DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 6, 2015

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

Re: K151623
Trade/Device Name: Penumbra System 110 Aspiration Tubing
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: July 6, 2015
Received: July 7, 2015

Dear Ms. 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,

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)*
K151623

Device Name
Penumbra System 110 Aspiration Tubing

Indications for Use *(Describe)*
The Penumbra System / Penumbra System MAX are 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.

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
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PRAStaff@fda.hhs.gov

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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)*
K151623

Device Name
Penumbra System 110 Aspiration Tubing

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. 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.

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)

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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 110 Aspiration Tubing.

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: michaela.mahl@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

August 06, 2015

1.4 Device Trade or Proprietary Name

Penumbra System® 110 Aspiration Tubing

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
K133317 [13MAY2014]	Penumbra System® and Penumbra System MAX®	Penumbra, Inc. One Penumbra Place Alameda, CA 94502 USA
K142458 [22May2015]	Penumbra System® ACE 64 and ACE 68 Reperfusion Catheters	

1.7 Predicate Comparison

Predicate 1:

	Predicate Device	Subject Device
Device Name	**MAX Aspiration Tubing**	**110 Aspiration Tubing**
510(k) No.	K133317	K151623
Classification	Class II, NRY	SAME
Indication	The Penumbra System / Penumbra System MAX are 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		
Luer fittings	Polycarbonate (2018-15-FC030004 or equivalent); Isoplast 2530; EPDM RED, Silicone coated	SAME
Adhesive	Loctite 3311 (Acrylated Urethane)	SAME
Solvent	Cyclohexanone, MEK solvent	SAME
Vacuum connector	Polyvinylchloride	SAME
Tubing	Polyurethane (Pellethane 2363-80A) and Nylon	SAME
Male/Female adaptor Luer	Polycarbonate (Makrolon or equivalent)	SAME
Flow control switch	Polycarbonate (Lexan or equiv); Acetal (Hostaform or equiv); ABS; Silicone	SAME
OFF label	Polyolefin (red)	SAME
ON label	MARAPROP PP black ink (solvent naphtha (petroleum); 2-methoxy-1-methylethyl acetate; xylene; ethylbenzene)	SAME
Dimensions		
Tubing OD	0.188in ± 0.005in	SAME
Tubing ID	0.088in ± 0.005in	0.110in ± 0.005in
Overall Length	112.0in ± 7.0in	SAME
Distal Length	7.0in ± 2.0in	SAME
Accessories	None	SAME
Packaging Materials		
Pouch	Polyester/Polyethylene/ Tyvek®	SAME
Display Carton	SBS Paperboard	SAME
Packaging Configuration	Individual	SAME
Sterilization	EO	SAME
Shelf-Life	36 Months	SAME

Predicate 2:

	Predicate Device	Subject Device
Device Name	**MAX Aspiration Tubing**	**110 Aspiration Tubing**
510(k) No.	K142458	K151623
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.	SAME
Materials		
Luer fittings	Polycarbonate (2018-15-FC030004 or equivalent); Isoplast 2530; EPDM RED, Silicone coated	SAME
Adhesive	Loctite 3311 (Acrylated Urethane)	SAME
Solvent	Cyclohexanone, MEK solvent	SAME
Vacuum connector	Polyvinylchloride	SAME
Tubing	Polyurethane (Pellethane 2363-80A) and Nylon	SAME
Male/Female adaptor Luer	Polycarbonate (Makrolon or equivalent)	SAME
Flow control switch	Polycarbonate (Lexan or equiv); Acetal (Hostaform or equiv); ABS; Silicone	SAME
OFF label	Polyolefin (red)	SAME
ON label	MARAPROP PP black ink (solvent naphtha (petroleum); 2-methoxy-1-methylethyl acetate; xylene; ethylbenzene)	SAME
Dimensions		
Tubing OD	0.188in ± 0.005in	SAME
Tubing ID	0.088in ± 0.005in	0.110in ± 0.005in
Overall Length	112.0in ± 7.0in	SAME
Distal Length	7.0in ± 2.0in	SAME
Accessories	None	SAME
Packaging Materials		
Pouch	Polyester/Polyethylene/ Tyvek®	SAME
Display Carton	SBS Paperboard	SAME
Packaging Configuration	Individual	SAME
Sterilization	EO	SAME
Shelf-Life	36 Months	SAME

