November 27, 2020

ClearMind Biomedical
℅ Craig Coombs
President
Coombs Medical Device Consulting, Inc
1100 Pacific Marina, Suite 806
Alameda, California 94501

Re: K201308
Trade/Device Name: Axonpen, Axonmonitor, Axonbox, Tablet
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG
Dated: October 27, 2020
Received: October 28, 2020

Dear Craig Coombs:

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,

Adam D. Pierce, Ph.D.
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)*
K201308

Device Name
Axonpen System

Indications for Use *(Describe)*

The Axonpen System is indicated for the illumination and visualization of intracranial tissue and fluids and the controlled aspiration of tissue and/or fluid during surgery of the Ventricular System or Cerebrum.

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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510(k) Summary

A. Device Information:

Category	Comments
Sponsor:	ClearMind Biomedical 5F, No. 167, Fuxing N. Rd., Songshan Dist., Taipei City 105, Taiwan, R.O.C. +886-2-22697417
Correspondent Contact Information:	Craig Coombs Coombs Medical Device Consulting 1100 Pacific Marina, Suite 806 Alameda, CA 94501 Tel: 510-995-8499
Device Common Name:	Endoscope, neurological
Device Classification & Name:	21 CFR 882.1480, Neurological endoscope
Device Classification & Product Code:	Class II, GWG
Device Proprietary Name:	Axonpen™ System

Predicate Device Information:

Predicate Device:	Artemis™ Neuro Evacuation Device
Predicate Device Manufacturer:	Penumbra Inc.
Predicate Device Premarket Notification #	K171332
Predicate Device Common Name:	Endoscope, neurological
Predicate Device Classification & Name:	21 CFR 882.1480, Neurological endoscope
Predicate Device Classification & Product Code:	Class II, GWG

Predicate Device Information:

Predicate Device:	Artemis™ Eye System
Predicate Device Manufacturer:	Penumbra Inc.
Predicate Device Premarket Notification #	K190719
Predicate Device Common Name:	Endoscope, neurological
Predicate Device Classification & Name:	21 CFR 882.1480, Neurological endoscope
Predicate Device Classification & Product Code:	Class II, GWG

B. Date Summary Prepared

24 Nov 2020

C. Description of Device

The Axonpen System consists of a neuroendoscope (Axonpen) and a monitor (Axonmonitor) to view the image from the distal end of the Axonpen.

The Axonpen is a steerable, single-use, neuroendoscope. It has an integrated camera and LED light source to allow the surgeon to view the surgical field at the distal end of the Axonpen.

The Axonpen has a working channel that can accept third-party neuroendoscopic tools with an OD of ≤2.5mm and a length of at least 41cm. That same channel can be used for irrigation and aspiration of the surgical target site. The Axonpen is connected to a hospital source vacuum to provide the aspiration feature and is connected to a third-party saline infusion bag to provide irrigation solution. The distal 2.57cm of the Axonpen can be steered to the left or right of the axis in the horizontal plane. Additionally, the end of the distal tube of the Axonpen can be extended an additional 3.2mm to facilitate aspiration of fluid and tissue.

The usable length of the Axonpen can be adjusted by setting the Stopper mechanism, which can limit the depth penetration of the device according to the physician's preference.

The steering, irrigation, aspiration, and distal tube extension are all hand-controlled with mechanical features in the handle of the Axonpen.

The Axonpen is connected by a cable to the Axonmonitor. The Axonmonitor is a combination of the Axonbox, which contains the firmware for the Axonpen camera and light, and a third-party tablet. The software on the tablet allows viewing of the camera image along with recording capabilities. The Axonmonitor is battery operated and provides all the electrical power needed by the Axonpen. The Axonmonitor is supplied with a battery charger that is plugged into the mains and can be charging when the Axonpen System is being used.

D. Indications for Use

The Axonpen™ System is indicated for the illumination and visualization of intracranial tissue and fluids and the controlled aspiration of tissue and/or fluid during surgery of the Ventricular System or Cerebrum.

E. Tabular Comparison of Application and Predicate Devices in Regard to Substantial Equivalence

Characteristic	**Application Device: Clearmind Axonpen™ System**	**Predicate Device: Penumbra Artemis™ Neuro Evacuation Device (K171332)**	**Predicate Device: Penumbra Artemis™ Eye System (K190719)**	**Impact on Substantial Equivalence**
Indications for Use	The Axonpen™ System is indicated for the illumination and visualization of intracranial tissue and fluids and the controlled aspiration of tissue and/or fluid during surgery of the Ventricular System or Cerebrum.	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.	The Artemis™ Eye System is indicated to provide visualization and illumination of intracranial tissue and fluids during diagnostic and therapeutic procedures.	The application device Indications for Use is a combination of the two predicates. This combination does not raise new questions of safety or efficacy that were not raised in the predicates

