November 7, 2023

Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
Lekshmi Pillai, MS
Senior Regulatory Affairs Specialist
5290 California Avenue
Irvine, California 92617

Re: K233420
Trade/Device Name: Axium Detachable Coil; Axium Prime Detachable Coil
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: October 9, 2023
Received: October 10, 2023

Dear Lekshmi Pillai:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233420

Device Name
Axium™ Detachable Coil;
Axium™ Prime Detachable Coil

Indications for Use *(Describe)*

Axium™ Detachable Coil:
Axium™ Detachable Coils are intended for the endovascular embolization of intracranial aneurysms. Axium™ Detachable Coils are also intended for the embolization of other neuro vascular abnormalities such as arteriovenous malformations and arteriovenous fistulae.

Axium™ Prime Detachable Coil:
(Models: APB-X-Y-3D-ES, APB-X-Y-3D-SS, APB-X-Y-HX-ES, APB-X-Y-HX-SS)
The Axium™ Prime Detachable Coils are intended for the endovascular embolization of intracranial aneurysms. The Axium™ Prime Detachable Coils are also intended for the embolization of other neuro vascular abnormalities such as arteriovenous malformations and arteriovenous fistulae.

Axium™ Prime Detachable Coil:
(Models: FC-X-Y-3D)
The Axium™ Prime Detachable Coil is intended 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 intended 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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K233420 510(k) Summary

510(k) Owner:	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618, USA Establishment Registration: 2029214
Contact Person:	Lekshmi Pillai Senior Regulatory Affairs Specialist Telephone: (917) 291-3810 Email : lekshmiajaykumar.pillai@medtronic.com

Date Summary Prepared:	06 November 2023
Trade Name of Device:	Axium™ Detachable Coil Axium™ Prime Detachable Coil
Common Name of Device:	Neurovascular Embolization Device, Vascular Embolization Device
Review Panel:	Neurology, Cardiovascular
Product Code:	HCG, KRD
Regulation Number:	21 CFR 882.5950; 21 CFR 870.3300
Regulation Name:	Neurovascular Embolization Device, Vascular Embolization Device
Device Classification	Class II
Predicate Device:	K203432 Axium™ Detachable Coil Axium™ Prime Detachable Coil

Device Description:

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

Indications for Use Statement:

Axium™ Detachable Coil and Axium Prime Detachable Coil Indications for Use		
Model Numbers	**Trade Name**	**Indications for Use**
QC-X-Y-HELIX	Axium™ Detachable Coil	Axium™ Detachable Coils are intended for the endovascular embolization of intracranial aneurysms. Axium™ Detachable Coils are also intended for the embolization of other neuro vascular abnormalities such as arteriovenous malformations and arteriovenous fistulae.
QC-X-Y-3D		
NC-X-Y-HELIX		
PC-X-Y-HELIX		
PC-X-Y-3D		

Axium™ Detachable Coil and Axium Prime Detachable Coil Indications for Use		
Model Numbers	**Trade Name**	**Indications for Use**
APB-X-Y-3D-ES APB-X-Y-3D-SS APB-X-Y-HX-ES APB-X-Y-HX-SS	Axium™ Prime Detachable Coil	The Axium™ Prime Detachable Coils are intended for the endovascular embolization of intracranial aneurysms. The Axium™ Prime Detachable Coils are also intended for the embolization of other neuro vascular abnormalities such as arteriovenous malformations and arteriovenous fistulae.
FC-X-Y-3D	Axium™ Prime Detachable Coil	The Axium™ Prime Detachable Coil is intended 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 intended for arterial and venous embolizations in the peripheral vasculature.

The model numbers are formatted to summarize sizes available, where X is the coil loop outer diameter in mm and Y is the implant length in cm.

Proposed Change:

Micro Therapeutics, Inc. d/b/a ev3 Neurovascular requests clearance for the Axium™ Detachable Coil and Axium™ Prime Detachable Coil with addition of fluorosafe markers on the proximal end of the coil delivery pusher.

