September 1, 2021

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

Re: K203625
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: July 30, 2021
Received: August 2, 2021

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 (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,

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

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)*
K203625

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

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, 222 Guangdan Road, Pudong New District, 201318 Shanghai, China
Contact Person	Name: Qiuhua Zou Phone Number: +86-21-38954600 ext. 3959
Date Prepared	August 25, 2021
Trade Name	Numen™ Coil Embolization System NumenFR™ Detachment System
Common Name	Detachable Coil, Power Supply
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 Devices	Predicate devices: Target® Detachable Coils (K161429), InZone Detachment System (K160096) Reference devices: Axium™ Detachable Coil System, K151447 Penumbra Smart Coil, K143218 Microplex Coil System, K132952

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 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 to the Predicate Devices

Comparison for Numen™ Coil Embolization System

The subject device Numen™ Coil Embolization System is substantially equivalent to the commercially available predicate device, Target® Detachable Coils (K161429) in terms of intended use/indications for use and technical characteristics.

The Numen™ Coil Embolization System has the same intended use/indications for use (endovascular embolization and occlusion of blood flow) as the Target® Detachable Coils.

The following table compares the main characteristics of the subject device Numen™ Coil Embolization System to the predicate device:

Characteristics	Target® Detachable Coils (K161429), (Predicate device)	Numen™ Coil Embolization System (K203625), (Subject device)	Similarities/ Differences
510(k) Number	K161429	K203625	N/A
Manufacturer	Stryker Neurovascular	MicroPort NeuroTech (Shanghai) Co., Ltd.	N/A
Device Classification	Class II	Class II	Same
Regulation Number and Regulation Description	21 CFR § 870.3300 Device, Vascular, for Promoting Embolization 21 CFR § 882.5950 Neurovascular embolization device	21 CFR § 870.3300 Device, Vascular, for Promoting Embolization 21 CFR § 882.5950 Neurovascular embolization device	Same
Classification Product Code	KRD HCG	KRD HCG	Same
Intended Use/Indications for Use	Target Detachable Coils are intended to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels. Target Detachable Coils are 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™ 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	Same
Dimension/Shape of Coil Embolization System			
Secondary Shape	3D, Helical	3D, Helical	Same
Coil Type	Stretch Resistance	Stretch Resistance	Same

Characteristics	Target® Detachable Coils (K161429), (Predicate device)	Numen™ Coil Embolization System (K203625), (Subject device)	Similarities/ Differences
Coil Secondary Diameter	1-24 mm	1-24 mm	Same
Coil Length	1-50 cm	1-70 cm	Longer length
Pusher length	185 cm	183.5 cm	Similar
Material of Coil Embolization System			
Primary Coil wire	Pt (92%) / W (8%)	Pt (92%) / W (8%)	Same
Stretch Resistant Thread	Polypropylene	Polypropylene	Same
Pusher (Body Hypotube)	SS 304	SS 304	Same
Introducer Sheath	HDPE	HDPE	Same
Other			
Detachment mechanism	Electrolytic	Electrolytic	Same
How Supplied	Sterile, for single use only	Sterile, for single use only	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same

The reference devices listed below are used in the verification testing of the Numen™ Coil Embolization System.

- K151447 (Axium Detachable Coil System)
- K143218 (Penumbra Smart Coil)
- K132952 (Microplex Coil System)

See the following table for the comparison between the subject device and reference devices:

Characteristics	Subject device	Reference device #1	Reference device #2	Reference device #3	Comparison Results
	Numen™ Coil Embolization System (K203625)	**Axium™ Detachable Coil System (K151447)**	**Penumbra Smart Coil™ (K143218)**	**MicroPlex Coil System (K132952)**	
510(k) Number	K203625	K151447	K143218	K132952	N/A
Manufacturer	MicroPort NeuroTech (Shanghai) Co., Ltd.	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular	Penumbra, Inc.	Microvention, Inc	N/A
Device Classification	Class II	Class II	Class II	Class II	Same
Regulation Number and Regulation Description	21 CFR § 870.3300 Device, Vascular, for Promoting Embolization 21 CFR § 882.5950 Neurovascular embolization device	21 CFR § 870.3300 Device, Vascular, for Promoting Embolization 21 CFR § 882.5950 Neurovascular embolization device	21 CFR § 870.3300 Device, Vascular, for Promoting Embolization 21 CFR § 882.5950 Neurovascular embolization device	21 CFR § 870.3300 Device, Vascular, for Promoting Embolization 21 CFR § 882.5950 Neurovascular embolization device	Same
Classification Product Code	KRD HCG	KRD HCG	KRD HCG	KRD HCG	Same

Characteristics	Subject device Numen™ Coil Embolization System (K203625)	Reference device #1 Axium™ Detachable Coil System (K151447)	Reference device #2 Penumbra Smart Coil™ (K143218)	Reference device #3 MicroPlex Coil System (K132952)	Comparison Results
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	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 Penumbra Smart Coil System is indicated for the embolization of: • Intracranial aneurysms • Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae • Arterial and venous embolizations in the peripheral vasculature	Intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. Also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature.	Similar
Coil Secondary Diameter	1-24 mm	1-25 mm	1-18 mm	1-24 mm	Similar
Coil Length	1-70 cm	1-50 cm	1-60 cm	1-68 cm	Similar

Comparison for NumenFR™ Detachment System

The subject device NumenFR™ Detachment System is substantially equivalent to the commercially available predicate device, the InZone Detachment System (K160096) in terms of intended use/indications for use, technical characteristics, and functional performance.

