November 18, 2020

Penumbra, Inc.
Michaela Mahl
Senior Manager of Regulatory Affairs
One Penumbra Place
Alameda, California 94502

Re: K202821
Trade/Device Name: Indigo Aspiration System - Aspiration Catheter 12 and Separator 12
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: September 22, 2020
Received: September 24, 2020

Dear Michaela Mahl:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202821

Device Name
Indigo Aspiration System - Aspiration Catheter 12 and Separator 12

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.

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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® System – Aspiration Catheter 12 and Separator 12.

1.1 Sponsor/Applicant Name and Address

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

1.2 Sponsor Contact Information

Michaela Mahl
Senior Manager of Regulatory Affairs
Phone: (510) 748-3288
FAX: (510) 217-6414
Email: mmahl@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

November 18, 2020

1.4 Device Trade or Proprietary Name

Indigo® Aspiration System – Aspiration Catheter 12 and Separator 12

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	Name of Device	Name of Manufacture
Predicate Device		
K192981	Indigo Aspiration System – Aspiration Catheter 12 and Separator 12	Penumbra, Inc.
Reference Device		
K192833	Indigo Aspiration System	Penumbra, Inc.
K180466	FlowTriever Retrieval/Aspiration System	Inari Medical, Inc.

1.7 Predicate Comparison

System Name	Indigo® Aspiration System		
	Predicate Device	**Reference Device**	**Subject Device**
Classification	**Class II, QEW**		SAME
510(k) no.	**K192981**	**K192833**	**K202821**
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. 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 Penumbra Aspiration Systems.	Same as Reference Device K192833
System Components	Reperfusion Catheter, Separator, Aspiration Tubing, Aspiration Source	SAME	SAME
Materials, Packaging & Configurations	Commonly utilized for interventional devices	SAME	SAME
Aspiration Source	Penumbra Aspiration Pump	SAME	SAME
Sterilization	EO	SAME	SAME
Shelf-Life	36 Months	36 Months	SAME

1.8 Device Description

The INDIGO® Aspiration System is comprised of:

- 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 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, and introducer. The INDIGO Separator may be provided with an introducer and torque device.

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

The subject and predicate Indigo System devices are identical. Therefore, previous device performance data regarding substantial equivalence described below remain unchanged.

1.10.1 Summary of Biocompatibility

There are no changes to the previously provided biocompatibility data of the Indigo System – Aspiration Catheter 12 and Separator 12 sterile device materials cleared in K192981 (predicate device).

1.10.2 Summary of Performance Testing - Bench-Top

There are no changes to the previously provided bench-top data of the devices cleared in K192981 (predicate and reference device).

1.11 Summary of Performance Data - Clinical

The Indigo System, clinical study (EXTRACT–PE) was cleared in K192833 (reference device). The EXTRACT-PE trial demonstrated that the Indigo Aspiration System showed substantially equivalent safety and effectiveness outcomes for acute PE. The primary efficacy and safety endpoints were met. No additional clinical study was conducted as bench and previously performed animal testing was determined sufficient for verification and validation purposes. A review of the technological characteristics of the subject and reference device supported leveraging the clinical outcomes of the EXTRACT-PE Clinical study for the subject device.

1.12 Summary of Shelf-Life

There are no changes to the previously provided shelf-life data of the devices cleared in K192981 (predicate device).

1.13 Summary of Packaging

There are no changes to the packaging material listing or the packaging process for the devices cleared in K192981 (predicate device).

1.14 Summary of Substantial Equivalence

The subject device is substantially equivalent to the predicate and reference devices with regard to indications, intended use, design, performance, materials, sterilization, and packaging.