May 28, 2020

Penumbra, Inc
Teri Nguyen
Regulatory Affairs Specialist II
One Penumbra Place
Alameda, California 94502

Re: K192981
Trade/Device Name: Indigo System Aspiration Catheter 12, Indigo Aspiration System Separator 12
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEW
Dated: May 15, 2020
Received: May 18, 2020

Dear Teri Nguyen:

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. 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.

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,

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Interventional Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192981

Device Name
Indigo Aspiration System - Aspiration Catheter 12 and Separator 12

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.

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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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 - Aspiration Catheter 12 and Separator 12.

1.1 Sponsor/Applicant Name and Address

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

1.2 Sponsor Contact Information

Teri Nguyen
Regulatory Affairs Specialist II
Phone: (510) 995-2012
FAX: (510) 217-6414
Email: tnguyen2@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

May 22, 2020

1.4 Device Trade or Proprietary Name

Indigo® Aspiration System - Aspiration Catheter 12 and Separator 12

1.5 Device Classification

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

1.6 Predicate and Reference Devices

510(k) Number	Name of Device	Name of Manufacture
Predicate Device		
K142870	Indigo Aspiration System – Aspiration Catheter 8 and Separator 8	Penumbra, Inc.
Reference Device		
K161523	Indigo Aspiration System – Advanced Separator 8	Penumbra, Inc.
K180939	Indigo Aspiration System – Modified Aspiration Tubing	
K180466	FlowTriever Retrieval/Aspiration System	Inari Medical, Inc.

1.7 Predicate Comparison

System Name	**Indigo® Aspiration System**			
	Predicate	**Reference**		**Subject**
Classification	Class II, DXE			QEW
510(k) no.	**K142870**	**K161523**	**K180939**	**K192981**
Indication	The Penumbra Embolectomy Aspiration System (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.	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.	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 AS REFERENCE K180939

Catheter		**CAT8 [Predicate]**	**CAT12 [Subject]**
510(k) No.		**K142870**	**K192981**
Materials			
Materials		Biocompatible, commonly utilized for interventional devices	SAME plus additional material compositions
Coating		Hydrophilic	SAME
Dimensions			
Proximal OD		Appropriately sized for the target vessel	SAME plus larger diameters
Proximal ID			
Distal OD			
Distal ID			
Effective Length			
Accessories			
Introducer		PTFE	Sheath: Grilamid ID Band: Polyolefin
Rotating Hemostasis Valve	Materials	Polycarbonate/Silicone/PTFE	SAME
	French Size	7.5F	10F
Kit Packaging Configuration		Pouch/Tray Retainer/Tray Base/Tray Cover/Aspiration Tubing Kit/Ruler Card/Product Box	SAME
Packaging Materials (Kit Configuration)		Commonly used materials for medical devices	SAME
Separator		**Advanced SEP8 [Reference]**	**SEP12 [Subject]**
510(k) No.		**K161523**	**K192981**
Materials			
Materials		Biocompatible, commonly utilized for interventional devices	SAME plus additional material compositions
Dimensions			
Wire			
OD Center Section		Appropriately sized for the target vessel	SAME
OD Proximal			
Proximal Length			
Working Length			
Total Length			
Cone			
Cone OD		0.072 in (1.82 mm)	0.110 in (2.79 mm)
Cone Shape		Diamond	SAME
Accessories			
Torque Device		Polycarbonate/Brass/Polypropylene	SAME
Introducer Sheath		Stainless Steel with Grilamid	N/A

Packaging Materials	Commonly used materials for medical devices	SAME
Aspiration Source	Penumbra Aspiration Pump	SAME
Sterilization	EO	SAME
Shelf-Life	36 Months	12 Months
Use	Single use, disposable	SAME

1.8 Device Description

The Indigo Aspiration System is intended for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems. The Aspiration Catheter, Separator and Aspiration Tubing are available in multiple configurations. The devices are provided sterile, non-pyrogenic, and intended for single use only. Intended users for this device are physicians who have received appropriate training in interventional techniques.

The INDIGO® Aspiration System is comprised of several devices:

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

The INDIGO Aspiration System is designed to remove thrombus from the vasculature using mechanical 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 INDIGO Aspiration Catheter is introduced through a guide catheter or vascular sheath into the peripheral vasculature and guided over a guidewire to the site of the primary occlusion. The INDIGO Aspiration Catheter is used with the Penumbra 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. The devices are visible under fluoroscopy. For the aspiration source, the INDIGO Aspiration Catheter is used in conjunction with the Penumbra Aspiration Pump, which is connected using the INDIGO Aspiration Tubing and

the INDIGO Aspiration Pump Canister. The INDIGO Aspiration Catheter may be provided with a steam shaping mandrel, rotating hemostasis valve, and introducer. The INDIGO Separator may be provided with an introducer and torque device.

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 (or rationale for not testing if not applicable) which substantiates the performance of the subject Indigo Aspiration Catheter 12 and Separator 12 as well as its substantial equivalence to the predicate device:

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

The subject Indigo Aspiration Catheter 12 and Separator 12 met all established requirements.