1.8 Device Description

The subject Penumbra System 110 Aspiration Tubing Assembly connects the Pump Canister to the Reperfusion Catheters, providing a means for introducing vacuum during procedures, which is identical to the predicate MAX Aspiration Tubing [K133317 and K142458]. Furthermore, the 110 Aspiration Tubing has a flow valve that allows the physician to start and stop the flow of aspiration, which is identical to the predicate MAX Aspiration Tubing [K133317 and K142458]. The Penumbra System 110 Aspiration Tubing has a slightly larger inner diameter of 0.110in compared to the predicate to accommodate larger clot burdens, this is the only difference to the predicate MAX Aspiration Tubing [K133317 and K142458]. The Penumbra System 110 Aspiration Tubing is compatible with all Penumbra System Reperfusion Catheters and Separators included in K133317 and K142458. The device is provided sterile, non-pyrogenic, and intended for single use only, which is identical to the predicate MAX Aspiration Tubing [K133317 and K142458].

1.9 Indications For Use

The Penumbra System / Penumbra System MAX are 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.

and

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.

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 performance of the subject Penumbra System 110 Aspiration Tubing as well as its substantial equivalence to the predicate device:

- Biocompatibility
- Design Verification (Bench-Top Testing)

The subject Penumbra System 110 Aspiration Tubing device met all established requirements.

1.10.1 Biocompatibility Testing

Evidence of the biocompatibility of the 110 Aspiration Tubing materials is derived from a series of previously successfully performed studies on the predicate device. The studies were selected in accordance with EN ISO 10993-1 guidelines. The studies were selected in accordance with EN ISO 10993-1 guidelines (Biological Evaluation of Medical Devices) for a limited exposure (≤ 24 hours), surface device, with skin contact. All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices (GLP). The following tests were previously performed and all tests passed successfully:

Test / Standard	Acceptance Criteria	Results	Pass / Fail
Cytotoxicity (MEM Elution) / EN ISO 10993-5	Sample extracts must yield a cell lysis grade of 2 or lower	Grade 0: None	Pass
Sensitization / EN ISO 10993-10	Test Group shall yield Grade < 1 score on Magnusson and Kligman scale (provided Control Grade < 1)	Grade 0: No visible change	Pass
Irritation (Intracutaneous Reactivity Irritation Test) / EN ISO 10993-10	The difference in the mean test article and mean control score must be grade 1.0 or lower	Grade 0.1 difference (saline extract) and Grade 0.2 difference (cottonseed oil extract)	Pass

As all materials of the subject 110 Aspiration Tubing are identical to the materials of the predicate device [K133317 and K142458] biocompatibility is established. In summary, non-clinical testing found the 110 Aspiration Tubing materials to be non-cytotoxic, non-sensitizing, and a non-irritant.

1.10.2 Bench-top Testing

The physical and mechanical properties of the Penumbra System 110 Aspiration Tubing was assessed using the identical test methods and acceptance criteria as

the predicate [K133317 and K142458]. The following tests were performed and all tests passed successfully:

Attribute	Specification	Acceptance Criteria	Results
Dimensional/ Visual Inspection	These evaluations confirm that the units used in this Design Verification testing meet all inspection criteria for release of finished goods (clinically acceptable) product.		Pass
Performance/Simulated Use and Leak Test			
Suction Connector	110 Aspiration Tubing securely attaches to canister lid	100% Must meet Specification	Pass
RHV Compatibility	110 Aspiration Tubing Assembly distal luer securely connects to RHV port	100% Must meet Specification	Pass
Lumen Ovalization	110 Aspiration Tubing maintains functionality and maintains an open lumen at vacuum pressure of 25inHg minimum for 30 seconds minimum	100% Must meet Specification	Pass
Joints Leak	110 Aspiration Tubing Assembly maintains functionality with no leaks at vacuum pressure of 25inHg minimum for 30 seconds minimum	100% Must meet Specification	Pass
Destructive Testing			
Suction Connector / Tubing Joint	2.0 lbf minimum	100% Must meet Specification	Pass
Distal Rotating Male Luer / Tubing Joint	2.0 lbf minimum	100% Must meet Specification	Pass
Proximal Rotating Male Luer / Tubing Joint	2.0 lbf minimum	100% Must meet Specification	Pass
Female Luer / Tubing Joint	2.0 lbf minimum	100% Must meet Specification	Pass

The results of the tests appropriately address the physical and mechanical performance expectations of the device. Based on these overall results, the physical and mechanical properties of the subject Penumbra System 110 Aspiration Tubing is acceptable for the intended use and substantially equivalent to the predicate device.

1.10.3 Summary of Substantial Equivalence

The subject Penumbra System 110 Aspiration Tubing is substantially equivalent to the predicate device [K133317 and K142458] with regard to intended use, operating principle, design concept, materials, shelf-life, packaging and sterilization processes.