May 3, 2018

Penumbra, Inc.
Mr. Richard Kimura
Senior Regulatory Specialist
One Penumbra Place
Alameda, California 94502

Re: K180939
Trade/Device Name: Indigo Aspiration System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: April 9, 2018
Received: April 10, 2018

Dear Mr. Kimura:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K180939

Device Name
Indigo Aspiration System

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.

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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 Aspiration System® with modified 110 Aspiration Tubing.

1.1 Sponsor/Applicant Name and Address

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

1.2 Sponsor Contact Information

Richard Kimura
Senior Regulatory Affairs Specialist
Phone: (510) 995-2034
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1.3 Date of Preparation of 510(k) Summary

April 9, 2018

1.4 Device Trade or Proprietary Name

Indigo Aspiration System®

1.5 Device Classification

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

1.6 Predicate Device

510(k) Number / Clearance Date	Name of Device	Name of Manufacturer
Predicate Device		
K180105 cleared on March 8, 2018	Indigo Aspiration System	Penumbra, Inc. One Penumbra Place Alameda, CA 94502 USA

1.7 Predicate Comparison

	Predicate Device	Subject Device[1]
Trade Name	Indigo Aspiration System	SAME
510(k) No.	K180105	To Be Determined
Classification	Class II, DXE	SAME
Indication 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.	SAME
Aspiration Tubing		
	Current 110 Aspiration Tubing	**Modified 110 Aspiration Tubing**
Tubing Inner Diameter (ID)	0.110 in	SAME
Tubing Outer Diameter (OD)	0.188 in	SAME
Overall Length	112.0 in	100.0 in
Distal Length	7.0 in	N/A (Single Piece Construction)
Materials	Biocompatible, commonly utilized for interventional devices	SAME
Packaging Configuration	Individually packaged	SAME
Sterilization	EO	SAME
Shelf Life	36 months	SAME

[1] The Indigo System Aspiration Catheters, Separators, and Aspiration Pumps are unchanged and remain identical to those of the currently cleared Indigo System (K180105).

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 K180105.

The Indigo System is designed to remove thrombus from the vasculature using continuous aspiration. The Aspiration Catheter targets aspiration from the Aspiration Pump directly to the thrombus. The Separator may be used to clear the lumen of the Aspiration Catheter should it become blocked with thrombus. The use of the Separator may not be necessary when using an Aspiration Catheter with an I.D. of 0.054in or larger. The Aspiration Catheter is introduced through a guide catheter or long femoral sheath and into the site of the primary occlusion. The Aspiration Catheter is used with the Aspiration Pump to aspirate thrombus from an occluded vessel. As needed, a Separator may be deployed from the Aspiration Catheter to assist with thrombus removal. The Separator is advanced and retracted through the Aspiration Catheter at the proximal margin of the primary occlusion to facilitate clearing of the thrombus from the Aspiration Catheter tip. For the aspiration source, the Aspiration Catheter is used in conjunction with the Aspiration Pump, which is connected using the Aspiration Tubing and Canister. The Aspiration Catheter may be provided with a steam shaping mandrel and rotating hemostasis valve, and a peelable sheath. The Separator is provided with an introducer and torque device. The Aspiration Catheters and Separators are visible under fluoroscopy.

The Indigo Aspiration Tubing

The Indigo Aspiration Tubing connects the Penumbra Aspiration Pump Canister to the Indigo Aspiration Catheter within the sterile field, providing a means for introducing vacuum during procedures. The Aspiration Tubing has a flow switch that allows the physician to start and stop the flow of aspiration. The Aspiration Tubing is available in three inner diameters: 0.071 in [1.80mm] for IST1, 0.088 in [2.24mm] for IST2, and 0.110 in [2.79mm] for IST3 and IST4. The Aspiration Tubing is designed and composed of materials which are commonly used in interventional devices.

