March 13, 2020

Penumbra, Inc.
Ms. Micaela Victoria
Regulatory Affairs Specialist III
One Penumbra Place
Alameda, California 94502

Re: K193244
Trade/Device Name: Indigo Aspiration System - Lightning Aspiration Tubing
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: February 11, 2020
Received: February 12, 2020

Dear Ms. Victoria:

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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193244

Device Name
Indigo Aspiration System - Lightning Aspiration Tubing

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.

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.

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 Aspiration Tubing.

1.1 Sponsor/Applicant Name and Address

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

1.2 Sponsor Contact Information

Micaela Victoria
Regulatory Affairs Specialist III
Phone: (510) 995-2082
FAX: (510) 217-6414
Email: mvictoria@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

January 14, 2020

1.4 Device Trade or Proprietary Name

Indigo® Aspiration System – Lightning Aspiration Tubing

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

510(k) Number/Clearance Date	Name of Device	Name of Manufacturer
Predicate Device		
K180939 cleared on May 3, 2018	110 Aspiration Tubing (Modified) – INDIGO Aspiration System	Penumbra, Inc. One Penumbra Place Alameda, CA 94502 USA
Reference Device		
K142870 cleared on May 26, 2015	110 Aspiration Tubing – INDIGO Aspiration System	Penumbra, Inc. One Penumbra Place Alameda, CA 94502 USA

1.7 Predicate Comparison

System Name	INDIGO® Aspiration System		
Device Name	**110 Aspiration Tubing (modified) [Predicate Device]**	**110 Aspiration Tubing [Reference Device]**	**Lightning Aspiration Tubing Subject Device**
510(k) Number	K180939	K142870	TBD
Classification	DXE	SAME	QEW
Indication 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. <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 Penumbra Aspiration Systems.	The Penumbra Embolectomy Aspiration System is intended for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems. Not for use in the coronaries or the neurovasculature.	SAME as Predicate Device
Materials	Biocompatible, commonly utilized for interventional devices	SAME	SAME
Dimensions			
Tubing inner diameter (ID)	0.110 in	SAME as Predicate Device	0.131 in

Tubing outer diameter (OD)	0.188 in	SAME as Predicate Device	0.237 in
Overall Length	100.0 in	112.0 in	SAME as Predicate Device
Distal length	N/A (Single piece construction)	7.9 in	8 in
Packaging Configurations	Individual and Kit	SAME as Predicate Device	Kit only
Packaging Materials	Commonly utilized for interventional devices	SAME	SAME
Aspiration Source	Penumbra Aspiration Pump	SAME	SAME
Sterilization	EO	SAME	SAME
Shelf Life	36 months	SAME as Predicate Device	12 months

1.8 Device Description

The Indigo Aspiration System ("Indigo System") is intended for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems using the Indigo Aspiration Catheter, Indigo Separator, Indigo Aspiration Tubing, and Penumbra Aspiration Pump. The Indigo System was most recently cleared under K180939.

The INDIGO® Aspiration System is comprised of the several devices:

- INDIGO Aspiration Catheter
- Penumbra Aspiration Pump
- INDIGO Pump/Canister Tubing
- 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, 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.

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

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 device follows.

Included in this section are summary descriptions of the testing (or rationale for not testing if not applicable) which substantiates the performance of the subject Indigo Aspiration System – Lightning Aspiration Tubing as well as its substantial equivalence to the predicate device:

- Biocompatibility (Leveraged)
- Design Verification (Bench-Top Testing)
- Shelf Life
- Sterilization
- Packaging
- Software
- Electrical/EMC

The subject Lightning Aspiration Tubing met all established requirements.

1.10.1 Biocompatibility (Leveraged)

Biocompatibility was leveraged for the subject Lightning Aspiration Tubing. The studies were selected in accordance with ISO 10993-1 guidelines (Biological Evaluation of Medical Devices) for a limited exposure (< 24 hours), externally communicating device with circulating blood contact. All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices (GLP).

Biocompatibility Test Summary		
Test	**Method**	**Results**
In Vitro Cytotoxicity	ISO Elution Test (MEM Elution)	Pass Non-Toxic
Sensitization	ISO Maximization Test (Magnusson and Kligman Method)	Pass Non-Sensitizing
Irritation	ISO Intracutaneous Reactivity	Pass Non-Irritant

1.10.2 Design Verification (Bench-Top Testing)

The physical and mechanical properties of the subject Lightning Aspiration Tubing was assessed using standard test methods and pre-determined acceptance criteria. The following tests were performed and all tests passed successfully:

Lightning Aspiration Tubing Design Verification Test Results Summary

Attribute	Specification	Results
Dimensional/Visual Inspection	These evaluations confirm that the units used in this Design Verification testing meet all product specification.	Pass
Simulated Use	Simulated use testing of the Aspiration Tubing was conducted to verify units met specifications	Pass
Tensile Strength	Minimum value per specification	Pass
Indigo Aspiration System Compatibility	Must meet specification	Pass
Lightning Aspiration Tubing Valve Sense Testing	Must meet specification	Pass

1.10.3 Shelf Life

Testing was performed on the subject Lightning Aspiration Tubing to support a 12-month shelf life based on accelerated aging.

1.10.4 Sterilization

The subject Lightning Aspiration Tubing is provided sterile and intended to be single-use. Ethylene Oxide (EO) gas exposure is used to sterilize the subject Lightning Aspiration Tubing accordance with BS EN ISO 11135.

1.10.5 Packaging

Packaging Validation Testing has been completed for the subject Lightning Aspiration Tubing. The subject device met all acceptance criteria.

1.10.6 Software Verification and Validation

Software verification and validation testing and documentation for the Lightning 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.

1.10.7 Electrical Safety/EMC Testing

Electrical Safety and EMC testing were conducted on the Lightning Aspiration Tubing. The subject device complies with the requirements of IEC/EN 60601-1, IEC/EN 60601-1-2, IEC 60601-1-6, and IEC/EN 62366-1

1.10.8 Animal Testing

Animal testing was not required for the determination of substantial equivalence.

1.10.9 Clinical Testing

Clinical testing was not required for the determination of substantial equivalence.

1.11 Summary of Substantial Equivalence

The subject Lightning Aspiration Tubing is substantially equivalent to the predicate device. The subject device has an identical intended use as the predicate device. The subject and the predicate devices differ slightly in regards to minor technological variations, while maintaining the same fundamental scientific technology. However, these differences do not raise different questions of safety and effectiveness.

The device testing described in the 510(k) Summary demonstrate the subject devices are substantially equivalent to the predicate device in regard to intended use, fundamental technology and device performance.