April 17, 2018

Penumbra, Inc.
Aditi Kolla
Regulatory Specialist III
One Penumbra Place
Alameda, California 94502

Re: K173614
Trade/Device Name: Penumbra Coil System (Penumbra Coil 400 and Ruby Coil System); POD System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: March 10, 2018
Received: March 13, 2018

Dear Aditi Kolla:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K173614

Device Name
Penumbra Coil System (Penumbra Coil 400 and Ruby Coil System)
POD System

Indications for Use *(Describe)*

Penumbra Coil 400

The Penumbra Coil 400 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.

Ruby Coil System

Ruby Coil System is indicated for arterial and venous embolizations in the peripheral vasculature.

POD System (For POD Coils with nominal sizes ≤ 6 mm)

The POD 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.

POD System (For POD Coils with nominal sizes > 6 mm)

The POD System is indicated for 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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510(k) Summary

K173614

(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 Coil System and POD System.

1. **Sponsor/Applicant Name and Address**

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

2. **Sponsor Contact Information**

Aditi Kolla
Regulatory Affairs Specialist III
Phone: (510) 995-2010
Fax: (510) 217-6414
Email: akolla@penumbrainc.com

3. **Date of Preparation of 510(k) Summary**

March 10, 2018

4. **Device Trade or Proprietary Name**

Penumbra Coil System (Penumbra Coil 400 and Ruby Coil System)

POD System

5. **Primary Device Classification**

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

6. **Secondary Device Classification**

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

7. **Predicate and Reference Devices**

510(k) Number	Clearance Date	of Predicate Device	Name of Manufacturer
Predicate Device			
K120330	April 02, 2012	Penumbra Coil System	Penumbra, Inc.
Reference Device			
K170852	July 19, 2017	POD Packing Coil	Penumbra, Inc.

8. Predicate Device Comparison

Attribute	Penumbra Coil System (Predicate Device)	POD Packing Coil (Reference Device)	Penumbra Coil System and POD System (Subject Device)
General			
510(k) No.	K120330	K170852	K173614
Classification	Class II (HCG, KRD)	SAME	SAME
Intended 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
Materials/ Construction			
Coil	Platinum/Tungsten (92% Pt, 8% W), Nitinol (55% Ni, 45% Ti), Adhesive, Gold/Tin (80% Au, 20% Sn), Polyethylene Terephthalate (PET), Titanium	Platinum/Tungsten (92% Pt, 8% W), Polymer, Adhesive, Polyethylene Terephthalate (PET), Titanium	SAME as Reference
Dimensions/Shape			
Coil Shape	Complex, Helical, J	Wave	SAME as Predicate
Coil Length	1 - 60 cm	2 – 60 cm	SAME as Predicate
Coil Secondary	2-32 mm	Not Present	2-40 mm

Attribute	Penumbra Coil System (Predicate Device)	POD Packing Coil (Reference Device)	Penumbra Coil System and POD System (Subject Device)
Diameter			
Coil Primary Diameter	0.022 in. max	SAME	SAME
Other			
Device Packaging	specified in K120330	SAME	SAME
Sterilization	Ethylene Oxide (EO)	SAME	SAME
Shelf-Life (Coil/Pusher assembly)	8 years	8 years	Penumbra Coil System: 8 years POD System: 5 years

9. Device Description

The subject devices (Penumbra Coil System and POD System) are designed for embolization in the neuro and/or peripheral vasculature. This is achieved by using coils to exclude the intended treatment area from blood flow, thus creating stasis and allowing thrombosis to occur. The subject devices consist of a bare platinum embolization coil for the treatment of aneurysms or other vascular abnormalities. The devices should only be used by physicians who have received appropriate training in interventional techniques.

The subject devices consist of the following components:

- Coil: The Coil is attached to a Delivery Pusher both contained within an Introducer Sheath. The Coil is an implantable medical device intended to exclude the treatment area from blood flow, thus creating stasis and allowing thrombosis to occur.
- Delivery Pusher: The Delivery Pusher is composed of a shaft with a radiopaque positioning marker, a Distal Detachment Tip (DDT) and a pull wire. The Delivery Pusher may also be referred to as the Detachment Pusher.
- Introducer Sheath: The Introducer Sheath is intended to cover the entire length of the Coil and the distal flexible segment of the Delivery Pusher. The Introducer Sheath is secured onto the Delivery Pusher with a friction lock to prevent unsheathing until use.
- Detachment Handle: The Detachment Handle is packaged separately. It is intended for use in multiple coil detachments performed during a single procedure.

