October 4, 2022

Penumbra, Inc.
Sindokht (Sisi) Soltanzadeh
Regulatory Specialist III
One Penumbra Place
Alameda, California 94502

Re: K220683
Trade/Device Name: INDIGO Aspiration System (CAT RX Aspiration Catheter and Separator 4)
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, QEX
Dated: August 30, 2022
Received: August 31, 2022

Dear Sindokht (Sisi) Soltanzadeh:

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 and the limitations described below. 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.

The OHT2: Office of Cardiovascular Devices has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Precautions section of the device's labeling:

1. The safety and effectiveness of this device for use in the treatment of ST-Elevation Myocardial Infarction (STEMI) have not been established. Complications from the use of this device in this

manner could lead to death, permanent impairment, and/or the need for emergency medical intervention.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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 Bram Zuckerman, M.D.
Director
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)*
K220683

Device Name
INDIGO Aspiration System (CAT RX Aspiration Catheter and Separator 4)

Indications for Use *(Describe)*

The INDIGO CAT RX Aspiration Catheters and INDIGO Separator 4
As part of the INDIGO Aspiration System, the INDIGO CAT RX Aspiration Catheters and INDIGO Separator 4 are indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature.

The INDIGO Aspiration Tubing
As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO CAT RX 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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Office of Chief Information Officer
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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."

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 INDIGO Aspiration System (CAT RX Aspiration Catheter and Separator 4).

1.1 Sponsor/Applicant Name and Address

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

1.2 Sponsor Contact Information

Sindokht (Sisi) Soltanzadeh
Regulatory Specialist III
Phone: (269) 330-9520
FAX: (510) 217-6414
Email: ssoltanzadeh@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

September 29, 2022

1.4 Device Trade or Proprietary Name

INDIGO Aspiration System (CAT RX Aspiration Catheter and Separator 4)

1.5 Device Classification

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

1.6 Predicate/Reference Device

510(k) Number	Name of Device
Predicate Device	
K180412	INDIGO Aspiration System (CAT RX Aspiration Catheter and Separator 4) - Penumbra Engine Pump and Canister
Reference Device	
K163618	INDIGO Aspiration System

1.7 Device Description

The INDIGO Aspiration System is comprised of several devices:

- INDIGO CAT RX Aspiration Catheter
- INDIGO Separator 4
- INDIGO Aspiration Tubing
- INDIGO Pump Canister/Tubing
- Penumbra Aspiration Pump

The INDIGO Aspiration System is designed to remove thrombus from the vasculature using continuous aspiration. The INDIGO CAT RX Aspiration Catheter is a dual lumen rapid exchange catheter that targets aspiration from the Pump directly to the thrombus, removing it via the INDIGO Aspiration Tubing and depositing it in the Pump Canister. The INDIGO Separator 4 may be used, if needed, to clear the lumen of the INDIGO CAT RX Aspiration Catheter should it become blocked with thrombus. The INDIGO CAT RX Aspiration Catheter is introduced through a guide catheter or long introducer sheath and into the coronary or peripheral vasculature and guided over a guidewire to the site of the primary occlusion. The INDIGO CAT RX Aspiration Catheter may be provided with a rotating hemostasis valve and a peelable sheath. The INDIGO Separator 4 is provided with an introducer and torque device. The INDIGO CAT RX Aspiration Catheter and INDIGO Separator 4 are visible under fluoroscopy.

1.8 Indications for Use

<u>The INDIGO CAT RX Aspiration Catheters and INDIGO Separator 4</u>

As part of the INDIGO Aspiration System, the INDIGO CAT RX Aspiration Catheters and INDIGO Separator 4 are indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature.

<u>The INDIGO Aspiration Tubing</u>

As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO CAT RX Aspiration Catheters to the Penumbra Aspiration Pump.

Penumbra Aspiration Pump

The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.

1.9 Technological Comparison

The Indigo System subject devices are identical to the predicate device and differ only by the removal of a labeling condition per FDA clearance letter for K163618. The technological characteristics and intended use remain unchanged. There are no changes in the device design, materials, packaging, and sterilization methods. At a high level, the subject and predicate devices are based on the following same technological characteristics:

- Device design and materials – Identical for Indigo System Devices: CAT RX Aspiration Catheters, Separator 4, and Aspiration Tubing
- Packaging materials – Commonly utilized for interventional devices
- Sterilization – Ethylene Oxide (EO)
- Shelf life – There are no changes to the shelf life of the subject devices due the labeling change.
- Single Use, disposable
- Aspiration Source – Penumbra Aspiration Pump

1.10 Performance Data – Non-Clinical

The subject and predicate Indigo System (CAT RX Aspiration Catheter and Separator 4) devices are identical. Therefore, previous device performance data regarding substantial equivalence described below remain unchanged.

1.11 Biocompatibility Testing

There are no changes to the previously provided biocompatibility data of the Indigo System (CAT RX Aspiration Catheter and Separator 4) sterile device materials, which were reviewed and cleared under the premarket notification listed in **Section 1.6**.

1.12 Design Verification – Bench Top Testing

There are no changes to the previously provided bench-top data of the devices, which were reviewed and cleared under the premarket notification listed in **Section 1.6**.

1.13 Shelf-Life

There are no changes to the previously performed shelf-life testing for these devices, which were reviewed and cleared under premarket notification listed in **Section 1.6**.

1.14 Packaging

There are no changes to the previously provided packaging material listing or the packaging process for these devices, which were cleared under the premarket notification listed in **Section 1.6**.

1.15 Design Validation – Animal Study

There are no changes to the previously provided animal testing data of the devices, which were reviewed and cleared under the premarket notification listed in **Section 1.6**.

1.16 Performance Data – Clinical

No clinical study was conducted as previously performed bench and animal testing was determined sufficient for verification and validation purposes for substantial equivalence determination.

1.17 Conclusions

Based on leveraged non-clinical bench testing and a benefit-risk assessment, the subject device is substantially equivalent to the predicate device and does not raise any new questions of safety and effectiveness.