Device Comparison:

Design Feature	**Predicate Devices (K203432): Axium™ Detachable Coil; Axium™ Prime Detachable Coil**	**Subject Devices: Axium™ Detachable Coil; Axium™ Prime Detachable Coil**
Indications for Use	Axium™ Detachable Coil: Axium™ Detachable Coils are intended for the endovascular embolization of intracranial aneurysms. Axium™ Detachable Coils are also intended for the embolization of other neuro vascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. Axium™ Prime Detachable Coil (APB-X-Y-3D-ES, APB-X-Y-3D-SS, APB-X-Y-HX-ES, APB-X-Y-HX-SS): The Axium™ Prime Detachable Coils are intended for the endovascular embolization of intracranial aneurysms. The Axium™ Prime Detachable Coils are also intended for the embolization of other neuro vascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. Axium™ Prime Detachable Coil (FC-X-Y-3D): The Axium™ Prime Detachable Coil is intended 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	Same

Design Feature	Predicate Devices (K203432): Axium™ Detachable Coil; Axium™ Prime Detachable Coil	Subject Devices: Axium™ Detachable Coil; Axium™ Prime Detachable Coil
	intended for arterial and venous embolizations in the peripheral vasculature.	
Visual Markers	None	Fluorosafe markers
Dimensions		
Device Size Range	Axium™ Bare Helix: 1.5-20 mm – Loop OD 1-50 cm – Length Axium™ Bare 3D: 2-25 mm – Loop OD 2-50 cm – Length Axium™ Nylon 3D: 2-4 mm – Loop OD 1-10 cm – Length Axium™ PGLA Helix: 2-10 mm – Loop OD 1-30 cm – Length Axium™ PGLA 3D: 2-18 mm – Loop OD 2-40 cm – Length Axium™ Prime 3D: 1-6 mm – Loop OD 2-20 cm – Length Axium™ Prime Helix: 1-6 mm – Loop OD 1-20 cm – Length Axium™ Prime 3D: 3-25 mm – Loop OD 6-50 cm – Length	Same
Coil Shape	Helical and 3D	Same
Compatible Accessories		
Catheter Compatibility	Axium™ Detachable Coils (Bare) should be delivered through microcatheters with minimum ID of 0.0165”. Axium™ Detachable Coils (Nylon and PGLA) should be delivered through microcatheters with minimum ID of 0.0165” – 0.020”. Axium™ Prime Detachable Coils should be delivered through microcatheters with minimum ID of 0.0165”– 0.017”.	Same Same Axium™ Prime Detachable Coils should be delivered through

Design Feature	Predicate Devices (K203432): Axium™ Detachable Coil; Axium™ Prime Detachable Coil	Subject Devices: Axium™ Detachable Coil; Axium™ Prime Detachable Coil
		microcatheters with minimum ID of 0.0165".
Guide Catheter Compatibility	6-8F	Same
Method of Coil Detachment	Instant Detacher – standalone hand-held mechanical unit that, when connected to the proximal end of the pusher, pulls the release element inside of the pusher, resulting in release of the implant from the distal end of the delivery pusher.	Same
Material of Construction		
Main Coil	Platinum/Tungsten alloy	Same
Tension Safe/ Stretch Resistant Filament	Polypropylene	Same
Delivery System	Pusher: Composite hypotube stainless steel with PTFE outer jacket and liner and PET & Pt/w alignment marker	Same
Introducer Sheath	Polypropylene and HDPE	Same
Sterilization		
Method of Supply	Sterile and single use	Same
Sterilization Method	Ethylene Oxide (EO)	Same
Packaging		
Pouch Material	For PC-X-Y-HELIX and PC-X-Y-3D: PLK235/Uncoated 2FS Tyvek For all other models: PET/Tyvek	Same For all other models: Nylon/Tyvek
Pouch Dimensions	For PC-X-Y-HELIX and PC-X-Y-3D: 17" X 9.8" (pre-sterilization) For all other models: 10 1/8" X 10.838"	Same For all other models: 11.98" X 10.94"
Carton	Cardboard, Solid Bleach Sulfate	Same
MRI Card	None	3 1/2" x 4" (+/- 1/8"), 1/1 Black - Black and white, 2 sided
Stability		
Shelf Life	36 months	Same
Magnetic Resonance Imaging		
MRI Compatibility	MR Conditional	Same

Biocompatibility:
The fluorosafe marker (subject to this submission) added onto the proximal end of the delivery pusher is considered external communicating device having indirect blood contact via the fluid path, as it is only in contact with the delivery catheter and does not have direct exposure to circulating blood. The distal end of the delivery pusher is categorized as external communicating device with limited exposure duration (≤ 24 hrs.) with circulating blood. The embolization coil is considered an implant with long-term (> 30 days) direct contact with circulating blood. There are no material or contact duration changes to the components of the device that directly contact circulating blood in the current submission. Therefore, prior hemocompatibility (complement activation, direct hemolysis, and thrombogenicity) tests demonstrate the biocompatibility of the unmodified regions and components of the subject device that contact blood directly.

