Penumbra, Inc.
Anush Puvvada
Regulatory Specialist III
One Penumbra Place
Alameda, California 94502

Re:  K192955
  Trade/Device Name:  Penumbra LP Coil System
  Regulation Number:  21 CFR 882.5950
  Regulation Name:  Neurovascular Embolization Device
  Regulatory Class:  Class II
  Product Code:  HCG, KRD
  Dated:  October 18, 2019
  Received:  October 21, 2019

Dear Anush Puvvada:

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. Although this letter refers to your product as a device, please be aware that
some cleared products may instead be combination products. The 510(k) Premarket Notification Database
located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination
product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.


For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Xiaolin Zheng -S

Xiaolin Zheng, Ph.D.
Director (Acting)
DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
Indications for Use

The Penumbra LP 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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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAS Staff@fda.hhs.gov

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of
information unless it displays a currently valid OMB number.*
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 subject Penumbra LP Coil System (herein after referred to as LP Coil).

1.1 Sponsor/Applicant Name and Address

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

1.2 Sponsor Contact Information

    Anush Puvvada
    Regulatory Specialist III
    Tel: (510) 440-5568
    Fax: (510) 217-6414
    E-mail: ypuvvada@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

    October 18, 2019

1.4 Device Trade or Proprietary Name

    Penumbra LP Coil System

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

<table>
<thead>
<tr>
<th>510(k) Number</th>
<th>Clearance Date</th>
<th>Name of Predicate Device</th>
<th>Name of Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Predicate Device</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>K143218</td>
<td>March 18, 2015</td>
<td>Penumbra Smart Coil</td>
<td>Penumbra, Inc.</td>
</tr>
<tr>
<td>K151572</td>
<td>July 10, 2015</td>
<td>Penumbra Smart Coil</td>
<td>Penumbra, Inc.</td>
</tr>
<tr>
<td>K160832</td>
<td>April 20, 2016</td>
<td>Penumbra Smart Coil</td>
<td>Penumbra, Inc.</td>
</tr>
<tr>
<td><strong>Reference Device</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>K173614</td>
<td>April 17, 2018</td>
<td>Penumbra Coil 400</td>
<td>Penumbra, Inc.</td>
</tr>
</tbody>
</table>

## 1.8 Predicate and Reference Device Comparison

<table>
<thead>
<tr>
<th>Attributes</th>
<th>Predicate Device</th>
<th>Reference Device</th>
<th>Subject Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade name</td>
<td>Penumbra Smart</td>
<td>Penumbra Coil 400</td>
<td>LP Coil</td>
</tr>
<tr>
<td>510(k)(s)</td>
<td>K143218, K151572, K160832</td>
<td>K173614</td>
<td>K192955</td>
</tr>
<tr>
<td>Classification</td>
<td>Class II: HCG, KRD</td>
<td>SAME</td>
<td>SAME</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>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</td>
<td>SAME</td>
<td>SAME</td>
</tr>
</tbody>
</table>

| **Coil Materials/Construction** | | | |
| Coil | 92% Platinum/8% Tungsten, 90% Platinum/10% Iridium, Stainless | 92% Platinum/8% Tungsten, Adhesive, Titanium, Polymer | SAME as Reference |
### Attributes

<table>
<thead>
<tr>
<th>Attributes</th>
<th>Predicate Device</th>
<th>Reference Device</th>
<th>Subject Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Steel, Adhesive,</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Titanium, Polymer</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Coil Dimensions/Shape

<table>
<thead>
<tr>
<th></th>
<th>Complex, Helical</th>
<th>Complex, Helical, Finish</th>
<th>Complex, Finish</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coil Secondary Shape</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coil Length</td>
<td>1-60 cm</td>
<td>SAME</td>
<td>SAME</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coil Primary Diameter</td>
<td>0.0105-0.0130 in.</td>
<td>0.020 in.</td>
<td>0.0135 in.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coil Secondary Diameter</td>
<td>1-18 mm</td>
<td>2-40 mm</td>
<td>1-8 mm</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Other

<table>
<thead>
<tr>
<th></th>
<th>EO</th>
<th>SAME</th>
<th>SAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization assurance level (SAL)</td>
<td>≥10⁻⁶</td>
<td>SAME</td>
<td>SAME</td>
</tr>
<tr>
<td>Use</td>
<td>Single Use</td>
<td>SAME</td>
<td>SAME</td>
</tr>
<tr>
<td>Shelf-life (coil implant &amp; detachment pusher)</td>
<td>5 Years</td>
<td>8 Years</td>
<td>SAME as Predicate</td>
</tr>
<tr>
<td>Shelf-life (detachment handle)</td>
<td>5 Years</td>
<td>3 Years</td>
<td>SAME as Predicate</td>
</tr>
<tr>
<td>Device Packaging Materials and Dimensions</td>
<td>As specified in K143218</td>
<td>As described in K173614</td>
<td>SAME as Predicate</td>
</tr>
</tbody>
</table>

### 1.9 Device Description

The LP Coil consists of a Coil Implant attached to a Detachment Pusher, both contained within a Sheath. The Detachment Pusher comprises a shaft with a radiopaque positioning marker, a Distal Detachment Tip (DDT), and a pull wire. A Detachment Handle (packaged separately) is used to detach the Coil Implant from the Detachment Pusher. The LP Coil is designed for endovascular embolization in the neuro and peripheral vasculature. Intended users for this device are physicians who have received appropriate training in interventional radiology. The LP Coil is a line extension to the Penumbra Smart Coil System (hereinafter referred to as Smart Coil) that uses the existing Sheath, Detachment Pusher, and Detachment Handle from the Smart Coil. This line extension includes two configurations:

- Ruby LP
- Finish LP
1.10 Indications For Use

The Penumbra LP 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

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 LP Coil based on a risk analysis of any technological changes compared to the predicate device. Design Verification (Bench-Top Testing and Sterilization Testing) was performed on the subject device as part of the design control activities. The subject device met all established requirements. No new biocompatibility testing was performed due to the same materials of construction between the subject and predicate devices.

1.11.1 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:

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Specification</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensional/Visual Inspection</td>
<td>Confirm the dimensions of the units meet all product specifications.</td>
<td>Pass</td>
</tr>
<tr>
<td>Friction Testing</td>
<td>Push/pull friction acceptable through a 0.0165 in. ID microcatheter</td>
<td>Pass</td>
</tr>
<tr>
<td>Fatigue Resistance</td>
<td>The Coil Implant retains its secondary shape after being cycled into/out of the 0.0165” ID microcatheter 5 times</td>
<td>Pass</td>
</tr>
<tr>
<td>Simulated Use Flow Model Testing</td>
<td>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.</td>
<td>Pass</td>
</tr>
<tr>
<td>Distal System Tensile Test</td>
<td>Minimum per specification</td>
<td>Pass</td>
</tr>
</tbody>
</table>
1.11.2 Sterilization Testing

The LP Coil System was tested to be sterile using identical acceptance criteria and testing methods as the predicate device. Testing was accordance with ISO 11135 and ISO 10993-7.

1.12 Summary of Substantial Equivalence

The subject LP Coil is substantially equivalent to the predicate device Smart Coil. The subject device has identical intended use as the predicate device. The subject and the predicate devices differ slightly in regard 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 regard to operating principle, fundamental technology and device performance.