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 14, 2017

Penumbra, Inc.
Mary Rose
Director, Regulatory Affairs
One Penumbra Place
Alameda, California 94502

Re: K171332
Trade/Device Name: Artemis Neuro Evacuation Device
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG
Dated: July 14, 2017
Received: July 17, 2017

Dear Ms. Rose:

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,

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)*
K171332

Device Name
Artemis™ Neuro Evacuation Device

Indications for Use *(Describe)*
The Artemis™ Neuro Evacuation Device is used for the controlled aspiration of tissue and/or fluid during surgery of the Ventricular System or Cerebrum in conjunction with a Penumbra Aspiration Pump.

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

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)

1.1 Sponsor/Applicant Name and Address

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

1.2 Sponsor Contact Information

Mary Rose
Director, Regulatory Affairs
Phone: 510-748-3346
FAX: 510-217-6414
email: mary.rose@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

July 14, 2017

1.4 Device Trade or Proprietary Name

Artemis™ Neuro Evacuation Device

1.5 Device Common/Usual or Classification Name

Endoscope, neurological (Product Code: GWG)

1.6 Primary Device Classification

Regulatory Class:	II
Classification Panel:	Neurology
Classification Name:	Endoscope, neurological
Regulation Number:	21 CFR 882.1480
Product Code:	GWG

1.7 Predicate Devices

510(k) Number	Clearance Date	Name of Predicate Device	Name of Manufacturer
K132931	01/17/14	Apollo System	Penumbra, Inc.
K152699	03/17/16	Apollo System	Penumbra, Inc.
Reference Devices			
K160533	05/24/16	Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System)	Penumbra, Inc.
K160449	05/25/16	Penumbra System® and Penumbra Pump MAX	Penumbra, Inc.

1.8 Predicate Comparison

	Apollo™ System	Subject Device: Artemis™ Neuro Evacuation Device
510(k) No.	K132931, K152699	K171332
Classification	Class II, GWG	Class II, GWG
Intended Use	Used for the controlled aspiration of tissue and/or fluid during surgery of the Ventricular System or Cerebrum.	SAME
Aspiration Control	Fingertip controlled via vacuum regulator hole on Wand handle.	SAME
Mechanism of Action	Vacuum Aspiration aided by Vibrational Energy	Vacuum Aspiration aided by Rotational Energy
Power Source for Mechanism of Action	Apollo Generator	Primary Cell Lithium Ion Battery, 1.5 Volt DC Motor contained within the handle
Aspiration Source	Apollo Pump	Penumbra Aspiration Pump
Wand Hypotube	304 Stainless Steel	SAME
Wand Materials	Polymer, Metal	SAME
Wand Dimensions	L: 27.0 cm – 28.0 cm ID: 0.060″ – 0.088″ OD: 0.072″ – 0.101″	L: 26.1 cm – 27.0 cm ID: 00.048″ – 0.100″ OD: 00.058″ – 0.109″
Aspiration Tubing Material	Polymer	SAME

	Apollo™ System	**Subject Device:** Artemis™ Neuro Evacuation Device
Aspiration Tubing Dimensions	OD: 0.188″ ID: 0.088″	OD: 0.263″ ID: 0.163″
Single Use or Reusable	Single Use	SAME
Sterilization	EO	Gamma
Shelf-Life	12-Months – Wand	SAME
Aspiration Pump	**Apollo System Pump**	**Penumbra Aspiration Pump**
IEC 60601-1 Compliance	Yes	SAME
IEC 60601-1-2 Compliance	Yes	SAME
Voltage	100-115 VAC/230 VAC	SAME
Frequency	50 Hz/60 Hz	SAME
Maximum Vacuum	29 inHg	SAME
Maximum Flow rate	0.8 SCFM	SAME

1.9 Device Description

The Artemis™ Neuro Evacuation Device, is a surgical instrument designed to aid a physician in the removal of tissue and/or fluid during image-guided neurosurgery. The Artemis Wand has two functions. These functions are control and transfer of aspiration and generation of rotational energy. Aspiration is generated by a Penumbra Aspiration Pump, which the Artemis Wand connects to through its flexible tubing. The Artemis Wand has a rigid hypotube containing a wire to facilitate removing tissue and/or fluid with the assistance of rotational energy and aspiration.

The Artemis Wand is designed to be image-guided, allowing visualization of the procedure. The method of removal is vacuum aspiration, which draws the tissue and/or fluid into the lumen of the Wand hypotube. The integrated wire is fully contained within the lumen of the Wand hypotube, and has rotational capability facilitating movement of any tissue and/or fluid that may otherwise clog the hypotube lumen.

