May 20, 2026

MicroPort NeuroTech (Shanghai) Co., Ltd.
% John Skousen
Regulatory Consultant
MicroPort CRM USA, Inc.
5677 Airport Rd.
Arlington, Tennessee 38002

Re: K260351
Trade/Device Name: Numen Helia Coil Embolization System; NumenFR Detachment System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: April 22, 2026
Received: April 22, 2026

Dear John Skousen:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Eda Gjika -S

For Sara S. Thompson, DVM
Assistant 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260351

Device Name
Numen Helia Coil Embolization System; NumenFR Detachment System

Indications for Use *(Describe)*

Numen Helia Coil Embolization System is intended to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.
Numen Helia Coil Embolization System is indicated for endovascular embolization of:
• Intracranial aneurysms
• Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae
• Arterial and venous embolizations in the peripheral vasculature

NumenFR Detachment System is intended for use with MicroPort NeuroTech detachable coils in the embolization of intracranial aneurysms and other vascular abnormalities of the neuro and 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.

510(k) Summary

Subject Device:

Numen™ Helia Coil Embolization System; NumenFR™ Detachment System

This 510(k) Summary is being submitted in accordance with the requirements of 21CFR § 807.92.

Submitter Name and Address	MicroPort NeuroTech (Shanghai) Co., Ltd. Building#16, 222 Guangdan Road, Pudong New District, Shanghai, China
Contact Person	Name: Yuying Chen Email: YuYing.Chen@microport.com Phone:+86 13311583098
Date Prepared	February 3, 2026
Trade Name	Numen™ Helia Coil Embolization System; NumenFR™ Detachment System
Common Name	Detachable Coil
Classification Name	Neurovascular Embolization Device (HCG); Device, Vascular, for Promoting Embolization (KRD)
Regulation Number	21 CFR 882.5950 (HCG); 21 CFR 870.3300 (KRD)
Product Code(s)	HCG, KRD
Classification	II
Review Panel	Neurology (HCG); Cardiovascular (KRD)
Use	Prescription Use Only
Legally Marketed Predicate Device	Numen™ Coil Embolization System; NumenFR™ Detachment System (K242154)

1. Device Description

MicroPort NeuroTech has developed the Numen™ Helia Coil Embolization System. The Numen™ Helia Coil Embolization System is designed to be used in conjunction with the NumenFR™ Detachment System (sold separately) for endovascular embolization of vascular abnormalities described in the intended use.

The Numen™ Helia Coil Embolization System is composed of two parts as described below:

- An introducer sheath: The function of the introducer sheath is to facilitate introduction of the coil into the microcatheter.
- The coil system: The coil system is composed of a pusher and coil implant. The coil is a permanent implant intended to occlude blood flow in vascular abnormalities. The pusher is used to deliver the coil implant to the target lesion.

The NumenFR™ Detachment System is a sterile, handheld, single-patient use device designed for use with the MicroPort NeuroTech detachable coils. The device is operated by two pre-loaded batteries.

2. Indications for Use

Numen™ Helia Coil Embolization System is intended to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.

Numen™ Helia Coil Embolization System is indicated for endovascular embolization of:

- Intracranial aneurysms
- Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae
- Arterial and venous embolizations in the peripheral vasculature

NumenFR™ Detachment System is intended for use with MicroPort NeuroTech detachable coils in the embolization of intracranial aneurysms and other vascular abnormalities of the neuro and peripheral vasculature.

3. Comparison of the Subject Device with the Predicate Device

Comparison for Numen™ Helia Coil Embolization System

Characteristics	Numen™ Coil Embolization System (Predicate device, K242154)	Numen™ Helia Coil Embolization System (Subject device, K260351)
Manufacturer	MicroPort NeuroTech (Shanghai) Co., Ltd	Same
Device Classification	Class II	Same
Regulation Number and Regulation Description	21 CFR §870.3300, Device, Vascular, for Promoting Embolization 21 CFR §882.5950 Neurovascular Embolization Device	Same
Classification Product Code	HCG KRD	Same
Intended Use/Indications for Use	Numen™ Coil Embolization System is intended to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels. Numen™ Coil Embolization System is indicated for endovascular embolization of: • Intracranial aneurysms • Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae • Arterial and venous embolizations in the peripheral vasculature	Numen™ Helia Coil Embolization System is intended to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels. Numen™ Helia Coil Embolization System is indicated for endovascular embolization of: • Intracranial aneurysms • Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae • Arterial and venous embolizations in the peripheral vasculature Same.
Types	MicroFrame, MicroFill, MicroFinish, SILK	Cube, Spiral Subject device introduces 2 additional types to MicroPort's Numen Coil Product Family.
No. of Models Offered	224	130
Dimension/Shape of Coil Embolization System		
Secondary Shape	3D, Helical	Same
Coil Type	Stretch Resistance	Same
Coil Primary Diameter	0.0100 inch-0.0140 inch	0.0110 inch - 0.0115 inch The primary coil diameter of the subject device falls within the range of that of the predicate device.

Characteristics	Numen™ Coil Embolization System (Predicate device, K242154)	Numen™ Helia Coil Embolization System (Subject device, K260351)
Coil Secondary Diameter	1-24 mm	1-3.5mm The coil secondary diameter of the subject device falls within the range of that of the predicate device.
Coil Length	1-70 cm	2-60cm The coil length of the subject device falls within the range of that of the predicate device.
Pusher Length	187.8 cm	Same
Material of Coil Embolization System		
Primary Coil Wire	Pt (92%) / W (8%)	Same
Stretch Resistant Thread	Polypropylene	Same
Pusher (Body Hypotube)	SS 304	Same
Introducer Sheath	HDPE	Same
Proximal Rod	Stainless Steel	Same
Adhesive	Epoxy 353ND	Same
Other		
Detachment Mechanism	Electrolytic	Same
How Supplied	Sterile, for single use only	Same
Sterilization Method	Ethylene Oxide	Same
Compatible Microcatheter Inner Diameter	≥ 0.0165 inch	≥ 0.013 inch ≥ 0.0165 inch Different, Numen Helia is additionally compatible with microcatheters with an inner diameter of ≥ 0.013 inches.

