DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

May 24, 2017

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

Re: K163618
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 21, 2017
Received: April 24, 2017

Dear Richard 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 and the limitations described below. 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 Office of Device Evaluation 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.

Furthermore, the indication for removal of fresh, soft emboli and thrombi from the coronary vasculature must be prominently displayed in all labeling, including pouch box, and carton

labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

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); 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,

Barbara A. Zimmerman -S
2017.05.24 16:45:39 -04'00'

for William H. Maisel, MD, MPH
Director, Office of Device Evaluation (Acting)
Deputy Director for Science and Chief Scientist
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)*
K163618

Device Name
INDIGO Aspiration System

Indications for Use *(Describe)*

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

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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 the subject CAT RX Aspiration Catheter and 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
Regulatory Affairs Specialist
Phone: (510) 995-2034
Fax: (510) 217-6414
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1.3 Date of Preparation of 510(k) Summary

April 21, 2017

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 Predicate Device	Name of Manufacturer
K161506	September 26, 2016	Penumbra Aspiration System	Penumbra, Inc.

1.7 Predicate Comparison

Common Device Name	Penumbra Aspiration System	
Trade Name	INDIGO Aspiration System	
510(k) No.	K161506	K163618
Classification	Class II, DXE	Class II, DXE
Indication	Penumbra Aspiration Catheters and Separators As part of the Penumbra Aspiration System, the Penumbra Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature. Penumbra Aspiration Tubing As part of the Penumbra Aspiration System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra 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 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. 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.
Catheter	**Aspiration Catheter**	**CAT RX Aspiration Catheter**
Materials	Biocompatible, commonly utilized for interventional devices	Same
Dimensions		
- Distal OD	0.072” max	0.069” max
- Effective Lengths	125, 127, 132 cm	120 – 160cm
Accessories	Torque Device, Introducer Sheath, and Shaping Mandrel	Torque Device and Introducer Sheath
Aspiration Tubing		
Materials	Biocompatible, commonly utilized for interventional devices	Same
Dimensions		
- ID	0.118”	Same
- OD	0.188”	Same
- Length	112.0”	105.0”
Packaging Materials & Configuration	Commonly utilized for interventional devices	Same
Aspiration Source	Penumbra Aspiration Pump	Same
Sterilization	EO	Same

Common Device Name	Penumbra Aspiration System	
Trade Name	INDIGO Aspiration System	
510(k) No.	K161506	K163618
Shelf-Life	36 Months	12 Months

1.8 Device Description

The Penumbra Aspiration System is designed to remove thrombus from the coronary and peripheral vessels by aspirating the proximal side of the thrombus using the Aspiration Catheter, Separator, and Aspiration Tubing. The Penumbra Aspiration System components were originally cleared under K161506.

The Penumbra Aspiration System is designed to remove thrombus from the vasculature using continuous aspiration. The Aspiration Catheter targets aspiration from the 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 Aspiration Catheter is introduced through a guide catheter or long femoral sheath and into the coronary or peripheral vasculature and guided over a guidewire to the site of the primary occlusion. The Aspiration Catheter is used with the Aspiration Pump to aspirate thrombus from an occluded vessel. As needed, the 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 the Pump Canister/Tubing. The Aspiration Catheter is provided with a rotating hemostasis valve and an introducer sheath. The Separator is provided with an introducer and torque device. The Aspiration Catheters and Separators are visible under fluoroscopy.

The CAT RX Aspiration Catheter

The CAT RX Aspiration Catheter is a dual lumen, rapid exchange, intravascular catheter. It is designed and composed of materials common to interventional devices. The distal lumen is PTFE lined and the shaft is reinforced with both nitinol round wire and a flexible laser cut stainless steel hypotube. The shaft has variable stiffness with progressively softer polymer extrusion materials moving distally along its length. The

distal portion of the shaft is hydrophilically coated for lubricity. The distal tip has a radiopaque platinum/iridium markerband.

The CAT RX Aspiration Catheter is available in effective lengths ranging from 120cm to 160cm and is provided sterile for single use. The CAT RX Aspiration Catheter is packaged in a kit with the Aspiration Tubing. The kit also contains a rotating hemostasis valve (RHV) and introducer sheath.

The Aspiration Tubing

The Aspiration Tubing connects the Penumbra Aspiration Pump to the CAT RX Aspiration Catheter within the sterile field. The Aspiration Tubing has a flow valve which connects directly to the CAT RX Aspiration Catheter hub or RHV and allows the physician to start and stop the flow of aspiration. The Aspiration Tubing is provided sterile, and is available either individually packaged or in a kit with the CAT RX Aspiration Catheter.

1.9 Indications For Use

INDIGO CAT RX Aspiration Catheters and INDIGO Separator 4

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

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.

1.10 Summary of Non-Clinical Data

Included in this section is a description of the testing, which substantiates the safe and effective performance of the subject CAT RX Aspiration Catheter and Aspiration Tubing as well as its substantial equivalence to the predicate device:

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

The subject CAT RX Aspiration Catheter and Aspiration Tubing met all predetermined test requirements.