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 which substantiates the performance of the subject Indigo System with modified 110 Aspiration Tubing as well as its substantial equivalence to the predicate device:

- Biocompatibility
- Design Verification (Bench-Top Testing)
- Shelf Life
- Sterilization
- Packaging

The subject Indigo System with modified 110 Aspiration Tubing met all established requirements.

1.10.1 Biocompatibility

Biocompatibility testing was performed on the modified 110 Aspiration Tubing and the results are summarized in the table below. The studies were selected in accordance with EN ISO 10993-1 guidelines (Biological Evaluation of Medical Devices) for a limited exposure (≤ 24 hours), surface device, with skin contact. All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices (GLP). The modified 110 Aspiration Tubing met all acceptance criteria and successfully passed all biocompatibility tests per EN ISO 10993-1 guidelines.

Summary of Biocompatibility Testing for Modified 110 Aspiration Tubing

Test / Standard	Acceptance Criteria	Results	Pass / Fail
Cytotoxicity (MEM Elution) / EN ISO 10993-5	Sample extracts must yield a cell lysis grade of 2 or lower	Grade 2: Mild	Pass
Sensitization / EN ISO 10993-10	Test Group shall yield Grade < 1 score on Magnusson and Kligman scale (provided Control Grade < 1)	Grade 0: No visible change	Pass
Irritation (Intracutaneous Reactivity Irritation Test) / EN ISO 10993-10	The difference in the mean test article and mean control score must be grade 1.0 or lower	Grade 0.0 difference (saline extract) and Grade 0.1 difference (sesame oil extract)	Pass

The subject and predicate Indigo System Aspiration Catheters and Separators are identical (most recently cleared under K180105). There are no changes to the materials and processes of the Indigo System Aspiration Catheters and Separators, the biocompatibility data of which were reviewed and cleared under previous premarket notifications for the Indigo System. Therefore, no additional biocompatibility testing is required or was performed for the Indigo System Aspiration Catheters and Separators.

The Penumbra Aspiration Pumps (Pump MAX and Engine Pump) are non-sterile reusable capital equipment and their associated canisters are non-sterile, single use only. The pumps and canisters do not contact the patient, nor are they introduced into the sterile field. As such, biocompatibility testing is not required and was not performed for the Aspiration Pumps and canisters.

1.10.2 Design Verification (Bench-top Testing)

With the exception of the modified flow switch assembly and the single piece of continuous tubing, the modified 110 Aspiration Tubing will have the same specifications as the current 110 Aspiration Tubing. Bench-top testing was conducted to evaluate the physical and mechanical properties of the modified 110 Aspiration Tubing. All bench-top studies were conducted using good scientific practices and statistical sampling methods as required by the Penumbra Design Control procedures. Performance testing was based on the design specifications, risk analysis, performance standards, and guidance documents. All testing was performed using units which were 2x EO-sterilized.

A summary of all testing performed on the modified 110 Aspiration Tubing is provided in the table below. The modified 110 Aspiration Tubing met all acceptance criteria and passed all tests.

Summary of Bench-Top Testing for Modified 110 Aspiration Tubing

Test/ Test Subject	Attribute	Acceptance Criteria	Result
Dimensional/ Visual Inspection	These evaluations confirm that the test units used in Design Verification testing meet all dimensional and visual specifications.	100% Must meet Specification	Pass
Suction Connector / Canister Lid Compatibility	Suction Connector of Aspiration Tubing Assembly securely attaches to Pump Canister lid via press fit.	100% Must meet Specification	Pass
Rotating Luer/ RHV Compatibility	Rotating Luer of Aspiration Tubing Assembly securely connects to RHV port.	100% Must meet Specification	Pass
Aspiration Tubing Lumen Ovalization under Vacuum	Aspiration Tubing Assembly maintains functionality and maintains an open lumen at vacuum pressure per product specification.	100% Must meet Specification	Pass
Aspiration Tubing Joint Leak under Vacuum	Aspiration Tubing Assembly maintains functionality with no leaks at vacuum pressure per product specification.	100% Must meet Specification	Pass
Flow Control Switch Function	Flow Control Switch completely and immediately stops fluid flow after a specified number of ON/OFF cycles.	100% Must meet Specification	Pass
Penumbra Aspiration System Compatibility with Aspiration	The Aspiration Tubing Assembly is compatible with Penumbra Aspiration System (Clot can be removed under minimum vacuum pressure per product specification).	100% Must meet Specification	Pass

