April 24, 2026

Penumbra, Inc.
Akshay Kulkarni
Regulatory Specialist III
One Penubra Place
Alameda, CA 94502

Re: K260599
Trade/Device Name: INDIGO® Aspiration System – INDIGO Link
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: February 24, 2026
Received: February 24, 2026

Dear Akshay Kulkarni:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 GREGORY W. O'CONNELL -S
Date: 2026.04.24 07:43:51 -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)*
K260599

Device Name
INDIGO® Aspiration System – INDIGO Link

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 Link
As part of the INDIGO Aspiration System, INDIGO Link is indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial system ≥ 2.5mm in diameter. INDIGO Link is not intended for use in pulmonary arteries, coronaries, or the neurovasculature.

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. Submitter

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

Contact Person:
Akshay Kulkarni
Email: akulkarni@penumbrainc.com

Date of Preparation: April 23, 2026

2. Subject Device

Device Name:	INDIGO® Aspiration System – INDIGO Link
Regulatory Class:	II
Classification Panel:	Cardiovascular
Regulation Name:	Embolectomy Catheter
Regulation Number:	21 CFR §870.5150
Product Code:	QEW

3. Predicate and Reference Devices

	510(k) Number	Name of Device
Predicate	K231022	Pounce™ LP Thrombectomy System
Reference	K190464	Penumbra System® (3D Revascularization Device)

4. Comparison of Technological Characteristics: Predicate / Reference vs Subject

Device Name	Pounce LP Thrombectomy System [Predicate]	Penumbra System – Penumbra 3D Revascularization Device [Reference]	INDIGO Aspiration System – INDIGO Link [Subject]
Classification	Class II, QEW	Class II, NRY	SAME as Predicate
510(k) no.	K231022	K190464	K260599
Indication	The Pounce Thrombectomy System is intended for the non-surgical removal of thrombi and emboli from the peripheral arterial vasculature.	Penumbra Reperfusion Catheters and Separators As part of the Penumbra System, the Reperfusion Catheters and Separators are indicated for use in the	INDIGO Aspiration Catheters and Separators As part of the INDIGO Aspiration System, the INDIGO Aspiration Catheters and Separators are

Device Name	Pounce LP Thrombectomy System [Predicate]	Penumbra System – Penumbra 3D Revascularization Device [Reference]	INDIGO Aspiration System – INDIGO Link [Subject]
	The Pounce LP Thrombectomy System is indicated for use in vessels ranging from 2 mm to 4 mm in diameter.	revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. <u>Penumbra 3D Revascularization Device</u> As part of the Penumbra System, the Penumbra 3D Revascularization Device is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral	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. <u>INDIGO Link</u> As part of the INDIGO Aspiration System, INDIGO Link is indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial system ≥2.5 mm in diameter. INDIGO Link is not intended for use in pulmonary arteries, coronaries, or the neurovasculature. <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. <u>Penumbra Aspiration Pump</u>

Device Name	Pounce LP Thrombectomy System [Predicate]	Penumbra System – Penumbra 3D Revascularization Device [Reference]	INDIGO Aspiration System – INDIGO Link [Subject]
		– M1 and M2 segments) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. <u>Penumbra Aspiration Tubing</u> As part of the Penumbra System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Aspiration Pump. <u>Penumbra Aspiration Pump</u> The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.	The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.
Materials			
Materials	Biocompatible, commonly utilized for interventional devices	Biocompatible, commonly utilized for interventional devices	SAME

Device Name	Pounce LP Thrombectomy System [Predicate]	Penumbra System – Penumbra 3D Revascularization Device [Reference]	INDIGO Aspiration System – INDIGO Link [Subject]
Dimensions			
Distal Device Working Length	Appropriately sized for target vessel	Appropriately sized for target vessel	SAME
Distal Device Outer Diameter			
Delivery Wire Outer Diameter			
Compatible Delivery Catheter Inner Diameter			
Attributes			
Packaging Materials	Commonly used materials for medical devices	Commonly used materials for medical devices	SAME
Sterilization	EO	EO	SAME
Shelf-Life	Unknown	36 months	SAME as Reference
Use	Single use, disposable	Single use, disposable	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 Link
- 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. INDIGO Link is used with INDIGO Aspiration Catheters to facilitate aspiration and removal of the thrombus from peripheral arteries ≥2.5 mm when needed, and is not intended for use in the pulmonary arteries, coronaries, or neurovasculature. Alternatively, an 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, Select Catheter, and introducer. INDIGO Link is provided with an introducer sheath. The INDIGO Separator may be provided with an introducer and torque device.

6. Indications for Use

<u>INDIGO Aspiration Catheters and Separators</u>

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<u>INDIGO Link</u>

As part of the INDIGO Aspiration System, INDIGO Link is indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial system ≥2.5 mm in diameter. INDIGO Link is not intended for use in pulmonary arteries, coronaries, or the neurovasculature.

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. Performance Data

7.1 Summary of Bench Performance Testing

Bench performance (design verification) testing conducted supports the subject device demonstrating substantial equivalence:

- Simulated Use Testing
- Visual Inspection
- Clot Removal Testing
- Coating Integrity Testing

Due to the similarities of the subject device and the reference Penumbra 3D Revascularization Device cleared under K190464, the following bench tests were leveraged from the reference device:

- Dimensional / Visual Inspection
- Radial Pressure Testing
- Simulated Use Testing
- Tensile Testing
- Corrosion Testing
- Particulate Testing
- Kink Resistance Testing
- Torsion Testing
- Device A_f Testing
- Radiopacity Testing
- Coating Integrity Testing
- Clot Removal Testing

All acceptance criteria were met.

7.2 Summary of Biocompatibility

Due to the similarities between the subject device and the reference device, biocompatibility testing was leveraged from the clearance of the reference Penumbra 3D Revascularization Device in K190464 and K162901. Biocompatibility was evaluated in accordance with ISO 10993-1 and the FDA Guidance for Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", for limited exposure (≤24 hours), externally communicating devices with circulating blood contact. All acceptance criteria were met.

7.3 Shelf-Life

The shelf-life is 36 months based on accelerated and real-time aging test data.

7.4 Animal and Clinical Data

Animal and Clinical studies previously conducted for clearance of the Penumbra 3D Revascularization Device in K162901 were leveraged to support substantial equivalence.

8 Summary of Substantial Equivalence

The subject INDIGO Aspiration System – INDIGO Link is substantially equivalent to the predicate Pounce LP Thrombectomy System. The predicate comparison and information in the 510(k) demonstrate that the subject device is substantially equivalent to the predicate device in regard to intended use, operating principle, design concept, fundamental technology, and device performance.