October 12, 2018

Penumbra, Inc.
Micaela Victoria
Regulatory Affairs Specialist II
One Penumbra Place
Alameda, California 94502

Re: K182522
Trade/Device Name: Penumbra System (Modified 110 Aspiration Tubing)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: September 11, 2018
Received: September 13, 2018

Dear Micaela Victoria:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Xiaolin Zheng -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182522

Device Name
Penumbra System (Modified 110 Aspiration Tubing)

Indications for Use *(Describe)*

Penumbra Reperfusion Catheters and Separators
As part of the Penumbra System, the Reperfusion Catheters and Separators are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

Penumbra 3D Revascularization Device
As part of the Penumbra System, the Penumbra 3D Revascularization Device is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

Penumbra Aspiration Tubing
As part of the Penumbra System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion 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.

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1 510(k) Summary – K182522

(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 System® with modified 110 Aspiration Tubing.

1.1 Sponsor/Applicant Name and Address

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

1.2 Sponsor Contact Information

Micaela Victoria
Regulatory Affairs Specialist II
Phone: (510) 995-2082
FAX: (510) 217-6414
Email: mvictoria@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

October 09, 2018

1.4 Device Trade or Proprietary Name

Penumbra System® (Modified 110 Aspiration Tubing)

1.5 Device Classification

Regulatory Class:	II
Classification Panel:	Neurology
Classification Name:	Percutaneous Catheter
Regulation Number:	21 CFR §870.1250
Product Code:	NRY

1.6 Predicate and Reference Devices

510(k) Number / Clearance Date	Name of Device	Name of Manufacturer
Predicate Device		
K151623 cleared on August 6, 2015	Penumbra System – 110 Aspiration Tubing	Penumbra, Inc. One Penumbra Place Alameda, CA 94502 USA
Additional Predicate Devices		
K162901 cleared on April 20, 2017	Penumbra System – 3D Revascularization Device	Penumbra, Inc. One Penumbra Place Alameda, CA 94502 USA
K173761 cleared on August 17, 2018	Penumbra System – Reperfusion Catheter JET 7	

Reference Device		
K180939 cleared on May, 3, 2018	Indigo Aspiration System – Advanced 110 Aspiration Tubing	Penumbra, Inc. One Penumbra Place Alameda, CA 94502 USA

1.7 Predicate Comparison

	Predicate Device	Subject Device[1]
Trade Name	Penumbra System	SAME
510(k) No.	K151623 [Primary Predicate]	K182522
Classification	Class II, NRY	SAME
Indication for Use	The Penumbra System / Penumbra System MAX are intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. The Penumbra System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. The Reperfusion Catheters ACE 64 and ACE 68 are intended for use in revascularization within the Internal Carotid Artery (ICA) within 8 hours of symptom onset.	<u>Penumbra Reperfusion Catheters and Separators</u> As part of the Penumbra System, the Reperfusion Catheters and Separators are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. <u>Penumbra 3D Revascularization Device</u> As part of the Penumbra System, the Penumbra 3D Revascularization Device is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. <u>Penumbra Aspiration Tubing</u> As part of the Penumbra System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra

[1] The Penumbra System Reperfusion Catheters, Separators, and Aspiration Pumps are unchanged and remain identical to those of the currently cleared Penumbra System (K162901, K173761, and K180008,).

	Predicate Device	Subject Device[1]
Trade Name	Penumbra System	SAME
510(k) No.	K151623 [Primary Predicate]	K182522
Classification	Class II, NRY	SAME
		Reperfusion 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.
Aspiration Tubing		
	Current 110 Aspiration Tubing	**Modified 110 Aspiration Tubing**
Tubing Inner Diameter (ID)	0.110 in	SAME
Tubing Outer Diameter (OD)	0.188 in	SAME
Overall Length	112.0 in	100.0 in
Distal Length	7.0 in	N/A (Single Piece Construction)
Materials		
Tubing Material	Polyurethane & Nylon	SAME
Rotating Male Luer	Polycarbonate with EPDM **<u>OR</u>** Silicone O-Ring	SAME
Tubing/Luer Joint Adhesive	Cyclohexanone	SAME
Female Luer	Polycarbonate	N/A
Suction Connector Material	Polyvinylchloride (PVC)	SAME
Tubing/Suction Connector Joint Adhesive	Loctite	Cyclohexanone
Flow Control Switch Body Material	Polycarbonate	SAME
Flow Control Switch Slider Material	Acetal	Acetal
Flow Control Switch Slider Material Pin	Acetal	Nylon
Collar	ABS	N/A
Valve	Silicone	N/A
“ON” Logo	Polyolefin	Heat Stamp Foil
“OFF” Logo	Polyolefin	Heat Stamp Foil

	Predicate Device		Subject Device[1]
Trade Name	Penumbra System		SAME
510(k) No.	K151623 [Primary Predicate]		K182522
Classification	Class II, NRY		SAME
Packaging Materials	Pouch	Polyester/Polyethylene/Tyvek®	Nylon/ADH/HDPE/Tyvek®
	Display Box	SBS Paperboard	SAME
	Label Stock	Label stock	SAME
Sterilization	EO		SAME
Shelf Life	36 months		SAME

1.8 Device Description

The Penumbra System is intended for the removal of thrombus from the neuro vasculature using continuous aspiration. Intended users for this device are physicians who have received appropriate training in interventional neuroradiology and the treatment of acute ischemic stroke.