Intended users for this device are physicians who have received appropriate training in image-guided neurosurgery.

1.10 Indications for Use

The Artemis™ Neuro Evacuation Device is used for the controlled aspiration of tissue and/or fluid during surgery of the Ventricular System or Cerebrum in conjunction with a Penumbra Aspiration Pump.

Penumbra Aspiration Pump:

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

1.11 Summary of Non-clinical Data

Included in this section is a description of the testing, which substantiates the safe and effective performance of the subject Artemis™ Neuro Evacuation Device as well as its substantial equivalence to the predicate device:

- Biocompatibility
- Design Verification (Bench-Top Testing)
- EMC
- Sterilization
- Shelf-life

1.11.1 Biocompatibility

Biocompatibility testing was performed on the subject Artemis™ Neuro Evacuation Device. Tests were selected in accordance with EN ISO 10993-1 guidelines (Biological Evaluation of Medical Devices) and FDA Guidance. All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices.

The following tests were performed based contact type and duration:

Test	Method	Conclusions
In vitro Cytotoxicity	MEM Elution Test	Non-toxic
Sensitization (Magnusson-Kligman Method)	ISO Guinea Pig Maximization Sensitization Test	Non-sensitizing

Test	Method	Conclusions
Irritation (Intracutaneous Reactivity (ISO))	ISO Tests for Irritation and Skin Sensitization	Non-irritant
Systemic Toxicity		
Systemic Injection (ISO)	ISO Acute Systemic Injection Test	Non-toxic
Material Mediated Pyrogen	ISO Materials-Mediated Rabbit Pyrogen Test	Non-pyrogenic
Hemocompatibility		
Thrombosis (Dog Thrombogenicity)	Thrombogenicity Study in Dogs - ISO	Non-Thrombogenic
Coagulation (PT)	Prothrombin Time (PT) Test	Non-hemolytic
Coagulation (PTT)	Partial Thromboplastin Time (PTT) Test	Non-hemolytic
Hematology (Hemolysis) – Direct Contact	ASTM Hemolysis (Direct Contact Method)	Non-hemolytic
Hematology (Hemolysis) – Indirect Contact	ASTM Hemolysis (Extract Method)	Non-hemolytic
Genotoxicity		
Ames Mutagenicity	Ames Test	Non-mutagenic
In vivo Mouse micronucleus	ISO In Vivo Mouse Micronucleus Assay	Non-mutagenic

The non-clinical testing found the Penumbra Artemis™ Neuro Evacuation Device to be biocompatible according to EN ISO 10993 requirements. Therefore, Penumbra Artemis™ Neuro Evacuation Device is substantial equivalent to the predicate device.

1.11.2 Bench-Top Testing

Design Verification testing was conducted to evaluate the physical and mechanical properties of the Artemis™ Neuro Evacuation Device and demonstrate substantial equivalence to predicate. The following tests were successfully performed:

Test	Test Method Summary	Results
Packaging Inspection	Confirm the packaging outputs meet all product specifications.	100% Pass
Dimensional / Visual Inspection	Confirm the dimensions / visual outputs meet all product specifications.	100% Pass
Dynamic Vacuum Testing	Wand can sustain maximum vacuum and transfer vacuum to distal tip of wand.	100% Pass
Simulated Use	Evaluate the effectiveness of the device to generate rotational energy to remove simulated clot.	100% Pass

Tensile/Torque	All components are tested to ensure connections/joints meet all product specifications.	100% Pass
Electric Safety Testing	Compliant to requirements of IEC 60601-1 (3rd Ed.), IEC 60601-1-2, 60601-1-6, and IEC 62366.	100% Pass

Design Verification (Bench-Top Testing) found the Penumbra Artemis™ Neuro Evacuation Device to meet all design inputs. Therefore, Penumbra Artemis™ Neuro Evacuation Device is substantially equivalent to the predicate device.

1.11.3 Sterilization

The Artemis™ Neuro Evacuation Device was validated for gamma irradiation sterilization to a 6-log sterility assurance utilizing the VDmax^{25} sterilization validation in accordance with ISO 11137 and ISO 11737.

1.11.4 Shelf Life

The Artemis™ Neuro Evacuation Device has a 12-month Shelf-life

1.12 Summary of Substantial Equivalence

The subject Artemis™ Neuro Evacuation Device is equivalent to the predicate Apollo System™. The subject device has an identical intended use as the predicate device. The subject device and predicate device differ slightly in regards to technological and material variations. However, these differences do not raise different questions of safety and effectiveness. The device testing described in Section 1.11 demonstrate the subject device is equivalent to the predicate device in regards to operating principle fundamental technology, materials, and device performance.