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

September 26, 2016

Penumbra, Inc.
Richard Kimura
Regulatory Affairs Specialist
1 Penumbra Place
Alameda, California 94502

Re: K161506
Trade/Device Name: Penumbra Aspiration System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: August 23, 2016
Received: August 24, 2016

Dear Mr. Kimura:

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" (21CFR 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,

Brian D. Pullin -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K161506

Device Name
Penumbra Aspiration System

Indications for Use *(Describe)*

Penumbra Aspiration Catheters and Separators

As part of the Penumbra Aspiration System, the Penumbra Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature.

Penumbra Aspiration Tubing

As part of the Penumbra Aspiration System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Aspiration 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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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 Aspiration System.

1.1 Sponsor/Applicant Name and Address

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

1.2 Sponsor Contact Information

Richard Kimura
Regulatory Affairs Specialist
Phone: (510) 995-2034
FAX: (510) 217-6414
Email: rkimura@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

May 31, 2016

1.4 Device Trade or Proprietary Name

Penumbra Aspiration System

1.5 Device Classification

Regulatory Class:	II
Classification Panel:	Cardiovascular
Classification Name:	Catheter, Embolectomy
Regulation Number:	21 CFR §870.5150
Product Code:	DXE

1.6 Predicate and Reference Devices

510(k) Number/ Clearance Date	Name of Device	Name of Manufacturer
Predicate Device		
K103405[22Dec2010]	Pronto V4 Extraction Catheter	Vascular Solutions, Inc.
Reference Devices		
K072718 [28Dec2007]	Penumbra System [026, 032, 041]	Penumbra, Inc.
K090752 [21Sep2009]	Penumbra System [054]	Penumbra, Inc.
K100769 [21May2010]	Penumbra System Separator Flex [026, 032,	Penumbra, Inc.

510(k) Number/ Clearance Date	Name of Device	Name of Manufacturer
	041, 054]	
K113163 [23Nov2011]	Penumbra System MAX	Penumbra, Inc.
K151623[06Aug2015]	Penumbra System 110 Aspiration Tubing	Penumbra, Inc.
K160449[25May2016]	Penumbra System	Penumbra, Inc.
K121917[19Sep2012]	Penumbra Embolectomy Aspiration System (INDIGO Aspiration System)	Penumbra, Inc.
K142870[26May2015]	Penumbra Embolectomy Aspiration System (INDIGO Aspiration System)	Penumbra, Inc.
K160533[24May2016]	Penumbra Embolectomy Aspiration System (INDIGO Aspiration System)	Penumbra, Inc.
K122756[02Oct2012]	Penumbra Pump MAX	Penumbra, Inc.

1.7 Predicate and Reference Device Comparison

	Predicate Device	Reference Devices		Subject Device
Trade Name	Pronto V4 Extraction Catheter	Penumbra System	INDIGO Aspiration System	Penumbra Aspiration System
510(k) No.	K103405	K072718, K090752, K100769, K113163, K151623, K122756, and K160449	K121917, K142870, and K160533	To be determined
Classification	Class II, DXE	SAME	SAME	SAME
Indication for Use	The Pronto Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature.	Penumbra Reperfusion Catheters and Separators As part of the Penumbra System, the Reperfusion Catheters and Separators are indicated for the 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.	INDIGO Aspiration Catheters and Separators As part of the Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System), the INDIGO Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli, and thrombi from vessels of the peripheral arterial and venous systems. Not for use in the coronaries or the neurovasculature. INDIGO Aspiration Tubing As part of the Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System), the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Pump MAX. Penumbra Pump MAX The Penumbra Pump MAX is indicated as a vacuum source for Penumbra Aspiration Systems.	Penumbra Aspiration Catheters and Separators As part of the Penumbra Aspiration System, the Penumbra Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature. Penumbra Aspiration Tubing As part of the Penumbra Aspiration System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Aspiration Catheters to the Penumbra Aspiration Pump. Penumbra Aspiration Pump The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.

