January 30, 2023

Penumbra, Inc.
Deanna Kimlinger
Senior Regulatory Specialist
One Penumbra Place
Alameda, California 95132

Re: K222358
Trade/Device Name: Indigo® Aspiration System – Lightning® Flash
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEW

Dear Deanna Kimlinger:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 20, 2022. Specifically, FDA is updating this SE Letter to correct a typo in the device trade name as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, by phone (301-796-6075), or email (gregory.oconnell@fda.hhs.gov).

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2023.01.30 12:06:11 -05'00'

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

December 20, 2022

Penumbra, Inc.
Deanna Kimlinger
Senior Regulatory Specialist
One Penumbra Place
Alameda, California 95132

Re: K222358
Trade/Device Name: Indigo® Aspiration System - Lighting® Flash
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: November 17, 2022
Received: November 18, 2022

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 2022.12.20 15:45:58 -05'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222358

Device Name
Indigo® Aspiration System – Lightning® Flash

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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

1 510(k) Summary

(as required by 21 CFR 807.92)

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Penumbra, Inc. is providing the summary of Substantial Equivalence for the Indigo® Aspiration System - Lightning® Flash.

1.1 Sponsor/Applicant Name and Address

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

1.2 Sponsor Contact Information

Deanna Kimlinger
Senior Regulatory Affairs Specialist
Phone: (925) 212-9088
FAX: (510) 217-6414
Email: dkimlinger@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

December 20, 2022

1.4 Device Trade or Proprietary Name

Indigo® Aspiration System – Lightning® Flash

1.5 Device Classification

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

1.6 Predicate and Reference Devices – Lightning Flash

510(k) Number		Name of Device
Lightning Flash Aspiration Tubing		
Predicate	K210323	Indigo Aspiration System – Lightning Aspiration Tubing
Reference	K202821	Indigo Aspiration System – Aspiration Catheter 12 and Separator 12
Flash Aspiration Catheter		
Predicate	K192981	Indigo Aspiration System – Aspiration Catheter 12 and Separator 12
Reference	K202821	Indigo Aspiration System – Aspiration Catheter 12 and Separator 12
Reference	K180466	FlowTriever Retrieval/Aspiration System
Select Catheter (Accessory)		
Predicate	K111380	Neuron MAX System

1.7 Predicate Comparison

System Name	**Indigo® Aspiration System**			
	Lightning Aspiration Tubing [Predicate]	**CAT12 & SEP12 [Predicate]**	**CAT12 & SEP12 with PE Treatment Indication [Reference]**	**Lightning Flash [Subject]**
Classification	Class II, QEW	Class II, QEW	Class II, QEW	**SAME**
510(k) no.	**K210323**	**K192981**	**K202821**	K222358
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.	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. 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.	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 AS PREDICATE K210323 and REFERENCE K202821

Aspiration Tubing		**Lightning Aspiration Tubing [Predicate]**	**Lightning Flash Aspiration Tubing [Subject]**
510(k) No.		**K210323**	K222358
Materials			
Materials		Biocompatible, commonly utilized for interventional devices	SAME
Dimensions			
Proximal OD		Appropriately sized for the Aspiration Catheter	SAME plus larger diameters
Proximal ID			
Distal OD			
Distal ID			
Effective Length			
Aspiration Catheter		**Indigo System – CAT12 [Predicate]**	**Indigo System – Flash Aspiration Catheter [Subject]**
510(k) No.		**K192981**	K222358
Materials			
Materials		Biocompatible, commonly utilized for interventional devices	SAME with subset of colorants
Coating		Hydrophilic	SAME
Dimensions			
Proximal OD		Appropriately sized for the target vessel	SAME plus larger diameters
Proximal ID			
Distal OD			
Distal ID			
Effective Length			
Accessories			
Introducer		Sheath: Grilamid	SAME
		ID Band: Polyolefin	SAME
Rotating Hemostasis Valve (RHV)	Materials	Polycarbonate/Silicone/PTFE	Polycarbonate/Silicone/PVC/PTFE/ Polyolefin with foil/Loctite/ Thermoplastic Polymer
	French Size	10F	13F
Select Catheter (Accessory)		**Neuron MAX – 6F Select Catheter [Predicate]**	**Indigo System – Select Catheter [Subject]**
510(k) No.		K111380	K222358
Materials			
Materials		Biocompatible, commonly utilized for interventional devices	SAME

