DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 1, 2016

Penumbra, Inc.
Ms. Aditi Kolla
Regulatory Affairs Manager
One Penumbra Place
Alameda, CA 94502

Re: K161523
Trade/Device Name: INDIGO™ Aspiration System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: June 1, 2016
Received: June 2, 2016

Dear Ms. Kolla:

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" (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.

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,

Brian D. Pullin -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)*
K161523

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 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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 subject Separator 8.

1.1 Sponsor/Applicant Name and Address

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

1.2 Sponsor Contact Information

Aditi Kolla
Regulatory Affairs Specialist
Phone: (510) 995-2010
Fax: (510) 217-6414
Email: akolla@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

June 24, 2016

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

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1.6 Predicate and Reference Devices

Predicate Device			
510(k) Number	**Clearance Date**	**Name of Predicate Device**	**Name of Manufacturer**
K160533	May 24, 2016	Separator 8	Penumbra, Inc.
Reference Devices			
510(k) Number	**Clearance Date**	**Name of Predicate Device**	**Name of Manufacturer**
K100826	13 July 2010	PX 400 Microcatheter	Penumbra, Inc.
K082290	31October 2008	Neuron 6F Delivery Catheters 053 and 070	Penumbra, Inc.

1.7 Predicate Comparison

Common Device Name	Penumbra Embolectomy Aspiration System	
Trade Name	INDIGO™ Aspiration System	
510(k) No.	K160533	K161523
Classification	Class II, DXE	Class II, DXE
Intended Use	<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. <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 the Penumbra Aspiration Systems.	Same
Separator	Separator 8	Subject Separator 8 (90 cm, 150 cm)
Materials		
Core Wire	Nitinol	Same
Coating	PTFE	Same
Distal External Coil	Platinum Alloy (92%Pt/8%W)	Same
Tip External Coil	Platinum Alloy (92%Pt/8%W)	Same

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Common Device Name	Penumbra Embolectomy Aspiration System	
Trade Name	INDIGO™ Aspiration System	
510(k) No.	K160533	K161523
Proximal Coil	Stainless Steel 304	Pebax 63D - colorant (green for 90 cm length/orange for 150 cm length)
Solder Joint	Gold Solder [Au/Sn] & Silver Solder [SN/Ag]	Same
Separator Cone Tip	Pebax 40D, Transparent Blue (or) Pebax 35D with 40% Alldyne Tungsten and 5% Titanium Oxide (TiO_2)	Same
Dimensions		
Total Length	150 cm	90 cm, 150 cm
Working Length	96cm	50cm, 96cm
Flex Length	30 cm	20 cm
Cone Shape	teardrop	diamond
Distal Cone OD	0.068″ (1.73mm)	0.072″ (1.83mm)
Center Section OD	0.021″ (0.533mm)	Same
Cone Length	5mm	7mm
Accessories	Torque Device & Introducer Sheath	Same
Packaging Materials & Configuration	Commonly utilized for interventional devices	Same
Aspiration Source	Aspiration Pump	Same
Sterilization	EO	Same
Shelf-Life	36 Months	Same

1.8 Device Description

The INDIGO Aspiration System is comprised of several devices:

- INDIGO Aspiration Catheter
- INDIGO Separator™
- INDIGO Aspiration Tubing
- INDIGO Pump/Canister Tubing
- Penumbra Aspiration Pump

The Aspiration Catheter is introduced through a guide catheter or long femoral sheath and into the peripheral vasculature and guided over a guidewire to the site of the primary occlusion. The INDIGO Aspiration Catheter is used in parallel with the INDIGO Separator and an aspiration source to separate the embolus or thrombus and aspirate it from the occluded vessel. The INDIGO Separator is deployed from the INDIGO Aspiration Catheter. The INDIGO Separator is advanced and retracted through the INDIGO Aspiration Catheter at the proximal margin of the primary occlusion. This facilitates aspiration and debulking of the thrombus and reduces or eliminates the endovascular clot burden. For the aspiration source, the INDIGO Aspiration Catheter is used in conjunction with the Aspiration Pump, which is connected using the INDIGO

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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 devices are visible under fluoroscopy.

1.9 Intended 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 Pump MAX.

Penumbra Pump MAX

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

1.10 Summary of Non-Clinical Data

Included in this section is a description of the testing, which substantiates the substantial equivalence of subject Separator 8 to the predicate device:

- Design Verification (Bench-Top Testing)
- Shelf-life

The subject Separator 8 met all predetermined requirements.

1.10.1 Biocompatibility Testing

Biocompatibility testing previously performed on the predicate and reference devices listed in Section 1.6 substantiate the biocompatibility of the subject Separator 8. Studies were selected in accordance with EN ISO 10993-1 guidelines (Biological Evaluation of Medical Devices). All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices.

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1.10.2 **Bench-top Testing**

Testing was based on the design specifications, risk analysis and available guidance documents. These guidance documents include:

- Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters (FDA – 1995)
- EN ISO 10555-1:2013 - Sterile, single-use intravascular catheters – Part 1: General Requirements

The physical and mechanical properties of subject Separator 8 devices were assessed using standard test methods and pre-determined acceptance criteria. Devices used for mechanical testing were assembled and packaged in the controlled production environment and sterilized twice using an ethylene oxide sterilization cycle. All established acceptance criteria were met. The summary of the testing performed on subject Separator 8 is listed below:

Attribute	Specification	Acceptance Criteria	Results
Dimensional/ 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.		100% Pass
Simulated Use (Peripheral Access, Vessel Access Entry Performance & Clot Removal)	Simulated use testing of the Aspiration Catheter and Separator was performed with accessory devices in an anatomical Vascular Flow model which simulated the tortuosity of the peripheral vasculature. Devices were delivered through the tortuous anatomical model to evaluate the effectiveness of the devices to remove clots and that the Aspiration Catheter does not collapse under vacuum.		100% Pass
Separator Shape	Must be diamond shaped	100% Must meet Specification	100% Pass
Advanced Separator 8 and Wire Joint Break Force	≥ 0.67 lb	100% Must meet Specification	100% Pass
Core Wire PTFE Coating Integrity	Coating has not delaminated, peeled, or flaked	100% Must meet Specification	100% Pass

Attribute	Specification	Acceptance Criteria	Results
	after simulated use		
Particulate Testing with Heparinized Saline (Separator)	The maximum number of particles: ≥ 10 µm will be ≤ 6000 particles ≥ 25 µm will be ≤ 600 particles.	100% Must meet Specification	10µm 100% Pass 25µm 100% Pass
	≥ 75 µm & ≥ 125 µm will be recorded	Data was recorded for informational purposes only	

All testing met specification. The results of the tests appropriately address the physical and mechanical performance expectations of the device. Based on these overall results, the physical and mechanical properties of the subject Separator 8 devices are acceptable for the intended use and substantially equivalent to the predicate device.

1.11 **Sterilization**

The sterilization data from previous pre-market notification listed in Section 1.6 are directly applicable to the subject devices and no additional testing was required or performed. The subject devices were adopted into the existing validated Ethylene Oxide (EO) sterilization cycle as per TIR28, Annex A. Therefore, the subject Separator 8 has proved to be sterile in accordance with EN ISO 11135:2014.

1.12 **Shelf-life**

The subject Separator 8 has proved to have a 36 month shelf-life.

1.13 **Summary of Substantial Equivalence**

The subject Separator 8 device is substantially equivalent to the predicate devices with regard to intended use, operating principle, design concept, materials, shelf-life, packaging and sterilization processes.