March 2, 2023

Neba Health, LLC
Howard Merry
President
2052 Gordon Highway, Ste B.
Augusta, Georgia 30909

Re: K223628
Trade/Device Name: NEBA® Compact EEG2R Mobile Headset
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMC, GXY
Dated: October 26, 2022
Received: December 5, 2022

Dear Howard Merry:

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,

Patrick Antkowiak -S

for
Jay Gupta
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)*
K223628

Device Name
NEBA® Compact EEG2R Mobile Headset

Indications for Use *(Describe)*
The NEBA® Compact EEG 2R Mobile Headset (NEBA Headset) is intended to capture, amplify, and wirelessly transmit electrical brain activity for review by a trained medical professional using the CEEG2R recording software.
The NEBA Headset comprises an electrode positioning system for placing single-use disposable electrodes on the head (Vermed® A10005, ANSI/AAMI EC12 compliant silver/silver-chloride (Ag/AgCl) electrodes).

Contained within the headset is a wireless EEG amplifier module.

The NEBA Headset and its associated software do not provide any diagnostic conclusion or automated alerts of any clinical event about a patient's condition.

The NEBA Headset transmits electrophysiological signals from the electrodes to a CEEG 2R IEC/UL 60950-1 safety compliant computer running the NEBA CEEG 2R recording software.

The system supports six electrode locations (CZ, left ocular, right ocular, left ear, right ear, and ground) on four flat flexible leads and one plastic tab (the latter to support the CZ electrode).

The CEEG2 Headset is intended for use in clinical settings in individuals six years of age and older.

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.

K223628 – Traditional 510(k) Summary

Submitter:

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Contact person:

E. Howard Merry,
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Date summary prepared: February 22, 2023

Subject device

Device trade name; proprietary name: NEBA® Compact EEG2R Mobile Headset (CEEG2R)

Common name: Electroencephalogram (EEG)

Product Code; Classification: OMC (Primary); Reduced montage electroencephalograph 21 CFR 882.1400; Electroencephalograph, Class II.

GXY (Secondary); Cutaneous Electrode 21 CFR 882.1320; Class II; Cutaneous Electrode

Review Panel: Neurology; Diagnostic Devices

Predicate and reference devices

Predicate Type	510K Number	Device	Manufacturer
Primary Predicate	K203827	REMI	Epitel, Inc.
Secondary Predicate	K183529	AE-120A EEG Headset	Nihon Kohden

Subject device description

The NEBA® Compact EEG2R Mobile Headset is a battery powered (3.7v Lithium-Ion battery wirelessly charged using a Qi-compliant receiver) wireless (Bluetooth LE) EEG headset which facilitates the placement of EEG electrodes. The NEBA® Compact EEG2R Mobile Headset (CEEG2R) has both hardware and software components. Hardware comprises an EEG electrode system that serves to conduct EEG potentials from the human scalp for transfer to a built-in wireless EEG amplifier. The software provides EEG amplifier hardware control, recording, storage, and user interfaces for waveform monitoring, patient information entry and storage, and accessing stored EEG data.

The CEEG2R Headset has two primary purposes:

- To aid in EEG electrode positioning on the head such that electrodes are positioned in intended locations accurately and reliably per the standard 10-20 International Electrode Placement System. The default leads configuration includes CZ, left ocular (OC-L), right ocular (OC-R), left ear (E-L), right ear (E-R), and Ground (GND) positions;
- To transmit electrophysiological signals from positioned electrodes to an EEG recording and monitoring device via an internal EEG amplifier with wireless transfer communication.

The CEEG2R Headset is constructed using biocompatible patient contact surfaces, the major components formed of polyurethane and polyester. The headset is held in place using a flexible platform at the top of the head and adjustable arms that terminate at lateral supports at the sides of the head.

The headset is designed for use with accessory disposable silver/silver-chloride (Ag/AgCl) electrodes (K781430).