	Predicate Device	Reference Devices		Subject Device
Trade Name	Pronto V4 Extraction Catheter	Penumbra System	INDIGO Aspiration System	Penumbra Aspiration System
510(k) No.	K103405	K072718, K090752, K100769, K113163, K151623, K122756, and K160449	K121917, K142870, and K160533	To be determined
Classification	Class II, DXE	SAME	SAME	SAME
Aspiration Catheter				
Materials	Biocompatible, commonly utilized for interventional devices	SAME	SAME	SAME
Coating	Hydrophilic	SAME	SAME	SAME
Markerband	Radiopaque	SAME	SAME	SAME
Guidewire compatible	Yes	SAME	SAME	SAME
Dimensions				
- OD [Maximum]	0.0645” – 0.0865” (1.64 – 2.20 mm)	0.037” – 0.083” (0.94mm – 2.1mm)	0.037” – 0.112” (0.94mm – 2.84mm)	SAME AS THE INDIGO SYSTEM
- Working Length	Approximately 138 cm	118m – 153cm	30cm – 153cm	SAME AS THE INDIGO SYSTEM
Separator				
Materials	N/A	Biocompatible, commonly utilized for interventional devices	Biocompatible, commonly utilized for interventional devices	Biocompatible, commonly utilized for interventional devices
Dimensions				
- Distal OD	N/A	0.022” – 0.045” (0.56mm – 1.1mm)	0.022” – 0.068” (0.56mm – 1.7mm)	SAME AS THE INDIGO SYSTEM
- Working Length	N/A	175cm – 200cm	150cm – 200cm	SAME AS THE INDIGO SYSTEM
Aspiration Tubing				
Materials	Biocompatible, commonly utilized for interventional devices	SAME	SAME	SAME
Dimensions				

	Predicate Device	Reference Devices		Subject Device
Trade Name	Pronto V4 Extraction Catheter	Penumbra System	INDIGO Aspiration System	Penumbra Aspiration System
510(k) No.	K103405	K072718, K090752, K100769, K113163, K151623, K122756, and K160449	K121917, K142870, and K160533	To be determined
Classification	Class II, DXE	SAME	SAME	SAME
- ID	unknown	0.071" – 0.110 " (1.8mm – 2.79mm)	0.071" – 0.110 " (1.8mm – 2.79mm)	0.088" and 0.110 " (2.2mm and 2.79mm)
- Length	unknown	112.0" (284.5cm)	112.0" (284.5cm)	112.0" (284.5cm)
Sterilization	**EO**	**SAME**	**SAME**	**SAME**
Shelf-Life	**36 months**	**SAME**	**SAME**	**SAME**
Aspiration Source				
	Aspiration Syringe	**Aspiration Pump**	**Aspiration Pump**	**Aspiration Pump**
IEC 60601-1 Compliance	N/A	Yes	Yes	Yes
IEC 60601-1-2 Compliance	N/A	Yes	Yes	Yes
Voltage	N/A	100-115 Vac/230 Vac	100-115 Vac/230 Vac	100-115 Vac/230 Vac
Frequency	N/A	50 Hz/60 Hz	50 Hz/60 Hz	50 Hz/60 Hz
Sterilization	unknown	Non sterile	Non sterile	Non sterile
Shelf Life	unknown	N/A	N/A	N/A

1.8 Device Description

The Penumbra Aspiration System

The Penumbra Aspiration System is indicated for the removal of fresh, soft emboli and thrombi from vessels of the coronary and peripheral vasculature. The Aspiration Catheter and Separator are available in multiple configurations. The devices are provided sterile, non-pyrogenic, and intended for single use only. Intended users for this device are physicians who have received appropriate training in interventional radiology.