1.10.1 Biocompatibility

Biocompatibility was conducted on the subject Indigo Aspiration Catheter 12 and Separator 12. The studies were selected in accordance with ISO 10993-1 guidelines (Biological Evaluation of Medical Devices) for a limited exposure (< 24 hours), externally communicating device with circulating blood contact. All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices (GLP). The following tests were successfully performed:

Tests
In-vitro Cytotoxicity: MEM Elution (10993-5)
Sensitization: Magnusson-Kligman Method (10993-10)
Irritation: Intracutaneous Toxicity (10993-10)
Systemic Toxicity: Acute Systemic Injection (10993-11)
Systemic Toxicity: Material Mediated Pyrogen (10993-11, USP)
Hemocompatibility: *In-vitro* Thrombogenicity (10993-4)
Hemocompatibility: Prothrombin Time (PT) (10993-4)
Hemocompatibility: Partial Thromboplastin Time (PTT) (10993-4)
Hemocompatibility: Complement Activation (10993-4)
Hemocompatibility: (indirect contact) (10993-4)
Hemocompatibility: (direct contact) (10993-4)

In summary, non-clinical testing substantiates that the Indigo Aspiration Catheter 12 and Separator 12 are non-cytotoxic, non-sensitizing, non-irritating, non-toxic, non-pyrogenic, non-hemolytic, and non-thrombogenic.

1.10.2 Design Verification (Bench-top Testing)

The physical and mechanical properties of the subject Aspiration Catheter 12 and Separator 12 devices were assessed using standard test methods and pre-determined acceptance criteria. The following tests were performed:

CAT12 Design Verification Test Results Summary

Attribute	Specification	Results
Dimensional/Visual Inspection	These evaluations confirm that the units used in this Design Verification testing meet all product specification.	Pass
Simulated Use (Peripheral Access, Vessel Access Entry Performance, Delivery/Retrieval & 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.	Pass
Aspiration Catheter/ 12F Sheath compatibility (Friction Force)	Maximum value per specification	Pass
Aspiration Catheter/ 0.038" Guidewire compatibility (Friction Force)	Maximum value per specification	Pass
Coating Integrity (Pre-Inspection/Post-Inspection)	Coating has not delaminated, peeled, or flaked prior to and after simulated use particulate testing.	Pass
Particulate Testing	≥ 10 μm will be ≤ 6000 particles ≥ 25 μm will be ≤ 600 particles	Pass
	≥ 75 μm particles will be recorded for informational purposes only ≥ 125 μm particles will be recorded for informational purposes only	Data was recorded for informational purposes only.
Hub Air Aspiration	No air leaks	Pass
Catheter Pressure (Lumen Burst Pressure)	Minimum value per specification	Pass
Hub / Shaft Tensile Strength	Minimum value per specification	Pass
Catheter Shaft Tensile (all joints)	Minimum value per specification	Pass

Attribute	Specification	Results
Elongation to Failure	Minimum value per specification	Pass
Corrosion	No visible corrosion on Catheter immediately after Corrosion Testing procedure.	Pass

SEP12 Design Verification Test Results Summary

Attribute	Specification	Results
Dimensional/Visual Inspection	These evaluations confirm that the units used in this Design Verification testing meet all product specification.	Pass
Separator Cone Shape	Must be Diamond (Teardrop) shape.	Pass
Coating Integrity (Pre-Inspection/Post-Inspection)	Coating has not delaminated, peeled, or flaked prior to or after simulated use particulate testing.	Pass
Particulate Testing	The maximum number of particles: ≥ 10 μm will be ≤ 6000 particles. ≥ 25 μm will be ≤ 600 particles.	Pass
	≥ 75 μm particles will be recorded for informational purposes only. ≥ 125 μm particles will be recorded for informational purposes only.	Data was recorded for informational purposes only.
Separator 12 Break Force (Cone/Wire)	Minimum value per specification	Pass

1.10.3 Performance Data – Clinical

No clinical study was conducted as bench and previously performed animal testing was determined sufficient for verification and validation purposes. A review was conducted considering published clinical study articles that featured the predicate device and other devices with similar dimensions used for direct aspiration. The literature review was used to support the determination of substantial equivalence by leveraging clinical outcomes from devices that are considered technologically equivalent.

1.10.4 Shelf Life

Testing was performed on the subject Aspiration Catheter 12 and Separator 12 to support a 12-month shelf life based on accelerated aging.

1.10.5 Sterilization

The subject Aspiration Catheter 12 and Separator 12 are provided sterile and intended to be single-use. Ethylene Oxide (EO) gas exposure is used to sterilize the subject Aspiration Catheter 12 and Separator 12 in accordance with BS EN ISO 11135.

1.10.6 Packaging

Packaging Validation Testing has been completed for the subject Indigo System Aspiration Catheter 12 and Separator 12. The subject devices met all acceptance criteria.

1.11 Summary of Substantial Equivalence

The subject Indigo System Aspiration Catheter 12 and Separator 12 are substantially equivalent to the predicate devices, provided in Section 1.6 with regards to intended use, operating principle, design concept, materials, sterilization processes and packaging processes.