



Food and Drug Administration  
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April 20, 2016

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

Re: K160832  
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: March 24, 2016  
Received: March 25, 2016

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. Peña 

Carlos L. Peña, PhD, MS  
Director  
Division of Neurological  
and Physical Medicine Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K160832

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.

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

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## **1 510(k) Summary, K160832**

(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**

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Regulatory Affairs Specialist III  
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### **1.3 Date of Preparation of 510(k) Summary**

April 19, 2016

### **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	Penumbra, Inc.
K151572	July 10, 2015		

## 1.8 Predicate Comparison

	Predicate: Penumbra Smart Coil	Subject: Penumbra Smart Coil
<b>510(k) No.</b>	K143218, K151572	K160832
<b>Classification</b>	Class II, HCG, KRD	Same
<b>Indications for Use</b>	Indicated for the embolization of: <ul style="list-style-type: none"> <li>• Intracranial aneurysms</li> <li>• Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae</li> <li>• Arterial and venous embolizations in the peripheral vasculature</li> </ul>	Same
<b>Materials</b>		
Coil	Platinum/Tungsten, Nitinol, Polymer, Adhesives	Same
Detachment Pusher	Stainless Steel, Polymer, Platinum/Tungsten, Nitinol	Same
Detachment Handle	Plastic, Stainless Steel	Same
<b>Dimensions/Shape</b>		
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
<b>Other</b>		
Packaging configurations	Individual	Same
Sterilization method	Ethylene oxide (EO)	Same
Shelf life	5 years	Same
Use	Single use, disposable	Same

## 1.9 Device Description

The Smart Coil is an endovascular embolization coil for the treatment of aneurysms or other vascular abnormalities. The Smart Coil functions to selectively embolize targeted segments of the vasculature by packing a sufficient quantity of platinum coils to achieve occlusion. The

Smart Coil consists of three components: a Coil, a Detachment Pusher (attached to Coil), and a Detachment Handle (packaged separately).

The purpose of this 510(k) pre-market notification is to change the detachment pusher pull wire tensile strength specification to a more relevant value as measured in engineering studies to improve device manufacturability.

### **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**

Design Verification testing was repeated for all attributes affected by change to device specifications. Results of testing demonstrate that Smart Coil with modified specification is substantial equivalence to predicate Smart Coil. The following tests were performed and all tests passed successfully:

<b>Test</b>	<b>Summary</b>	<b>Results</b>
Tensile	Minimum break force value measured per specification	Pass
Simulated Use	Simulated use testing of the Smart Coil in an anatomical model which simulated the tortuosity of the neurovasculature. Devices were delivered through the tortuous anatomical model to evaluate the ability of the device to deliver and detach embolic coils.	Pass

### **1.12 Summary of Substantial Equivalence**

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