To assess the addition of fluorosafe markers on the proximal end of the delivery pusher, the following biocompatibility tests were performed on the final, finished delivery pusher subassemblies incorporating the fluorosafe marker.

Test Description	Study Method	Results
Cytotoxicity	Axium™ Detachable Coil and Axium™ Prime Detachable Coil were evaluated per ISO 10993-5: 2009, using the MEM elution method.	The Axium™ Detachable Coil and Axium™ Prime Detachable Coil did not induce cytotoxicity.
Sensitization	Axium™ Detachable Coil and Axium™ Prime Detachable Coil were evaluated per ISO 10993-10:2021, using a guinea pig maximization test.	The Axium™ Detachable Coil and Axium™ Prime Detachable Coil were not considered a sensitizer.
Irritation	Axium™ Detachable Coil and Axium™ Prime Detachable Coil were evaluated per ISO 10993-23:2021, using a rabbit intracutaneous reactivity test.	The Axium™ Detachable Coil and Axium™ Prime Detachable Coil are considered non-irritant.
Acute Systemic Toxicity	Axium™ Detachable Coil and Axium™ Prime Detachable Coil were evaluated per ISO 10993-11:2017, using an acute systemic injection test in mice.	The Axium™ Detachable Coil and Axium™ Prime Detachable Coil showed no mortality or evidence of acute systemic toxicity.
Indirect (extract) Hemolysis	Axium™ Detachable Coil and Axium™ Prime Detachable Coil were evaluated per ISO 10993-4:2017, using ASTM hemolysis study.	The Axium™ Detachable Coil and Axium™ Prime Detachable Coil are considered non-hemolytic.
Material-Mediated Pyrogenicity	Axium™ Detachable Coil and Axium™ Prime Detachable Coil were evaluated per USP 151 (2020), using USP rabbit pyrogen test - material-mediated.	The Axium™ Detachable Coil and Axium™ Prime Detachable Coil met the requirements and were found to be non-pyrogenic.

The Axium™ Detachable Coil and Axium™ Prime Detachable Coil have been evaluated to meet requirements specified in FDA guidance, "Use of International Standard ISO 10993-1, "Biocompatibility Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process"," issued

on September 8, 2023.

Performance Data – Bench:

Non-clinical bench testing was conducted to evaluate the performance of Axium™ Detachable Coil and Axium™ Prime Detachable Coil in a clinically representative neurovascular access model. The successful results of the testing demonstrated that the changes do not raise new questions of safety and effectiveness, supporting the substantial equivalence to the predicate devices.

The following non-clinical bench tests were conducted:

Design Verification		
Test	**Test Method Summary**	**Results**
Visual Inspection	Visual inspection verified for the darkness of the etch mark of fluorosafe markers and the 360° etch mark around the delivery pusher.	Axium™ Detachable Coil and Axium™ Prime Detachable Coil met the acceptance criteria for visual inspection.
Marker Dimensional (Marker Position and Total Marker Length) Inspection	Marker dimensional inspection verified the total length of the fluorosafe markers and their position on the delivery pusher.	Axium™ Detachable Coil and Axium™ Prime Detachable Coil met the acceptance criteria for marker dimensional inspection.
Corrosion Resistance	The test verified the corrosion resistance on the delivery pusher using the method of soaking the devices in saline followed by immersion in boiling water per the method specified in Annex A of ISO 10555-1.	Axium™ Detachable Coil and Axium™ Prime Detachable Coil met the acceptance criteria for corrosion resistance.

Design Validation		
Test	**Test Method Summary**	**Results**
Fluorosafe Marker Visibility	The clinical users evaluated the devices under simulated use conditions and rated fluorosafe marker visibility.	The devices met the user needs for which it was designed and tested.

Performance Data – Animal and Clinical:

The determination of substantial equivalence is based upon non-clinical bench testing as there is no change to the indications for use statement, fundamental scientific technology, principles of operation or materials of construction except for the addition of fluorosafe markers. No clinical data or animal study were deemed necessary to support the subject device submission.

Conclusion:

There is no change to the indications for use statement, fundamental scientific technology or principle of operation of the Axium™ Detachable Coils and Axium™ Prime Detachable Coils in comparison to the predicate devices. The addition of fluorosafe markers on the proximal end of the embolization coil delivery pusher does not raise new questions of safety and effectiveness and is supported by non-clinical bench testing using well-established acceptable scientific methods. The information provided in this submission supports a determination of substantial equivalence for Axium™ Detachable Coils and Axium™ Prime Detachable Coils to the predicate devices.