June 16, 2019

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

Re: K190010
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: May 16, 2019
Received: May 17, 2019

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.
Assistant 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)*
K190010

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 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

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

May 16, 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** | | |
| K173761 cleared on August 8, 2018 | Penumbra System – JET 7 Reperfusion Catheter | Penumbra, Inc. One Penumbra Place Alameda, CA 94502 USA |
| **Reference Device** | | |
| K161640 cleared on July 12, 2016 (applicable to packaging validation only) | Penumbra System – ACE 68 Reperfusion Catheter | Penumbra, Inc. One Penumbra Place Alameda, CA 94502 USA |

## 1.7 Predicate Comparison

| System Name | Penumbra System® | |
|---|---|---|
| **Device Name** | **JET 7 (Predicate)** | **Modified JET 7 (Subject)** |
| **510(k) No.** | K173761 (applicable for JET 7)<br>K161640 (applicable for packaging validation only – Reference Device) | K190010 |
| **Classification** | Class II, NRY | SAME |
| **Indication** | Penumbra Reperfusion Catheters and Separators<br>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.<br><br>Penumbra 3D Revascularization Device<br>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.<br><br>Penumbra Aspiration Tubing<br>As part of the Penumbra System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Aspiration Pump.<br><br>Penumbra Aspiration Pump<br>The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems. | SAME |

| System Name | Penumbra System® | |
|---|---|---|
| **Device Name** | **JET 7 (Predicate)** | **Modified JET 7 (Subject)** |
| **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 black [white foil] | SAME |
| Liner | PTFE | SAME |
| **Catheter Shaft** | | |
| Extrusions | Polyurethane | Equivalent |
| | Polyether Block Amide | SAME |
| | Nylon 12 | 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) | Equivalent |
| **Dimensions** | | |
| Proximal OD | 0.085 in Max | SAME |
| Proximal ID | 0.072 in Min | SAME |
| Distal OD | 0.085 in Max | SAME |
| Distal ID | 0.072 in Min | SAME |
| 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** | | |

| System Name | Penumbra System® | |
|---|---|---|
| **Device Name** | **JET 7 (Predicate)** | **Modified JET 7 (Subject)** |
| 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 | 12 Months |
| **Use** | Single use, disposable | SAME |

## 1.8 Device Description

The Penumbra System Reperfusion Catheter JET 7 (modified) is a component to the currently available Penumbra System. The Reperfusion Catheter JET 7 (modified) delivers aspiration from the Aspiration Pump directly to the site of occlusion 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 safe and effective performance of the subject Penumbra System JET 7 (modified) device as well as its substantial equivalence to the predicate device:

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

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

### 1.10.1 Biocompatibility Testing

Biocompatibility was conducted on the subject Reperfusion Catheter JET 7 (modified). The studies were selected in accordance with EN 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).

**Biocompatibility Test Results**

| Tests | Acceptance Criteria | Results | Conclusion |
|---|---|---|---|
| Cytotoxicity: MEM Elution<br><br>(10993-5) | Sample extracts must have a cytotoxic reactivity score of grade 2 or lower | Grade = 0 (Reactivity None) | Pass<br>Non-cytotoxic |

