packaging and indications for use.

Device Description:

The Axium™ Detachable Coil System consists of a platinum/tungsten embolization coil attached to a composite implant delivery pusher with a radiopaque positioning marker and a hand-held Axium™ I.D. (Instant Detacher) which, when activated, detaches the coil from the delivery pusher tip. The Axium™ I.D. (Instant Detacher) is sold separately.

This submission expands the size offerings of the Axium™ Detachable Coil (subject device) by adding thirty-five (35) new model numbers to the currently cleared Axium product portfolio (predicate device). These new model numbers are a line extension of the currently sold predicate device and range in size from 1mm diameter x 1cm length to 3.5mm diameter x 10cm length. All thirty-five (35) new SKUs have a smaller primary wire diameter than the predicate device. This line extension includes six (6) coils having a 1mm diameter which is outside of the currently cleared Axium size range of 1.5mm diameter x 1cm length to 25mm diameter x 50cm length.

The second modification features a change to the Implant Delivery Pusher by replacing the PET material of the Positive Load Indicator (PLI) and Hypotube Break Indicator (BI) with a laser mark.

These modifications to the currently cleared predicate device were made solely to accommodate the new smaller implant coil size of the subject line extension. All other aspects of the subject device (materials of construction of the implant coil, principles of operation, packaging, labeling and indications for use) are identical to the predicate device.

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.

Device Comparison:

The table below provides a comparison of the technological characteristics of the subject Axium device line extension and the currently cleared predicate Axium device line.

Characteristics	Predicate Device Axium™ (K133310, (K081465, K060747)	Subject Device Axium Line Extension	Rationale for Difference (if applicable)
Indication 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.	Same	N/A
Method of Supply	Stored within dispenser coil, Tyvek pouch, & shipping carton	Same	N/A
Sterilization Method	Ethylene Oxide	Same	N/A
Device Size Range (Coil Diameter x Coil Length)	1.5mm x 1cm – 25mm x 50cm	1mm x 1cm – 3.5mm x 10cm	Difference in size is due to the smaller diameter primary wire. Bench testing has demonstrated that the smaller dimensions do not affect the safety and effectiveness of the device.
Materials (Implant Coil)			
Characteristics	**Predicate Device** **Axium™ (K133310, (K081465, K060747)**	**Subject Device** **Axium Line Extension**	**Rationale for Difference (if applicable)**
Implant Coil Wire	Pt (92%)/ W (8%)	Same	N/A

Characteristics	Predicate Device	Subject Device	Rationale for Difference (if applicable)
	Axium™ (K133310, (K081465, K060747)	Axium Line Extension	
Stretch Resistant Member	Polypropylene	Same	N/A
Coil Shell	Pt (92%)/ W (8%)	Same	N/A
Detach Subassembly	SS 316LVM	Same	N/A
Materials (Implant Delivery Pusher)			
Characteristics	**Predicate Device**	**Subject Device**	**Rationale for Difference (if applicable)**
	Axium™ (K133310, K081465, K060747)	**Axium Line Extension**	
Unibody	SS 304	Same	N/A
Outer Jacket	PTFE	Same	N/A
Marker Coil	Pt (92%)/ W (8%)	Same	N/A
Lumen Stop	SS 304	Same	N/A
Inner Liner	PTFE	Same	N/A
Coupler Tube	SS 304	Same	N/A
Actuator Interface	SS 304	Same	N/A
Release Wire	SS 304	Same	N/A
Retainer Ring	SS 304	Same	N/A
Break Indicator	PET shrink tubing	Laser mark	Bench testing confirmed that the change in indicator design does not affect the safety and effectiveness of the device
Positive Load Indicator	PET shrink tubing	Laser mark	Bench testing confirmed that the change in indicator design does not affect the safety and effectiveness of the device
Materials (Introducer sheath)			
Introducer sheath	Polypropylene/HDPE	Same	N/A

Sterilization and Shelf Life

The subject device was adopted into the EO sterilization cycle originally cleared under K060747 for the predicate device. The manufacturing process and packaging are identical to the predicate device. The smaller dimensions and the replacement of the PET shrink

tubing with laser marking for the PLI and BI indicators on the Implant Delivery Pusher result in a reduction of mass/material.

EO residual testing for the subject device was adopted, as the materials of construction of the implant coil and the manufacturing process are identical to the currently cleared predicate device. In addition, the smaller dimensions and the replacement of the PET shrink tubing with laser marking for the PLI and BI indicators on the Implant Delivery Pusher result in a reduction of mass/material.

Aging and packaging studies for the predicate device have established the product and packaging remain functional and maintain sterility for 3 years. Aging studies for packaging integrity (per ASTM F2096-11) and conditioning (ASTM-4169, ISTA-2A) and device functionality were adopted from the predicate device and met all acceptance criteria. The materials of implant coil construction, manufacturing process, and packaging of the new smaller sized models of the subject device are identical to the predicate device.

Biocompatibility

Biocompatibility data for the subject device has been adopted from the predicate device. Physicochemical and cytotoxicity testing were performed on the laser marks of the Implant Delivery Pusher for reference only. Passing results provide confirmation that the laser marks do not impact the safety of the device and add justification for adopting previous biocompatibility studies conducted for the Axium coil predicate device.

Performance Data – Bench

A summary of the non-clinical bench testing performed for the subject device is presented in the table below:

Test	Test Method	Conclusion
Visual and Dimensional Inspection: • Coil • Sheath • Implant Delivery Pusher	Dimensions (ID, OD, length) were measured and key characteristic were inspected of the implant coil, sheath and coupler tube	All devices met acceptance criteria.
Softness and Conformability • Coil Deformation	The first loop of the coil is advanced until it exits the sheath and is compressed to a deformation distance that is a percentage of the coil's loop OD. The peak force is recorded.	All devices met acceptance criteria.
Ease of Deliverability • Force Transfer • Friction Testing • Fatigue and Knotting	• Peak delivery force was measured through a representative tortuous anatomical model. • The proximal end of the device is advanced until the distal force	All devices met acceptance criteria.

Test	Test Method	Conclusion
	exceeds a specified value. The force transfer is calculated. • The device is placed inside the microcatheter and advanced until the coil is deployed completely inside the aneurysm model. The device is retracted and the cycle is repeated. After the required number of cycles the device is inspected.	
Detachment • Coil Tensile – Polypropylene • Coil Tensile – Implant/Weld (Implant Coil to Coil Shell Weld)	• The coil is stretched until the stretch resistant member breaks. The peak force result was recorded • The primary wire of the coil is stretched until the coil-coil shell weld breaks. The peak force result was recorded	All devices met acceptance criteria.
Labeling Verification	Text and format of drawings were visually compared to labeling and packaging product specifications.	All devices met acceptance criteria.
Physician Usability Testing	The device was navigated through a tortuous benchtop model and deployed into a simulated silicone aneurysm in order to assess coil softness, conformability, ease of delivery and biomechanical stability.	All test results met the acceptance criteria.

Performance Data – Animal

No animal study was performed as there is no change to the indications for use or the fundamental scientific technology for the new model numbers. Substantial equivalence of the subject device has been established to the predicate device through the results of the bench testing that was performed as well as the testing that was adopted from the predicate device.

Performance Testing – Clinical

No clinical study was performed as there is no change to the indications for use or the fundamental scientific technology for the new model numbers. Substantial equivalence of the subject device has been established to the predicate device through the results of the bench testing that was performed as well as the testing that was adopted from the predicate device.