February 27, 2020

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

Re: K191946
Trade/Device Name: Penumbra System® [JET™ 7 Reperfusion Catheter with MAX Delivery Device (JET™ 7MAX)]
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: January 27, 2020
Received: January 28, 2020

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/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,

Xiaolin Zheng, Ph.D., M.S.
Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K191946

Device Name
Penumbra System® [JET™ 7 Reperfusion Catheter with MAX Delivery Device (JET™ 7MAX)]

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

(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® Penumbra JET™ 7MAX (Penumbra JET™ 7 Reperfusion Catheter with MAX Delivery Device)

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 III
Phone: (510) 748-2082
FAX: (510) 217-6414
Email: mvictoria@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

January 24, 2020

1.4 Device Trade or Proprietary Name

Penumbra System® [JET™ 7 Reperfusion Catheter with MAX Delivery Device (JET™ 7MAX)]

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		
K190010 cleared on June 16, 2019	Penumbra System® – Penumbra JET™ 7 Reperfusion Catheter	Penumbra, Inc. One Penumbra Place Alameda, CA 94502 USA
Reference Device		

K173761 cleared on August 8, 2018 (Animal Testing only)	Penumbra System® – Penumbra JET™ 7 Reperfusion Catheter	Penumbra, Inc. One Penumbra Place Alameda, CA 94502 USA
K083125 cleared on November 21, 2008 (Biocompatibility Testing only)	Neuron Intracranial Access System – Neuron Select Catheter 070	Penumbra, Inc. One Penumbra Place Alameda, CA 94502 USA

1.7 Predicate Comparison

System Name	**Penumbra System®**	
Device Name	**Penumbra JET 7 (Predicate)**	**Penumbra JET 7MAX (Subject)**
510(k) No.	K190010 (applicable for Penumbra JET 7 with Access Assist Tool) K173761 (applicable for Animal Testing – Reference Device)	K191946
Classification	Class II, NRY	SAME

System Name	Penumbra System®	
Device Name	**Penumbra JET 7 (Predicate)**	**Penumbra JET 7MAX (Subject)**
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
Reperfusion Catheter	Penumbra JET™ 7	SAME
Accessories		
Peelable Sheath	PTFE	SAME
Rotating Hemostasis Valve	Polycarbonate, silicone o-ring	SAME

System Name	Penumbra System®	
Device Name	**Penumbra JET 7 (Predicate)**	**Penumbra JET 7MAX (Subject)**
Shaping Mandrel	Stainless Steel	SAME
Access Assist Tool	N/A – not included	**Materials:** Nylon 12, Copolyester, Polyolefin, Polyurethane, Polyether Block Amide, PTFE, Platinum/Tungsten, Hydrophilic Coating **Dimensions:** ID: 0.018in OD: 0.071in Extension Length: 1.5cm
Packaging Materials		
Pouch	Polyester/Polyethylene/Tyvek	SAME
Packaging Tray (Kit Configuration)	Polyethylene terephthalate, Polystyrene	SAME
Display Carton	SBS Paperboard	SAME
Kit Packaging Configuration	Tray/Retainer/Lid/Aspiration Tubing/Accessory Pouch/Pouch/Box	SAME
Sterilization	EO	SAME
Shelf-Life	36 Months	12 Months
Use	Single use, disposable	SAME

1.8 Device Description

The Penumbra JET 7 with MAX Delivery Device, known as Penumbra JET 7MAX, is an additional configuration being added to the currently available Penumbra System. The MAX Delivery Device is an optional accessory for use with the Penumbra JET 7 Reperfusion Catheter and is removed prior to aspiration. The Reperfusion Catheter Penumbra JET 7 delivers aspiration from the Aspiration Pump directly to the site of occlusion to assist in the 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 safe and effective performance of the subject Penumbra JET 7 with MAX Delivery Device as well as its substantial equivalence to the predicate and reference devices:

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

The subject Penumbra JET 7 with MAX Delivery Device met all established requirements.

1.10.1 Biocompatibility Testing

Biocompatibility was conducted on the subject Penumbra JET 7 with MAX Delivery Device. 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). Reperfusion Catheter testing was previously performed on the predicate Penumbra JET 7 [K190010]; therefore, the scope of the testing (in the table below) was only performed on the MAX Delivery Device.

Biocompatibility Test Results

Tests	Acceptance Criteria	Results	Conclusion
Cytotoxicity: MEM Elution (10993-5)	Sample extracts must have a cytotoxic reactivity score of grade 2 or lower	Grade = 0 (Reactivity None)	Pass Non-cytotoxic
Sensitization: Magnusson-Kligman Method (10993-10)	Test Group shall yield Grade < 1 score on Magnusson and Kligman scale (provided Control Group yields Grade < 1)	NaCl Extract Grade = 0 CSO Extract Grade = 0	Pass Non-sensitizing
Irritation: Intracutaneous Reactivity (10993-10)	The difference between the average scores for the extract of the test article and the control is ≤ 1.0	NaCl Extract Difference = 0.0 CSO Extract Difference = 0.0	Pass Non-irritating
Systemic Toxicity: Acute Systemic Injection (10993-11)	Sample extracts must not cause significant biological reaction greater than control. That is: • Death in 2 or more animals • Signs of toxicity in 2 or more animals (i.e. convulsions, prostration) • Weight loss > 10% in 3 or more animals	No evidence of systemic toxicity from sample extracts (both NaCl and CSO extracts). That is: No deaths • No signs consistent with toxicity No weight loss > 10%	Pass Non-toxic
Systemic Toxicity: Material Mediated Pyrogen (10993-11, USP)	Sample extracts must not cause a total rise in body temperature of ≥ 0.5 ˚C	Non-pyrogenic: no single animal had an individual rise in body temperature ≥ 0.5 ˚C	Pass Non-pyrogenic
Hemocompatibility: Prothrombin Time (PT)	Clotting times of test article must be similar to predicate values using analysis of variance.	Test article coagulation times are statistically similar to predicate	Pass Hemocompatible

