October 25, 2023

Penumbra, Inc.
Samyukta Rangachari
Regulatory Specialist II
One Penumbra Place
Alameda, California 94502

Re: K230284
Trade/Device Name: Penumbra LP Coil System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: September 26, 2023
Received: September 28, 2023

Dear Samyukta Rangachari:

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

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)*
K230284

Device Name
Penumbra LP Coil System

Indications for Use *(Describe)*
The Penumbra LP 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

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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1 510(k) Summary K230284

(as required by 21 CFR 807.92)

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Penumbra, Inc. is providing the summary of Substantial Equivalence for the subject Penumbra LP Coil System (herein after referred to as LP Coil).

1.1 Sponsor/Applicant Name and Address

Penumbra, Inc.
One Penumbra Place
Alameda, CA 94502 USA

1.2 Sponsor Contact Information

Samyukta Rangachari
Regulatory Affairs Specialist
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E-mail: srangachari@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

October 25, 2023

1.4 Device Trade or Proprietary Name

Penumbra LP Coil System

1.5 Primary Device Classification

Regulatory Class:	II
Classification Panel:	Neurology
Classification Name:	Neurovascular embolization device
Regulation Number:	21 CFR 882.5950
Product Code:	HCG

1.6 Secondary Device Classification

Regulatory Class:	II
Classification Panel:	Cardiovascular
Classification Name:	Vascular embolization device
Regulation Number:	21 CFR 870.3300
Product Code:	KRD

1.7 Predicate Device

510(k) Number	Device Name
K192955	Penumbra LP Coil System

1.8 Comparison of Technological Characteristics with the Predicate Device

Attributes	Predicate Device	Subject Device
General		
Trade Name	Penumbra LP Coil System	Penumbra LP Coil System
510(k) Number	K192955	K230284
Classification	Class II: HCG, KRD	SAME
Indications for Use	The Penumbra LP 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	SAME
Materials		
Coil	Platinum/Tungsten, Adhesive, Titanium, Polymer	SAME
Introducer Sheath	Polymer	Equivalent
Detachment Handle	Plastic, Stainless Steel	SAME
Dimensions/Shape		
Coil Secondary Shape	Complex, Finish	Complex, Finish, Helical, Hybrid
Coil Length	1-60 cm	1-70 cm
Coil Primary Diameter	0.0135 in.	0.0115 in.- 0.0135 in.
Coil Secondary Diameter	1-8 mm	1-10 mm
Detachment Pusher Length	185 cm	SAME
Introducer Sheath Length	125 cm max	126 cm max
Other		
Sterilization	EO	SAME
Sterilization Assurance Level (SAL)	$\geq 10^{-6}$	SAME

Attributes	Predicate Device	Subject Device
Use	Single Use	SAME
Shelf-life (coil implant & detachment pusher)	5 Years	1 year
Shelf-life (detachment handle)	5 Years	SAME
Device Packaging Materials and Dimensions	As specified in K192955	SAME

1.9 Device Description

The Penumbra LP Coil System is comprised of the Penumbra LP Coil, a platinum embolization coil attached to a composite delivery pusher with a radiopaque positioning marker and the Penumbra LP Coil Detachment Handle.

The coil/delivery pusher is packaged separately from the Penumbra LP Coil Detachment Handle. Penumbra LP Coil includes the following coil configurations:

- Ruby Coil LP
- Packing Coil LP
- PTC Coil LP
- Helical Coil LP
- Hybrid Coil LP

1.10 Indications For Use

The Penumbra LP 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

1.11 Summary of Non-Clinical Data

Included in this section are summary descriptions of the testing performed on the subject Penumbra LP Coil System based on the risk analysis of changes compared to the predicate device.

1.11.1 Bench-top Testing

Design Verification testing was conducted to evaluate the physical and mechanical properties of the subject devices and demonstrate substantial equivalence to predicate. The following tests were performed, and all tests passed:

Table 1: Bench-Top Testing Summary

Attribute	Specification	Results
Dimensional/Visual Inspection	Confirm the dimensions of the test units meet all product specifications.	Pass
Friction Testing	Confirm that the friction within a microcatheter is acceptable.	Pass
Fatigue Resistance Testing	Confirm that the coil implant retains its shape after being cycled into/out of the microcatheter.	Pass
Simulated Use Testing	Simulated use testing in an anatomical model and post-detachment dimensional inspection.	Pass
Radiopacity Testing	Confirm fluoroscopic visibility of test units.	Pass
Torsional Resistance Testing	Confirm torsional resistance of test units.	Pass
Corrosion Testing	Confirm that there is no visible corrosion after testing.	Pass
Coil Stiffness Testing	Confirm that test units meet product specifications related to coil stiffness.	Pass
Tensile Testing	Confirm tensile strength of coil implant and Detachment Pusher joints.	Pass

1.11.2 Biocompatibility Testing

Non-clinical testing determined the Penumbra LP Coil System to be biocompatible according to the requirements of ISO 10993-1. Some biocompatibility testing of the predicate Penumbra LP Coil System was deemed applicable considering the same materials.

The following tests were performed for the Detachment Pusher of the subject Penumbra LP Coil System:

- Cytotoxicity
- Hemocompatibility

The following tests were performed for the Introducer Sheath of the subject Penumbra LP Coil System:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Hemocompatibility
- Material-Mediated Pyrogenicity

1.11.3 Sterilization Testing

The Penumbra LP Coil System was tested to be sterile using identical acceptance criteria and testing methods as the predicate device in accordance with ISO 11135 and ISO 10993-7.

1.12 Performance Data – Animal, Clinical

No animal or clinical studies were conducted because bench testing was determined sufficient for verification and validation purposes.

1.13 Summary of Substantial Equivalence

The subject Penumbra LP Coil System is substantially equivalent to the predicate device Penumbra LP Coil System. The subject device has identical intended use as the predicate device. The subject and the predicate devices differ with minor technological variations, while maintaining the same fundamental scientific technology. However, these differences do not raise different questions of safety and effectiveness.

The device testing described in the 510(k) Summary demonstrates the subject device is substantially equivalent to the predicate device with regards to operating principle, fundamental technology, and device performance.