An integral, counter posing pressure tab accepts a disposable electrode for placement at the top medial portion of the head (at location CZ of the 10-20 International Electrode Placement System). Connection components facilitate the quick insertion and removal of the electrodes and flexible leads. Electrodes for use on the scalp and hair bearing scalp region use a low-viscosity integrated wet-gel conductive medium embedded in the electrodes along with integrated low-tack adhesive optimized for hair compatibility and system stability.

The system is stabilized on the head through use of low tack adhesive-lined electrodes, conformable lateral support linings, spring hinges, and a flexible headband platform.

The system interfaces with the CEEG2R recording and monitoring software for signal acquisition, signal measurement, and electrode impedance measurement by way of a built-in wireless amplifier. The battery, wireless battery charger, wireless communication transmitter and amplifier printed circuit board (PCB) are located atop a midline-located headband platform of the headset.

Subject device Intended Use

The NEBA® Compact EEG 2R Mobile Headset (NEBA Headset) is intended to capture, amplify, and wirelessly transmit electrical brain activity for review by a trained medical professional using the CEEG2R recording software. The NEBA Headset comprises an electrode positioning system for placing single-use disposable electrodes on the head (Vermed® A10005, ANSI/AAMI EC12 compliant silver/silver-chloride

(Ag/AgCl) electrodes cleared in K781430). Contained within the headset is a wireless EEG amplifier module. The NEBA Headset and its associated software do not provide any diagnostic conclusion or automated alerts of any clinical event about a patient's condition. The NEBA Headset transmits electrophysiological signals from the electrodes to a CEEG 2R IEC/UL 60950-1 safety compliant computer running the NEBA CEEG 2R recording software. The system supports six electrode locations (CZ, left ocular, right ocular, left ear, right ear, and ground) on four flat flexible leads and one plastic tab (the latter to support the CZ electrode). The CEEG2 Headset is intended for use in clinical settings in individuals six years of age and older. (Rx only).

Comparison of predicate devices to subject device

The NEBA® Compact EEG2R Mobile Headset (CEEG2R) is substantially equivalent to the REMI device when combined with the Nihon Kohden AE-120A EEG headset. NEBA shares the same technological characteristics as the predicate devices, but there are some differences. Both battery-powered predicates are reduced montage EEG devices that wirelessly transmit EEG data to an accessory device running software.

The **primary predicate** is the REMI device. The NEBA® Compact EEG2R Mobile Headset (CEEG2R) is designed to amplify, capture, and wirelessly transmit EEG data from the CZ channel to an accessory software intended for monitoring and reviewing EEG data. Similarly, the REMI device is called out as the primary predicate as it is intended to wirelessly transmit a *single* channel of electrical activity for subsequent review. Both are intended for professional prescription use only and for patients 6 years and older.

Neither the REMI device nor the NEBA® Compact EEG2R Mobile Headset are indicated for making any diagnosis or diagnostic recommendations and both are intended only to facilitate the monitoring and review of physiological signals.

The **secondary predicate**, the Nihon Kohden AE-120A, is called out to achieve the NEBA® Compact EEG2R Mobile Headset positioning functionality. Both the Nihon Kohden AE-120A and the NEBA® Compact EEG2R Mobile Headset use mechanical headsets to aid in EEG electrode positioning to approximate the 10-20 International Electrode Placement System.

The predicate systems and the NEBA® Compact EEG2R Mobile Headset were evaluated for safety and effectiveness in quality systems per FDA guidance and using compliance standards. The predicate systems and the NEBA® Compact EEG2R Mobile Headset were evaluated according to ISO 10993-1 biological evaluation and associated FDA guidance.

Given the discussion above and the substantial equivalence table below, NEBA Health asserts that the differences between the NEBA® Compact EEG2R Mobile Headset and the predicate devices do not raise different questions of safety and effectiveness based on the performance testing used to address the technological characteristics.

