November 20, 2019

Penumbra, Inc.
Anush Puvvada
Regulatory Specialist III
One Penumbra Place
Alameda, California 94502

Re: K192955
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: October 18, 2019
Received: October 21, 2019

Dear Anush Puvvada:

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 (*Acting*)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192955

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

(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

Anush Puvvada
Regulatory Specialist III
Tel: (510) 440-5568
Fax: (510) 217-6414
E-mail: ypuvvada@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

October 18, 2019

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 and Reference Devices

510(k) Number	Clearance Date	Name of Predicate Device	Name of Manufacturer
Predicate Device			
K143218	March 18, 2015	Penumbra Smart Coil	Penumbra, Inc.
K151572	July 10, 2015		
K160832	April 20, 2016		
Reference Device			
K173614	April 17, 2018	Penumbra Coil 400	Penumbra, Inc.

1.8 Predicate and Reference Device Comparison

Attributes	Predicate Device	Reference Device	Subject Devices
General			
Trade name	Penumbra Smart Coil	Penumbra Coil 400	LP Coil
510(k)(s)	K143218, K151572, K160832	K173614	K192955
Classification	Class II: HCG, KRD	SAME	SAME
Indications for Use	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	SAME
Coil Materials/Construction			
Coil	92% Platinum/8% Tungsten, 90% Platinum/10% Iridium, Stainless	92% Platinum/8% Tungsten, Adhesive, Titanium, Polymer	SAME as Reference

Attributes	Predicate Device	Reference Device	Subject Devices
	Steel, Adhesive, Titanium, Polymer		
Coil Dimensions/Shape			
Coil Secondary Shape	Complex, Helical	Complex, Helical, Finish	Complex, Finish
Coil Length	1-60 cm	SAME	SAME
Coil Primary Diameter	0.0105-0.0130 in.	0.020 in.	0.0135 in.
Coil Secondary Diameter	1-18 mm	2-40 mm	1-8 mm
Other			
Sterilization	EO	SAME	SAME
Sterilization assurance level (SAL)	$\geq 10^{-6}$	SAME	SAME
Use	Single Use	SAME	SAME
Shelf-life (coil implant & detachment pusher)	5 Years	8 Years	SAME as Predicate
Shelf-life (detachment handle)	5 Years	3 Years	SAME as Predicate
Device Packaging Materials and Dimensions	As specified in K143218	As described in K173614	SAME as Predicate

1.9 Device Description

The LP Coil consists of a Coil Implant attached to a Detachment Pusher, both contained within a Sheath. The Detachment Pusher comprises a shaft with a radiopaque positioning marker, a Distal Detachment Tip (DDT), and a pull wire. A Detachment Handle (packaged separately) is used to detach the Coil Implant from the Detachment Pusher. The LP Coil is designed for endovascular embolization in the neuro and peripheral vasculature. Intended users for this device are physicians who have received appropriate training in interventional radiology. The LP Coil is a line extension to the Penumbra Smart Coil System (hereinafter referred to as Smart Coil) that uses the existing Sheath, Detachment Pusher, and Detachment Handle from the Smart Coil. This line extension includes two configurations:

- Ruby LP
- Finish 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

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, a summary of information regarding Substantial Equivalence of the device is as follows.

Included in this section are descriptions of the design control testing performed on the subject LP Coil based on a risk analysis of any technological changes compared to the predicate device. Design Verification (Bench-Top Testing and Sterilization Testing) was performed on the subject device as part of the design control activities. The subject device met all established requirements. No new biocompatibility testing was performed due to the same materials of construction between the subject and predicate devices.

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:

Attribute	Specification	Results
Dimensional/Visual Inspection	Confirm the dimensions of the units meet all product specifications.	Pass
Friction Testing	Push/pull friction acceptable through a 0.0165 in. ID microcatheter	Pass
Fatigue Resistance	The Coil Implant retains its secondary shape after being cycled into/out of the 0.0165” ID microcatheter 5 times	Pass
Simulated Use Flow Model Testing	Simulated use testing with accessory devices in an anatomical model which simulated the tortuosity of the neurovasculature. Devices were delivered through the model to evaluate the effectiveness of the devices to embolize targeted vasculature.	Pass
Distal System Tensile Test	Minimum per specification	Pass

1.11.2 Sterilization Testing

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

1.12 Summary of Substantial Equivalence

The subject LP Coil is substantially equivalent to the predicate device Smart Coil. The subject device has identical intended use as the predicate device. The subject and the predicate devices differ slightly in regard to 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 demonstrate the subject devices are substantially equivalent to the predicate device in regard to operating principle, fundamental technology and device performance.