Dimensions		
OD [Maximum] ID [Minimum] Working Length	Appropriately sized for the introduction of interventional devices into the target vessel	SAME plus expanded working length range
Accessories		
Torque Device	Polycarbonate/Brass/Polypropylene	SAME
Packaging Materials	Commonly used materials for medical devices	SAME
Aspiration Source	Penumbra Aspiration Pump	SAME
Sterilization	EO	SAME
Shelf-Life	36 Months	12 Months
Use	Single use, disposable	SAME

1.8 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.

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.

1.9 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.

1.10 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.

1.10.1 Biocompatibility

Biocompatibility testing was conducted on the subject Lightning Flash. Biocompatibility testing was leveraged for the Introducer (K192981) and Select Catheter (K111380) accessories. The following tests were performed:

- Lightning Flash Aspiration Tubing
  - Cytotoxicity
  - Sensitization
  - Irritation
- Flash Aspiration Catheter
  - Cytotoxicity
  - Sensitization
  - Irritation
  - Systemic Toxicity
    - Acute Systemic Injection
    - Material Mediated Pyrogen
  - Hemocompatibility
    - Thrombogenicity
    - Prothrombin Time (PT)
    - Partial Thromboplastin Time (PTT)
    - Complement Activation
    - Direct/Indirect hemolysis
- RHV, Reducer, Connector Cap (Accessories)
  - Cytotoxicity
  - Sensitization
  - Irritation
  - Systemic Toxicity
    - Acute Systemic Injection
    - Material Mediated Pyrogen
  - Hemocompatibility
    - Direct/Indirect hemolysis

The results from the testing performed showed the subject devices to be biocompatible.

1.10.2 Design Verification (Bench-Top) Testing

Non-clinical laboratory testing was performed on the subject Lightning Flash devices to determine substantial equivalence. The following tests were performed:

- Lightning Flash Aspiration Tubing
  - Dimensional/Visual Inspection
  - Performance/Simulated Use Testing
  - Tensile Testing
- Flash Aspiration Catheter and Select Catheter
  - Dimensional/Visual Inspection
  - Friction Testing
  - Performance/Simulated Use and Torsion Testing
  - Vacuum Test

- Indigo Aspiration System Compatibility
- Valve Sense Testing
- Coating Integrity Testing
- Particulate Testing
- Hub Air Aspiration
- Catheter Pressure
- Hub / Shaft Tensile Strength
- Catheter Shaft Tensile
- Elongation to Failure
- Corrosion

The in vitro bench-top tests demonstrated that the subject Lightning Flash met all acceptance criteria and performed similarly to the predicate devices. Performance data demonstrate that the Lightning Flash devices function as intended and does not raise any new questions of safety and effectiveness compared to the predicate devices.

1.10.3 Performance Data – Clinical

No clinical study was conducted as bench and previously performed animal testing was determined sufficient for verification and validation purposes. A review was conducted considering published clinical study articles that featured the predicate device and other devices with similar dimensions used for direct aspiration. The literature review was used to support the determination of substantial equivalence by leveraging clinical outcomes from devices that are considered technologically equivalent.

1.10.4 Electrical Safety/EMC Testing

Electrical Safety and EMC testing were conducted on the Lightning Flash Aspiration Tubing. The subject device complies with the requirements of IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, and ISO 10079-1.

1.10.5 Software

Software verification and validation testing and documentation for the Lightning Flash Aspiration Tubing was provided as recommended by FDA's Guidance for Industry and FDA Staff, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*" (issued May 11, 2005). The software for this device was considered as a Minor Level of Concern.

1.11 Summary of Substantial Equivalence

The subject Indigo Aspiration System - Lightning Flash is substantially equivalent to the predicate devices, provided in **Section 1.6** with regards to intended use, operating principle, design concept, materials, sterilization processes and packaging processes.