NEBA Health asserts the NEBA Health device (CEEG2R) is substantially equivalent to the combined predicate devices.

Table 5a compares the technical characteristics of the subject device to the primary and secondary predicate devices.

Table 5a – Technical Characteristics Comparison

Attribute	**REMI** **K203827**	**NKC** **K183529**	**NEBA CEEG 2R mobile Headset** **K223628**	**Discussion**
classification regulation	Class II per 21 CFR 882.1400 Electroencephalograph (Head Set)	Class II per 21 CFR 882.1400 Electroencephalograph (Head Set) Class II per 21 CFR 882.1320 (for electrodes within headset)	Class II per 21 CFR 882.1400 Electroencephalograph (Head Set) Class II per 21 CFR 882.1320 (for electrodes within headset)	Same.
Product code	OMC / GXY	OMC/GXY	OMC/GXY	Same.
IFU	the REMI Platform is intended to be used in healthcare settings where near real-time and/or remote EEG is warranted. REMI consists of epilog disposable Sensors a single use, single patient, disposable, wearable sensor intended to amplify, capture, and wirelessly transmit a single channel of electrical activity of the brain for up to 48 hours. The REMI-Mobile software and REMI-Tablet are intended to receive and transmit data from four Epilog Sensors to secure cloud storage for subsequent viewing and reviewing of EEG on third-party software. REMI does not make any	The AE-120A EEG Head Set is intended to amplify, capture, and wirelessly transmit electrical activity of the brain for review by a trained medical professional using the previously cleared and validated Nihon Kohden electroencephalograph systems (EEG-1200A series and EEG-9100) to assist in the diagnosis of neurological disorders. The AE-120A EEG Head Set and its associated EEG Software do not provide any diagnostic conclusion or automated alerts of an adverse clinical event about a patient's condition. The device is intended for use by trained medical professionals	The NEBA® Compact EEG 2R Mobile Headset (NEBA Headset) is intended to capture, amplify, and wirelessly transmit electrical brain activity for review by a trained medical professional using the CEEG2R recording software. The NEBA Headset comprises an electrode positioning system for placing single-use disposable electrodes on the head (Vermed® A10005, ANSI/AAMI EC12 compliant silver/silver-chloride (Ag/AgCl) electrodes). Contained within the headset is a wireless EEG amplifier module. The NEBA Headset and its associated software do not provide any diagnostic	The NEBA Headset and the predicate devices are all reduced montage EEGs with the intended use to amplify, record and wirelessly transmit EEG data to accessories running software for monitoring and reviewing EEG data. All 3 devices are for prescription use only by professionals. All devices have similar intended use environments. The primary predicate, the REMI device and the NEBA Headset have the same population age range. The Nihon Kohden device and the NEBA headset have in common an EEG positioning system.

Attribute	REMI K203827	NKC K183529	NEBA CEEG 2R mobile Headset K223628	Discussion
	diagnosis or recommendations and is intended only as a physiological signal monitor. Epilog Sensors are intended for use by trained medical professionals in a professional healthcare facility environment. Epilog Sensors are intended for use with adult and pediatric patients (6+). (Rx only).	in a medical facility such as a physician's office, laboratory, or clinic. The device is intended for use on adults (ages 18 and above). (Rx Only).	conclusion or automated alerts of a clinical event about a patient's condition. The NEBA Headset transmits electrophysiological signals from the electrodes to a CEEG 2R IEC/UL 60950-1 safety compliant computer running the NEBA CEEG 2R recording software. The system supports six electrode locations (CZ, left ocular, right ocular, left ear, right ear, and ground) on four flat flexible leads and one plastic tab (the latter to support the CZ electrode). The CEEG2 Headset is intended for use in clinical settings in individuals six years of age and older. (Rx only).	
Physiological signal acquired	EEG	EEG	EEG	Same.
Type of patient contact	Contacts patient scalp	contacts patient scalp	Contacts patient scalp	Same.
electrodes	2 passive gold electrodes using a conductive hydrogel	10 passive Ag/AgCl electrodes	6 passive Ag/AgCl electrodes	The electrodes for the Nihon Kohden device and the NEBA Headset are the same. The disposable electrode for the NEBA Headset is 510(k) approved and ANSI/AAMI EC12 compliant and is manufactured by a