Comparison for NumenFR™ Detachment System

The subject device and predicate device are identical, and there are no changes to the NumenFR™ Detachment System (K242154) except for a minor wording revision to its indication.

Characteristics	NumenFR™ Detachment System (Predicate device, K242154)	NumenFR™ Detachment System (Subject device, K260351)
Manufacturer	MicroPort NeuroTech (Shanghai) Co., Ltd	Same
Device Classification	Class II	Same
Regulation Number and Regulation Description	21 CFR §870.3300, Device, Vascular, for Promoting Embolization	Same

Characteristics	NumenFR™ Detachment System (Predicate device, K242154)	NumenFR™ Detachment System (Subject device, K260351)
	21 CFR §882.5950 Neurovascular Embolization Device	
Classification Product Code	HCG KRD	Same
Intended Use/Indications for Use	NumenFR™ Detachment System is intended for use with MicroPort NeuroTech Numen™ Coil Embolization System in the embolization of intracranial aneurysms and other vascular abnormalities of the neuro and peripheral vasculature.	NumenFR™ Detachment System is intended for use with MicroPort NeuroTech detachable coils in the embolization of intracranial aneurysms and other vascular abnormalities of the neuro and peripheral vasculature. Minor wording change to the indication of NumenFR™ Detachment System with the addition of the Numen™ Helia Coil Embolization System to the MicroPort NeuroTech Numen family coils

4. Performance Testing

The following non-clinical bench testing was performed to evaluate the new Numen™ Helia Coil Embolization System and to demonstrate substantial equivalence of the subject device to the predicate device. The testing was performed on test units representative of final finished devices.

Test	Test Method Summary	Test Results
Visual Inspection	Examine the test sample surface under specific magnification.	Pass
Dimensional Verification	Implant coil, pusher and introducer sheath dimensions are measured to match the specifications.	Pass
Simulated Use	Verify that the coil embolization system performs as intended in a representative tortuous anatomical model.	Pass
Fatigue Testing	Verify the durability of the coil embolization system by repeating the simulated use six times, including coil retraction into microcatheter and re-deployment	Pass
Detachment Time and Detachment Reliability	Verify the reliability of intentional detachment as well as reliability of the coil attachment after fatigue testing of the coil embolization system in a representative tortuous anatomical model.	Pass

Test	Test Method Summary	Test Results
Delivery and Retraction Friction in Introducer Sheath	Measured by max friction force when advancing or retracting the coil system in introducer sheath.	Pass
Delivery, Deployment and Retraction Friction in Microcatheter	Measured by max friction force when advancing, deploying or retracting the coil system through microcatheter in a relevant, tortuous, anatomical model.	Pass
Kink Resistance	Demonstrate that the resistance to kinking of the device meets pre-specified acceptance criteria, and could withstand bending forces that the device may encounter in clinical usage.	Pass
Torque Strength	Verify the torque strength by rotating the proximal end of the device for 8 turns.	Pass
Flexing Test	Per ISO 11070, Annex G Test method for resistance of guidewires to damage by flexing	Pass
Fracture Test	Per ISO 11070, Annex F Test method Test method for fracture of guidewires	Pass

5. Shelf-life

The Numen™ Helia Coil Embolization System is constructed using the same materials, packaging, and manufacturing process as the predicate device. The storage and transport conditions for both devices are also the same. There is no increased risk of device failure due to material degradation. Therefore, the shelf-life testing previously established for the predicate devices is also applicable to the subject device, and the shelf-life claims of three (3) years for the Numen™ Helia Coil Embolization System are the same as for the predicate device.

6. Biocompatibility

The materials and processing methods of the Numen™ Helia Coil Embolization System are the same as those of the predicate device. There are no material or contact duration changes to the components of the device that contact circulating blood. Therefore, part of the biocompatibility performances of Numen™ Helia could be adopted from the predicate device.

To evaluated the biocompatibility impact of design modifications relative to the predicate device, the following biocompatibility tests were performed on the final finished device of Numen™ Helia.

Test	Test Method	Results
Partial Thromboplastin Time	Partial Thromboplastin Time per ISO 10993-4.	Pass
Thrombogenicity	Standard Thrombogenicity in Canine per ISO 10993-4.	Pass

The Numen™ Helia Coil Embolization System has 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".

7. Conclusion

MicroPort NeuroTech has made minor modifications to the design of the implanted coil and pusher of the Numen™ Coil Embolization System. The modified device will be marketed under a new trade name: Numen™ Helia Coil Embolization System. The intended use and indications for use of the Numen™ Helia device remain unchanged in comparison with the predicate device, and the minor modifications do not affect the fundamental scientific technology of the predicate device. There is no modification to the NumenFR™ Detachment System except the minor wording revision to the indications for use of the NumenFR™ device because of the addition of the Numen™ Helia Coil Embolization System to the MicroPort NeuroTech Numen family.

A comprehensive risk assessment of the modification and successful verification testing have been performed, which did not raise any new questions regarding safety and effectiveness. Based on these evaluations, MicroPort NeuroTech has concluded that the subject device is substantially equivalent to the predicate device.