



April 22, 2020

Penumbra, Inc.  
Micaela Victoria  
Regulatory Specialist III  
One Penumbra Place  
Alameda, California 94502

Re: K200771

Trade/Device Name: Indigo Aspiration System Lightning Aspiration Tubing  
Regulation Number: 21 CFR 870.5150  
Regulation Name: Embolectomy Catheter  
Regulatory Class: Class II  
Product Code: QEW  
Dated: March 24, 2020  
Received: March 25, 2020

Dear Ms. Victoria:

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.

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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Gregory O'Connell  
Assistant Director  
DHT2C: Division of Coronary  
and Peripheral Intervention Devices  
OHT2: Office of Cardiovascular Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K200771

Device Name

Indigo Aspiration System Lightning Aspiration Tubing

Indications for Use (Describe)

**INDIGO Aspiration Catheters and Separators:**

As part of the INDIGO Aspiration System, the INDIGO Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems, and for the treatment of pulmonary embolism.

**INDIGO Aspiration Tubing:**

As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Aspiration Pump.

**Penumbra Aspiration Pump:**

The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.

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**

(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 Indigo<sup>®</sup> System - Lightning Aspiration Tubing.

**1.1 Sponsor/Applicant Name and Address**

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

**1.2 Sponsor Contact Information**

Micaela Victoria  
Regulatory Affairs Specialist III  
Phone: (510) 995-2082  
FAX: (510) 217-6414  
Email: mvictoria2@penumbrainc.com

**1.3 Date of Preparation of 510(k) Summary**

April 16, 2020

**1.4 Device Trade or Proprietary Name**

Indigo<sup>®</sup> Aspiration System Lightning Aspiration Tubing

**1.5 Device Classification**

Regulatory Class: II  
Classification Panel: Cardiovascular  
Classification Name: Catheter, Embolectomy  
Regulation Number: 21 CFR §870.5150  
Product Code: QEW

**1.6 Predicate and Reference Devices**

510(k) Number/Clearance Date	Name of Device	Name of Manufacture
<b>Predicate Device</b>		
K193244 cleared on March 13, 2020	Indigo System – Lightning Aspiration Tubing	Penumbra, Inc. One Penumbra Place Alameda, CA 94502 USA
<b>Reference Device</b>		
K192833 cleared on December 20, 2019	Indigo Aspiration System	Penumbra, Inc. One Penumbra Place Alameda, CA 94502 USA

1.7 Predicate Comparison

System Name	Indigo Aspiration System		
	Predicate Device	Reference Device	Subject Device
<b>510(k) No.</b>	K193244	K192833	To be determined
<b>Classification</b>	QEW	SAME	SAME
<b>Indication for Use</b>	<p>INDIGO Aspiration Catheters and Separators: As part of the INDIGO Aspiration System, the INDIGO Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems.</p> <p>INDIGO Aspiration Tubing: As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Aspiration Pump.</p> <p>Penumbra Aspiration Pump: The Penumbra Aspiration Pump is indicated as a vacuum source for the Penumbra Aspiration Systems.</p>	<p>INDIGO Aspiration Catheters and Separators: As part of the INDIGO Aspiration System, the INDIGO Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems, and for the treatment of pulmonary embolism.</p> <p>INDIGO Aspiration Tubing: As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Aspiration Pump.</p> <p>Penumbra Aspiration Pump: The Penumbra Aspiration Pump is indicated as a vacuum source for the Penumbra Aspiration Systems.</p>	<p>Same as Reference Device (K192833)</p>

System Name	Indigo Aspiration System		
	Predicate Device	Reference Device	Subject Device
<b>Packaging, Materials &amp; Configurations</b>	Commonly utilized for interventional devices	SAME	SAME
<b>Aspiration Source</b>	Penumbra Aspiration Pump	SAME	SAME
<b>Sterilization</b>	EO	SAME	SAME
<b>Shelf-Life</b>	12 Months	36 Months	SAME as Predicate Device (K193244)

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## 1.8 Device Description

The INDIGO<sup>®</sup> Aspiration System is comprised of several devices:

- INDIGO Aspiration Catheter
- Penumbra Aspiration Pump
- INDIGO Aspiration Pump Canister
- INDIGO Aspiration Tubing
- INDIGO Separator<sup>™</sup>

The INDIGO Aspiration System is designed to remove thrombus from the vasculature using mechanical aspiration. The INDIGO Aspiration Catheter targets aspiration from the pump directly to the thrombus. The INDIGO Separator may be used to clear the lumen of the INDIGO Aspiration Catheter should it become blocked with thrombus. The INDIGO Aspiration Catheter is introduced through a guide catheter or vascular sheath and into the peripheral vasculature and guided over a guidewire to the site of the primary occlusion. The INDIGO Aspiration Catheter is used with the Penumbra Aspiration Pump to aspirate thrombus from an occluded vessel. As needed, an INDIGO Separator may be deployed from the INDIGO Aspiration Catheter to assist with thrombus removal. The INDIGO Separator is advanced and retracted through the INDIGO Aspiration Catheter at the proximal margin of the primary occlusion to facilitate clearing of the thrombus from the INDIGO Aspiration Catheter tip. The devices are visible under fluoroscopy. For the aspiration source, the INDIGO Aspiration Catheter is used in conjunction with the Penumbra Aspiration Pump, which is connected using the INDIGO Aspiration Tubing and the INDIGO Aspiration Pump Canister. The INDIGO Aspiration Catheter may be provided with a steam shaping mandrel, rotating hemostasis valve, and introducer. The INDIGO Separator may be provided with an introducer and torque device.

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## 1.9 Indications for Use

INDIGO Aspiration Catheters and Separators:

As part of the INDIGO Aspiration System, the INDIGO Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems, and for the treatment of pulmonary embolism.

INDIGO Aspiration Tubing:

As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Aspiration Pump.

Penumbra Aspiration Pump:

The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.

## 1.10 Summary of Non-Clinical Data

The subject and predicate Indigo System devices are identical. Therefore, previous device performance data regarding substantial equivalence described below remain unchanged.

### 1.10.1 Summary of Biocompatibility

There are no changes to the previously provided biocompatibility data of the Indigo System Lightning Aspiration Tubing sterile device materials cleared in K193244 (predicate device).

### 1.10.2 Summary of Performance Testing - Bench-Top

There are no changes to the previously provided bench-top data of the devices cleared in K193244 (predicate device).

## 1.11 Summary of Performance Data - Clinical

The predicate, Indigo System, clinical study (EXTRACT-PE) was cleared in K192833 (reference device). The EXTRACT-PE trial demonstrated that the Indigo Aspiration System showed substantially equivalent safety and effectiveness outcomes for acute PE. The primary efficacy and safety endpoints were met. No additional clinical data is required or was performed for these devices.

## 1.12 Summary of Shelf-Life

There are no changes to the previously provided shelf-life data of the devices cleared in K193244 (predicate device).



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**1.13 Summary of Packaging**

There are no changes to the packaging material listing or the packaging process for the devices cleared in K193244 (predicate device).

**1.14 Summary of Substantial Equivalence**

The subject device is substantially equivalent to the predicate and reference devices, as provided in Section 1.7, with regard to indications, intended use, design, performance, materials, sterilization and packaging.