DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 19, 2017

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

Re: K170852
Trade/Device Name: POD Packing Coil
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: May 25, 2017
Received: May 25, 2017

Dear Ms. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170852

Device Name
POD Packing Coil

Indications for Use *(Describe)*
POD is indicated for the endovascular 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Penumbra

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 POD Packing Coil.

1.1 Sponsor/Applicant Name and Address

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

1.2 Sponsor Contact Information

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

1.3 Date of Preparation of 510(k) Summary

July 18, 2017

1.4 Device Trade or Proprietary Name

POD Packing Coil

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 Device	Name of Manufacturer
Predicate Device			
K141134	July 03, 2014	POD System	Penumbra, Inc.
Reference Device			
K160832	April 20, 2016	Penumbra Smart Coil	Penumbra, Inc.

1.8 Device Description

The Penumbra Occlusion Device (POD), including the subject device, is a bare platinum embolization coil for the treatment of aneurysms or other vascular abnormalities. It is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous fistulae. It is also intended for arterial and venous embolization in the peripheral vasculature. The POD System should only be used by physicians who have received appropriate training in interventional techniques.

The POD System consists 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

1.9 Indications For Use

POD is indicated for the endovascular embolization of:

- Intracranial aneurysms
- Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae
- Arterial and venous embolizations in the peripheral vasculature

1.10 Predicate Device Comparison

Attribute	POD System (Predicate Device)	Penumbra Smart Coil (Reference Device)	POD Packing Coil (Subject Device)
General			
510(k) No.	K141134	K160832	K170852
Classification	Class II (HCG, KRD)	SAME	SAME
Intended Use	Indicated for the endovascular 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
Introducer Sheath	Polypropylene, PET	High Density Polyethylene, PET	SAME as Reference
Dimensions/Shape			
Coil Shape	Complex	Complex, Helical	Wave (two dimensional shape)
Coil Length	1 - 60 cm	SAME	2 - 60 cm
Coil Primary Diameter	0.022 in. max	0.0135 in. max	SAME as Predicate
Other			
Device Packaging	As specified in K141134	SAME	SAME
Sterilization	Ethylene Oxide (EO)	SAME	SAME
Pyrogenicity (Coil/Pusher)	< 2.15 EU/device	SAME	SAME
Pyrogenicity (Detachment Handle)	< 20 EU/device	SAME	SAME
Shelf-Life (Coil/Pusher assembly)	8 years	5 years	SAME as Reference
Shelf-Life (Detachment Handle)	3 years	5 years	SAME as Predicate

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 POD Packing Coil. Design Verification (Bench-Top Testing) was performed on the subject device as a part of the design control activities. The subject POD Packing Coil met all established requirements.

1.11.1 Bench-top Testing

Design Verification testing was conducted to evaluate the physical and mechanical properties of the POD Packing Coil 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.	100% Pass
Fatigue Resistance	The Coil retains its secondary shape after being cycled into / out of the 0.025 in. ID microcatheter.	100% Pass
Torsional Resistance	Minimum value per specification	100% Pass
Friction through a 0.025 in. ID microcatheter – Pull & Push	Maximum value per specification	100% Pass
Simulated Use Flow Model Testing	Simulated use testing of POD Packing Coil 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.	100% Pass
Distal System Tensile Test	Minimum per specification	100% Pass

1.11.2 Biocompatibility Testing

Biocompatibility testing previously performed on the predicate device and reference device substantiates the biocompatibility of the subject device POD Packing Coil. 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 POD Packing Coil is non-cytotoxic, non-sensitizing, non-irritating, non-toxic, non-pyrogenic, non-mutagenic, non-genotoxic, non-hemolytic, and non-thrombogenic.

1.12 Summary of Substantial Equivalence

The subject device POD Packing Coil device is substantially equivalent to the predicate device POD System. The subject device has identical intended use as the predicate device. The subject device 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 Section 1.11 demonstrate the subject device is substantially equivalent to the predicate device in regards to operating principle, fundamental technology and device performance.