The intended use/indications for use of the NumenFR™ Detachment System are the same as that of the InZone Detachment System.

The following table compares the main characteristics of the subject device NumenFR™ Detachment System to the predicate device:

Characteristics	InZone Detachment System (K160096), (Predicate device)	NumenFR™ Detachment System (K203625), (Subject device)	Similarities/ Differences
510(k) Number	K160096	K203625	N/A
Manufacturer	Stryker Neurovascular	MicroPort NeuroTech (Shanghai) Co., Ltd.	N/A

Characteristics	InZone Detachment System (K160096), (Predicate device)	NumenFR™ Detachment System (K203625), (Subject device)	Similarities/ Differences
Device Classification	Class II	Class II	Same
Regulation Number and Regulation Description	21 CFR § 870.3300 Device, Vascular, for Promoting Embolization 21 CFR § 882.5950 Neurovascular embolization device	21 CFR § 870.3300 Device, Vascular, for Promoting Embolization 21 CFR § 882.5950 Neurovascular embolization device	Same
Classification Product Code	KRD HCG	KRD HCG	Same
Intended Use/Indications for Use	The InZone Detachment System is intended for use with all versions of Stryker Neurovascular detachable coils in the embolization of intracranial aneurysms and other vascular malformations of the neuro and 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.	Same
Dimension	140.0 mm x 58.0 mm x 28.0 mm	140.0 mm × 45.0 mm × 28.0 mm	Similar
Weight	80 g	65.0g - 75.0g	Similar
Key Characteristic	Sterile, hand-held, single-patient-use powered by pre-loaded alkaline batteries, disposable unit	Sterile, hand-held, single-patient-use powered by pre-loaded alkaline batteries, disposable unit	Same
Power Source	Two 1.5 V (AAAA) DC alkaline batteries (in series)	Two 1.5 V (AAAA) DC alkaline batteries (in series)	Same
Max Voltage Output	28 V DC	28 V DC	Same
Max Current Output	2.4 mA	1.8 mA	Similar
Max Time of Single Cycle	10 seconds	10 seconds	Same
Number of Detachments	Minimum of 20 detachments	Minimum of 20 detachments	Same
Power Switch	Inserting coil delivery wire turns the unit on. Removing the delivery wire turns the unit off. Unit turns off after 2 minutes if unit detects no activity.	Inserting coil delivery wire turns the unit on. Removing the delivery wire turns the unit off. Unit turns off after 2 minutes if unit detects no activity.	Same
To start detachment	Press Detachment Button	Press Detachment Button	Same
Other			
Detachment mechanism	Electrolytic	Electrolytic	Same
How Supplied	Sterile, for single use only	Sterile, for single use only	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same

There are some device characteristics that differ as shown in the comparison tables above. Verification and validation testing has been completed and test results show that the subject devices, Numen™ Coil Embolization System and NumenFR™ Detachment System, are substantially equivalent to the predicate devices.

The differences do not affect the intended use/indications for use of the devices, nor do they alter their fundamental scientific technology compared to the predicate devices.

4. Performance Testing

Numen™ Coil Embolization System

All necessary testing has been performed for the Numen™ Coil Embolization System to demonstrate that the device performs as intended and that it is substantially equivalent to the predicate. 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 for 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
Ease of delivery	Measured by max friction force when advancing, deploying or retracting the coil system through the introducer sheath and microcatheter in a relevant tortuous anatomical model.	Pass
Kink resistance	Demonstrate that kink resistance of the device meets pre-specified acceptance criteria, and could withstand bending forces that the device may encounter during clinical use.	Pass
Torque strength	Verify the torque strength by rotating the proximal end of the device for 8 turns.	Pass
Radiopacity	Qualitatively assess the radiopacity of the device under X-ray to demonstrate the equivalence to the control device.	Pass
Particulate testing	Verify that the quantity and size of particulates generated during simulated use in a clinically relevant tortuous anatomical model with all recommended ancillary devices meet the acceptance criteria based on the comparison with the predicate.	Pass
Coil deformation force	To verify that the coil implants are not too stiff to loop adequately and achieve their intended secondary shape.	Pass