| | | | |
|---|---|---|---|
| Delayed-type hypersensitivity (Sensitization)<br><br>(10993-10) | Test Group shall yield Grade < 1 score on Magnusson and Kligman scale (provided Control Group yields Grade < 1) | NaCl Extract<br>Grade = 0<br><br>CSO Extract<br>Grade = 0 | Pass<br>Non-sensitizing |
| Intracutaneous Reactivity (Irritation)<br><br>(10993-10) | The difference between the average scores for the extract of the test article and the control is ≤ 1.0 | NaCl Extract<br>Difference = 0.0<br><br>CSO Extract<br>Difference = 0.0 | Pass<br>Non-irritating |
| Systemic Toxicity: Acute Systemic Injection<br>(10993-11) | Sample extracts must not cause significant biological reaction greater than control. That is:<br>• Death in 2 or more animals<br>• Signs of toxicity in 2 or more animals (i.e. convulsions, prostration)<br>• Weight loss > 10% in 3 or more animals | No evidence of systemic toxicity from sample extracts (both NaCl and CSO extracts). That is:<br>• No deaths<br>• No signs consistent with toxicity<br>No weight loss > 10% | Pass<br>Non-toxic |
| Systemic Toxicity: Material Mediated Pyrogen<br>(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<br>Non-pyrogenic |
| Hemocompatibility: *In vitro* Thrombogenicity<br><br>(10993-4) | The test article must have similar or less thrombus formation than predicate after 4 hours in vitro | Test Article: 1, Thromboresistant<br>Control Article: 1, Thromboresistant | Pass<br>Thromboresistant |
| Hemocompatibility: Prothrombin Time (PT)<br><br>(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<br>Hemocompatible |
| Hemocompatibility: Partial Thromboplastin Time (PTT)<br><br>(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<br>Hemocompatible |
| Hemocompatibility: Complement Activation<br><br>(10993-4) | The concentrations of C3a and SC5b-9 of test article must be similar to predicate values using analysis of variance | C3a<br>Test article concentrations are statistically similar to predicate at all exposure time points:<br>• 30 min<br>• 60 min<br>• 90 min<br><br>SC5b-9<br>Test article concentrations are statistically similar to | Pass<br>Hemocompatible |

| | | | |
|---|---|---|---|
| | | predicate at all exposure time points:<br>• 30 min<br>• 60 min<br>• 90 min | |
| Hemocompatibility: Hemolysis, indirect contact<br><br>(10993-4) | Sample extracts must be non-hemolytic (≤ 2% hemolytic index) | Hemolytic Index = 0.00% | Pass<br>Non-hemolytic |
| Hemocompatibility: Hemolysis, direct contact<br><br>(10993-4) | Sample must be non-hemolytic (≤ 2% hemolytic index) | Hemolytic Index = 0.00% | Pass<br>Non-hemoloytic |

In summary, non-clinical testing substantiates that the Penumbra System Reperfusion Catheter JET 7 (modified) 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 Reperfusion Catheter JET 7 (modified) 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 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 JET 7 and ACE 68 used as a baseline. | Pass |

| Attribute | Specification | Results |
|---|---|---|
| Reperfusion Catheter / Sheath or 8F Guide compatibility (Friction Force) | Maximum value per specification | Pass |
| Reperfusion Catheter / 0.014" Guidewire compatibility (Friction Force) | Maximum value per specification | Pass |
| Markerband Visibility | The markerband is fluoroscopically visible | Pass |
| Torsion | Number of turns will be recorded for informational purposes only [FIPO]. | FIPO |
| Corrosion | No visible corrosion on Reperfusion Catheter 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 |
| | ≥ 125 µm particles will be recorded for informational purposes only | FIPO |
| Coating Integrity | Coating has not delaminated, peeled, or flaked after simulated use particulate testing | Pass |
| Hub/Air Aspiration | When negative pressure is pulled, no air may leak into hub | Pass |
| Pressure Test | Minimum value per specification | Pass |
| Markerband Section Bond Strength | Minimum value per specification | Pass |
| Bond Strength Distal Joint 1 | Minimum value per specification | Pass |
| Bond Strength Distal Joint 2 | Minimum value per specification | Pass |

| Attribute | Specification | Results |
|---|---|---|
| Bond Strength Midjoint | Minimum value per specification | Pass |
| Proximal Joints: | 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 – Reperfusion Catheter | Elongation ≥ 5% | Pass |

### 1.10.3 Design Validation - Animal Study

The safety and efficacy of the predicate Reperfusion Catheter JET 7 when "wedged" in a vessel and using maximum aspiration, was evaluated in the accepted porcine model [K173761]. The purpose of this study was to evaluate the aspiration vascular response of the predicate Reperfusion Catheter JET 7. The subject Reperfusion Catheter JET 7 (modified) dimensions are identical to that of the predicate device JET 7. Furthermore, the changes in material in the subject JET 7 compared to the predicate JET 7 have been evaluated in distal tip stiffness testing [bench model], and the subject JET 7 distal tip was measured to be less stiff than the predicate JET 7, as well as the reference device ACE 68. 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 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 Reperfusion Catheter JET 7 (modified) 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.