The Penumbra System is designed to remove thrombus from the vasculature using continuous aspiration. The Reperfusion Catheter targets aspiration from the pump directly to the thrombus. The 3D Revascularization Device is used with Reperfusion Catheters to facilitate aspiration and removal of the thrombus when needed. The Separator may be used to clear the lumen of the Reperfusion Catheter should it become blocked with thrombus. The use of the Separator may not be necessary when using a Reperfusion Catheter with an I.D. of 0.054in or larger. The Reperfusion Catheter is introduced through a guide catheter or long femoral sheath and into the intracranial vasculature and guided over a neurovascular guidewire to the site of the primary occlusion. The Penumbra Reperfusion Catheter is used with the Aspiration Pump to aspirate thrombus from an occluded vessel. As needed, a Penumbra Separator may be deployed from the Reperfusion Catheter to assist with thrombus removal. The Penumbra Separator is advanced and retracted through the Penumbra Reperfusion Catheter at the proximal margin of the primary occlusion to facilitate clearing of the thrombus from the Reperfusion Catheter tip. For the aspiration source, the Penumbra Reperfusion Catheter is used in conjunction with the Aspiration Pump, which is connected using the Penumbra Aspiration Tubing and the Penumbra Pump/Canister Tubing. The Penumbra Reperfusion Catheter is provided with a steam shaping mandrel and rotating hemostasis valve, and a peelable sheath. The Penumbra 3D Revascularization Device is provided with an introducer sheath. The Penumbra Separator is provided with an introducer and torque device. The Penumbra Reperfusion Catheters, 3D Revascularization Device and Separators are visible under

fluoroscopy.

The Penumbra Aspiration Tubing connects the Penumbra Aspiration Pump Canister to the Penumbra Reperfusion Catheter within the sterile field, providing a means for introducing vacuum during procedures. The Aspiration Tubing has a flow switch that allows the physician to start and stop the flow of aspiration. The Aspiration Tubing is available in three inner diameters: 0.071 in [1.80mm] for PST1, 0.088 in [2.24mm] for PST2, and 0.110 in [2.79mm] for PST3 and PST4. The Aspiration Tubing is designed and composed of materials which are commonly used in interventional devices. The Modified 110 Aspiration Tubing (PST4) is the subject device for this submission (K182522).

1.9 Indications for Use

Penumbra Reperfusion Catheters and Separators

As part of the Penumbra System, the Reperfusion Catheters and Separators are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

Penumbra 3D Revascularization Device

As part of the Penumbra System, the Penumbra 3D Revascularization Device is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

Penumbra Aspiration Tubing

As part of the Penumbra System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion 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 which substantiates the performance of the subject Penumbra System with modified 110 Aspiration Tubing as well as its substantial equivalence to the predicate device:

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

The subject Penumbra System with modified 110 Aspiration Tubing met all established requirements.

1.10.1 Biocompatibility

Biocompatibility testing was performed on the modified 110 Aspiration Tubing and the results are summarized in the table below. The studies were selected in accordance with EN ISO 10993-1 guidelines (Biological Evaluation of Medical Devices) for a limited exposure (≤ 24 hours), surface device, with skin contact. All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices (GLP). The modified 110 Aspiration Tubing met all acceptance criteria and successfully passed all biocompatibility tests per EN ISO 10993-1 guidelines.

Summary of Biocompatibility Testing for Modified 110 Aspiration Tubing

Test / Standard	Acceptance Criteria	Results	Pass / Fail
Cytotoxicity (MEM Elution) / EN ISO 10993-5	Sample extracts must yield a cell lysis grade of 2 or lower	Grade 2: Mild	Pass
Sensitization / EN ISO 10993-10	Test Group shall yield Grade < 1 score on Magnusson and Kligman scale (provided Control Grade < 1)	Grade 0: No visible change	Pass
Irritation (Intracutaneous Reactivity Irritation Test) / EN ISO 10993-10	The difference in the mean test article and mean control score must be grade 1.0 or lower	Grade 0.0 difference (saline extract) and Grade 0.1 difference (sesame oil extract)	Pass

The Aspiration Tubing is classified as skin contact only and no contact (direct or indirect) with patient blood; there is no blood going back to the patient. All components of the Aspiration Tubing Assembly are categorized as limited exposure (≤24 hours), surface device, with skin contact. Please see table below for patient contact information for each component of the Aspiration Tubing.

The subject and predicate Penumbra System Reperfusion Catheters, Separators, and 3D Revascularization Device are identical. There are no changes to the materials and processes of the Penumbra System Reperfusion Catheters, Separators, 3D Revascularization Device, the biocompatibility data of which were reviewed and cleared under previous premarket notifications. Therefore, no additional biocompatibility testing is required or was performed for the Penumbra System Reperfusion Catheters, Separators and 3D Revascularization Device.

