



May 15, 2018

Penumbra, Inc.
Michaela Mahl
Senior Manager of Regulatory Affairs
One Penumbra Place
Alameda, California 94502

Re: K180412

Trade/Device Name: Indigo Aspiration System (CAT RX and Separator 4) - Penumbra Engine Pump
and Canister
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: DXE
Dated: March 14, 2018
Received: March 15, 2018

Dear Michaela Mahl:

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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

for
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K180412

Device Name

Indigo Aspiration System (CAT RX Aspiration Catheter and Separator 4) - Penumbra Engine Pump and Canister

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.

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1 510(k) Summary (K180412)

(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® (CAT RX and Separator 4) - Penumbra Engine™ Pump and Canister.

1.1 Sponsor/Applicant Name and Address

Penumbra, Inc.
One Penumbra Place
Alameda, CA 94502 USA
Phone: (510) 748-3200

1.2 Sponsor Contact Information

Michaela Mahl
Senior Manager of Regulatory Affairs
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Email: mmahl@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

May 14, 2018

1.4 Device Trade or Proprietary Name

Indigo Aspiration System® (CAT RX and Separator 4) - Penumbra Engine™ Pump and Canister

1.5 Device Classification

Regulatory Class: II
Classification Panel: Cardiovascular
Classification Name: Catheter, Embolectomy
Common Name: Embolectomy Aspiration System
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		
K163618 cleared on May 24, 2017	Indigo Aspiration System (CAT RX Aspiration Catheter and Separator 4)	Penumbra, Inc. One Penumbra Place Alameda, CA 94502 USA

510(k) Number / Clearance Date	Name of Device	Name of Manufacturer
Reference Device		
K122756 cleared on October 2, 2012	Penumbra Pump MAX	Penumbra, Inc. One Penumbra Place Alameda, CA 94502 USA

1.7 Predicate Comparison

	Predicate Device	Subject Device
Trade Name	Indigo System (CAT RX and Separator 4) (with Penumbra Pump MAX and Canister)	Indigo System (CAT RX and Separator 4) (with Penumbra Engine Pump and Canister)
510(k) No.	K163618	K180412
Classification	Class II, DXE	SAME
Indication for Use	<u>INDIGO CAT RX Aspiration Catheters and INDIGO Separator 4</u> 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. <u>INDIGO Aspiration Tubing</u> 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. <u>Penumbra Aspiration Pump</u> The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.	SAME
Aspiration Pump		
Trade Name	Penumbra Pump MAX and Canister	Penumbra Engine Pump and Canister
IEC 60601-1 Compliance	Yes	SAME
IEC 60601-1-2 Compliance	Yes	SAME
Voltage	100-115 Vac/230 Vac	100-240 Vac
Frequency	50 Hz/60 Hz	SAME
Sterilization	Non sterile	SAME
Shelf Life	N/A	SAME

	Predicate Device	Subject Device
Trade Name	Indigo System (CAT RX and Separator 4) (with Penumbra Pump MAX and Canister)	Indigo System (CAT RX and Separator 4) (with Penumbra Engine Pump and Canister)
510(k) No.	K163618	K180412
Classification	Class II, DXE	SAME
The Aspiration Catheters, Separators, and Aspiration Tubings are unchanged and remain identical (including all labelling) to those of the currently cleared Indigo System (CAT RX and Separator 4) (K163618).		

1.8 Device Description

The Indigo System (CAT RX and Separator 4) is designed to remove thrombus from the coronary and peripheral vessels by aspirating the proximal side of the thrombus. The intended users for this device are physicians who have received appropriate training in interventional techniques. The Indigo System (CAT RX and Separator 4) was most recently cleared under K163618.

