DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 24, 2016

Penumbra, Inc.
Mr. Richard Kimura
Regulatory Affairs Specialist
One Penumbra Place
Alameda, CA 94502

Re: K160533
Trade/Device Name: Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System)
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: April 25, 2016
Received: April 29, 2016

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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)*
K160533

Device Name
Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System)

Indications for Use *(Describe)*

INDIGO Aspiration Catheters and Separators:

As part of the Penumbra Embolectomy Aspiration System (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. Not for use in the coronaries or the neurovasculature.

INDIGO Aspiration Tubing:

As part of the Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System), the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Pump MAX.

Penumbra Pump MAX:

The Penumbra Pump MAX 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.

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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 Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System)

1.1 Sponsor/Applicant Name and Address

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

1.2 Sponsor Contact Information

Richard Kimura
Regulatory Affairs Specialist
Phone: (510) 995-2034
FAX: (510) 217-6414
Email: rkimura@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

May 19, 2016

1.4 Device Trade or Proprietary Name

Penumbra Embolectomy Aspiration System (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 and Reference Devices

510(k) Number/ Clearance Date	Name of Device	Name of Manufacturer
Predicate Device		
K142870[26May2015]	Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System)	Penumbra, Inc.
Reference Devices		
K121917[19Sep2012]	Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System)	Penumbra, Inc.
K122756[02Oct2012]	Penumbra Pump MAX	Penumbra, Inc.

1.7 Predicate Comparison

	Predicate Device	Subject Device
Trade Name	Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System)	Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System) (including Penumbra Pump MAX)
Predicate 510(k) No.	INDIGO Aspiration System : K142870	K160533
Reference 510(k) No.	INDIGO Aspiration System: K121917 Penumbra Pump MAX: K122756	
Classification	INDIGO Aspiration System: Class II, DXE Penumbra Pump MAX: Class II, JCX	Class II, DXE
Indication for Use	<u>INDIGO™ Aspiration System</u> The INDIGO™ 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. <u>Penumbra Aspiration Pump</u> The Penumbra Pump MAX is intended for general suction use in hospitals or clinics.	<u>INDIGO Aspiration Catheters and Separators</u> As part of the Penumbra Embolectomy Aspiration System (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. Not for use in the coronaries or the neurovasculature. <u>INDIGO Aspiration Tubing</u> As part of the Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System), the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Pump MAX. <u>Penumbra Pump MAX</u> The Penumbra Pump MAX is indicated as a vacuum source for Penumbra Aspiration Systems.
Aspiration Catheter		
Materials	Biocompatible, commonly utilized for interventional devices	SAME
Coating	Hydrophilic	SAME
Markerband	Radiopaque	SAME
Guidewire compatible	Yes	SAME
Dimensions		
- OD [Maximum]	0.051” – 0.080” [1.295mm – 2.030mm]	SAME
- Working Length	125cm – 153cm	SAME
Separator		

	Predicate Device	Subject Device
Trade Name	Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System)	Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System) (including Penumbra Pump MAX)
Predicate 510(k) No.	INDIGO Aspiration System : K142870	K160533
Reference 510(k) No.	INDIGO Aspiration System: K121917 Penumbra Pump MAX: K122756	
Classification	INDIGO Aspiration System: Class II, DXE Penumbra Pump MAX: Class II, JCX	Class II, DXE
Materials	Biocompatible, commonly utilized for interventional devices	SAME
Dimensions		
- Distal OD	0.022" – 0.045" [0.56mm – 1.14mm]	SAME
- Working Length	135cm – 155cm	SAME
Aspiration Tubing		
Materials	Biocompatible, commonly utilized for interventional devices	SAME
Dimensions		
- ID	0.071" – 0.110 " [1.8mm – 2.8mm]	SAME
- Length	112.0" [284.5cm]	SAME
Sterilization	**EO**	**SAME**
Shelf-Life	**36-Months**	**SAME**
Aspiration Pump		
IEC 60601-1 Compliance	Yes	SAME
IEC 60601-1-2 Compliance	Yes	SAME
Voltage	100-115 Vac/230 Vac	SAME
Frequency	50 Hz/60 Hz	SAME
Sterilization	Non sterile	SAME
Shelf Life	N/A	SAME

1.8 Device Description

The Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System)

The Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System) is intended for the removal of fresh, soft emboli and thrombi from vessels of the arterial and venous systems. The Aspiration Catheter and Separator are available in multiple configurations. The devices are provided sterile, non-pyrogenic, and intended for single use only. Additionally, a pre-packaged configuration (KIT packaging) for the Aspiration

Catheters with Aspiration Tubing is available. Intended users for this device are physicians who have received appropriate training in interventional radiology.