Test	Test method summary	Test results
Tensile strength testing	Verify that detachment zone tensile strength, stretch resistance tensile strength, pusher joints tensile strength, and introducer sheath tensile strength meet the acceptance criteria based on a control device.	Pass
Corrosion Resistance	Corrosion resistance testing per ASTM F2129 for coil implant, per ISO 11070 for pusher.	Pass
MR Compatibility	MR testing performed per ASTM F2119, ASTM F2213, ASTM F2052 and additional MRA characterization testing.	Testing demonstrated the device is MR conditional.
Packaging and Shelf Life	Package verification and shelf-life testing performed to demonstrate the integrity of the sterile barrier packaging throughout the proposed shelf life and its ability to protect the packaged devices from damage and maintain sterility during transport and storage conditions.	Packaging and device testing demonstrate the ability to perform as intended through the labeled 2-year shelf life of the device.
Sterilization Validation	Per ISO 11135, Annex B Overkill Method.	Sterilization process achieves sterility assurance level of 10^{-6}.
Endotoxin Testing	Bacterial endotoxin assay validation per USP 85.	The endotoxin levels for the device are below 2.15 EU/device.
GLP animal study	Animal testing to evaluate the in vivo performance of the device in a canine model, reporting both acute and chronic time points.	Pass
Cytotoxicity (coil implant, pusher and sheath)	Cytotoxicity - MEM Elution per ISO 10993-5.	Pass Non-cytotoxic
Sensitization (coil implant, pusher and sheath)	ISO Guinea Pig Maximization Sensitization Test per ISO 10993-10.	Pass Non-sensitizer
Irritation (coil implant, pusher and sheath)	ISO Intracutaneous Irritation Test per ISO 10993-10.	Pass Non-irritant
Acute Toxicity (coil implant, pusher and sheath)	ISO Acute Systemic Injection Test per ISO 10993-11.	Pass Non-toxic
Pyrogenicity (coil implant, pusher and sheath)	ISO Material Mediated Rabbit pyrogen per ISO 10993- 11.	Pass Non-pyrogenic
Hemocompatibility (coil implant, pusher and sheath)	ASTM Hemolysis Study – Direct Contact and Extract method per ISO 10993-4.	Pass Non-hemolytic
Hemocompatibility (coil implant, pusher and sheath)	Complement Activation SC5b-9 Assay per ISO 10993- 4.	Pass Non-activator
Hemocompatibility (coil implant, pusher and sheath)	Partial Thromboplastin Time (PTT) per ISO10993-4.	Pass
Hemocompatibility (pusher and sheath)	In vivo Thromboresistance Study in Dogs per ISO 10993-4.	Pass

Test	Test method summary	Test results
Hemocompatibility (pusher and sheath)	In vivo Thromboresistance Study in Dogs, heparinized model per ISO 10993-4.	Pass Thromboresistant
Genotoxicity (coil implant)	Bacterial Mutagenicity Test per ISO 10993-3.	Pass Non-genotoxic
Genotoxicity (coil implant)	In vitro Mouse Lymphoma Assay per ISO 10993-3.	Pass Non-genotoxic
Implantation (coil implant)	ISO Muscle Implantation Study in Rabbits – 1 week, 4 weeks, 13 weeks per ISO 10993-6.	Pass
Subchronic toxicity (coil implant)	ISO Systemic Toxicity Study in Rats Following Subcutaneous Implantation, 13 Weeks per ISO 10993-6 and per ISO 10993-11.	Pass No evidence of systemic toxicity.
Carcinogenicity (coil implant)	Toxicological Risk Assessment	Pass
Chronic Toxicity (coil implant)	Toxicological Risk Assessment	Pass

Biocompatibility

The coil implant of the Numen ™ Coil Embolization System is classified as permanent implant in contact with circulating blood >30 days contact duration.

The delivery system including the pusher and introducer sheath of the Numen ™ Coil Embolization System, is classified as externally communicating device in contact with circulating blood < 24 h contact duration.

Refer to the table above for the biocompatibility testing of the coil system.

NumenFR™ Detachment System

Performance testing of the NumenFR™ Detachment System consisted of the following:

- Functional performance testing to assess proper operation of the NumenFR™ Detachment System at start-up and during the detachment process when used in combination with MicroPort NeuroTech Numen™ Coil Embolization System.
- Software verification in accordance with IEC 62304:2015 Ed. 1.1 and risk assessment conducted in accordance with ISO 14971:2007/(R) 2010.
- Electrical Safety Testing and EMC Testing in accordance with AAMI/ANSI ES 60601-1:2005, IEC 60601-1-2:2014 Ed. 4 and IEC 60601-1-6 Ed.3.1.

- The subject device is sterilized with Ethylene Oxide. The sterility assurance level (SAL) of at least 10^{-6} is assured by using a validated sterilization method per ISO 11135:2014.
- The device is labeled with two years (2) shelf life, which is supported by accelerated aging shelf-life study.

5. Conclusion

Based on the similarities of the intended use/indications for use, technological and functional characteristics and the results of the non-clinical performance testing, the subject devices, the Numen™ Coil Embolization System and NumenFR™ Detachment System, are substantially equivalent to the legally marketed predicate devices.