October 16, 2025

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

Re: K252612
Trade/Device Name: INDIGO® Aspiration System - Lightning® Flash Aspiration Tubing; INDIGO® Aspiration System - Lightning® Bolt Aspiration Tubing
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEW
Dated: August 18, 2025
Received: August 19, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2025.10.16 10:54:54 -04'00'

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.

510(k) Number *(if known)*
K252612

Device Name
INDIGO® Aspiration System – Lightning® Flash Aspiration Tubing
INDIGO® Aspiration System – Lightning® Bolt 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.

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

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"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."

510(k) Summary

1 Submitter

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

Contact Person:
Nikita Patel
Phone: (408) 823-1820
Email: npatel@penumbrainc.com

Date of Preparation: August 18, 2025

2 Subject Devices

1. Indigo® Aspiration System – Lightning® Flash Aspiration Tubing

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

2. Indigo® Aspiration System – Lightning® Bolt Aspiration Tubing

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

3 Predicate and Reference Devices

510(k) Number	Name of Device
Predicate	
K240030	Indigo® Aspiration System - Lightning® Flash Aspiration Tubing
Reference	
K242075	Indigo® Aspiration System - Lightning® Bolt Aspiration Tubing
K222358	Indigo® Aspiration System - Lightning® Flash
K241399	Indigo® Lightning Flash Aspiration System - Select +™ Catheter
K242520	Element Vascular Access System

4 Predicate/Reference Comparison

System Name	Indigo® Aspiration System			
	Lightning Flash Aspiration Tubing [Predicate]	**Lightning Bolt Aspiration Tubing [Reference]**	**Lightning Flash Aspiration Tubing [Subject]**	**Lightning Bolt Aspiration Tubing [Subject]**
Classification	Class II, QEW	SAME	SAME	
510(k) no.	K240030	K242075	K252612	
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	SAME	

System Name	Indigo® Aspiration System			
	Lightning Flash Aspiration Tubing [Predicate]	**Lightning Bolt Aspiration Tubing [Reference]**	**Lightning Flash Aspiration Tubing [Subject]**	**Lightning Bolt Aspiration Tubing [Subject]**
Materials				
Materials	Biocompatible, commonly utilized for interventional devices	SAME	Mostly the same; differences are supported by bench, biocompatibility, and shelf-life testing	
Dimensions				
Tubing Inner Diameter (ID)	Appropriately sized for Aspiration Catheters		SAME plus larger diameters	
Distal Tubing Outer Diameter (OD)				
Paratubing Outer Diameter (OD)				
Saline/Vent Tubing Outer Diameter (OD)				
Overall Length	100 ± 7 in	114 in ± 7 in	SAME as Reference	
Indigo System Attributes				
Packaging Materials	Commonly used materials for interventional devices	SAME	SAME	
Aspiration Source	Penumbra Aspiration Pump	SAME	SAME	
Sterilization	EO	SAME	SAME	
Shelf-Life	36 Months	SAME	12 Months	
Use	Single use, disposable	SAME	SAME	

5 Device Description

The INDIGO® Aspiration System is comprised of 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 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. 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.

<u>Lightning Flash and Lightning Bolt Aspiration Tubing:</u>

The Lightning Flash and Lightning Bolt Aspiration Tubing (INDIGO Aspiration Tubing) is designed to serve as a conduit to assist in thrombus removal, facilitating the transfer of vacuum between the Penumbra Aspiration Pump and the INDIGO Aspiration Catheter while providing intermittent, continuous, or modulated aspiration. Modulated aspiration is provided when the Lightning Bolt Aspiration Tubing alternates between connecting the

INDIGO Aspiration Catheter to the Penumbra Aspiration Pump and a sterile saline intravenous (IV) bag at ambient pressure.

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 Summary of Non-Clinical Data/ Performance Data

As required under Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, a summary of any information regarding substantial equivalence of the devices follows. Included in this section are summary descriptions of the testing which substantiates the performance of the subject Lightning Flash Aspiration Tubing and Lightning Bolt Aspiration Tubing.

7.1 Design Verification (Bench-Top) Testing

The following tests were performed on the subject devices to determine substantial equivalence:

- Dimensional/Visual Inspection
- Pressurization Testing
- INDIGO Aspiration System Compatibility/Simulated Use Testing
    - Thrombus Removal Testing
- System Durability Testing
- Valve Testing
- Tensile Testing
- Post Destructive Testing Dimensional Inspection

Bench-top tests demonstrate that the subject Indigo® Aspiration System with Lightning Flash Aspiration Tubing and Lightning Bolt Aspiration Tubing met all acceptance criteria and performed similarly to the predicate device. Performance data demonstrate that the subject Lightning Flash Aspiration Tubing and Lightning Bolt Aspiration Tubing devices function as intended and have a safety and effectiveness profile that is similar to the predicate device.

7.2 Biocompatibility

Biocompatibility testing was conducted on the subject devices (i.e., Lightning Bolt Aspiration Tubing as worst case). The following tests were performed:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Hemocompatibility

7.3 Shelf-Life

The shelf-life is 12 months based on accelerated aging data. Similar test methods, specifications, and acceptance criteria were used as described in **K240030** (predicate device).

7.4 Summary of Performance Data – Animal, Clinical

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

7.5 Electrical Safety/EMC Testing

Electrical Safety and EMC testing were conducted on the subject devices. The subject devices comply with the requirements of IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, and AIM 7351731.

7.6 Software

Software verification and validation testing and documentation for the subject Indigo® Aspiration System with Lightning Flash Aspiration Tubing and Lightning Bolt 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).

8 Summary of Substantial Equivalence

The subject Indigo® Aspiration System with Lightning Flash Aspiration Tubing and Lightning Bolt Aspiration Tubing are substantially equivalent to the predicate device, provided in **Section 3** with regards to intended use, operating principle, design concept, materials, sterilization processes and packaging processes.