February 2, 2024

Penumbra, Inc.
Nikita Patel
Regulatory Specialist II
One Penumbra Place
Alameda, California 94502

Re: K240030
Trade/Device Name: Indigo® Aspiration System - Lightning® Flash
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEW
Dated: January 3, 2024
Received: January 4, 2024

Dear Nikita Patel:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2024.02.02 15:10:18 -05'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240030

Device Name

Indigo® Aspiration System - Lightning® Flash

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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® Flash.

1.1 Sponsor/Applicant Name and Address

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

1.2 Sponsor Contact Information

Nikita Patel
Regulatory Affairs Specialist II
Phone: (408) 823-1820
FAX: (510) 217-6414
Email: npatel@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

February 02, 2024

1.4 Device Trade or Proprietary Name

Indigo® Aspiration System - Lightning® Flash

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 Device

510(k) Number	Name of Device
K222358	Indigo Aspiration System – Lightning Flash Aspiration Tubing

1.7 Predicate Comparison

System Name	**Indigo® Aspiration System**	
	Lightning Flash Aspiration Tubing [Predicate]	**Lightning Flash Aspiration Tubing [Subject]**
Classification	Class II, QEW	**SAME**
510(k) no.	K222358	K240030
Indication	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 the Penumbra Aspiration Systems.	SAME
Aspiration Tubing	**Lightning Flash Aspiration Tubing [Predicate]**	**Lightning Flash Aspiration Tubing [Subject]**
510(k) No.	K222358	K240030
Materials		
Materials	Biocompatible, commonly utilized for interventional devices	SAME
Indigo System Attributes		
Packaging Materials	Commonly used materials for medical devices	SAME
Aspiration Source	Penumbra Aspiration Pump	SAME
Sterilization	EO	SAME
Shelf-Life	36 Months*	SAME
Use	Single use, disposable	SAME

***** Shelf-life was extended from 12 months to 36 months in a letter-to-file change submitted on 23 Jan 2024 for the Lightning Flash system.

1.8 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, Select Catheter, and introducer. The INDIGO Separator may be provided with an introducer and torque device.

<u>Lightning Aspiration Tubing</u>

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.

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

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Penumbra Aspiration Pump

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

1.10 Summary of Non-Clinical Data/Performance Data

Included in this section are summary descriptions of the testing which substantiates the performance of the subject Lightning Flash.

1.10.1 Summary of Performance Testing - (Bench-Top) Testing

Bench-top performance (design verification) was performed to evaluate the subject Indigo Aspiration System – Lightning Flash Aspiration Tubing to demonstrate substantial equivalence to the predicate Indigo Aspiration System – Lightning Flash Aspiration Tubing (K222358). The same Design Verification test methods, specifications, and acceptance criteria were used for the subject device compared to the predicate. In addition, an equivalent test was conducted to verify additional software features. The following tests were performed:

- Dimensional/Visual Inspection
- Performance/Simulated Use Testing
- Tensile Testing
- Indigo Aspiration System Compatibility
- Valve Sense Testing
- Vacuum Testing

The subject Indigo Aspiration System – Lightning Flash Aspiration Tubing met all established requirements.

1.10.2 Summary of Software Testing

Software verification and validation testing and documentation for the Lightning Flash Aspiration Tubing was provided as recommended by FDA's Guidance for Industry and FDA Staff, "*Content of Premarket Submissions for Device Software Functions*" (issued June 14, 2023).

1.10.3 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 K222358 (predicate device).

1.10.4 Summary of Shelf-Life

The shelf-life is 36 months based on accelerated aging data. The same test methods, specifications, and acceptance criteria were used as described in K222358.

1.10.5 Summary of Packaging

There are no changes to the packaging materials, configuration, or the packaging process for the devices cleared in K222358 (predicate device).

1.10.6 Summary of Performance Data - Animal, Clinical

No animal or clinical study was conducted as bench testing was determined sufficient for verification and validation purposes.

1.11 Summary of Substantial Equivalence

The subject Indigo Aspiration System - Lightning Flash is substantially equivalent to the predicate device, Indigo Aspiration System - Lightning Flash with regards to intended use, operating principle, design concept, fundamental technology, and device performance.