August 30, 2019

Penumbra, Inc.
Aditi Kolla
Regulatory Affairs Specialist
One Penumbra Place
Alameda, California 94502

Re: K190719
Trade/Device Name: Artemis Eye System
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG
Dated: July 30, 2019
Received: August 1, 2019

Dear Aditi Kolla:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Matthew Krueger
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190719

Device Name
Artemis™ Eye System

Indications for Use *(Describe)*
The Artemis™ Eye System is indicated to provide visualization and illumination of intracranial tissue and fluids during diagnostic and therapeutic procedures.

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 Artemis™ Eye System.

1.1 Sponsor/Applicant Name and Address

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

1.2 Sponsor Contact Information

Aditi Kolla
Regulatory Affairs Specialist
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1.3 Date of Preparation of 510(k) Summary

August 29, 2019

1.4 Device Trade or Proprietary Name

Artemis™ Eye System

1.5 Primary Device Classification

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

1.6 Predicate & Reference Devices

510(k) Number	Clearance Date	Device	Name of Manufacturer
Predicate Device			
K002572	November 16, 2000	Medtronic High Resolution Channel Neuroendoscope	Medtronic PS Medical

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510(k) Number	Clearance Date	Device	Name of Manufacturer
Reference Device			
K162475	September 16, 2016	Trice Mi-eye 2, Mi-eye 2 Monitor	Trice Medical Inc.

1.7 Predicate Comparison

Table 1: Predicate Device Comparison

Attribute	Predicate Device	Subject Device
Trade Name	**Medtronic High Resolution Channel Neuroendoscope**	**Penumbra Artemis Eye System**
510(k) No.	K002572	To be determined
Classification	Class II, GWG (882.1480)	Class II, GWG (882.1480)
Indications For Use	The High Resolution Channel Neuro-endoscope is indicated for diagnostic and intraoperative procedures where the physician desires direct vision of intracranial tissue where cerebrospinal fluid (CSF) may be contacted.	The Artemis Eye System is indicated to provide visualization and illumination of intracranial tissue and fluids during diagnostic and therapeutic procedures.
Intended Use	Intended for visualization of intracranial tissue during diagnostic and intraoperative procedures.	SAME
Portability	Hand-Held	SAME
Weight	Not published in the 510(k) Summary	≤ 300 g
Video Output	LCD monitor	SAME
Illumination Light Source	1 mm CAMLite Light Cable	Surface Mount LED
Neuroendoscope Probe Material	Stainless Steel	SAME
Working Length	13 cm or 21.6 cm	15 cm
Total Length	17.2 cm or 25.8 cm	25 cm
Working Tube/Probe OD	4.2 mm	6 mm
Working Channel Diameter	2.15 mm	3.1 mm
Camera Resolution	High (30,000 optical fibres) or Standard (10,000 optical fibres)	200 pixels x 200 pixels

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Table 1: Predicate Device Comparison

Attribute	Predicate Device	Subject Device
Trade Name	**Medtronic High Resolution Channel Neuroendoscope**	**Penumbra Artemis Eye System**
Video Output/ Tablet Dimensions	Not Applicable	31.0 x 20.0 x 3.8 cm (12.2 x 7.9 x 1.5 in.)
Display Screen Resolution	Not Applicable	≥ 1920 pixels x 1280 pixels
Video Output/ Tablet Battery Life	Not Applicable	3 hours (may vary based upon usage)
Accessories	Peelaway Introducer Sheath	Stopcock
Neuro-Endoscope Use	Single-Use	SAME
Sterilization	EO	SAME
Shelf-Life	36-Months	Artemis Eye: 12-Month data currently available

1.8 Device Description

The Artemis Eye System is indicated to provide visualization and illumination of intracranial tissue and fluids during diagnostic and therapeutic procedures. The System consists of two components:

- Artemis Eye - a single-use neuro-endoscope consisting of a camera, two pathways for irrigation and/or drain, and a working channel for a surgical tool.
- Artemis Eye Tablet - a reusable component that connects to the Artemis Eye and displays live imaging captured by the Artemis Eye camera.

1.9 Indications for Use

The Artemis™ Eye System is indicated to provide visualization and illumination of intracranial tissue and fluids during diagnostic and therapeutic procedures.

1.10 Summary of Non-Clinical Data

Pursuant to 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 Artemis Eye System.

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1.10.1 Sterilization

The subject Artemis Eye has proved to be sterile in accordance with EN ISO 11135:2014.

1.10.2 Biocompatibility Testing

Biocompatibility test studies were selected in accordance Guidance for Industry and FDA Staff: *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* (issued June 16, 2016). All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices. The following tests were successfully conducted on the patient-contacting Artemis Eye component of the subject device:

Test	Method	Results
In Vitro Cytotoxicity	ISO Elution Test (MEM Extract)	Non-Toxic
Sensitization	Magnusson-Kligman Method	Non-Sensitizing
Irritation (Intracutaneous Reactivity)	ISO Intracutaneous (Intradermal) Injection Test	Non-Irritant
Systemic Toxicity (Acute)		
Acute Systemic Toxicity	ISO Acute Systemic Injection Test	Non-Toxic
Material Mediated Pyrogen	USP Material-Mediated Rabbit Pyrogen Test	Non-pyrogenic
Hemo-compatibility		
In-Vitro Hemolysis	ASTM Method (Indirect & Direct Contact)	Non-Hemolytic
Coagulation	PT and PTT Test	Non-Thrombogenic

1.10.3 Bench-Top Performance (Design Verification)

Performance testing was conducted to evaluate the physical and mechanical properties of the Artemis Eye System and to demonstrate substantial equivalence to the predicate device. The following tests were performed and all tests passed successfully:

- Dimensional / visual inspection
- Design Feature Testing
- Simulated Use
- Destructive Testing

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1.10.4 Shelf-life

The physical and mechanical performance of the Artemis Eye was evaluated for 12 months through accelerated aging studies to demonstrate device stability for the duration of the labeled shelf-life. Test results confirm the subject device will maintain device performance for the entirety of the proposed shelf-life.

1.10.5 Software Verification & Validation

Software verification and validation testing and documentation for the Artemis Eye System was provided as recommended by FDA's Guidance for Industry and FDA Staff, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*" (issued May 11, 2005). The software for this device was considered as a "major" level of concern.

1.10.6 Electrical Safety/EMC Testing

Electrical safety and EMC testing were conducted on the Artemis Eye System. The system complies with the requirements of IEC/EN 60601-1, IEC/EN 60601-1-2, IEC 60601-1-6, and IEC/EN 62366.

1.11 Summary of Substantial Equivalence

The subject Artemis Eye System is substantially equivalent to the predicate device. The subject device has an identical intended use as the predicate device. The subject and the predicate devices differ slightly in regards to minor technological variations, while maintaining the same fundamental scientific technology. However, these differences do not raise different questions of safety and effectiveness.

The device testing described in the 510(k) Summary demonstrate the subject devices are substantially equivalent to the predicate device in regards to operating principle, fundamental technology and device performance. It also demonstrates the Artemis Eye System should perform as intended in the specified use conditions.