The Penumbra Aspiration Pumps (Pump MAX and Engine Pump) are non-sterile reusable capital equipment and their associated canisters are non-sterile, single use only. The pumps and canisters do not contact the patient, nor are they introduced into the sterile field. As such, biocompatibility testing is not required and was not performed for the Aspiration Pumps and canisters.

1.10.2 Design Verification (Bench-top Testing)

With the exception of the modified flow switch assembly and the single piece of continuous tubing, the modified 110 Aspiration Tubing will have the same specifications as the current 110 Aspiration Tubing. Bench-top testing was conducted to evaluate the physical and mechanical properties of the modified 110 Aspiration Tubing. 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. All testing was performed using units which were 2x EO-sterilized.

A summary of bench top testing performed on the modified 110 Aspiration Tubing is provided in the table below. The modified 110 Aspiration Tubing met all acceptance criteria and passed all tests.

Summary of Bench-Top Testing for Modified 110 Aspiration Tubing

Test/ Test Subject	Attribute	Acceptance Criteria	Result
Dimensional/ Visual Inspection	These evaluations confirm that the test units used in Design Verification testing meet all dimensional and visual specifications.	100% Must meet Specification	Pass
Suction Connector / Canister Lid Compatibility	Suction Connector of Aspiration Tubing Assembly securely attaches to Pump Canister lid via press fit.	100% Must meet Specification	Pass
Rotating Luer/ RHV Compatibility	Rotating Luer of Aspiration Tubing Assembly securely connects to RHV port.	100% Must meet Specification	Pass
Aspiration Tubing Lumen Ovalization under Vacuum	Aspiration Tubing Assembly maintains functionality and maintains an open lumen at vacuum pressure per product specification.	100% Must meet Specification	Pass
Aspiration Tubing Joint Leak under Vacuum	Aspiration Tubing Assembly maintains functionality with no leaks at vacuum pressure per product specification.	100% Must meet Specification	Pass
Flow Control Switch Function	Flow Control Switch completely and immediately stops fluid flow after a specified number of ON/OFF cycles.	100% Must meet Specification	Pass
Penumbra Aspiration System Compatibility with Aspiration Catheter and Separator	The Aspiration Tubing Assembly is compatible with Penumbra Aspiration System (Clot can be removed under minimum vacuum pressure per product specification).	100% Must meet Specification	Pass
Penumbra Aspiration System Compatibility with Aspiration Catheter	The Aspiration Tubing Assembly is compatible with Penumbra Aspiration System (Clot can be removed under minimum vacuum pressure per product specification).	100% Must meet Specification	Pass
Suction Connector / Tubing Joint Tensile	Break force per product specification.	100% Must meet Specification	Pass
Rotating Male Luer / Tubing Joint Tensile	Break force per product specification.	100% Must meet Specification	Pass

1.10.3 Shelf Life

The modified 110 Aspiration Tubing has demonstrated device stability for 36 months based on accelerated aging and may be labelled with a 36 month shelf life. Test units were 2x

EO-sterilized and underwent transportation conditioning per ASTM D4169, Distribution Cycle 3, Assurance Level 2.

The subject and predicate Penumbra System Reperfusion Catheters Separators, and 3D Revascularization Device are identical. Therefore, there are no changes to the previously determined stability of the Reperfusion Catheters, Separators, and 3D Revascularization Device, the data for which were reviewed and cleared under previous Penumbra System premarket notifications. No additional shelf life testing is required or was performed for the Penumbra System Reperfusion Catheters Separators, and 3D Revascularization Device.

The subject and predicate Penumbra Aspiration Pumps (Pump MAX and Engine Pump) and their associated canisters are identical. Furthermore, the Aspiration Pumps are non-sterile reusable capital equipment. Therefore, shelf life testing is not applicable to the Aspiration Pumps. Both the Pump MAX and Engine Pump have established a 500 hour minimum operating life based on completed testing, the data for which were reviewed and cleared under previous Penumbra System premarket notifications.

1.10.4 Sterilization

The modified 110 Aspiration Tubing has demonstrated sterility by EO in accordance with EN ISO 11135. All test samples met the acceptance criteria for EO residual testing per EN ISO 10993-7, Comparative Resistance Testing per AAMI TIR 28, and Endotoxin (LAL) Testing per ANSI/AAMI ST72.

The subject and predicate Penumbra System Reperfusion Catheters, Separators, and 3D Revascularization Device are identical. There are no changes to the previously provided sterilization data of these devices, which were reviewed and cleared under previous Penumbra System premarket notifications. No additional sterilization testing is required or was performed for these devices.

Sterilization testing is not applicable to the Penumbra Aspiration Pumps (Pump MAX/Canister Tubing and Engine Pump/Canister). Both are supplied non-sterile and are not intended to be sterilized.

1.11 Summary of Substantial Equivalence

The subject Penumbra System with modified 110 Aspiration Tubing is substantially equivalent to the predicate and references devices, provided in Section 1.6, with regard to indications, intended use, design, performance, materials, sterilization, and packaging.