February 26, 2021

Penumbra, Inc.
Micaela Victoria
Regulatory Specialist III
One Penumbra Place
Alameda, California 94501

Re: K210323
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: February 2, 2021
Received: February 4, 2021

Dear Micaela 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210323

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.

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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® Aspiration System – Lightning™ Aspiration Tubing.

2. Sponsor/Applicant Name and Address

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

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

Date of Preparation: February 25, 2021

3. Subject Device

Indigo® Aspiration System – Lightning™ Aspiration Tubing

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

4. Predicate and Reference Device Information

Primary Predicate:

K193244 – Indigo Aspiration System – Lightning Aspiration Tubing

Reference Devices:

K200771 – Indigo Aspiration System – Lightning Aspiration Tubing

K202821 – Indigo Aspiration System – Indigo Aspiration Catheter 12, Separator 12, and Lightning 12

K180939 (Biocompatibility only) – Indigo Aspiration System

5. Device Description

The INDIGO® Aspiration System is comprised of the several devices:

- INDIGO Aspiration Catheter
- Penumbra Aspiration Pump
- INDIGO Aspiration Pump Canister
- INDIGO Aspiration Tubing
- INDIGO Separator™

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 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.

Lightning Aspiration Tubing

The Lightning Aspiration Tubing is a component to the currently available Indigo Aspiration System. The Lightning Aspiration Tubing facilitates the transfer of vacuum between the INDIGO Aspiration Catheter and the Penumbra Aspiration Pump while providing aspiration. Intended users for this device are physicians who have received appropriate training in surgical procedures and/or interventional techniques. The device is provided sterile, non-pyrogenic, and intended for single use only.

6. 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.

7. Comparison of Technological Characteristics with the Predicate Device

The Indigo Aspiration System – Lightning Aspiration Tubing has similar technological characteristics as its predicate Indigo Aspiration System – Lightning Aspiration Tubing (K193244). Both facilitate the transfer of vacuum between the INDIGO Aspiration Catheter and the Penumbra Aspiration Pump while providing aspiration. Like the predicate device, vacuum is controlled using a flow switch located near the distal end of the Lightning Aspiration Tubing, which operates a solenoid valve on the base unit to obstruct flow and stop vacuum. The subject Lightning Aspiration Tubing has the same intended use, packaging materials, sterilization method, and aspiration source as the predicate Indigo Aspiration System – Lightning Aspiration Tubing.

The Indigo Aspiration System – Lightning Aspiration Tubing is packaged with the Indigo Aspiration Catheter 8 or Aspiration Catheter 12, and catheter accessories.

The subject Indigo Aspiration System – Lightning Aspiration Tubing utilizes a new Male Luer which is made of the same materials used in the predicate device. New materials in the subject Indigo Aspiration System – Lightning Aspiration Tubing have been incorporated to non-patient contacting components. Materials present in patient-contacting components of the Indigo Aspiration System – Lightning Aspiration Tubing are the same as those in the predicate device. Dimensional changes were made to different components of the subject device; however, these changes do not impact the overall dimensions, which remain identical to the predicate device. Hardware updates were made to improve manufacturability. Software updates were made to accommodate changes to hardware; however, the fundamental software function remains unchanged.

8. Performance Data

The following nonclinical performance testing has been conducted, using the established test methods used in the cleared predicate device, to support the substantial equivalence of the Lightning Aspiration Tubing to its predicate device. In all instances, the Lightning Aspiration Tubing met all specifications and testing requirements under the previously established test methods.

- Bench-top performance (design verification) was performed to evaluate the physical and mechanical properties of the subject Indigo Aspiration System – Lightning Aspiration Tubing to demonstrate substantial equivalence to the predicate Indigo Aspiration System – Lightning Aspiration Tubing. Additional testing performed was the same to that performed on the predicate device, including the test methods, specifications and acceptance criteria. The subject Indigo Aspiration System – Lightning Aspiration Tubing met all established requirements.
- Electrical Safety and Suction Equipment Testing completed on the predicate Indigo Aspiration System – Lightning Aspiration Tubing has been leveraged for the subject Indigo Aspiration System – Lightning Aspiration Tubing due to the identical design outputs and substantial equivalence between both devices. Additional testing per IEC 60601-1, IEC 60601-1-2 & -6 has been completed to support all risks associated with the subject Indigo Aspiration System – Lightning Aspiration Tubing and have been fully mitigated. The subject Indigo Aspiration System – Lightning Aspiration Tubing successfully met all applicable requirements under the previously established test methods as evaluated in the predicate Indigo Aspiration System – Lightning Aspiration Tubing.

The subject device utilizes equivalent materials and identical packaging to the predicate device. Therefore, the biocompatibility, sterilization, and packaging characteristics of the predicate device were maintained.

9. Summary of Substantial Equivalence

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

10. Conclusion

The subject device has been evaluated in nonclinical testing in accordance with FDA's recognized standards and pre-established acceptance criteria. Testing demonstrates the device performs as intended. Therefore, the subject Indigo Aspiration System – Lightning Aspiration Tubing is substantially equivalent to the predicate device, Indigo Aspiration System – Lightning Aspiration Tubing (K193244).