May 20, 2021

Penumbra, Inc.
Aditi Kolla
Regulatory Affairs Program Manager
One Penumbra Place
Alameda, California 94502

Re: K203440
Trade/Device Name: Penumbra System (Reperfusion Catheter RED 62)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: April 14, 2021
Received: April 15, 2021

Dear Aditi Kolla:

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,

Naira Muradyan, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203440

Device Name
Penumbra System (Reperfusion Catheter RED 62)

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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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 subject Penumbra System® (Reperfusion Catheter RED™ 62).

1.1 Submitter

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

Contact Person:
Aditi Kolla
Regulatory Affairs Program Manager
Tel: (510) 995-2010
Fax: (510) 217-6414
E-mail: akolla@penumbrainc.com

Date of Preparation:

May 19, 2021

1.2 Subject Device

Penumbra System® (Reperfusion Catheter RED™ 62)

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

1.3 Predicate Devices

510(k) Number	Name of Device	Name of Manufacturer
K161640	Penumbra System ACE 68 Reperfusion Catheter	Penumbra, Inc.
K162901	Penumbra 3D Revascularization Device	Penumbra, Inc.

1.4 Device Description

The Penumbra System® is comprised of the following devices:

- Penumbra Reperfusion Catheter
- Penumbra Aspiration Pump
- Penumbra Aspiration Pump/Canister Tubing
- Penumbra Aspiration Tubing
- Penumbra Separator
- Penumbra 3D Revascularization Device

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 ID of 0.054 in. 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.

1.5 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.

1.6 Comparison of Indications for Use and Technological Characteristics with the Predicate Devices

Device Attribute	Predicate Device	Subject Device
Trade Name	Penumbra System ACE 68 Reperfusion Catheter	Penumbra System (Reperfusion Catheter RED 62)
FDA Product Classification	Class II, NRY, 21 CFR 870.1250	SAME
510(k) Number	K161640	K203440
Indications for Use	Penumbra Reperfusion Catheters and Separators As part of the Penumbra System, the Reperfusion Catheters and Separators	Same as Predicate Device with K162901

Device Attribute	Predicate Device	Subject Device
	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. 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 Pump MAX. Penumbra Pump MAX The Penumbra Pump MAX is indicated as a vacuum source for Penumbra Aspiration Systems.	
Principles of Operation	See Section 1.4	SAME
Device Materials	Stainless Steel, PTFE, Polyurethane, Polyether Block Amide, Nylon 12, Nitinol, Platinum/Iridium	SAME
ID Band Color	Yellow [black text]	Black [white text]
Coating	Hydrophilic coating (proprietary)	Equivalent
Min. ID	0.068 in. (1.73 mm)	0.062 in. (1.57 mm)
Max. OD	0.084 in. (2.13 mm)	0.076 in. (1.93 mm)
Distal Flex Length	30 cm	SAME
Coating Length	30 cm	SAME
Effective Lengths	115, 120, 125, 127, 132 cm	115, 120, 125, 127, 132, 138, 160 cm
Accessories	Peelable Sheath, Shaping Mandrel, RHV	SAME
Packaging Materials	Polyester/Polyethylene/Tyvek, Polystyrene, SBS Paperboard	SAME
Condition Supplied	Sterile and Single Use	SAME
Sterilization Method	EO	SAME

Device Attribute	Predicate Device	Subject Device
Trade Name	Penumbra 3D Revascularization Device	Penumbra System (Reperfusion Catheter RED 62)
FDA Product Classification	Class II, NRY, 21 CFR 870.1250	SAME
510(k) Number	K162901	K203440
Indications For Use	<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.	SAME

Device Attribute	Predicate Device	Subject Device
	Penumbra Aspiration Pump The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.	

1.7 Performance Data

The following performance data were provided in support of the substantial equivalence determination:

- Design Verification
- Biocompatibility
- Shelf Life
- Sterilization
- Packaging Validation

The subject device met all established requirements.

