October 13, 2023

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

Re: K230125
Trade/Device Name: Neuroblade System
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG, GEI
Dated: September 11, 2023
Received: September 12, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S
Digitally signed by Adam D. Pierce -S
Date: 2023.10.13 09:19:04 -04'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230125

Device Name
Neuroblade System

Indications for Use *(Describe)*
The Neuroblade System is a neuroendoscopy system indicated for the illumination and visualization of intracranial tissue and fluids, controlled aspiration of tissue and/or fluid, powered cutting of soft tissue, and coagulation of tissue under direct visualization 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
Date Prepared:	October 12, 2023
Applicant	ClearMind Biomedical 5F., No. 167, Fuxing N. Rd., Songshan Dist., Taipei City 105, Taiwan, R.O.C. +886-2-2269-7417
Primary Correspondent	Shaun Lin Senior Regulatory Affairs Specialist Clearmind Biomedical 5F., No. 167, Fuxing N. Rd., Songshan Dist., Taipei City 105, Taiwan, R.O.C. Phone: +886-2-2269-7417-108 E-mail: Shaun@theclearmindgroup.com (preferred)
Secondary Correspondent	Craig Coombs Coombs Medical Device Consulting 427 14th Ave, San Francisco, CA 94118 Tel: 650-380-2474
Device Classification & Name	21 CFR 882.1480, Neurological endoscope 21 CFR 878.4400, Electrosurgical cutting and coagulation device and accessories
Device Classification & Product Code	Class II, GWG
Secondary Product Code	GEI
Device Proprietary Name	Neuroblade System

Predicate Device Information

Predicate Device (Primary)	Axonpen System
Predicate Device Manufacturer	ClearMind Biomedical
Predicate Device Premarket Notification #	K201308
Predicate Device Classification & Name	21 CFR 882.1480, Neurological endoscope
Predicate Device Classification & Product Code	Class II, GWG

Predicate Device Information

Predicate Device	AURORA Evacuator + Coag
Predicate Device Manufacturer	Rebound Therapeutics
Predicate Device Premarket Notification #	K203745
Predicate Device Classification & Name	21 CFR 878.4400, Electrosurgical cutting and coagulation device and accessories
Predicate Device Classification & Product Code	Class II, GEI

Reference Device Information

Reference Device	Kirwan Bipolar Suction Coagulator
Reference Device Manufacturer	Kirwan Surgical Products
Reference Device Premarket Notification #	K960455
Reference Device Classification & Name	21 CFR 878.4400, Electrosurgical cutting and coagulation device and accessories
Reference Device Classification & Product Code	Class II, GEI

B. Description of Device

The Neuroblade System is comprised of three components: Neuroblade, Neuropad and Cart.

The Neuroblade is a hand-held, sterile neuroendoscope with lighting and camera at its distal end. The camera images are displayed on the Neuropad via a connecting cable that extends from the proximal end of the Neuroblade. It has integrated irrigation and aspiration functions. The distal bipolar electrode allows the application of RF energy from a third-party radiofrequency (RF) generator for coagulation of bleeding vessels in the neuro space. A cutting window on the side of distal end is for the removal of blood clots.

The Neuroblade System, like other neuroendoscopes, is advanced into the brain through a burr hole created in the patient's skull. The tip of the Neuroblade is advanced under visualization via the illuminated camera image transmitted from the distal tip of the Neuroblade to the Neuropad.

The Neuroblade has irrigation and vacuum tubing (2.0 m) that allows for connection to a third party saline infusion bag and a vacuum waste bucket, respectively. The waste bucket is

connected to a vacuum regulator which is attached to the hospital's vacuum system.

The bipolar electrode is incorporated into the distal tip of the Neuroblade and has a bipolar plug (20 cm) on the proximal end that allows for connection to a third-party bipolar cord. The proximal end of that bipolar cord connects to the RF Generator. An RF Generator and bipolar cord are common accessories in the operating room.

The Neuroblade has a working channel that will facilitate the introduction of flexible endoscopic surgical devices (≤1.7 mm outer diameter) into the surgical site. That same working channel will also facilitate irrigation of the target site and is the channel that supports the aspiration of fluid and tissues.

The Neuropad can be installed onto the Cart and adjusted by the user for height and tilt. The Neuropad allows the user to input patient data, control some aspects of the image, and record the case.

C. Indications for Use

The Neuroblade System is a neuroendoscopy system indicated for the illumination and visualization of intracranial tissue and fluids, controlled aspiration of tissue and/or fluid, powered cutting of soft tissue, and coagulation of tissue under direct visualization during surgery of the ventricular system or cerebrum.