Test/ Test Subject	Attribute	Acceptance Criteria	Result
Catheter and Separator			
Penumbra Aspiration System Compatibility with Aspiration Catheter	The Aspiration Tubing Assembly is compatible with Penumbra Aspiration System (Clot can be removed under minimum vacuum pressure per product specification).	100% Must meet Specification	Pass
Suction Connector / Tubing Joint Tensile	Break force per product specification.	100% Must meet Specification	Pass
Rotating Male Luer / Tubing Joint Tensile	Break force per product specification.	100% Must meet Specification	Pass

1.10.3 Shelf Life

The modified 110 Aspiration Tubing has demonstrated device stability for 36 months based on accelerated aging and may be labelled with a 36 month shelf life. Test units were 2x EO-sterilized and underwent transportation conditioning per ASTM D4169, Distribution Cycle 3, Assurance Level 2.

The subject and predicate Indigo System Aspiration Catheters and Separators are identical. Therefore, there are no changes to the previously determined stability of the Aspiration Catheters and Separators, the data for which were reviewed and cleared under previous Indigo System premarket notifications. No additional shelf life testing is required or was performed for the Indigo System Aspiration Catheters and Separators.

The subject and predicate Penumbra Aspiration Pumps (Pump MAX and Engine Pump) and their associated canisters are identical. Furthermore, the Aspiration Pumps are non-sterile reusable capital equipment. Therefore, shelf life testing is not applicable to the Aspiration Pumps. Both the Pump MAX and Engine Pump have established a 500 hour minimum operating life based on completed testing, the data for which were reviewed and cleared under previous Indigo System premarket notifications.

1.10.4 Sterilization

The modified 110 Aspiration Tubing has demonstrated sterility by EO in accordance with EN ISO 11135. All test samples met the acceptance criteria for EO residual testing per EN ISO 10993-7, Comparative Resistance Testing per AAMI TIR 28, and Endotoxin (LAL) Testing per ANSI/AAMI ST72.

The subject and predicate Indigo System Aspiration Catheters and Separators (most recently cleared under K180105) are identical. There are no changes to the previously provided sterilization data of these devices, which were reviewed and cleared under previous Indigo System premarket notifications. No additional sterilization testing is required or was performed for these devices.

Sterilization testing is not applicable to the Penumbra Aspiration Pumps (Pump MAX/Canister Tubing and Engine Pump/Canister). Both are supplied non-sterile and are not intended to be sterilized.

1.10.5 Packaging

The packaging for the modified 110 Aspiration Tubing utilizes materials that are commonly used in other Penumbra device packaging. The modified 110 Aspiration Tubing is placed in a Nylon/ADH/HDPE/ Tyvek® pouch which is heat-sealed to maintain sterility post EO sterilization. The inner pouch is then placed in a display box for further protection. Both the inner pouch and display box receive a product label. An Instruction for Use (IFU) is placed inside the display box of each unit.

The packaging materials and process of the subject and predicate Indigo System Aspiration Catheters, Separators, and Aspiration Pumps (Pump MAX/Canister Tubing and Engine Pump/Canister) are identical (most recently cleared under K180105). There are no changes to the previously provided packaging material listing or the packaging process for these devices, which were reviewed and cleared under previous Indigo System premarket notifications. No additional packaging testing is required or was performed for these devices.

1.11 Summary of Substantial Equivalence

The subject Indigo System with modified 110 Aspiration Tubing is substantially equivalent to the predicate Indigo System with regard to indications, intended use, design, performance, materials, sterilization, and packaging.