



February 5, 2026

Penumbra, Inc.
Deanna Kimlinger
Regulatory Affairs Program Manager
One Penumbra Place
Alameda, California 94502

Re: K251949

Trade/Device Name: INDIGO® Aspiration System - Lightning Flash Aspiration Tubing with LINK
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: January 2, 2026
Received: January 5, 2026

Dear Deanna Kimlinger:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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
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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)

K251949

Device Name

INDIGO® Aspiration System - Lightning Flash Aspiration Tubing with LINK

Indications for Use (Describe)

INDIGO Aspiration Catheters and Separators

As part of the Indigo INDIGO Aspiration System, the Indigo 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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510(k) Summary

1. Submitter

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

Contact Person:
 Deanna Kimlinger

Email: dkimlinger@penumbrainc.com

Date of Preparation: February 04, 2026

2. Subject Device

INDIGO® Aspiration System - Lightning Flash Aspiration Tubing with LINK

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

3. Predicate/Reference Devices

510(k) Number	Name of Device
Predicate	
K240030	INDIGO® Aspiration System – Lightning® Flash
Reference	
K222358	INDIGO® Aspiration System – Lightning® Flash
K241399	INDIGO® Lightning Flash Aspiration System – Select +™ Catheter
K242520	Element Vascular Access System

4. Predicate Comparison

System Name	INDIGO Aspiration System	SAME
Device Name	Lightning Flash 1.1 Aspiration Tubing [Predicate]	Lightning Flash Aspiration Tubing with LINK [Subject]
510(k) No.	K240030	K251949
Classification	Class II, QEW	SAME
Indication	<p><u>INDIGO Aspiration Catheters and Separators:</u> 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><u>INDIGO Aspiration Tubing:</u> 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><u>Penumbra Aspiration Pump:</u> The Penumbra Aspiration Pump is indicated as a vacuum source for the Penumbra Aspiration Systems.</p>	SAME
Aspiration Tubing	Lightning Flash 1.1 Aspiration Tubing [Predicate]	Lightning Flash Aspiration Tubing with LINK [Subject]
510(k) No.	K240030	K251949
Materials	Biocompatible, commonly utilized for interventional devices	SAME
Aspiration Catheter	Flash Aspiration Catheter	SAME

System Name	INDIGO Aspiration System	SAME
Device Name	Lightning Flash 1.1 Aspiration Tubing [Predicate]	Lightning Flash Aspiration Tubing with LINK [Subject]
Accessories	Introducer Rotating Hemostasis Valve (RHV) Reducer RHV Connector Cap Select Catheter	SAME with the replacement of Introducer and Select Catheter accessories with Element Introducer* and Select+ Catheter**
Packaging Configuration	System Only	SAME
Aspiration Source	Penumbra Aspiration Pump	SAME
Sterilization	EO	SAME
Shelf-Life	36 months	SAME
Use	Single use, disposable	SAME

* K242520

** K241399

5. Summary of Technical Differences between Subject and Predicate

- The subject device includes an alternative internal electrical connector for the solenoid valve and minor dimensional updates to the solenoid valve pinch tubing and proximal tubing (paratubing).
- The subject device includes a modified electrical subsystem with a wireless radio, increased memory on the main PCBA, and an updated power delivery cable to enable optional data transfer. The subject device software was updated only as needed to support these changes.
- The subject device includes BLE and USB connectivity.

6. 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 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.

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.

7. 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.

8. 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 Aspiration Tubing with LINK.

8.1 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 with LINK to demonstrate substantial equivalence to the predicate INDIGO Aspiration System - Lightning Flash Aspiration Tubing (K240030). The same Design Verification test methods, sample sizes, specifications, and acceptance criteria were used for the subject device compared to the predicate. Additional testing was conducted to assess new features. The subject device met all established requirements.

The following Design Verification testing was performed:

- Performance/Simulated Use Testing
- Valve Sense Testing

The following Design Verification testing was leveraged from the predicate device (**K240030**):

- Dimensional/Visual Testing
- System Durability Testing
- Tensile Testing
- Post Destructive Testing Dimensional Inspection

8.2 Summary of Software Testing

Software verification and validation testing and documentation for the subject Lightning Flash Aspiration Tubing with LINK 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).

8.3 Cybersecurity

Cybersecurity documentation has been developed in accordance with FDA Guidance, "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*" (issued September 27, 2023).

8.4 Other Performance Testing

The following testing of the reference devices was used in support of the subject device:

- Biocompatibility
- Shelf life
- Sterilization
- Packaging

8.5 Summary of Performance Data – Animal, Clinical

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

8.6 Electrical Safety/EMC Testing

Electrical, Mechanical, and Thermal (EMT) Testing was performed per IEC 60601-1, IEC 60601-1-2, ISO 10079-1, ISO-10079-4, AIM 7351731, FCC Title 47 CFR Part 15 Subpart B: Unintentional Radiators, and FCC 47 CFR PT 15.247 Spurious Emissions.

9. Summary of Substantial Equivalence

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