The Penumbra Aspiration System is designed to remove thrombus from the coronary and peripheral vasculature using continuous aspiration. The Aspiration Catheter targets aspiration from the pump directly to the thrombus. The Separator may be used to clear the lumen of the Aspiration Catheter should it become blocked with thrombus. The use of the Separator may not be necessary when using an Aspiration Catheter with an I.D. of 0.054 in or larger. The Aspiration Catheter is introduced through a guide catheter or long introducer sheath and into the coronary or peripheral vasculature and guided over a guidewire to the site of the primary occlusion. The Aspiration Catheter is used with the Penumbra Pump MAX to aspirate thrombus from an occluded vessel. As needed, the Separator may be deployed from the Aspiration Catheter to assist with thrombus removal. The Separator is advanced and retracted through the Aspiration Catheter at the proximal margin of the primary occlusion to facilitate clearing of the thrombus from the Aspiration Catheter tip. For the aspiration source, the Aspiration Catheter is used in conjunction with the Penumbra Pump MAX, which is connected using the Aspiration Tubing and the Penumbra Pump/Canister Tubing. The Separator is provided with an introducer and torque device. The Aspiration Catheter may be provided with a steam shaping mandrel, rotating hemostasis valve, and a peelable sheath. The Separator is provided with an introducer and torque device. The Aspiration Catheter and Separator are visible under fluoroscopy.

The Penumbra Pump MAX

The Penumbra Pump MAX is the aspiration source for the Penumbra Aspiration System. The Penumbra Pump MAX operates using AC power and is designed to be portable if needed. The Penumbra Pump MAX provides vacuum of up to 29 inHg. The pump is available in both 110Vac and 230Vac versions.

The front face of the pump has a display panel with a vacuum gauge, vacuum regulator dial, and power switch. The pump connects to the canister reservoir with a tubing assembly (Penumbra Pump/Canister Tubing), which is provided as an accessory. The Penumbra Pump/Canister Tubing consists of a short tubing segment with an inline filter and connectors on each end to facilitate attachment to the pump's vacuum port. The tubing is provided pre-attached to the canister reservoir lid. The Penumbra Pump/Canister Tubing is provided non-sterile and is used outside the sterile field.

1.9 Indications for Use

Penumbra Aspiration Catheters and Separators

As part of the Penumbra Aspiration System, the Penumbra Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels of the coronary and peripheral vasculature.

Penumbra Aspiration Tubing

As part of the Penumbra Aspiration System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Aspiration Catheters to the Penumbra Aspiration Pump.

Penumbra Aspiration Pump

The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.

1.10 Leveraged Non-Clinical Data

The subject Penumbra Aspiration System devices are identical to the reference Penumbra System and INDIGO System devices. All bench top testing conducted on the reference Penumbra System and INDIGO System devices to evaluate the physical and mechanical properties of the system are therefore applicable to the subject Penumbra Aspiration System. The following bench top tests were performed and all established requirements and acceptance criteria were met:

- Visual & Dimensional
- Pouch Seal Strength
- Tensile Test
- Friction Test
- Flow Rate Test
- Elongation Test

- Bond Strength
- Hub Air Aspiration
- Burst Test
- Particulate Test
- Packaging Test
- Corrosion Test
- Torsion Test
- Simulated Use Test
- Flexibility Test

In addition, the Penumbra Aspiration System devices are manufactured using identical materials, and utilize the same manufacturing, packaging, and sterilization methods as the reference Penumbra System and INDIGO System devices. Therefore, biocompatibility data, sterilization data, and stability data from previous pre-market notifications listed in Section 1.6 are directly applicable and no additional testing was required or was performed to support the Penumbra Aspiration System.

1.11 Leveraged Animal Studies

The subject Penumbra Aspiration System is identical to the reference Penumbra System and reference INDIGO System. Design Validation (GLP Animal Testing) was conducted on the reference Penumbra System and INDIGO System, the results are which are also applicable to the subject Penumbra Aspiration System. Therefore, Animal Testing data from previous pre-market notifications listed in Section 1.6 are directly applicable and no further Animal Testing was required or was performed to support the Penumbra Aspiration System.

The studies concluded that:

- No vessel injury was noted on the final angiograms following the vessel response procedure.
- No abnormal gross or histology findings were noted in test vessel segments.
- The use of the devices resulted in no significant vascular response in these experimental conditions.

1.12 Summary of Substantial Equivalence

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