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 10, 2015

Penumbra, Inc.
Mr. Charles DeNault
Regulatory Affairs Specialist
One Penumbra Place
Alameda, California 94502

Re: K151572
Trade/Device Name: Penumbra Smart Coil™
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: June 10, 2015
Received: June 11, 2015

Dear Mr. DeNault:

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 yours,

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)*
K151572

Device Name
Penumbra Smart Coil

Indications for Use *(Describe)*

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

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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 Penumbra Smart Coil™.

1.1 Sponsor/Applicant Name and Address

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

1.2 Sponsor Contact Information

Charles DeNault
Regulatory Affairs Specialist
Phone: (510) 748-3302
Fax: (510) 217-6414
Email: cdenault@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

July 6, 2015

1.4 Device Trade or Proprietary Name

Penumbra Smart 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 Devices

510(k) Number	Clearance Date	Name of Predicate Device	Name of Manufacturer
K143218	March 18, 2015	Penumbra Smart Coil System	Penumbra, Inc.

1.8 Predicate Comparison

	Penumbra Smart Coil	Penumbra Smart Coil
Classification	Class II, HCG, KRD	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
Materials		
Coil Implant	Platinum/Tungsten, Nitinol, Polymer, Adhesives	Same
Inner Coil	Stainless Steel, Polymer, Platinum/Tungsten, Nitinol	Same
Detachment Handle	Plastic	Same
Dimensions/Shape		
Coil Secondary Diameter	1-18 mm	Same
Coil Length	1-60 cm	Same
Coil Secondary Shape	Complex, Helical (Curve)	Same
Pusher Length	185 cm	Same
Sterilization		
Sterilization Method	EtO	Same

1.9 Device Description

The Smart Coil functions to selectively embolize targeted segments of the vasculature by packing a sufficient quantity of bare platinum coils to achieve occlusion. The Smart Coil System consists of three components: a Coil Implant attached to a Detachment Pusher and a Detachment Handle.

The purpose of this 510(k) pre-market notification is to implement the following modifications to the Instructions for Use (IFU):

- Revise precaution
- Update legal address of manufacturer

1.10 Indications for Use

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

1.11 Summary of Non-Clinical Data

A literature review was conducted to substantiate the safe and effective performance of the Smart Coil and Smart Coil Detachment Handle, as well as its substantial equivalence to the predicate device. Current literature was reviewed in relationship to device precautions. Review concluded that revised labeling is appropriate. Additionally, revised labeling was found to have a safety and effectiveness profile that is similar to the predicate device.

1.12 Summary of Substantial Equivalence

The Penumbra Smart Coil was found to have a safety and effectiveness profile that is similar to the predicate device.

1.13 Conclusion

The non-clinical data supports the safety of the device and the Penumbra Smart Coil should perform as intended in the specified use conditions.