April 30, 2019

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

Re: K190464
Trade/Device Name: Penumbra System (3D Revascularization Device)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: February 25, 2019
Received: February 26, 2019

Dear Michaela Mahl:

This letter corrects our substantially equivalent letter of April 26, 2019.

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)*
K190464

Device Name
Penumbra System (3D Revascularization Device)

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.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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"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® 3D Revascularization Device.

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

February 22, 2019

1.4 Device Trade or Proprietary Name

Penumbra System® (3D Revascularization Device)

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 Retriever)

1.6 Predicate and Reference Devices

510(k) Number/Clearance Date	Name of Device	Name of Manufacturer
Predicate Device		
K162901 cleared on April 20, 2017	Penumbra 3D Revascularization Device	Penumbra, Inc. One Penumbra Place Alameda, CA 94502 USA

1.7 Predicate Comparison

System Name	Penumbra System®	
Device Name	**Predicate Device**	**Subject Device**
	Penumbra 3D Revascularization Device	**Penumbra 3D Revascularization Device (Modified)**
510(k) No.	K162901	K190464
Classification	Class II, NRY	SAME
Indication 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.	SAME
System Components	Reperfusion Catheter and Separators	SAME
	3D Revascularization Device	SAME
	Aspiration Tubing	SAME
	Aspiration Pump & Pump Canister	SAME
Materials	Penumbra 3D Revascularization Device	Penumbra 3D Revascularization Device (Modified)
Delivery-Wire		
Core wire	Stainless Steel	SAME
Coating	PTFE Green PC 8-403G	SAME
Outer coil	Stainless Steel	SAME
Proximal Solder	Silver Solder	SAME

System Name	Penumbra System®	
Distal Inner Coil	N/A	Platinum Alloy
Distal Solder	Silver Solder	SAME
Distal Tip		
Outer coil	Stainless Steel	SAME
Radiopaque Markers	Platinum Alloy	SAME
Attachment Tip	Stainless Steel	SAME
Solder joint	Gold Solder / Silver Solder	Silver Solder
3D Nitinol Device		
3D lattice	Nitinol	SAME
Introducer sheath	FEP	SAME
Dimensions		
- Device Nominal Total Length	26 mm	SAME
- Device Nominal OD	4.5 mm	SAME
- Device Nominal Usable Length	20 mm	SAME
- Delivery Wire Distal OD	0.014”	SAME
- Delivery Wire Length	200 cm	SAME
Sterilization	**EO**	**SAME**
Shelf-Life	**36 Months**	**SAME**

1.8 Device Description

The Penumbra System 3D Revascularization Device is designed to revascularize patients experiencing acute ischemic stroke as a component of the Penumbra System. The Penumbra System's fundamental mechanism of action is aspiration. Aspiration removes clot by drawing it into the Penumbra Reperfusion Catheter. The 3D Revascularization Device is designed to assist the Reperfusion Catheter with thrombus removal if needed. Intended users for this device are physicians who have received appropriate training in interventional neuro-endovascular techniques and treatment of acute ischemic stroke. The device is 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

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Penumbra Aspiration Tubing

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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 descriptions of the testing, which substantiates the safe and effective performance of the subject Penumbra System 3D Revascularization Device as well as its substantial equivalence to the predicate device:

- Biocompatibility
- Design Verification (Bench-Top Testing)
- Design Validation (Animal Study)
- Performance Data

The subject, Penumbra System 3D Revascularization Device met all established requirements.

1.10.1 Previously Completed Biocompatibility Testing

The materials used in the subject Penumbra System 3D Revascularization Device [modified] are identical to those in the predicate device, Penumbra System 3D Revascularization Device [K162901]. The subject Penumbra System 3D Revascularization Device [modified] uses identical materials, equivalent processing, and identical sterilization methods as products that Penumbra has already successfully conducted biocompatibility testing per BS EN ISO 10993. The studies were selected in accordance with ISO 10993-1 guidelines (Biological Evaluation of Medical Devices) for a limited exposure (< 24 hours), external communicating device with circulating blood contact. All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices (GLP).

The classification for the predicate, Penumbra System 3D Revascularization Device [K162901] and subject device, Penumbra System 3D Revascularization Device [modified] are identical. All biocompatibility risks have been mitigated through successful completion of prior biocompatibility testing per ISO 10993-1:2009/AC: 2010 which will be used to support the biocompatibility for the subject Penumbra System 3D Revascularization Device [modified]. Therefore, no further biocompatibility testing was conducted on the subject device.

1.10.2 Design Verification - Bench-top Testing

The physical and mechanical properties of the 3D Revascularization Device was assessed using standard test methods and pre-determined acceptance criteria. The following tests were performed and all tests passed successfully:

Attribute	Specification	Result
Pouch Seal Strength	Minimum value per specification	Pass
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 & Clot Removal]	Simulated use testing of the Reperfusion Catheter and 3D Revascularization Device 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.	Pass
Physician Evaluation [Deliverability & Clot Removal]	Multiple Physician performance evaluation of the subject Penumbra System 3D Revascularization Device in a simulated neurovascular tortuosity model with the Penumbra System 3D Revascularization Device used as a baseline.	Pass
Particulate Testing	The maximum number of particles:	Pass

Attribute	Specification	Result
	≥ 10 µm will be ≤ 6000 particles	
	≥ 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
Radial Pressure	Value within the specification range	Pass
Torsion	Minimum value per specification	Pass
Kink Resistance	No kinking when formed in a defined radius	Pass
Device Af	Maximum value per specification	
Corrosion	Specimens will be free from signs of corrosion	
Tensile Strength - Markerband	Minimum value per specification	Pass
Tensile Strength -Wire Attachment	Minimum value per specification	Pass

1.10.3 Design Validation - Previously Completed Animal Study

The subject, 3D Revascularization Device [modified] uses the same materials, has the same indication for use, and has the same intended use as the predicate, 3D Revascularization Device. In addition, the subject, 3D Revascularization Device [modified] will be held to the same maximum radial pressure specification as the predicate, 3D Revascularization Device [K162901]. Therefore, the subject, 3D Revascularization Device [modified] presents an equivalent challenge for vessel response compared to the predicate device. Rabbit vessel response studies have been performed for the predicate, 3D Revascularization Device [K162901] with successful results. Based on the existing GLP test results, the interaction of the predicate, 3D Revascularization Device [K162901] with the rabbit vasculature is well understood. Therefore, the existing rabbit vessel response animal study results mitigate all vessel response risks for the subject, 3D Revascularization Device [modified].

1.10.4 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 clot removal. The literature review was used to support the determination of substantial equivalence by using clinical outcomes from devices that are considered technologically equivalent.

1.11 Summary of Substantial Equivalence

The subject, Penumbra System 3D Revascularization Device is substantially equivalent to the predicate device with regard to intended use, operating principle, design concept, materials, shelf-life, packaging and sterilization processes.