DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 18, 2015

Penumbra, Inc.
% Charles DeNault
Regulatory Affairs Specialist
1351 Harbor Bay Parkway
Alameda, California 94502

Re: K143218
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: January 23, 2015
Received: January 26, 2015

Dear Mr. Charles 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)*
K143218

Device Name
Penumbra Smart Coil

Indications for Use *(Describe)*
The Smart Coil 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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11 510(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™.

11.1 Sponsor/Applicant Name and Address

Penumbra, Inc.
1351 Harbor Bay Parkway
Alameda, CA 94502 USA

11.2 Sponsor Contact Information

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

11.3 Date of Preparation of 510(k) Summary

March 18, 2015

11.4 Device Trade or Proprietary Name

Penumbra Smart Coil™

11.5 Primary Device Classification

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

11.6 Secondary Device Classification

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

11.7 Predicate Devices

510(k) Number	Clearance Date	Name of Predicate Device	Name of Manufacturer
K103305	January 26, 2011	Penumbra Coil System	Penumbra, Inc.
K120330	April 02, 2012	Penumbra Coil System	Penumbra, Inc.

11.8 Predicate Comparison

	Penumbra Coil System	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. Adhesive	Platinum/Tungsten, Nitinol, Polymer, Adhesives
Inner Coil	Stainless Steel, Polymer, Platinum/Tungsten, Nitinol	Same
Detachment Handle	Plastic	Same
Dimensions/Shape		
Coil Secondary Diameter	2-32 mm	1-18 mm
Coil Length	1-60 cm	Same
Coil Secondary Shape	Complex, Helical (Curve), J	Complex, Helical (Curve)
Pusher Length	175 cm	185 cm
Sterilization		
Sterilization Method	EtO	Same

11.9 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 in an identical fashion to the Penumbra Coil System. The Smart Coil System consists of three components: a Coil Implant attached to a Detachment Pusher and a Detachment Handle.

11.10 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

11.11 Summary of Non-Clinical Data

Included in this section is a description of the testing, which substantiates the safe and effective performance of the Smart Coil and Smart Coil Detachment Handle as well as its substantial equivalence to the predicate devices:

- Biocompatibility
- Design Verification (Bench-Top Testing)
- MR Environment
- Sterilization
- Shelf Life

The subject Smart Coil met all predetermined requirements.

11.11.1 Biocompatibility Testing

Non-clinical testing found the Smart Coil and Smart Coil Detachment Handle to be biocompatible according to the requirements of EN ISO 10993mbra Smart Coil should perform as intended in the specified use conditions. requirements. Studies were selected in accordance with EN ISO 10993-1:2009 guidelines (Biological Evaluation of Medical Devices). All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices. The following tests were performed:

Biocompatibility Testing Summary – Coil Implant/Detachment Pusher

Test	Acceptance Criteria	Results	Conclusions
In vitro Cytotoxicity (MEM Elution)	Sample extracts must yield cell lysis grade ≤ 2	Grade: 0	Non-toxic
Sensitization (Magnusson-Kligman Method)	Test Group shall yield Grade < 1 score on Magnusson and Kligman scale (provided Control Grade < 1)	Grade: 0 (No Sensitization response)	Non-sensitizing
Irritation (Intracutaneous Reactivity (ISO))	The difference in the mean test article and mean control score must be grade 1.0 or lower	Grade 0.0 difference (saline extract) and Grade 0.2 difference (sesame oil extract)	Non-irritant
Implant Study			

Test	Acceptance Criteria	Results	Conclusions
Implant Study	Overall interpretation of biocompatibility exhibited by the test article based on the clinical observations, and gross and microscopic analysis comparing the test article to the control, shall show the test article to be a non-irritant.	Test article is considered a non-irritant	Non-irritant
Systemic Toxicity (Acute)			
Systemic Injection (ISO)	Sample extracts must not cause significant biological reaction greater than control. That is: • Death in 2 or more animals • Toxic signs (i.e. convulsions, prostration) • Weight loss > 10% in 3 or more animals	No evidence of systemic toxicity from sample extracts: • No deaths • No toxic signs • No weight loss > 10% in any animals	Non-toxic
Material Mediated Pyrogen	Sample extracts must not cause a total rise in body temperature of ≥ 0.5° C	Non-pyrogenic: no animals had a temperature rise ≥ 0.5°C	Non-pyrogenic
Sub-Chronic Toxicity (Sub-Acute Toxicity)			
Sub-Chronic/Sub-Acute Toxicity: 14 day / 14 dose IV study (mice)	The following parameters will be used as signs of toxicity; however final evaluation of the test article will involve correlation of all data for patterns of toxicity: • Death of more than one animal in group • Mean body weight change in group relative to control • Clinical signs of toxicity in more than one animal in group • Hematology and clinical chemistry values for animal groups will be reviewed for patterns of toxicity • Histopathology of tissues will be evaluated for patterns of toxicity	Negative for systemic toxicity: • No deaths • No statistically significant differences between the test and control mice body weights • No abnormal clinical signs of toxicity • Hematology showed no findings indicative of a pattern of toxicity • Histopathology showed no adverse findings attributed to the test article	Non-toxic
Hemocompatibility			
Thrombosis (Dog Thrombogenicity)	Device must be non-thrombogenic after 4 hours *in vivo* when compared to a predicate device	Test device was not thrombogenic when compared to the predicate. The device exhibited acceptable interaction with blood	Non-hemolytic
Coagulation (PT)	Coagulation times must be similar to the predicate or negative control values using analysis of variance.	Test article coagulation times are statistically similar to the predicate (p-value=1.000)	