D. Tabular Comparison of Subject and Predicate Devices

Characteristic	Application Device	Predicate Devices		Impact on Substantial Equivalence
Device	**Neuroblade System**	**Axonpen System**	**AURORA Evacuator + Coag**	
510(k)	K230125	K201308	K203745	Same
Regulation Number	882.1480	882.1480	878.4400	
Regulation Class	Class II	Class II	Class II	
Product Code	GWG	GWG	GEI	
Secondary Product Code	GEI	---	---	
Indications for Use	The Neuroblade System is a neuroendoscopy system indicated for the illumination and visualization of intracranial tissue and fluids, controlled aspiration of tissue and/or fluid, powered cutting of soft tissue, and coagulation of tissue under direct visualization during surgery of the ventricular system or cerebrum.	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 and Cerebrum.	The AURORA Evacuator + Coag is a powered instrument with a handpiece intended for removal of soft tissue and fluids, and coagulation of tissue under direct visualization. Types of direct visualization may include laparoscopic, pelviscopic, endoscopic, percutaneous, and open. Applications include those when access to the surgical site is limited, such as neurosurgical.	Same
Technology	- Endoscope provides single channel for irrigation, aspiration, cutting along with tool placement for neurosurgical field - The distal end of the scope has a camera + LED lighting	- Endoscope provides single channel for irrigation, aspiration along with tool placement for neurosurgical field - The distal end of the scope has a camera + LED lighting		Similar

Characteristic	Application Device	Predicate Devices		Impact on Substantial Equivalence
Device	**Neuroblade System**	**Axonpen System**	**AURORA Evacuator + Coag**	
	- The reusable monitor displays and records the live imaging captured by the endoscope camera - Irrigation - Removal of fluid by suction lumen and relies upon regulation hospital vacuum for aspiration. - Rotating debrider incorporated into the suction lumen at distal tip for removal of soft tissue (i.e., blood clot) powered by an electric motor in the handle. - Bipolar electrodes at distal tip for coagulation of tissue	- The reusable monitor displays and records the live imaging captured by the endoscope camera - Irrigation - Removal of fluid by suction lumen and relies upon regulated hospital vacuum for aspiration.	- Irrigation lumen for saline drip - Removal of fluid by suction lumen (wall vacuum source) - Rotating debrider incorporated into the suction lumen at distal tip for removal of soft tissue (i.e., blood clot) powered by an electric motor in the handle. - Bipolar electrodes at distal tip for coagulation of tissue	
Available Modes	- Irrigation - Suction/Aspiration - Suction with Cutting Internal to Channel - RF Coagulation	- Irrigation - Suction/Aspiration	- Irrigation - Suction/Aspiration - Suction with Cutting Internal to Channel - RF Coagulation	Same All Application Modes can be found in the predicate devices
Patient Contacting Wand Materials	SUS 304	SUS 304, TPU	SUS 304	Similar

Characteristic	Application Device	Predicate Devices		Impact on Substantial Equivalence
Device	**Neuroblade System**	**Axonpen System**	**AURORA Evacuator + Coag**	
Working Length	16.4 cm	Up to 20.0 cm with the stopper mechanism removed.	7 – 13 cm	Different
Outside Diameter (OD)	18F (6.1 mm)	20F (6.6 mm)	12F (4 mm)	Different
Aspiration Window	Window at side of distal end	Window at the distal end of the distal tip	Window at side of distal end	Similar
Debrider	- Located internal at aspiration window - Scissoring action between rotational inner cannula and stationary outer cannula - SUS 304	N/A	- Located and fully contained rotating debrider within inner lumen at aspiration window - Flat member with notches - SUS 301	Different
Power Source for Motor for Internal Debrider	Electrically powered by Neuroblade system	N/A	Battery located in handle-one 6V Alkaline	Different
Vacuum Source	Endoscope vacuum tubing connects to Operating Room suction machine.	Endoscope vacuum tubing connects to Operating Room suction machine.	Connect to barb on device handle to Operating Room suction (i.e., wall)	Identical
Vacuum Control	Suction button on handpiece that is fingertip controlled.	Same	Same	Identical
Type	Bipolar	Not Applicable	Bipolar	Same
Shape	2 rectangular components	---	2 rectangular components	
Material	Stainless steel with coating	---	Silver	
Insulation	Polyphenylsulfone	---	Polyphenylsulfone	
Rated Voltage	450 Vp-p	---	450 Vp-p	
Power Source for Bipolar Electrodes	Cable to electrosurgical generator (external) connected to AC mains. Cable will include in the system and Electrosurgical	Not Applicable	Cable to electrosurgical generator (external) connected to AC mains. Cable and Electrosurgical generator are third party	Similar