Characteristic	Application Device: Clearmind Axonpen™ System	Predicate Device: Penumbra Artemis™ Neuro Evacuation Device (K171332)	Predicate Device: Penumbra Artemis™ Eye System (K190719)	Impact on Substantial Equivalence
Technology	The Axonpen neuro-endoscope provides single channel for irrigation, aspiration and tool placement for neurosurgical field. The distal tip is steerable. Relies upon regulated Hospital vacuum for aspiration. The distal end of the scope has a camera + LED lighting. The reusable Axonmonitor displays and records live imaging captured by the Axonpen camera	Provides aspiration of neurosurgical targets via a tube that is placed in a neuroendoscope's working channel. The tube includes a macerator to facilitate the movement of tissue and fluids through tube. Provides proprietary vacuum pump for the aspiration	The Artemis Eye is a neuro-endoscope consisting of a camera, two channels for irrigation and aspiration/drainage, 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.	Technology is identical. The application device is a combination of the two Artemis predicates. The application device does not have an internal macerator, rather it relies on using a larger diameter aspiration tube to facilitate evacuation of tissue and fluids.

Characteristic	Application Device: Clearmind Axonpen™ System	Predicate Device: Penumbra Artemis™ Neuro Evacuation Device (K171332)	Predicate Device: Penumbra Artemis™ Eye System (K190719)	Impact on Substantial Equivalence
Manufacturer Provided System Components	Neuro endoscope (Axonpen™) that provides working channel for endoscopic tools, along with irrigation and aspiration. Handpiece has integrated camera & lighting. Reusable Axonmonitor tablet style display for camera image and recording. Battery Charger.	Hand piece that provides powered clot maceration within its aspiration tube. Aspiration pump & pump tubing to hand piece	A neuro endoscope that has an Artemis Eye camera at its distal end. Channels for suction and irrigation if required Working channel to allow passage of the Artemis Neuro Evacuation device. Tablet style display for camera image Battery Charger	Both the predicate devices (in combination) and the application device are neuroendoscopes. They both have distal cameras and lighting that are displayed on a tablet sized monitor. They both have at least one working channel for neuroendoscopic tools, irrigation and aspiration/drainage. The predicate device has a macerator in its aspiration device along with its own vacuum source.
Hospital Supplied Components	Vacuum source Vacuum regulator Irrigation fluid Waste bucket	Endoscope Vacuum source Vacuum regulator	Camera Lighting Irrigation fluid drain	Achieves same clinical effect

Characteristic	Application Device: Clearmind Axonpen™ System	Predicate Device: Penumbra Artemis™ Neuro Evacuation Device (K171332)	Predicate Device: Penumbra Artemis™ Eye System (K190719)	Impact on Substantial Equivalence
Aspiration Source	Regulated hospital vacuum	Penumbra Aspiration Pump	Not described	The predicate and application devices have different sources of regulated vacuum. The source of the vacuum does not raise new questions of safety or efficacy.
Aspiration Control	Fingertip controlled via pressing button on Axonpen handle.	Fingertip controlled via vacuum regulator hole on Wand handle.	Not Described	Vacuum activation controlled by user
Aspiration regulation	Manually regulated at hospital vacuum regulator	Manually regulated at Artemis System Pump	Not Described	Vacuum regulated by user
Mechanism of Clot Aspiration	Vacuum aspiration aided by large aspiration tube inner diameter (0.248” ID) and extender tube	Vacuum Aspiration aided by a battery-powered macerator in Evacuator and ability to advance 20mm beyond distal end of Artemis Eye neuro endoscope	None	Both devices use vacuum to aspirate clots and tissue. The predicate uses a macerator to facilitate passage of debris from the surgical field. The application device uses a larger diameter tube (i.e. 0.248” ID vs 0.048” – 0.100” ID) to facilitate debris passage.

Characteristic	Application Device: Clearmind Axonpen™ System	Predicate Device: Penumbra Artemis™ Neuro Evacuation Device (K171332)	Predicate Device: Penumbra Artemis™ Eye System (K190719)	Impact on Substantial Equivalence
Power Source for Clot Aspiration	Hospital sourced regulated vacuum	Primary Cell Lithium Ion Battery, 1.5 Volt DC Motor contained within the handle to power the macerator Proprietary vacuum source	None	Same as previous
Steering	10° Steerable in both directions from axis along horizontal plane.	Non steerable	Non steerable	Steerable application device may allow for clean-up of larger surgical field without requiring repositioning of the entire endoscope. May pose less risk than predicate neuroendoscope.
Camera	Integrated, 80° visualization at distal end.	None	Integrated, visualization at distal end	Clinically identical
Lighting	Fiber optic Integrated LED light source in Axonpen handle.	None	Fiber optic Integrated LED light source in handle	Identical

