DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 3, 2016

Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
Joyce Zhong, PhD, RAC
Regulatory Affairs Specialist
9775 Toledo Way
Irvine, California 92618

Re: K162704
Trade/Device Name: Axium™ Prime Detachable Coil System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: November 18, 2016
Received: November 21, 2016

Dear Dr. Zhong:

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,

William J. Heetderks -A

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -A
Date: 2017.01.03 16:31:53 -05'00'

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

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)*
K162704

Device Name
Axium Prime Detachable Coil System

Indications for Use *(Describe)*

The Axium Prime 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 Prime 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 for K162704

510(k) Owner:	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 Establishment Registration No. 2029214
Contact Person:	Joyce Zhong Regulatory Affairs Specialist Telephone: (949) 680-1307 E-mail: joyce.zhong@medtronic.com
Date Summary Prepared:	December 19, 2016
Trade Name of Device:	Axium™ Prime 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: • K151447, cleared July 28, 2015 • 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 models to the Axium coil portfolio and to establish substantial equivalence to predicate Axium™ Detachable Coil System : • Visual and Dimensional Inspection • First loop OD post-sterilization Dimensional Inspection • Deformation Force • Friction in Sheath • Friction in Catheter • Force Transfer • Stretch Resistant Polypropylene Tensile Test • Coil Shell Tensile Test • Fatigue and Knotting • Labeling verification • Physician use testing The following testing was adopted from existing test data for currently cleared Axium™ coil sizes: • Torque Response • Pusher Dimensions

- Shield Coil Weld
- Coil Tensile – Assembly
- Marker Radiopacity
- Tip Buckling
- Detachment Zone Stiffness
- Detachment Reliability
- Kink Resistance
- Hypotube and Weld Tensile Strength
- Pusher Elongation
- Pusher Tensile
- Positive Load Indicator Dimension
- Break Indicator Dimension
- Sheath wave-lock
- Thrombogenicity
- MRI Compatibility

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

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 any additional testing.

Conclusion: The forty-four (44) new Axium™ Prime Detachable Coil System models 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. The subject device has a similar safety profile and a similar effectiveness profile when compared to the predicate device.

Device Description:

The Axium™ Prime 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 Axium™ Detachable Coil (subject device) family by adding forty-four (44) new model numbers to the currently cleared Axium product portfolio (predicate device). These new model numbers come in the 3D configuration only and are a line extension of the currently sold predicate device, ranging in size from 3mm diameter x 6cm length to 25mm diameter x 50cm length. All forty-four (44) new SKUs fall within the currently cleared Axium size range of 1mm diameter x 1cm length to 25mm diameter x 50cm length.

The subject device was modified to change the 3D loop configuration from a 4-loop configuration to a 6-loop configuration and to slightly increase the primary wire diameter size for the 7 – 10mm and the 12 – 25mm size coils.

All other aspects of the subject device design (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 Prime 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 Prime 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 device and the currently cleared predicate Axium device line.

Characteristics	Predicate Device	Subject Device	Rationale for Difference (if applicable)
	Axium™ Detachable Coil System (K133310, K081465, K060747, K151447)	**Axium™ Prime Detachable Coil System (K162704)**	
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)	1mm x 1cm – 25mm x 50cm	3mm x 6cm – 25mm x 50cm	Subject device size range falls within the currently cleared predicate device size range
3D Loop Configuration	4 loops	6 loops	Additional loops provide improved stability
Primary wire diameter	0.0015'' for 3-3.5 mm size coils 0.0020'' for 4-6 mm size coils 0.00225'' for 7-10mm size coils	same same 0.0025'' for 7-10mm size coils	Larger wire diameter provide improved stability

	0.00275” for 12-25mm size coils	0.0030” for 12-25mm size coils	
Materials (Implant Coil)			
Characteristics	**Predicate Device**	**Subject Device**	**Rationale for Difference (if applicable)**
	Axium™ Detachable Coil System (K133310, K081465, K060747, K151447)	**Axium™ Prime Detachable Coil System (K162704)**	
Implant Coil Wire	Pt (92%)/ W (8%)	Same	N/A
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™ Detachable Coil System (K133310, K081465, K060747, K151447)	**Axium™ Prime Detachable Coil System (K162704)**	
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 or Laser mark	PET shrink tubing	N/A
Positive Load Indicator	PET shrink tubing or Laser mark	PET shrink tubing	N/A
Materials (Introducer sheath)			
Introducer sheath	Polypropylene/HDPE	Same	N/A

*product name has been rebranded to Axium™ Prime, otherwise identical.

Sterilization and Shelf Life
The subject device was adopted into the EO sterilization cycle originally cleared under K060747 for the predicate device. The materials of construction of the subject device, packaging and overall manufacturing process are the same to the predicate device. EO residual, bioburden and pyrogen testing were adopted as well for these reasons.

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 line extension 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. A summary of adopted biocompatibility tests is provided in the table below.

Test	Test method	Results	Conclusion
Cytotoxicity	MEM Elution Using L-929 Mouse Fibroblast Cells	Pass	Non-cytotoxic
Sensitization	Guinea Pig Maximization Sensitization	Pass	A Grade I sensitization rate is not significant
Irritation	Intracutaneous Irritation Test	Pass	Negligible irritant
Acute Systemic Toxicity	Acute Systemic Injection Test	Pass	No significant difference comparing to the control
	Materials Mediated Rabbit Pyrogen	Pass	Non-pyrogenic
Genotoxicity	Bacterial Mutagenicity Test (Ames Assay)	Pass	Not mutagenic
	In Vitro Mouse Lymphoma Assay	Pass	Not mutagenic
	Chromosomal Aberration Assay	Pass	Non-clastogenic
Hemo-compatibility	Thrombosis (In Vivo) – Dog (4hr)	Pass	Insignificant thrombosis
	Lee & White Clotting Time/Coagulation	Pass	Not significant different comparing to controls
	Unactivated Partial Thromboplastin Time (UPTT)	Pass	No significant difference comparing to controls
	In Vitro Hemocompatibility (includes Platelet count)	Pass	No adverse effects
	Hemolysis (Direct Contact)	Pass	Non-hemolytic
	Hemolysis (Extract)	Pass	Non-hemolytic
	Complement Activation C3a and	Pass	No difference from

	SC5b-9 Assay		controls
In Vivo Animal Study (systemic effects – SubAcute /SubChronic)	SubChronic (14-day) Intravenous Toxicity Study in Rats or Mice, with Histopathology	Pass	Non-toxic
In Vivo Animal Study (localized effects) Implantation	Intramuscular Implantation Test (Rabbits) with Histopathology – 1 wk	Pass	No significant difference comparing to the control
	Intramuscular Implantation Test (Rabbits) with Histopathology – 4wk	Pass	No significant difference comparing to the control
	Intramuscular Implantation Test (Rabbits) with Histopathology – 13wk	Pass	No significant difference comparing to the control

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 of Coil: • Length • First Loop OD	Dimensions were measured and key characteristics of the implant coil were inspected.	All devices met acceptance criteria.
Coil Deformation Force	The first loop is compressed to a deformation distance of 20% of the coil's loop OD. The peak force is recorded.	All devices met acceptance criteria.
Ease of Deliverability • Friction Testing • Force Transfer • 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 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.	All devices met acceptance criteria.

Test	Test Method	Conclusion
Detachment • Stretch Resistant Polypropylene Tensile test • Coil-Coil Shell Tensile Test	• 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 stability, neck coverage, conformability, softness and smoothness of delivery.	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.