DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 12, 2016

Penumbra, Inc.
Mr. Charles DeNault
Regulatory Affairs Specialist III
One Penumbra Place
Alameda, California 94502

Re: K161064
Trade/Device Name: Penumbra System ACE 68 Reperfusion Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: May 23, 2016
Received: May 24, 2016

Dear Mr. Charles DeNault:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161064

Device Name
Penumbra System ACE 68 Reperfusion Catheter

Indications for Use *(Describe)*
The Penumbra System is intended 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.

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® ACE™ 68 Reperfusion Catheter.

1.1 Sponsor/Applicant Name and Address

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

1.2 Sponsor Contact Information

Charles DeNault
Regulatory Affairs Specialist III
Phone: (510) 748-3302
FAX: (510) 217-6414
Email: cdenault@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

June 1, 2016

1.4 Device Trade or Proprietary Name

Penumbra System® ACE™ 68 Reperfusion Catheter

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 Predicate Device	Name of Manufacturer
K152541	January 13, 2016	Penumbra System® ACE™ 68 Reperfusion Catheter	Penumbra, Inc. One Penumbra Place Alameda, CA 94502 USA

1.7 Predicate Comparison

Design modifications were made to the subject device. Changes include a reduction of the device markerband length as well as dimensional changes to the device PTFE liner, coil reinforcement filaments, and extrusions.

	Predicate: ACE 68	Subject: ACE 68
General		
510(k) No.	K152541	K161064
Classification	Class II, NRY	SAME
Indication	The Penumbra System is intended 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.	SAME
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 ink]	SAME
Liner	PTFE	SAME
Coil Reinforcement	304V SS, Nitinol (55% Ni, 45% Ti)	SAME
Proximal Extrusions	Vestamid, Pebax 72D, Pebax 55D/72D blend	SAME
Distal Extrusions	Pebax 63D, Pebax 55D, Pebax 40D/55D Blend, Pebax 40D, Pebax 35D/40D Blend, Pebax 35D, Tecoflex 80A/Pebax 35D, Tecoflex 80A, Pellethane 80A	SAME
Extrusion Colorants	Clear/Natural or Purple	SAME
Markerband	Platinum/Iridium (90% Pt, 10% Ir)	SAME
Coating	SRDX Harmony (proprietary)	SAME
Dimensions		
Proximal OD	0.084 in. max	SAME
Proximal ID	0.068 in. min	SAME
Distal OD	0.084 in. max	SAME
Distal ID	0.068 in. min	SAME
Effective Lengths	115, 120, 125, 127, 132 cm	SAME
Distal Flex Length	30 cm	SAME
Coating Length	30 cm	SAME

	Predicate: ACE 68	Subject: ACE 68
Tip Shape	Straight	SAME
Accessories		
Peelable Sheath	PTFE	SAME
Rotating Hemostasis Valve	Polycarbonate, silicone o-ring	SAME
Shaping Mandrel	0.038 in. 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
Other		
Sterilization	EO	SAME
Shelf-Life	36 Months	8 Months
Use	Single use, disposable	SAME

1.8 Device Description

The Penumbra System ACE 68 Reperfusion Catheter is a component to the currently available Penumbra System. The ACE 68 Reperfusion Catheter is used with the Aspiration Pump to aspirate thrombus from an occluded vessel in the neurovasculature. ACE 68 is provided sterile, non-pyrogenic, and intended for single use only.

1.9 Indications for Use

The Penumbra System is intended 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.

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 devices follows.

Included in this section is a summary description of the testing, which substantiates the performance of the subject ACE 68 Reperfusion Catheter as well as its substantial equivalence to the predicate devices:

- Design Verification (Bench-Top Testing)

- Shelf Life Testing

The subject ACE 68 Reperfusion Catheters met all established requirements.

1.10.1 Design Verification (Bench-Top Testing)

The physical and mechanical properties of the ACE 68 Reperfusion Catheter were assessed using standard test methods and pre-determined acceptance criteria. The following tests were performed and all tests passed successfully:

Attribute	Specification	Results
Packaging Inspection	Confirm the packaging and dimensions of the units meet all product specifications.	Pass
Dimensional/Visual		Pass
Kink Resistance	No kinking when formed in a defined radius	Pass
Markerband Visibility	The markerband is fluoroscopically visible	Pass
Simulated Use (Intracranial Access, Vessel Access Entry Performance & Clot Removal)	Simulated use testing of the Reperfusion Catheter and Separator 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
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
Hub Air Aspiration	No leaks detected when vacuum is pulled on the injection lumen	Pass
Static Burst Pressure Test	45 psi for 30 sec minimum	Pass
ACE 68 / Sheath or 8F Guide Catheter Friction Force	Minimum value per specification	Pass
ACE 68 / 0.014 in. Guidewire Friction Force	Minimum value per specification	Pass
Joint sections bond strength	Minimum value per specification	Pass
Hub to shaft tensile strength	Minimum value per specification	Pass
Hub to hypotube tensile 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

1.10.2 Shelf Life Testing

The device stability and packaging integrity of the ACE 68 Reperfusion Catheter were assessed using standard test methods and pre-determined acceptance criteria. Devices underwent transportation conditioning per ASTM D4169 and accelerated aging equal to 8 months. Results of successful testing verify the ACE 68 Reperfusion Catheter may be labeled with an 8-month shelf life.

1.11 Summary of Substantial Equivalence

The subject Penumbra System ACE 68 Reperfusion Catheter is substantially equivalent to the predicate device with regard to intended use, operating principle, design concept, materials, shelf-life, packaging and sterilization processes.