The Indigo System (CAT RX and Separator 4) is designed to remove thrombus from the vasculature using continuous aspiration. The INDIGO CAT RX Aspiration Catheter is a dual lumen rapid exchange catheter that targets aspiration from the Pump directly to the thrombus, removing it via the INDIGO Aspiration Tubing and depositing it in the Pump Canister. The INDIGO Separator 4 may be used, if needed, to clear the lumen of the INDIGO CAT RX Aspiration Catheter should it become blocked with thrombus. The INDIGO CAT RX Aspiration Catheter is introduced through a guide catheter or long introducer sheath and into the coronary or peripheral vasculature and guided over a guidewire to the site of the primary occlusion. The INDIGO CAT RX Aspiration Catheter may be provided with a rotating hemostasis valve and a peelable sheath. The INDIGO Separator 4 is provided with an introducer and torque device. The INDIGO CAT RX Aspiration Catheter and INDIGO Separator 4 are visible under fluoroscopy.

The Penumbra Engine Pump and Canister

The Penumbra Engine Pump (“Engine Pump”) is an electromechanical device designed to create vacuum pressure for use with the Indigo System (CAT RX and Separator 4). The

Engine Pump maintains vacuum pressure for 3 hours of continuous use and has an operating life of ≥ 500 hours. The pump can be used in environments with 100 – 240 Vac and 50/60 Hz. The Engine Pump is intended for use in operating rooms or interventional catheterizations laboratories. The Engine Pump and Canister do not come into contact with the patient. The Engine Pump Canister is a 1000 mL minimum volume reservoir which is an accessory to the Engine Pump. The Canister has a lid with a stop-flow filter to prevent excess fluid from entering the pump. The patient port on the lid is sized to accept the Suction Connector on the Indigo Aspiration Tubing.

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

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 to the Engine Pump and Canister) which substantiates the performance of the subject Indigo System (CAT RX and Separator 4) with Engine Pump and Canister as well as its substantial equivalence to the predicate device:

- Biocompatibility
- Design Verification (Bench-Top Testing and Electrical Safety/EMC Testing)
- Shelf Life
- Sterilization
- Packaging

The subject Indigo System (CAT RX and Separator 4) with Engine Pump and Canister met all established requirements.

1.10.1 Biocompatibility

The subject and predicate Indigo System (CAT RX and Separator 4) sterile devices are identical. There are no changes to the previously provided biocompatibility data of the Indigo System (CAT RX and Separator 4) materials sterile devices, which were reviewed and cleared under K163618. No additional biocompatibility testing is required or was performed for the Indigo System (CAT RX and Separator 4) sterile devices.

The Indigo System (CAT RX and Separator 4) Engine Pump is a non-sterile reusable piece of capital equipment. The pump does not contact the patient, nor is it introduced into the sterile field. As such, biocompatibility testing is not required and was not performed for the pump. The Indigo System (CAT RX and Separator 4) Engine Pump Canister also does not contact the patient, nor is it introduced into the sterile field. Furthermore, blood or body fluids collected in the canister are not re-introduced to the patient. As such, biocompatibility testing is not required and was not performed for the Canister.

1.10.2 Design Verification (Bench-top Testing and Electrical Safety/EMC Testing)

The subject and predicate Indigo System (CAT RX and Separator 4) sterile devices are identical. There are no changes to the design specifications and performance characteristics of the Indigo System (CAT RX and Separator 4) sterile devices. Therefore, all previous bench-top testing data which were reviewed and cleared under K163618 continue to support the subject Indigo System (CAT RX and Separator 4) sterile devices. No additional bench-top testing is required or was performed for the Indigo System (CAT RX and Separator 4) sterile devices.

Bench-top testing was conducted to evaluate the physical and mechanical properties of the subject Indigo System (CAT RX and Separator 4) Engine Pump and Canister. 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.

The Indigo System (CAT RX and Separator 4) Engine Pump and Canister also underwent electrical safety and EMC testing in accordance with the requirements of IEC 60601-1 and IEC 60601-1-2. Testing was performed by Intertek, a nationally recognized test laboratory. The Engine Pump and Canister passed all tests and met all acceptance criteria.

