



January 10, 2024

MicroPort NeuroTech (Shanghai) Co., Ltd.
% Ivory Chang
Regulatory Consultant
BioDesign Regulatory Services, LLC
16185 Los Gatos Boulevard, Suite 205
Los Gatos, California 95032

Re: K232955

Trade/Device Name: Numen 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: December 13, 2023
Received: December 14, 2023

Dear Ivory Chang:

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

and Neurodiagnostic Devices

OHT5: Office of Neurological

and Physical Medicine Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K232955

Device Name

Numen™ Coil Embolization System

NumenFR™ Detachment System

Indications for Use (Describe)

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

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.

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**K232955****Subject Device:****Numen™ Coil Embolization System****NumenFR™ Detachment System**

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

Submitter Name and Address	MicroPort NeuroTech (Shanghai) Co., Ltd. Building 16, Guangan Road 222, Pudong New District, Shanghai, China
Contact Person	Name: Jiayin Sun Email: JiaYin.Sun@microport.com Phone: +86 13662109935
Date Prepared	December 17, 2023
Trade Name	Numen™ 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 (K203625)

1. Device Description

MicroPort NeuroTech has developed the Numen™ Coil Embolization System and NumenFR™ Detachment System. The Numen™ 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™ 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 MicroPort NeuroTech NumenFR™ Detachment System is a sterile, handheld, single-patient use device designed for use with the MicroPort NeuroTech Numen™ Coil Embolization System. The device is operated by two pre-loaded batteries.

2. 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

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.

3. Comparison of the Subject Device with the Predicate Device

Comparison for Numen™ Coil Embolization System

Characteristics	Numen™ Coil Embolization System (Predicate device, K203625)	Numen™ Coil Embolization System (Subject device, K232955)
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

Characteristics	Numen™ Coil Embolization System (Predicate device, K203625)	Numen™ Coil Embolization System (Subject device, K232955)
Classification Product Code	KRD HCG	Same
Intended Use/Indications for Use	<p>Numen™ Coil Embolization System is intended to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.</p> <p>Numen™ Coil Embolization System is indicated for endovascular embolization of:</p> <ul style="list-style-type: none"> • Intracranial aneurysms • Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae • Arterial and venous embolizations in the peripheral vasculature <p>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.</p>	Same
Dimension/Shape of Coil Embolization System		
Secondary Shape	3D, Helical	Same
Coil Type	Stretch Resistance	Same
Coil Secondary Diameter	1-24 mm	Same
Coil Length	1-70 cm	Same
Pusher Length	183.5 cm	187.8 cm
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/ Proximal Anchor	Pt/Ir	Stainless steel
Adhesive	Epoxy 353ND Epoxy H20E	Epoxy 353ND
Other		
Detachment Mechanism	Electrolytic	Same
How Supplied	Sterile, for single use only	Same
Sterilization Method	Ethylene Oxide	Same

Comparison for NumenFR™ Detachment System

There are no changes to the NumenFR™ Detachment System.

4. Performance Testing

The following non-clinical bench testing was performed to evaluate the device changes and to demonstrate substantial equivalence of the modified Numen™ Coil Embolization System to the predicate device. The testing was performed on test units representative of final finished devices. The device is labeled with two years (2) shelf life, which is supported by accelerated aging shelf-life study.

Test	Test Method Summary	Test Results
Visual Inspection of Pusher	Examine the test sample surface under specific magnification.	Pass
Dimensional Verification of Pusher	Pusher diameters and pusher length 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 the 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
Pusher Proximal Hypotube Contact Tensile Strength	Verify that the tensile strength meets the acceptance criteria.	Pass
Pusher Corrosion Resistance	Corrosion resistance testing per ISO 10555-1 Annex A methods for the pusher.	Pass
Sterilization Validation	Per ISO 11135, Annex B Overkill Method to ensure that the sterilization process achieves sterility assurance level of 10^{-6} .	Pass
Endotoxin Testing	Bacterial endotoxin assay validation per USP <85> to ensure the endotoxin levels for the device are below 2.15 EU/device.	Pass
Electrical Safety	Electrical safety testing in accordance with IEC 60601-1.	Pass

Biocompatibility

The design modifications to the proximal portion of the pusher of the Numen™ Coil Embolization System were limited to components that do not contact the patient. Additional biocompatibility assessments were not deemed necessary to support the design change to the pusher of the Numen™ Coil Embolization System.

5. Conclusion

MicroPort NeuroTech has made modifications to the Numen™ Coil Embolization System. The intended use and indications for use of the device remain unchanged, and the modifications do not affect the fundamental scientific technology of the device. A comprehensive risk assessment of the modifications 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 modified Numen™ Coil Embolization System and the NumenFR™ Detachment System are substantially equivalent to the predicate devices.