Characteristic	**Application Device: Clearmind Axonpen™ System**	**Predicate Device: Penumbra Artemis™ Neuro Evacuation Device (K171332)**	**Predicate Device: Penumbra Artemis™ Eye System (K190719)**	**Impact on Substantial Equivalence**
Display	Axonmonitor component controls lighting and visualization. Direct electrical/ data connection to Axonpen. Video and still picture recording. Battery powered.	None	Artemis Eye Tablet - a reusable component that connects to the Artemis Eye and displays live imaging captured by the Artemis Eye camera. Battery powered.	Functionally identical
Handpiece Dimensions	L: 33.0 cm ID: 0.248” OD: 0.256” (6.6mm)	L: 26.1 cm – 27.0 cm ID: 0.048” – 0.100” OD: 00.058” –0.109”	Length: 25 cm OD: 6 mm	The Axonpen and the Artemis Eye neuroendoscopes are nearly the same outside diameter
Wand Usable Length	5.0 to 10.0cm (12.0cm with the adjustable Stopper mechanism fully compressed); 20.0cm with the Stopper mechanism removed.	Increases usable length of Artemis Eye by 2cm because the Device can extend beyond the distal tip of the scope by 2cm.	15cm	Application neuroendoscope has a shorter potential usable length than the predicate. No new questions of safety or efficacy raised by this 3cm difference.
Patient contacting Wand Materials	304 Stainless Steel. Polyurethane Fiber optic line, TPU	304 Stainless Steel	304 Stainless Steel Fiber optic line	Clinically identical; all materials in all devices have passed appropriate biocompatibility testing.

Characteristic	Application Device: Clearmind Axonpen™ System	Predicate Device: Penumbra Artemis™ Neuro Evacuation Device (K171332)	Predicate Device: Penumbra Artemis™ Eye System (K190719)	Impact on Substantial Equivalence
Aspiration Tubing Material	Polymers	Polymer	Not applicable	Clinically identical; all materials in all devices have passed appropriate biocompatibility testing.
Irrigation Tubing Material	PVC	None, provided via endoscope	Not applicable	Clinically identical; all materials in all devices have passed appropriate biocompatibility testing.
Single use? Sterile?	Axonpen- single use, sterile Display- reusable, nonsterile	Hand Piece-single use, sterile Vacuum pump- reusable, nonsterile.	Artemis Eye- single use, sterile Artemis Eye tablet- reusable, nonsterile	In both cases the components that are inserted into the patient's brain are single-use and provided sterile and the image monitors are reusable. The predicate's vacuum pump is also reusable.

F. Summary of Supporting Data

Biocompatibility data demonstrates that the device is in compliance with ISO 10993. Testing was conducted with fully manufactured Axonpen devices. The following tests were conducted and passed to demonstrate substantial equivalence with the predicate devices:

Test Name	Standard	Methodology
Cytotoxicity	ISO 10993-5:2009	L929 Mem Elution
Sensitization	ISO 10993-10:2010	Kligman Maximization
Irritation	ISO 10993-10:2010	Intracutaneous Injection: NaCl, CSO extracts
Systemic toxicity	ISO 10993-11:2017	Intravenous or intraperitoneal Injection: NaCl, CSO extracts
Material Mediated pyrogenicity	ISO 10993-5:2009	Rabbit pyrogen
Hemolysis	ASTM F756-17	Rabbit blood

The Axonpen System was demonstrated to be in compliance with all pertinent FDA recognized consensus standards including the ISO 8600 series (Endoscopes- Medical endoscopes and endotherapy devices), the ISO 60601 series (Medical electrical equipment- Part 1: General requirements for safety and essential performance) including IEC 60601-2-18 for endoscopes.

Bench testing demonstrated that the Axonpen System could successfully aspirate fluid and clots without damaging adjacent tissue.

Additional Testing included:

- Optical Performance including:
  - Image processing architecture verification
  - Noise Reduction
  - Contrast Enhancement
  - Color Management (Performance)
  - Display Nonlinear Transformations
  - Image Intensity Uniformity
  - Image Resolution
  - Depth of Field
  - Quantification of Geometric Distortion
  - Dynamic Range of Visualization
- Photobiological Safety Validation
- Water Ingress IPX Rating
- Packaging Verification
- Shelf life testing

G. Conclusion

Based on intended use, performance, and supporting documentation, Clearmind concludes that the Axonpen™ System is substantially equivalent in intended use, Indications for Use, technology, design, materials, physician use, and energy source as a combination of the predicate Artemis Eye System (K190719) and the Artemis Neuro Evacuation Device (K171332).