September 3, 2024

Penumbra, Inc.
Samyukta Rangachari
Regulatory Affairs Specialist III
One Penumbra Place
Alameda, California 94502

Re: K242319
Trade/Device Name: Indigo® Aspiration System - Aspiration Catheter 6X
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: August 2, 2024
Received: August 5, 2024

Dear Samyukta Rangachari:

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,

Ariel G. Ash-shakoor -S

Digitally signed by Ariel G. Ash-shakoor -S
Date: 2024.09.03 14:20:05 -04'00'

For

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)*

K242319

Device Name

Indigo® Aspiration System – Aspiration Catheter 6X

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:
Samyukta Rangachari
Regulatory Affairs Specialist III
Phone: (763) 742-9306
Email: srangachari@penumbrainc.com

Date of Preparation: August 29, 2024

2. **Subject Device**

Indigo® Aspiration System – Aspiration Catheter 6X

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	
K192833	Indigo Aspiration System – Aspiration Catheter 5
Reference	
K211654	Penumbra System (Reperfusion Catheter RED 72)
K191946	Penumbra System – MAX Delivery Device

4. Predicate Comparison

System Name	**INDIGO Aspiration System**	**Penumbra System**	**INDIGO Aspiration System**
Device Name	**Indigo Aspiration Catheter 5 [Predicate]**	**Reperfusion Catheter RED 72 [Reference]**	**Indigo Aspiration Catheter 6X [Subject]**
510(k) No.	K192833	K211654	K242319
Classification	Class II, QEW	Class II, NRY	SAME as Predicate
Indication	<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. <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> The Penumbra Aspiration Pump is indicated as a vacuum source for the Penumbra Aspiration Systems.	<u>Penumbra Reperfusion Catheters and Separators</u>: As part of the Penumbra System, the Reperfusion Catheters and Separators are 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 – 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 – M1 and M2 segments) within 8 hours of symptom onset.	SAME as Predicate

System Name	**INDIGO Aspiration System**	**Penumbra System**	**INDIGO Aspiration System**
Device Name	**Indigo Aspiration Catheter 5 [Predicate]**	**Reperfusion Catheter RED 72 [Reference]**	**Indigo Aspiration Catheter 6X [Subject]**
		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.	
Catheter	**Aspiration Catheter 5**	**Reperfusion Catheter RED 72**	**Aspiration Catheter 6X**
Materials	Biocompatible, commonly utilized for interventional devices	Biocompatible, commonly utilized for interventional devices	SAME
Coating	Hydrophilic (proprietary)	Hydrophilic (proprietary)	SAME as Reference
Proximal and Distal OD	Appropriately sized for the target vessel	SAME, with larger diameters and additional effective length offerings	SAME as Reference
Proximal and Distal ID			
Effective Lengths			

System Name	**INDIGO Aspiration System**	**Penumbra System**	**INDIGO Aspiration System**
Device Name	**Indigo Aspiration Catheter 5 [Predicate]**	**Reperfusion Catheter RED 72 [Reference]**	**Indigo Aspiration Catheter 6X [Subject]**
Accessories	Introducer, Shaping Mandrel, RHV	Introducer, Shaping Mandrel, RHV, SENDit Technology (Optional)	Introducer, Shaping Mandrel, RHV, TraX (Optional)
Aspiration Tubing	Modified 110 Aspiration Tubing (**K180939)**	Modified 110 Aspiration Tubing	SAME
Packaging Materials	Commonly used materials for medical devices	Commonly used materials for medical devices	SAME
Aspiration Source	Aspiration Pump	Aspiration Pump	SAME
Sterilization	EO	EO	SAME
Shelf-Life	36 months	12 months	SAME as Reference
Use	Single use, disposable	Single use, disposable	SAME

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. TraX may be used with its prepackaged Aspiration Catheter to facilitate access to 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, introducer, and TraX. TraX compatibility is limited to its prepackaged Aspiration Catheter. The INDIGO Separator may be provided with an introducer and torque device.

6. Indications for Use

<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.

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

Included in this section are summary descriptions of the testing which substantiates the performance of the subject Aspiration Catheter 6X.

7.1 Summary of Performance Testing – (Bench-Top) Testing

The following bench-top performance (design verification) tests were used in support of the subject device to determine substantial equivalence:

- Particulate Testing
- Dimensional/Visual Inspection
- Friction Testing
- Performance/Simulated Use Testing
- Markerband Visibility
- Tensile Testing
- Pressure Testing
- Elongation Testing
- Torsion Testing
- Hub Air Aspiration
- Corrosion Testing

7.2 Summary of Biocompatibility

Biocompatibility was evaluated for the subject device 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. The subject device met all requirements.

7.3 Summary of Shelf-Life

The shelf-life of the subject device is established for 12 months based on accelerated aging data.

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.

8. Summary of Substantial Equivalence

The subject Aspiration Catheter 6X is substantially equivalent to the predicate device, Aspiration Catheter 5, with regards to intended use, operating principle, design concept, fundamental technology, and device performance.