Characteristic	Application Device	Predicate Devices		Impact on Substantial Equivalence
Device	**Neuroblade System**	**Axonpen System**	**AURORA Evacuator + Coag**	
	generator is third party devices.		devices.	
Irrigation	Capability for saline irrigation delivery to distal tip. Irrigation rate controlled on handle.	Capability for saline irrigation delivery to distal tip. Irrigation rate controlled on handle.	Capability for saline drip irrigation delivery to distal tip. Connection on device handle to saline bag with line clamp for clinician to control irrigation rate.	Similar
Main Components	Handpiece - Single Use Display - Reusable Cart - Reusable	Handpiece - Single Use Display - Reusable Cart - None	Single use	Same
Sterile	Handpiece- Sterile Display - Nonsterile Cart - Nonsterile	Handpiece - Sterile Display - Nonsterile	Sterile	
Sterilization Method	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Same

E. Summary of Supporting Data

The following biocompatibility, electrical safety, electromagnetic compatibility, software verification and validation, bench testing, usability testing and animal testing have been conducted to provide evidence in support of the substantial equivalence determination.

Test	Test Method Summary	Results
Biocompatibility: - Cytotoxicity (MEM Elution) - Sensitization (Kligman Maximization) - Irritation (intracutaneous Injection) - Systemic toxicity (Systemic Injection) - Materials Mediated Pyrogenicity - Hemocompatibility s (Indirect Contact)	ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process per FDA biocompatibility guidance	Pass
Electrical safety and Enclosure Protection	IEC 60601-1 Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment. IEC 60601-2-2 Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories IEC 60601-2-18 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment IEC 62471 Photobiological Safety of Lamps and Lamp Systems	Pass
Emissions and Immunity	IEC 60601-1-2:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests IEC 61000-4-39 Electromagnetic compatibility (EMC) - Part 4-39: Testing and measurement techniques - Radiated fields in close proximity - Immunity test	Pass
Sterilization Validation (SAL of 10^{-6})	ISO 11135-1 Sterilization of health care products – Ethylene Oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	Pass
Packaging and Shelf Life	ISTA 2A simulation performance test procedure ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	Pass
Ex-vivo tissue studies (porcine brain, liver, and kidney)	Demonstrated equivalent performance to the predicate device by evaluating the correlation between the power setting and the lesion size/tissue damage (coagulation zone) and the correlation of	Pass

	time to tissue temperature per power setting for the subject device and predicate device.	
Software Test	In accordance with IEC 62304:2015, and FDA guidance documents: - "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," - "Content of Premarket submissions for Management of Cybersecurity in Medical Devices," - "Off-the-Shelf Software Use in Medical Devices."	Pass
Bench Testing	Suction/Irrigation functionality Debridement efficiency Image orientation Durability of feature IPX testing Evaluated device performance and demonstrated that the subject device can accurately and consistently deliver varying power across a range of power settings.	Pass
Image Quality Test	ISO 12233:2017, Photography— Electronic still picture imaging — Resolution and spatial frequency responses ISO 15739:2017, Photography — Electronic still-picture imaging— Noise measurements ISO 8600-1:2015 Endoscopes — Medical endoscopes and endotherapy devices — Part 1: General requirements ISO 8600-3:2019 Endoscopes — Medical endoscopes and endotherapy devices — Part 3: Determination of field of view and direction of view of endoscopes with optics ISO 8600-4: Endoscopes — Medical endoscopes and endotherapy devices — Part 4: Determination of maximum width of insertion portion ISO 8600-6: Endoscopes — Medical endoscopes and endotherapy devices — Part 6: Vocabulary FDA guidance: Color Performance Review Tool for Endoscopy Devices Demonstrated comparable color performance using camera, optical system, image processing chip and monitor when compared with predicate device.	Pass
Usability Study	Evaluated use for neurosurgeons of all integrated functions of the Neuroblade System in a simulated use model	Pass

Animal Study

An animal study was conducted in accordance with the provisions of FDA Good Laboratory Practice (GLP) Regulations, 21 CFR 58, in a kaolin-induced experimental hydrocephalus porcine model. A hydrocephalus model was necessary to increase the volume of cerebrospinal fluid (CSF) to permit endoscopic neurosurgical procedures to be evaluated in the ventricles. Magnetic resonance imaging (MRI) was used to verify the increase in CSF volume prior to surgical procedures, which were performed 3-4 weeks after hydrocephalus induction. The safety and performance of the Neuroblade System was based on successful management of hemorrhage under endoscopic visualization in the cortex and ventricles. Five neurosurgeons evaluated the performance and handling of the Neuroblade System by manipulating various features simultaneously under bleeding conditions. The participants gave high scores to the usability elements included in the study survey. Necropsy and histopathology of the brain confirmed that the effects of using the Neuroblade System were limited to the surgical areas. The study results support the safety and performance of the Neuroblade System for the proposed intended use.

F. Conclusion

Based on intended use, performance and supporting documentation, the Neuroblade System is substantially equivalent in intended use, indications for use, technology, design, materials, physician use, and energy source to the predicate Axonpen System (K201308) and the AURORA Evacuator + Coag (K203745).