August 17, 2018

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

Re: K173761
Trade/Device Name: Penumbra System (Reperfusion Catheter JET 7)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: July 17, 2018
Received: July 18, 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. 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)*
K173761

Device Name
Penumbra System (Reperfusion Catheter JET 7)

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.

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 Penumbra System® Reperfusion Catheter JET 7.

1.1 Sponsor/Applicant Name and Address

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

1.2 Sponsor Contact Information

Michaela Mahl
Senior Manager, Regulatory Affairs
Phone: (510) 748-3288
FAX: (510) 217-6414
Email: mmahl@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

July 17, 2018

1.4 Device Trade or Proprietary Name

Penumbra System® (Reperfusion Catheter JET 7)

1.5 Device Classification

Regulatory Class:	II
Classification Panel:	Neurology
Classification Name:	Percutaneous Catheter
Regulation Number:	21 CFR §870.1250
Product Code:	NRY (Catheter, Thrombus Removal)

1.6 Predicate Devices

510(k) Number / Clearance Date	Name of Device	Name of Manufacturer
Primary Predicate Device		
K161640 cleared on July 12, 2016	Penumbra System – ACE 68 Reperfusion Catheter	Penumbra, Inc. One Penumbra Place Alameda, CA 94502 USA
Additional Predicate Device		
K162901 (applicable for indication only) cleared on April 20, 2017	Penumbra System – 3D Revascularization Device	Penumbra, Inc. One Penumbra Place Alameda, CA 94502 USA

1.7 Predicate Comparison

System Name	Penumbra System®	
Device Name	**ACE™ 68**	**JET 7**
510(k) No.	K161640 (applicable for ACE 68) K162901 (applicable for indication only)	K173761
Classification	Class II, NRY	SAME
Indication	<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 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.	SAME

System Name	Penumbra System®	
Device Name	**ACE™ 68**	**JET 7**
Materials		
Proximal hub	Grilamid (TR55-LX)	SAME
Strain Relief [Hub Sleeve]	Grilamid (TR55)	SAME
Strain Relief	304 Stainless Steel (SS)	SAME
ID Band	Polyolefin, PET yellow [black foil]	Polyolefin, PET black [white foil]
Liner	PTFE	SAME
Catheter Shaft		
Extrusions	Polyurethane, Polyether Block Amide, Nylon12	SAME
Distal Coil Reinforcement	NiTi wire	SAME
Proximal Coil Reinforcement	SS wire and NiTi wire	SAME
Extrusion Colorants	Clear/ Natural or Purple	SAME
Tip Shape	Straight	SAME
Markerband	Platinum/Iridium (90% Pt, 10% Ir)	SAME
Coating	Hydrophilic (proprietary)	SAME
Dimensions		
Proximal OD	0.084 in Max	0.085 in Max
Proximal ID	0.068 in Min	0.072 in Min
Distal OD	0.084 in Max	0.085 in Max
Distal ID	0.068 in Min	0.072 in Min
Effective Length	115, 120, 125, 127, 132 cm	SAME
Distal Flex Length	30 cm	SAME
Coating Length	30 cm	SAME
Accessories		
Peelable Sheath	PTFE	SAME
Rotating Hemostasis Valve	Polycarbonate, silicone o-ring	SAME
Shaping Mandrel	0.038in OD stainless steel	SAME
Packaging Materials		
Pouch	Polyester/Polyethylene/Tyvek	SAME
Packaging Hoop	Polyethylene	SAME
Packaging Tray (Kit Configuration)	Polyethylene terephthalate, Polystyrene	SAME
Packaging Card	Polyethylene	SAME
Display Carton	SBS Paperboard	SAME
Packaging Configuration	Hoop: Hoop/Packaging Card/Pouch/Box	SAME
	Kit: Tray/Retainer/Lid/Aspiration Tubing/Accessory Pouch/Pouch/Box	SAME
Sterilization	EO	SAME
Shelf-Life	36 Months	6 Months

System Name	Penumbra System®	
Device Name	**ACE™ 68**	**JET 7**
Use	Single use, disposable	SAME

1.8 Device Description

The Penumbra System Reperfusion Catheter JET 7 is a component to the currently available Penumbra System. The Reperfusion Catheter JET 7 component provides a larger lumen to assist in the efficient removal of thrombus from the neurovasculature. The devices are provided sterile, non-pyrogenic, and intended for single use only.