Test	Acceptance Criteria	Results	Conclusions
Coagulation (PTT)	Coagulation times must be similar to the predicate or negative control values using analysis of variance.	Test article coagulation times are statistically similar to the predicate (p-value=0.105)	
Hematology (Hemolysis) – Direct Contact	Sample extracts must be nonhemolytic (≤2% hemolytic index)	Nonhemolytic: Hemolytic index = 1.25% Corrected hemolytic index = 0.40%	
Hematology (Hemolysis) – Indirect Contact	Sample extracts must be nonhemolytic (≤2% hemolytic index)	Nonhemolytic: Hemolytic index = 0.37% Corrected hemolytic index = 0.00%	
Complement Activation	The concentrations of C3a and SC5b-9 in the test samples are statistically similar to or lower than the predicate	Concentrations of test article compared to predicate: C3a = similar at 30, 60, and 90 minutes SC5b-9 = lower at 30 and 60 minutes / similar at 90 minutes	
Genotoxicity			
Ames Mutagenicity	Sample extracts must be non-mutagenic	Non-mutagenic	Non-mutagenic
Mouse Lymphoma	Sample extracts must be non-mutagenic	Non-mutagenic	
In vivo Mouse micronucleus	Sample extracts must be non-mutagenic	Non-mutagenic	

Biocompatiblity Testing Summary – Detachment Handle

Test	Acceptance Criteria	Results	Conclusion
In vitro Cytotoxicity (MEM Elution)	Sample extracts must yield cell lysis grade ≤ 2	Grade: 0	Non-toxic
Sensitization (Magnusson-Kligman Method)	Test Group shall yield Grade < 1 score on Magnusson and Kligman scale (provided Control Grade < 1)	Grade: 0 (No Sensitization response)	Non-sensitizing
Irritation (Intracutaneous Reactivity (ISO))	The difference in the mean test article and mean control score must be grade 1.0 or lower	Grade 0.0 difference (saline extract) and Grade 0.2 difference (sesame oil extract)	Non-irritant

11.11.2 Bench-top Testing

The physical, mechanical and performance testing of the Smart Coil components demonstrate that the devices are substantially equivalent to the currently marketed predicate devices.

Design Verification testing was conducted to evaluate the physical and mechanical properties of Smart Coil components. The tests performed on the Smart Coil and Smart Coil Detachment Handle components included:

Attribute	Specification	Results
Dimensional / Visual Inspection	These evaluations confirm that the units used in this Design Verification testing meet all inspection criteria for release of finished goods (clinically acceptable) product.	Pass
Simulated Use/Detachment Reliability	These evaluations confirm that the units used in this Design Verification testing meet all inspection criteria for release of finished goods (clinically acceptable) product.	Pass
Fatigue Testing	The Coil Implant shall retain its secondary shape after being cycled into/out of introducer sheath 5 times	Pass
Torsion Resistance	The Coil Implant can be subjected to 8 turns minimum	Pass
Corrosion Resistance	No visible corrosion after testing	Pass
Friction Testing	Push/pull friction acceptable through a 0.0165 in. ID microcatheter	Pass
Distal System Tensile Test	Coil Implant and Detachment Pusher joints has sufficient tensile strength	Pass
Coil Dimensional Inspection (after simulated use testing)	These evaluations confirm that the units used in this Design Verification testing withstood the simulated use testing	Pass
Distal System Tensile Test	Coil Implant and Detachment Pusher joints has sufficient tensile strength	Pass

All testing met specification. The results of the tests appropriately address the physical and mechanical performance expectations of the device. Based on these overall results, the physical and mechanical properties of the Smart Coil and Smart Coil Detachment Handle are acceptable for the intended use and substantially equivalent to the predicate devices.

11.11.3 Sterilization

The Smart Coil and Smart Coil Detachment Handle were tested to be sterile using identical acceptance criteria and testing methods as the predicate device. Testing was accordance with EN ISO 11135-1:2007.

11.11.4 Shelf Life

The Smart Coil and Smart Coil Detachment Handle were tested to have a minimum one year shelf life using identical acceptance criteria and testing methods as the predicate device. Testing was done in accordance to ASTM D4169:2009 and ASTM F2096:2004.

11.11.5 MR Environment

The Smart Coil was tested in the MR environment to advise the MR Conditional statement in the IFU. Testing was done in accordance to standards ASTM F2182-11, ASTM F2052-06, ASTM F2213-06, and ASTM F2119-07 (R 13).

11.12 Summary of Substantial Equivalence

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

11.13 Conclusion

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