Attribute	Sample Size	Specification	Acceptance Criteria	Results
Pump - Electrical Safety	N=1	The Pump conforms to IEC 60601-1 and IEC 60601-1-2 requirements including international worldwide variants (CB Scheme). The Pump is compliant with EN ISO 10079-1.	100% Pass	100% Pass
Pump - Environmental Testing	N=5	Pump performance specifications under environmental conditions	100% Pass	100% Pass
Pump - Dimensional Inspection	N=5	Dimensional specifications per Product Specification	100% Pass	100% Pass
Pump - Inspection of Design Features	N=5	Design specifications per Product Specification	100% Pass	100% Pass
Pump - Performance	N=5	Performance specifications per Product Specification	100% Pass	100% Pass
Pump - Performance at variable voltage and frequency	N=5	Performance specifications per Product Specification	100% Pass	100% Pass
Pump and Canister - 500 hour Use Testing	N=5	Performance specifications after 500 hour use	100% Pass	100% Pass

Attribute	Sample Size	Specification	Acceptance Criteria	Results
Pump Canister – Inspection of Design Features	N=5	Design specifications per Product Specification	100% Pass	100% Pass
Pump Canister - Performance	N=5	Performance specifications per Product Specification	100% Pass	100% Pass
Pump and Canister – Simulated Use	N=5	Pump and Canister use specifications	100% Pass	100% Pass

1.10.3 Shelf Life

The subject and predicate Indigo System (CAT RX and Separator 4) sterile devices are identical. There are no changes to the previously provided shelf life data for the sterile devices which were reviewed and cleared under K163618. No additional shelf life testing is required or was performed for the Indigo System (CAT RX and Separator 4) sterile devices.

The proposed Indigo System (CAT RX and Separator 4) Engine Pump is a reusable piece of capital equipment that is provided non-sterile. Therefore, shelf life testing is not applicable to the Engine Pump and shelf life testing was not performed. The Engine Pump is established for 500 hours of use based on completed life (reliability) testing. The Engine Pump Canister does not have an established shelf life.

1.10.4 Sterilization

The subject and predicate Indigo System (CAT RX and Separator 4) sterile devices are identical. There are no changes to the previously provided sterilization data of the devices, which were reviewed and cleared under K163618. No additional sterilization testing is required or was performed for these devices.

Sterilization testing is not applicable to the proposed Indigo System (CAT RX and Separator 4) Engine Pump and Canister. Both are supplied non-sterile and are not intended to be sterilized.

1.10.5 Packaging

The packaging materials and process of the subject and predicate Indigo System (CAT RX and Separator 4) sterile devices are identical. There are no changes to the previously provided packaging material listing or the packaging process for these devices, which were reviewed and cleared under K163618. No additional packaging testing is required or was performed for the Indigo System (CAT RX and Separator 4) sterile devices.

The packaging materials for the proposed Indigo System (CAT RX and Separator 4) Engine Pump and Canister are similar to those used for the predicate Indigo System (CAT RX and Separator 4) Penumbra Pump MAX and Canister. The Engine Pump and Canister are packaged to ensure that damage does not occur during shipping. The Engine Pump is packaged in a protective, corrugated, cardboard 275 B/C Flute Double Wall RSC shipping container with custom shaped foam inserts. Pumps used for Design Verification and Packaging Validation testing first underwent transportation conditioning per ASTM D4169, Distribution Cycle 3, Assurance Level 3 to ensure packaging integrity. The Canister is packaged individual in Clay coated Solid Bleach Sulfate product boxes. The Canister box is then packaged in protective, corrugated, cardboard 275 B/C Flute Double Wall RSC shipping containers (18 canister boxes per shipper).

1.11 Summary of Substantial Equivalence

The subject Indigo System (CAT RX and Separator 4) disposable devices are unchanged and remain identical to those of the predicate Indigo System (CAT RX and Separator 4) with regard to indications, function, design, materials, biocompatibility, packaging, and sterilization. The subject Indigo System (CAT RX and Separator 4) Engine Pump and Canister are substantially equivalent to the predicate device with regard to intended use, operating principle, design concept, materials, and packaging processes.