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 substantially equivalent performance of the subject Penumbra System JET 7 device to the predicate device:

- Biocompatibility
- Design Verification (Bench-Top Testing)
- Design Validation (GLP Animal Testing)

The subject Penumbra System Reperfusion Catheter JET 7 met all established requirements.

1.10.1 Leveraged Biocompatibility Testing

The materials used in Reperfusion Catheter JET 7 are currently utilized in the currently available predicate device, Reperfusion Catheter ACE 68. The JET 7 device is manufactured using the same processes and in the same environment as ACE 68. The predicate, ACE 68 is classified as an externally communicating device with circulating blood contact and limited exposure less than 24 hours, which is the same proposed classification for JET 7. All biocompatibility risks have been mitigated through successful completion of prior biocompatibility testing per

EN ISO 10993-1:2009/AC: 2010 which will be leveraged for the JET 7 device. Therefore, no further biocompatibility testing is required.

Evidence of the biocompatibility of the Reperfusion Catheter JET 7 is derived from a series of previously performed studies listed and summarized in the table below. The studies were selected in accordance with EN ISO 10993-1[1] guidelines (Biological Evaluation of Medical Devices) for a limited exposure (< 24 hours), externally

[1] EN ISO 10993-1: 2009/AC:2010 Biological Evaluation of Medical Devices, Part 1: Evaluation and testing within a risk management process

communicating device with circulating blood contact. All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices (GLP).

EN ISO-10993 GLP Testing Summary

Test	Acceptance Criteria	Results	Pass / Fail
In Vitro Cytotoxicity	Sample extracts must yield cell lysis grade 2 or lower	Grade 1: Slight	Pass
Sensitization	Test Group shall yield Grade < 1 score on Magnusson and Kligman scale (provided control Grade < 1)	Grade 0: No visible change	Pass
Acute Intracutaneous Reactivity (Irritation)	The difference in the mean test article and mean control score must be grade 1.0 or lower	Grade ≤ 1.0 difference between mean test article and mean control score	Pass
Systemic Toxicity			
Acute Systemic Toxicity	Sample extracts must not cause the following: • > 10% weight loss in 3 or more test animals • Mortality of 2 or more test animals • Abnormal behavior in 2 or more test animals	No evidence of systemic toxicity from sample extracts • No weight loss (all gained weight) • No death • All test animals appeared normal	Pass
Rabbit Pyrogen Study	Sample Extracts must not cause a total rise in body temperature of ≥0.5°C	Non-pyrogenic: No evidence of material-mediated pyrogenicity; no single animal had a total body temperature rise of ≥0.5°C	Pass
Hemocompatibility			
In Vitro Hemolysis	Sample extracts must be non-hemolytic (≤ 2% hemolytic index)	Non-hemolytic: Hemolytic Index = 0.70% Corrected Hemolytic index = 0.00%	Pass
Coagulation (Prothrombin Time)	Clotting times must be similar to negative control values	Test article coagulation times were statistically lower than negative control	Pass
Coagulation (Partial Thromboplastin Time)	Clotting times must be similar to predicate (negative control) values using analysis of variance	Test article coagulation times were statistically similar to the predicate	Pass

Test	Acceptance Criteria	Results	Pass / Fail
Complement Activation	The concentrations of C3a and SC5b-9 in the test samples are statistically similar to the predicate (Exposure Control & Ref Material) control and statistically lower than the positive control for all exposure times	The test sample concentrations of C3a and SC5b-9 were statistically similar or lower than the predicate control sample concentrations, and statistically lower than the positive control sample concentrations at all three exposure times	Pass
Dog Thrombogenicity	The device must be non-thrombogenic after 4 hours *in vivo* when compared to a control device (Boston Scientific Excelsior SL-10 microcatheter)	No significant thrombosis with a Grade of 0 was observed in 2 out 2 test site and 2 out of 2 control sites. Based on the evaluation criteria, the amount of thrombosis was not considered significant	Pass

In summary non-clinical testing substantiates that the Penumbra System Reperfusion Catheter JET 7 device is non-cytotoxic, non-sensitizing, non-irritating, non-toxic, non-pyrogenic, non-hemolytic, and non-thrombogenic.