The INDIGO Aspiration System is designed to remove thrombus from the vasculature using continuous 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 use of the INDIGO Separator may not be necessary when using an INDIGO Aspiration Catheter with an I.D. of 0.054in [1.37mm] or larger. The INDIGO Aspiration Catheter is introduced through a guide catheter or long introducer 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 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. For the aspiration source, the INDIGO Aspiration Catheter is used in conjunction with the Aspiration Pump, which is connected using the INDIGO Aspiration Tubing and the INDIGO Pump/Canister Tubing. The INDIGO Separator is provided with an introducer and torque device. The INDIGO Aspiration Catheter is provided with a steam shaping mandrel and rotating hemostasis valve, and a peelable sheath. The INDIGO Separator is provided with an introducer and torque device. The devices are visible under fluoroscopy.

<u>The Penumbra Pump MAX</u>

The Penumbra Pump MAX is the aspiration source for the INDIGO Aspiration System. The Penumbra Pump MAX operates using AC power and is designed to be portable if needed. The Penumbra Pump MAX provides vacuum of up to 29 inHg. The pump is available in both 110Vac and 230Vac versions.

The front face of the Penumbra Pump MAX has a display panel with a vacuum gauge, suction regulating valve, and power switch. The Penumbra Pump MAX connects to the canister reservoir with a tubing assembly (Penumbra Pump/Canister Tubing), which is provided as an accessory. The Penumbra Pump/Canister Tubing consists of a short tubing segment with an inline filter and connectors on each end to facilitate attachment to the pump's vacuum port. The tubing is provided pre-attached to the canister reservoir lid.

The Penumbra Pump/Canister Tubing is provided non-sterile and is used outside the sterile field.

1.9 Indications for Use

INDIGO Aspiration Catheters and Separators

As part of the Penumbra Embolectomy Aspiration System (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. Not for use in the coronaries or the neurovasculature.

INDIGO Aspiration Tubing

As part of the Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System), the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Pump MAX.

Penumbra Pump MAX

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

1.10 Leveraged Non-Clinical Data – Individual Packaged Devices

The subject and predicate devices are identical. There are no changes in the device design, materials, manufacturing, packaging and sterilization methods. Therefore, biocompatibility data, bench top data, sterilization data, and stability data from previous pre-market notifications listed in Section 1.6 are directly applicable and no additional testing was required or was performed to support the consolidation of the INDIGO Aspiration System and Penumbra Pump MAX under the same product code (DXE), clarifications of the Indications for Use statements, and Instructions for Use (IFU) and Operation, Maintenance, and Service Manual revisions.

1.11 Non-Clinical Data – KIT Configuration

Included in this section is a brief summary of additional testing performed for the KIT configuration packaging:

- Packaging Validation Testing

The KIT configuration met all established requirements.

1.11.1 Packaging Validation

The physical and mechanical properties of the KIT configuration were assessed using standard test methods and pre-determined acceptance criteria. The following tests were performed and all tests passed successfully:

Attribute	Specification	Acceptance Criteria	Results
Visual Inspection	These evaluations confirm that the units used in this Design Verification testing meet all inspection criteria for release of finished goods (clinically acceptable) product.		Pass
Simulated Use (Vessel Access Entry Performance & Clot Removal)	Simulated use testing of the Catheter and Separator was performed with accessory devices in an anatomical model which simulated the tortuosity of the vasculature. Devices were delivered through the tortuous anatomical model to evaluate the effectiveness of the devices to remove clots and that the Catheter does not collapse under vacuum.		100% Pass
Catheter Coating	Coating has not delaminated, peeled, or flaked after simulated use.		100% Pass
Gross Leak	Pouch seals, pouch front, and pouch back material do not leak.		100% Pass

The results of the tests appropriately address the physical and mechanical performance expectations of the KIT configuration. Based on these overall results, the physical and mechanical properties of the KIT configuration devices are acceptable for the intended use and substantially equivalent to the predicate device.

1.12 Leveraged Animal Study – Individual Packaged Devices and KIT Configuration

The subject and predicate devices are identical. Therefore, Animal Testing data from previous pre-market notifications listed in Section 1.6 are directly applicable and no further Animal Testing was required or was performed to support the consolidation of the INDIGO Aspiration System and Penumbra Pump MAX under the same product code (DXE), clarifications in the Indications for Use statements, and IFU and Operation, Maintenance, and Service Manual revisions.

1.13 Summary of Substantial Equivalence

The subject INDIGO Aspiration System is substantially equivalent to the predicate devices with regard to intended use, operating principle, design concept, materials, shelf-life, packaging and sterilization processes.