1.7.1 Design Verification Testing

The following design verification tests were performed on the subject device:

Test	Test Method Summary	Conclusion
Dimensional/Visual Test	Confirms the units meet all dimensional and visual product specifications.	Acceptance Criteria Met
Friction Test	Confirms units meet product specification related to friction.	Acceptance Criteria Met
Fluoroscopy Test	Confirms the marker band is fluoroscopically visible.	Acceptance Criteria Met
Simulated Use Test	Confirms the functionality of units using clinically relevant benchtop model.	Acceptance Criteria Met
Particulate Test	Particulates generated during simulated use (including multiple deployment cycling) were evaluated.	Acceptance Criteria Met
Hub Air Test	Confirms units have no leaks when tested.	Acceptance Criteria Met
Tensile Test	Confirms units meet product specification related to tensile strength.	Acceptance Criteria Met
Pressure Test	Confirms units meet product specification related to pressure.	Acceptance Criteria Met
Elongation Test	Confirms units meet product specification related to elongation.	Acceptance Criteria Met
Corrosion Resistance Test	Confirms there is no visible corrosion on the units when tested.	Acceptance Criteria Met
Torque Strength Test	Confirms units have sufficient torque strength.	Acceptance Criteria Met
Burst Pressure Test	Confirms units can withstand sufficient pressure.	Acceptance Criteria Met
Distal Tip Stiffness Test	Confirms units have appropriate distal tip stiffness.	Acceptance Criteria Met
Shelf-Life	Confirms expiration date based on accelerated aging test studies.	Acceptance Criteria Met
Packaging Validation Test	Confirms the packaging of the units meet all product specifications.	Acceptance Criteria Met

Test	Test Method Summary	Conclusion
Sterilization Test	Confirms the units are sterilized in accordance with ISO 11135 and ISO 10993-7.	Acceptance Criteria Met

1.7.2 Biocompatibility

The biocompatibility evaluation for the subject device was conducted in accordance with ISO 10993-1, USP standards, and FDA Good Laboratory Practices (GLP) as recognized by FDA. The battery of testing included the following tests:

Tests	Results	Conclusion
Cytotoxicity: MEM Elution (ISO 10993-5)	No evidence of cell lysis or toxicity (Grade = 0, Reactivity None).	Pass
Sensitization: Magnusson-Kligman Method (ISO 10993-10)	Both Test Group & Control Group Grade = 0 None of the treated or negative control animals exhibited any reaction at the challenge. The positive control article elicited discrete reactions in all animals.	Pass
Irritation: Intracutaneous Reactivity (ISO 10993-10)	None of the animals exhibited overt signs of toxicity at any of the observation points. The test article sites did not show a significantly greater biological reaction than the sites injected with the control article.	Pass
Systemic Toxicity: Acute Systemic Injection (ISO 10993-11)	No evidence of systemic toxicity from sample extracts. That is: • No deaths; • No signs consistent with toxicity; • No weight loss > 10%.	Pass
Systemic Toxicity: Material Mediated Pyrogen (ISO 10993-11)	Non-pyrogenic: no single animal had an individual rise in body temperature ≥ 0.5 °C.	Pass
Hemocompatibility: In-vitro Thrombogenicity (ISO 10993-4)	Device non-thrombogenic in vitro when compared to a predicate device.	Pass
Hemocompatibility: Partial Thromboplastin Time (PTT) (ISO 10993-4)	Test article coagulation times are statistically similar to predicate.	Pass
Hemocompatibility: Complement Activation (ISO 10993-4)	Test article concentrations of Sc5b-9 are statistically similar to predicate.	Pass
Hemocompatibility: Hemolysis, indirect contact (ISO 10993-4)	Hemolytic Index = 0.00%.	Pass

Tests	Results	Conclusion
Hemocompatibility: Hemolysis, direct contact (ISO 10993-4)	Hemolytic Index = 0.00%.	Pass

Biocompatibility test results demonstrate biological safety per ISO 10993 and USP requirements.

1.7.3 Performance Data – Animal, Clinical

No animal or clinical study was conducted as bench testing was determined sufficient for verification and validation purposes.

1.8 Conclusions

The subject Penumbra System® (Reperfusion Catheter RED™ 62) is substantially equivalent to the predicate devices Penumbra System ACE 68 Reperfusion Catheter and Penumbra 3D Revascularization Device. The subject device has the same intended use as the predicate devices. The device testing described in the 510(k) Summary demonstrates the subject device is substantially equivalent to the predicate devices in regard to intended use, operating principle, design concept, fundamental technology and device performance.