1.10.2 Bench-top Testing

The physical and mechanical properties of the Reperfusion Catheter JET 7 device was assessed using standard test methods and pre-determined acceptance criteria. The following tests were performed and all tests passed successfully:

Attribute	Specification	Results
Dimensional / Visual Inspection	These evaluations confirm that the units used in this Design Verification testing meet all product specifications.	Pass
Simulated Use [Intracranial Access, Vessel Access Entry Performance, Delivery/Retrieval Forces & Clot Removal]	Simulated use testing of the Penumbra System Reperfusion Catheter JET 7 was performed with accessory devices in an anatomical model which simulated the tortuosity of the neurovasculature. Devices were delivered through the tortuous anatomical model to evaluate the effectiveness of the devices to remove clots and that the Reperfusion Catheter does not collapse under vacuum.	Pass
Physician Evaluation [Deliverability & Clot Removal]	Multiple Physician performance evaluation of the Penumbra System Reperfusion Catheter JET 7 in a simulated neurovascular tortuosity model with the predicate Penumbra System Reperfusion Catheter ACE 68 used as a baseline.	Pass
Kink Resistance (Distal, Midshaft, Proximal)	No kinking when formed in a 2.5 mm, 10 mm, and 25 mm radius	Pass

Attribute	Specification	Results
Particulate testing	≥ 10 µm will be ≤ 6000 particles	Pass
	≥ 25 µm will be ≤ 600 particles	Pass
	≥ 75 µm will be measured for informational purposes only (FIPO)	FIPO
	≥ 125 µm will be measured for informational purposes only (FIPO)	FIPO
Coating Integrity	Coating has not delaminated, peeled, or flaked prior to or after simulated use particulate testing	Pass
Markerband Visibility	The markerband is fluoroscopically visible	Pass
Hub Air Aspiration	No leaks detected when vacuum is pulled on the injection lumen	Pass
Pressure Test	45 psi for 30 sec minimum	Pass
JET 7 / Sheath or 8F Guide Catheter Friction Force	Maximum value per specification	Pass
JET 7 / 0.014 in. Guidewire Friction Force	Maximum value per specification	Pass
Joint sections bond strength	Minimum value per specification	Pass
Markerband Section Bond Strength	Minimum value per specification	Pass
Hub to Shaft Bond Strength	Minimum value per specification	Pass
Hub to Hypotube Bond Strength	Minimum value per specification	Pass
Elongation to failure	Elongation ≥ 5%	Pass
Torsion	Number of turns will be recorded for informational purposes only.	FIPO
Corrosion	No visible corrosion on Reperfusion Catheter immediately after corrosion testing procedure	Pass

1.10.3 Animal Study

The safety and performance of the Reperfusion Catheter JET 7 compared to the predicate Reperfusion Catheter ACE 68, when "wedged" in a vessel and using maximum aspiration, was evaluated in the accepted porcine vascular model. One side of each swine was treated with the Reperfusion Catheter JET 7 and the contralateral side was treated with predicate device. The purpose of this study was to evaluate the Reperfusion Catheter JET 7 aspiration vascular response when "wedged" within a swine artery compared to the predicate device. Safety of the test articles was assessed by consideration of the acute and chronic vascular response. Vascular response was assessed by contrast angiography and by gross necropsy and histopathology of associated vasculature performed by the Sponsor Pathologist. As testing included the predicate device, results were compared to demonstrate substantial equivalence.

1.11 Performance Data – Clinical:

No clinical study was conducted as bench and 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.

1.12 Summary of Substantial Equivalence

The subject Penumbra System Reperfusion Catheter JET 7 device is substantially equivalent to the predicate device with regard to intended use, operating principle, design concept, materials, shelf-life, packaging and sterilization processes.