



Food and Drug Administration
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January 13, 2016

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

Re: K152541

Trade/Device Name: Penumbra System ACE 64 and ACE 68 Reperfusion Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: December 11, 2015
Received: December 14, 2015

Dear Ms. Michaela Mahl:

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,

Michael J. Hoffmann -A

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

Indications for Use

510(k) Number (if known)

K152541

Device Name

Penumbra System® ACE 64 and ACE 68 Reperfusion Catheters

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 - K152541

(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 64 and ACE 68 Reperfusion Catheters .

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
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Email: michaela.mahl@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

December 11, 2015

1.4 Device Trade or Proprietary Name

Penumbra System[®] ACE 64 and ACE 68 Reperfusion Catheters

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
K142458 / 22May2015	Penumbra System [®] ACE 64 and ACE 68 Reperfusion Catheters	Penumbra, Inc. One Penumbra Place Alameda, CA 94502 USA

1.7 Predicate Comparison

System Name	Predicate Reperfusion Catheters		Subject Reperfusion Catheters	
	ACE 64	ACE 68	ACE 64	ACE 68
Device Name	ACE 64	ACE 68	ACE 64	ACE 68
510(k) No.	K142458		K152541	
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. The Reperfusion Catheters ACE 64 and ACE 68 are intended for use in revascularization within the Internal Carotid Artery (ICA) within 8 hours of symptom onset.		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.	
Materials				
Proximal hub	Grilamid (TR55-LX)		SAME	
Strain Relief [Hub Sleeve]	Grilamid (TR55)		SAME	
Strain Relief	Stainless Steel, 304		SAME	
ID Band	Polyolefin, PET yellow [black ink]		SAME	
Catheter Shaft				
Distal Extrusions	Pellethane 80A, Tecoflex 80A, Tecoflex 80A/Pebax 35D, Pebax 35D, Pebax 35D/40D Blend, Pebax 40D, Pebax 40D/55D Blend, Pebax 55D, Pebax 63D		SAME	
Proximal Extrusions	Pebax 55D, Pebax 72D, Vestamid	Pebax 55D/72D Blend, Pebax 72D, Vestamid	SAME	SAME
Proximal Coil Reinforcement	SS flat (0.0015 in x 0.006 in) and SS round (0.0025 in)	SS flat (0.0015 in x 0.006 in) and NiTi round (0.0025 in)	SAME	SAME
Extrusion Colorants	Clear/ Natural or Purple		SAME	
Tip Shape	Straight		SAME	
Markerband	C-cut Pt/Ir band		SAME	
Coating	SRDX Harmony (proprietary)		SAME	
Dimensions				
Proximal OD	0.084 in Max	0.084 in Max	SAME	SAME
Proximal ID	0.068 in Min	0.068 in Min	SAME	SAME
Distal OD	0.080 in Max	0.084 in Max	SAME	SAME
Distal ID	0.064 in Min	0.068 in Min	SAME	SAME
Effective Length	115, 120, 125, 127, 132 cm		SAME	
Coating Length	30 cm		SAME	
Accessories				
Peelable Sheath	PTFE		SAME	

System Name	Predicate Reperfusion Catheters		Subject Reperfusion Catheters	
	ACE 64	ACE 68	ACE 64	ACE 68
Rotating Hemostasis Valve	Polycarbonate, silicone o-ring		SAME	
Shaping Mandrel	0.038in OD		SAME	
Packaging Materials				
Pouch	Polyester/Polyethylene/ Tyvek [®]		SAME	
Packaging Hoop	Polyethylene		SAME	
Packaging Card	Polyethylene		SAME	
Display Carton	SBS Paperboard		SAME	
Packaging Configuration	Individual		SAME	
Sterilization	EO		SAME	
Shelf-Life	36 Months		SAME	

1.8 Device Description

The Penumbra System ACE 64 and ACE 68 Reperfusion Catheters are components to the currently available Penumbra System. The Penumbra System ACE AC 64 and ACE 68 Reperfusion Catheters are used with the Aspiration Pump to aspirate thrombus from an occluded vessel in the neurovasculature. The devices are 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 Penumbra System ACE 64 and ACE 68 Reperfusion Catheters as well as its substantial equivalence to the predicate devices:

- Design Validation (GLP Animal Testing)

The subject Penumbra System ACE 64 and ACE 68 Reperfusion Catheters met all established requirements.

1.10.1 Animal Study

The safety and performance of the ACE 64 and ACE 68 Reperfusion Catheters, when “wedged” in a vessel and using maximum aspiration, was evaluated in the accepted porcine vascular model. The purpose of this study was to evaluate the Reperfusion Catheter ACE aspiration vascular response when “wedged” within a swine artery. Safety of the test articles was assessed by consideration of the acute and chronic vascular response. Vascular response was assessed by contrast angiography and by gross necropsy and histopathology of associated vasculature performed by the Sponsor Pathologist.

The study concluded that:

- No significant vessel response was noted on the contrast angiograms following the aspiration treatment with the test article in a wedged position.
- No significant pathological findings were identified during the gross or histopathological evaluation.

1.10.2 Leveraged Non-Clinical Data

The subject and predicate devices are identical. There are no changes in the device design, materials, manufacturing, packaging and sterilization methods, therefore biocompatibility data, bench-top data, sterilization data and stability data from the predicate devices (K142458) are directly applicable and no additional testing is required or was performed.

1.11 Summary of Substantial Equivalence

The subject Penumbra System ACE 64 and ACE 68 Reperfusion Catheters are substantially equivalent to the predicate device with regard to intended use, operating principle, design concept, materials, shelf-life, packaging and sterilization processes.