10. Indications for Use

Penumbra Coil 400

The Penumbra Coil 400 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.

Ruby Coil System

Ruby Coil System is indicated for arterial and venous embolizations in the peripheral vasculature.

POD System (For POD Coils with nominal sizes ≤ 6 mm)

The POD 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.

POD System (For POD Coils with nominal sizes > 6 mm)

The POD System is indicated for arterial and venous embolizations in the peripheral vasculature.

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 Penumbra Coil System and POD System. Design Verification (Bench-Top Testing and MR Characterization Testing) was performed on the subject devices as a part of the design control activities. The subject devices met all established requirements.

12. 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
Fatigue Resistance	The Coil retains its secondary shape after being cycled into/out of the 0.025 inch inner diameter (ID) microcatheter.	Pass
Torsional Resistance	Minimum value per specification	Pass
Friction through a 0.025 in. ID microcatheter – Pull & Push	Maximum value per specification	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
Stiffness Testing	Maximum value per specification	Pass

12.1. Biocompatibility Testing

Biocompatibility testing previously applicable to the predicate device and reference device substantiates the biocompatibility of the subject devices. Studies were selected in accordance with EN ISO 10993-1 guidelines (Biological Evaluation of Medical Devices). All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices. The following tests were performed on the predicate and reference devices:

Test	Method	Results
In Vitro Cytotoxicity	ISO Elution Test (MEM Extract)	Non-Toxic
Sensitization	Magnusson-Kligman Method	Non-Sensitizing
Irritation (Intracutaneous Reactivity)	ISO Intracutaneous (Intradermal) Injection Test	Non-Irritant
Implant study	Intramuscular Implant Test	Non-Irritant
Systemic Toxicity (Acute)		
Acute Systemic Toxicity	ISO Acute Systemic Injection Test	Non-Toxic
Material Mediated Pyrogen	USP Material-Mediated Rabbit Pyrogen Test	Non-pyrogenic
Sub-Chronic Toxicity (Sub-Acute Toxicity)		
Sub-Chronic/Sub-Acute Toxicity	14 day / 14 dose Repeat Dose study	Non-Toxic
Hemo-compatibility		
In Vitro Hemolysis	ASTM Method (Extraction & Direct Contact)	Non-Hemolytic
Dog Thrombogenicity	Thrombogenicity Study in Dogs - ISO	Non-Thrombogenic
Coagulation	PT and PTT Test	Non-Thrombogenic

Complement Activation	C3a and SC5b-9 through Enzyme Assay	No greater biological response than corresponding control
Genotoxicity		
Mouse Lymphoma	ISO *In Vitro* Mouse Lymphoma	Non-Mutagenic
Ames Mutagenicity	Salmonella typhimurium Reverse Mutation Assay (Ames Test)	Non-Mutagenic
In Vivo Mouse Micronucleus	ISO *In Vivo* Mouse Micronucleus Assay	Non-Mutagenic

The leveraged non-clinical testing substantiates that the subject Penumbra Coil System and POD System is non-cytotoxic, non-sensitizing, non-irritating, non-toxic, non-pyrogenic, non-mutagenic, non-genotoxic, non-hemolytic, and non-thrombogenic.

12.2. MR Compatibility Testing

Testing in 1.5T & 3T MR environment was performed to advise the MR conditional statement in the Instructions for Use (IFU). Testing was done in accordance to standards ASTM F2182-11, ASTM F2052-15, ASTM F2213-06 (R-11), and ASTM F2119-07 (R-13).

12.3. MRA Testing

MRA artifact associated with a Penumbra coil array in the form of an 8 mm diameter sphere was assessed per ASTM F2119-07 (R-13) using a clinical MRA sequence. The maximum artifact distance beyond the implant was 2 mm using this sequence.

13. Summary of Substantial Equivalence

The subject Penumbra Coil System (i.e., Penumbra Coil 400 and Ruby Coil System) and POD System are substantially equivalent to the predicate device Penumbra Coil System. The subject devices have identical intended use as the predicate device. The subject and the predicate devices differ slightly in regards 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 regards to operating principle, fundamental technology and device performance.