Tests	Acceptance Criteria	Results	Conclusion
(10993-4)			
Hemocompatibility: Partial Thromboplastin Time (PTT) (10993-4)	Clotting times of test article must be similar to predicate values using analysis of variance	Test article coagulation times are statistically similar to predicate	Pass Hemocompatible
Hemocompatibility: Complement Activation (10993-4)	The concentration of SC5b-9 of test article must be similar to predicate values using analysis of variance	SC5b-9 Test article concentrations are statistically similar to predicate at all exposure time points: • 30min • 60min • 90min	Pass Hemocompatible
Hemocompatibility: Hemolysis (indirect contact) (10993-4)	Sample extracts must be non-hemolytic (≤ 2% hemolytic index)	Hemolytic Index = 0.22%	Pass Non-hemolytic
Hemocompatibility: Hemolysis (direct contact) (10993-4)	Sample must be non-hemolytic (≤ 2% hemolytic index)	Hemolytic Index = 0.00%	Pass Non-hemolytic
Hemocompatibility: *In vitro* Thrombogenicity (10993-4)	Device must be non-thrombogenic *in vitro* when compared to predicate device	Test article performed equal or better than predicate in three separate *in vitro* assays	Pass Non-thrombogenic

In summary, non-clinical testing substantiates that the Penumbra System Penumbra JET 7 with MAX Delivery Device is 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 Penumbra JET 7 with MAX Delivery 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]	Simulated use testing of the Access Assist Tool with Penumbra JET 7 Reperfusion Catheter and relevant 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 device to assist in the delivery of the Reperfusion Catheter to the target site.	Pass
Reperfusion Catheter / Access Assist Tool compatibility (Friction Force)	Maximum value per specification	Pass
Access Assist Tool / 0.016" Guidewire compatibility (Friction Force)	Maximum value per specification	Pass
Markercoil Visibility	The markercoil is fluoroscopically visible	Pass
Torsion	Number of turns will be recorded for informational purposes only [FIPO].	FIPO
Corrosion	No visible corrosion immediately after Corrosion Testing procedure	Pass
Particulate Testing	≥ 10 µm will be ≤ 6000 particles	Pass
	≥ 25 µm will be ≤ 600 particles	Pass
	≥ 75 µm particles will be recorded for informational purposes only [FIPO]	FIPO
	≥ 125 µm particles will be recorded for informational purposes only [FIPO]	FIPO
Coating Integrity (Pre-Inspection)	Coating has not delaminated, peeled, or flaked prior to simulated use particulate testing	Pass
Coating Integrity (Post-Inspection)	Coating has not delaminated, peeled, or flaked after simulated use particulate testing	Pass

Attribute	Specification	Results
Hub/Air Aspiration	When negative pressure is pulled, no air may leak into hub	Pass
Bond Strength Distal Joint 1	Minimum value per specification	Pass
Bond Strength Distal Joint 2	Minimum value per specification	Pass
Bond Strength Midjoint 1	Minimum value per specification	Pass
Bond Strength Midjoint 2	Minimum value per specification	Pass
Proximal Joint	Minimum value per specification	Pass
Hub to Shaft Bond Strength	Minimum value per specification	Pass
Elongation to Failure – Access Assist Tool	Meets value per specification	Pass
Pressure Test	Minimum value per specification	Pass

1.10.3 Design Validation - Animal Study

The safety and efficacy of the reference device, Penumbra JET 7 Reperfusion Catheter (Penumbra JET 7) was evaluated in the accepted porcine model [K173761]. The purpose of this study was to evaluate the aspiration vascular response of the reference device Penumbra JET 7. The subject Penumbra JET 7 with MAX Delivery Device consists of a Penumbra JET 7 Reperfusion Catheter and optional catheter accessory, which is removed from the Reperfusion Catheter prior to aspiration. The subject, Penumbra JET 7 with MAX Delivery Device, Reperfusion Catheter dimensions are identical to that of the reference device Penumbra JET 7. As a result, no additional animal testing was required.

1.11 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 for devices with similar dimensions used for direct aspiration. The literature review was used to support the determination of substantial equivalence by using clinical outcomes from devices that are considered technologically equivalent.

1.12 Summary of Substantial Equivalence

The Penumbra JET 7 with MAX Delivery Device is substantially equivalent to the predicate and reference devices, provided in Section 1.6, with regard to indications, intended use, design, performance, materials, sterilization and packaging.