July 7, 2021

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

Re: K203432
Trade/Device Name: Axium Detachable Coil and Axium Prime Detachable Coil
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: June 3, 2021
Received: June 4, 2021

Dear Bhavika Patel:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Xiaolin Zheng, Ph.D.
Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203432

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 (Model Numbers APB-X-Y-3D/HX-ES/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 (Model Numbers 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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K203432 510(k) Summary

510(k) Owner:	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 Establishment Registration: 2029214
Contact Person:	Bhavika Patel Senior Regulatory Affairs Specialist Telephone: (949) 434-5030 Email: bhavika.patel@medtronic.com

Date Summary Prepared:	06 July 2021
Trade Name of Device:	Axium™ Detachable Coil Axium™ Prime Detachable Coil
Common Name of Device:	Neurovascular Embolization Device
Review Panel:	Neurology
Product Code:	HCG , KRD
Regulation Number:	21 CFR 882.5950
Regulation Name:	Neurovascular Embolization Device
Device Classification	Class II
Predicate Device:	K133310 Axium™ Detachable Coil System K151447 Axium™ Detachable Coil System K162704 Axium™ Prime Detachable Coil System

Device Description:
The Axium™ Detachable Coil and Axium™ Prime Detachable Coil (referred to collectively as "Axium™ device family"), consists 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 Instant Detacher (I.D.) is sold separately.

Indication for Use Statement:
The Axium™ device family product model numbers and associated indications for use are outlined in the table below. 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.

Axium™ Device Family Indications for Use		
Model Numbers	Trade Name	Indications for Use
QC-X-Y-HELIX QC-X-Y-3D NC-X-Y-HELIX PC-X-Y-HELIX PC-X-Y-3D	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.
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.

Axium™ Device Family Indications for Use		
Model Numbers	Trade Name	Indications for Use
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.

Proposed Change:

Medtronic requests clearance of Axium™ Detachable Coil and Axium™ Prime Detachable Coil (referred to collectively as the "Axium™ device family") for revised labeling that includes changes to the directions for use to modify the accessory sheath required to perform a procedure, from femoral sheath to arterial sheath. The proposed change will allow the physician to use radial artery route during access as an alternative to femoral artery for the introduction of the device during a procedure if deemed appropriate. Axium™ Detachable Coil and Axium™ Prime Detachable Coil revised labeling also includes removal of the indication "The Axium™ [Prime] Detachable Coils are also indicated for arterial and venous embolizations in the peripheral vasculature" for Axium™ Detachable Coil and Axium™ Prime Detachable Coil (excludes Model Numbers FC-X-Y-3D).

Device Comparison:

Design Feature	Predicate: Axium™ Detachable Coil System (K133310, K151447) Axium™ Prime Detachable Coil System (K162704)	Subject: Axium™ Detachable Coil Axium™ Prime Detachable Coil
Indications for Use for Axium™ Detachable Coil	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.	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.
Indications for Use for Axium™ Prime Detachable Coil (Model Numbers APB-X-Y-3D/HX-ES/SS)	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.	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.
Indications for Use for Axium™ Prime Detachable Coil (Model Numbers FC-X-Y-3D)	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.	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

Design Feature	Predicate: Axium™ Detachable Coil System (K133310, K151447) Axium™ Prime Detachable Coil System (K162704)	Subject: Axium™ Detachable Coil Axium™ Prime Detachable Coil
		for arterial and venous embolizations in the peripheral vasculature.
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 only be delivered through a microcatheter with a minimum inside diameter of 0.0165”– 0.017” with two marker bands.	Same

Design Feature	Predicate: Axium™ Detachable Coil System (K133310, K151447) Axium™ Prime Detachable Coil System (K162704)	Subject: Axium™ Detachable Coil Axium™ Prime Detachable Coil
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
Sterilization		
Method of Supply	Sterile and single use	Same
Sterilization Method	Ethylene Oxide (EO)	Same
Stability		
Shelf Life	3 years	Same
Magnetic Resonance Imaging		
MRI Compatibility	MR Conditional	Same

Biocompatibility:
There is no change to the biocompatibility of the products associated with the proposed changes.

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 access model.

The following non-clinical bench tests were conducted:

Design Verification		
Test	Test Method Summary	Results
Ease of Delivery – Friction	Device navigated through tortuous bench top model in order to assess friction	All test results met acceptance criteria

Design Validation		
Test	Test Method Summary	Results
Ease of Delivery	Device navigated through tortuous bench top model in order to assess deliverability	All test results met acceptance criteria
Detachment Reliability and Retractability	Cycle the coil (manipulate within the embolic target) without premature detachment	All test results met acceptance criteria
Detachment Reliability and Retractability	Detach the coil successfully in 3 or fewer attempts	All test results met acceptance criteria
Retrieval	Retrieve the pusher through the microcatheter after detachment	All test results met acceptance criteria

Performance Data – Animal:
The determination of substantial equivalence is based upon non-clinical bench testing as there is no change to the intended use, fundamental scientific technology, or materials of construction.

Performance Data – Clinical:
The determination of substantial equivalence is based upon non-clinical bench testing as there is no change to the intended use, fundamental scientific technology, or materials of construction.

Conclusion:
Axium™ Detachable Coil and Axium™ Prime Detachable Coil revised labeling includes changes to the directions for use to modify the accessory sheath required to perform a procedure, from femoral sheath to arterial sheath. Axium™ Detachable Coil and Axium™ Prime Detachable Coil revised labeling also includes removal of the indication "The Axium™ [Prime] Detachable Coils are also indicated for arterial and venous embolizations in the peripheral vasculature" for Axium™ Detachable Coil and Axium™ Prime Detachable Coil (excludes Model Numbers FC-X-Y-3D). The proposed changes do not alter the intended use, design, materials, or fundamental scientific technology. The successful results of the performance evaluation verify that the proposed changes do not raise new questions of safety and efficacy. Therefore, Axium™ Detachable Coil and Axium™ Prime Detachable Coil are substantially equivalent to the predicate devices.