1.10.1 **Biocompatibility Testing**

Biocompatibility testing performed on the proposed CAT RX Aspiration Catheter substantiates the biocompatibility of the CAT RX Aspiration Catheter. 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. The following tests were performed:

Biocompatibility Test Summary		
Test	**Method**	**Results**
In Vitro Cytotoxicity	ISO Elution Test (MEM Extract)	Non-Toxic
Sensitization	ISO Maximization Test for Delayed Hypersenitivity	Non-Sensitizing
Acute Intracutaneous Reactivity (Irritation)	ISO Intracutaneous (Intradermal) Injection Test	Non-Irritant
Acute Systemic Toxicity	ISO Acute Systemic Injection Test	Non-Toxic
Rabbit Pyrogen Study	USP Material-Mediated Rabbit Pyrogen Test	No evidence of material-mediated pyrogenicity
Hemo-compatibility		
In Vitro Hemolysis	ASTM Method (Extraction & Direct Contact)	Non-Hemolytic
In Vitro Coagulation (PT, PTT)	Prothrombin Time (PT) Assay	No Statistical Difference from control
	Partial Thromboplastin Time (PTT) Assay	Non-Thrombogenic
Complement Activation	C3a and SC5b-9 through Enzyme Assay	No greater biological response than corresponding control
Dog Thrombogenicity	Thrombogenicity Study in Dogs - ISO	Non-Thrombogenic

The subject Aspiration Tubing uses identical raw materials and processes/environment as the predicate Aspiration Tubing, therefore biocompatibility of the predicate Aspiration Tubing can be applied to the subject Aspiration Tubing, which can be considered biocompatible for a limited exposure (<24 hours), surface device with skin contact.

1.10.2 **Bench-top Testing**

The physical and mechanical properties of subject CAT RX Aspiration Catheter 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. The subject Aspiration Tubing and predicate Aspiration Tubing are identical with the exception of the presence of a distal tubing section on the predicate Aspiration Tubing. Therefore, previous Design Verification test results for the predicate Aspiration Tubing apply to the subject Aspiration Tubing. The subject Aspiration Tubing was tested for overall length and compatibility with a standard luer connection (RHV).

A summary of the testing performed on subject CAT RX Aspiration Catheter and Aspiration Tubing are provided in the table below:

Test/ Test Subject	Attribute	Sample Size	Acceptance Criteria	Result
Dimensional/ Visual Inspection	These evaluations confirm that the CAT RX Aspiration Catheter and Aspiration Tubing test units used in this Design Verification testing meet all product specifications.			Pass
Simulated Use (Peripheral Access, Vessel Access Entry Performance & Clot Removal)	Simulated use testing of the CAT RX Aspiration Catheter and Aspiration Tubing was performed with accessory devices in an anatomical Vascular Flow model which simulated the tortuosity of the peripheral and coronary vasculature. Devices were delivered through the tortuous anatomical model to evaluate the effectiveness of the devices to track to the target site, to remove clots and that the Aspiration Catheter does not collapse under vacuum.			Pass
CAT RX Aspiration Catheter	Shaft Kink Resistance (distal, midshaft, proximal)	30	No kinking when formed in 5 mm (distal) or 25 mm (midshaft and proximal) radius loop	Pass
	Markerband Visibility	30	Markerband is fluoroscopically visible	Pass
	Particulate Testing (particulates generated in simulated tortuosity, coating integrity and printed band integrity)	10	The maximum number of particles: ≥ 10 µm will be ≤ 6000 particles	Pass

Test/ Test Subject	Attribute	Sample Size	Acceptance Criteria	Result
			≥ 25 µm will be ≤ 600 particles Coating and printed bands have not delaminated, peeled, or flaked prior to and after particulate testing	
	Hub/Air Aspiration	30	No leakage of air when negative pressure is pulled	Pass
	Static Burst Pressure	30	45 psi for 30 sec min	Pass
	Friction	30	1.25 lbf maximum with 6F guide catheter; 0.50 lbf maximum with 0.014" guidewire.	Pass
	Markerband/Distal Guidewire lumen section bond strength	30	0.50 lbf minimum	Pass
	Distal Shaft/Guidewire lumen section 1 bond strength		0.75 lbf minimum	Pass
	Distal Shaft/Guidewire lumen section 2 bond strength		0.75 lbf minimum	Pass
	Midjoint/Proximal Guidewire lumen section bond strength		0.75 lbf minimum	Pass
	Hub/Shaft bond strength		2.0 lbf minimum	Pass
	Elongation to failure	30	≥ 5%	Pass
	Torsion	30	Must rotate at least 2 times prior to failure	Pass
	Corrosion	30	No visible catheter corrosion after ISO corrosion testing	Pass
Aspiration Tubing	Compatibility with RHV (performed as part of Simulated Use)	30	Aspiration Tubing attaches to side port of RHV	Pass

All testing met the acceptance criteria. The results of the tests appropriately address the physical and mechanical performance expectations of the devices. Based on these overall results, the physical and mechanical properties of the subject CAT RX Aspiration Catheter and Aspiration Tubing are acceptable for the intended use and substantially equivalent to the predicate device.

1.10.3 **Sterilization**

The subject CAT RX Aspiration Catheter and Aspiration Tubing have been proven to be sterile in accordance with EN ISO 11135:2014.

1.10.4 **Shelf-life**

The subject CAT RX Aspiration Catheter and Aspiration Tubing have a 12-month shelf life.

1.11 **Summary of Substantial Equivalence**

The subject CAT RX Aspiration Catheter and Aspiration Tubing are substantially equivalent to the predicate Penumbra Aspiration System devices with regard to intended use, operating principle, design concept, materials, shelf-life, packaging and sterilization processes.