



June 10, 2024

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

Re: K241399

Trade/Device Name: Indigo® Lightning Flash Aspiration System - Select +™ Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: May 15, 2024
Received: May 16, 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.

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-
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Digitally signed by Ariel G.
Ash-shakoor -S
Date: 2024.06.10 13:58:53
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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

Indications for Use

510(k) Number (if known)

K241399

Device Name

Indigo® Lightning Flash Aspiration System – Select +™ Catheter

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 the 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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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:
June 07, 2024

2. Subject Device

Indigo® Lightning Flash Aspiration System – Select +™ Catheter

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	
K222358	Indigo Aspiration System – Lightning Flash Select Catheter
Reference	
K111380	Neuron Max System – Select Catheter

4. Predicate Comparison

System Name	Indigo Lightning Flash Aspiration System	
	Select Catheter [Predicate]	Select+ Catheter [Subject]
Classification	Class II, QEW	SAME
510(k) no.	K222358	K241399
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
Dimensions and Construction		
Tip Shape	H1 Shape Berenstein Shape	SAME
OD [Max]	Appropriately sized for the introduction of interventional devices into the target vessel	SAME with increased OD on the distal shaft and shorter working section length appropriately sized for introduction of Flash Aspiration Catheter into the target vessel
ID [Max]		
Working Section Length		

System Name	Indigo Lightning Flash Aspiration System	
	Select Catheter [Predicate]	Select+ Catheter [Subject]
Effective Length		SAME
Materials		
Materials	Biocompatible, commonly utilized for interventional devices	SAME
Indigo Aspiration System Attributes		
Aspiration Catheter	Flash Aspiration Catheter	SAME
Accessories	Introducer Rotating Hemostasis Valve (RHV) Reducer RHV Connector Cap Select Catheter	SAME, with Select+ Catheter
Packaging Materials	Commonly used materials for medical devices	SAME
Aspiration Source	Penumbra Aspiration Pump	SAME
Sterilization	Ethylene Oxide (EO)	SAME
Shelf Life	36 months	12 months
Use	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. 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.

Select+ Catheter

The Select+ Catheter is an accessory within kitted configurations of the INDIGO Lightning Flash Aspiration System. The Select+ Catheter is used to aide in access to the site of occlusion and is removed prior to initiating aspiration with the aspiration catheter. The use of the Select+ Catheter to facilitate access to the site of the occlusion is an optional procedural step for INDIGO Lightning Flash Aspiration Catheters. Intended users for this device are physicians who have received appropriate training in interventional techniques.

The device is provided sterile and intended for single use only.

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

Included in this section are summary descriptions of the testing which substantiates the performance of the subject Select+ Catheter.

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

Bench-top performance (design verification) was performed to evaluate the subject Select+ Catheter to demonstrate substantial equivalence to the predicate Lightning Flash Select Catheter (K222358). The same Design Verification test methods, specifications, and acceptance criteria were used for the subject device compared to the predicate.

The following tests were performed:

- Dimensional/Visual Inspection
- Performance/Simulated Use and Torsion Testing
- Radiopacity Testing
- Friction Testing
- Hub Air Aspiration
- Pressure Testing
- Tensile Testing
- Elongation Testing

- Corrosion Testing

The subject Select+ Catheter met all established requirements.

7.2 Summary of Biocompatibility

Biocompatibility testing was leveraged for the subject Select+ Catheter (K111380).

7.3 Summary of Shelf-Life

The shelf-life is 12 months based on accelerated aging data. The same test methods, specifications, and acceptance criteria were used as described in K222358.

7.4 Summary of Packaging

There are no changes to the packaging materials, or packaging configuration compared to the devices cleared in K222358 (predicate device). Packaging testing of the predicate device was used in support of the subject device.

7.5 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. Summary of Substantial Equivalence

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