Attribute	REMI K203827	NKC K183529	NEBA CEEG 2R mobile Headset K223628	Discussion
				NEBA approved vendor.
type of use	Epilog Disposable is single use, non-sterile, disposable	Electrodes: Single use, non-sterile, disposable. EEG Device: AE-120A EEG Head set is reusable and nonpatient contacting. Belts are patient contacting and reusable.	Electrodes: Single use, non-sterile, disposable. The NEBA Headset is reusable and comprises both patient and non-patient contacting parts. The headset is reusable and designed for cleaning between uses.	The intended use of the Nihon Kohden device and the NEBA device are similar and differences do not raise questions of safety and effectiveness.
Channel #	0-10	8	1	Same. The NEBA Headset total EEG channel number is within the range established by the predicates.
Montage	10/20 system - Epilog-Disposable can be placed anywhere in the 10/20 system where each channel represents a bipolar derivation approximation of the 10/20 system	10/20 System - AE-120A EEG Head Set approximates the 10/20 montage but may deviate slightly depending on the patient's head shape.	10/20 System - the NEBA Headset is intended to facilitate the placement of electrodes per the 10/20 montage	Same.
Electrical safety and EMC	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-26	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-26	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-26	Same.
Input dynamic range	1 mVp-p	1 mVp-p	±187.5 mV peak-to-peak input	The difference between the predicate devices and the CEEG2R device for the Input Dynamic Range is negligible when compared to EEG signals in the low micro-volt range and does not affect safety and effectiveness.

Attribute	REMI K203827	NKC K183529	NEBA CEEG 2R mobile Headset K223628	Discussion
input noise	5 µVp-p	5 µVp-p or less (0.53 to 60 Hz)	± 4 µV maximum peak-peak 0.5 Hz through 50 Hz a noise limit	Same.
data transfer	Bluetooth 2.4 GHz	Bluetooth 2.4 GHz	Bluetooth LE 2.4 GHz	Same.
power source	CR2016 primary lithium (not rechargeable)	2 AA (LR6) alkaline batteries (not rechargeable)	The NEBA CEEG 2R mobile Headset has a built-in 3.7v Lithium Ion battery which is charged using a Qi-compliant wireless power receiver.	The NEBA Headset use a lithium battery like the REMI device. Like both devices the NEBA Headset does not connect to mains power for charging. The NEBA Headset has no user accessible charging port or interface and charges wirelessly. The differences do not raise issues of safety and effectiveness.
data format	Lay-Dat (Persyst)	Nihon Kohden original format	European Data Format (EDF) | NEBA file format 2.4	The data format does not raise questions of safety and effectiveness.
compatibility	Epilog Disposable works only with REMI App software and tablet	Works only with Nihon Kohden specified EEG's: EEG-1200A series (KO80546) EEG-9100 (KO 11204)	The NEBA CEEG 2R mobile Headset works only with NEBA software	Same.
software	Epilog Disposable uses integrated firmware only for transmitting EEC to REMI App software and tablet	AE-120A EEG Head Set comes with EEG software to be placed on the compatible EEG for interaction with and viewing of EEG data	The NEBA headset uses integrated firmware only for transmitting EEG to NEBA software and computer accessory	Same.
connector	Epilog Disposable uses a USB protocol on a non-standard connector for programming only	Single connector of electrodes to AE-120A Head Set	The CEEG 2R mobile Headset is wireless. There is no patient or operator accessible connector for the NEBA CEEG 2R mobile headset.	Improved. The NEBA Headset presents no external connector and no user accessible connectors.

Attribute	REMI K203827	NKC K183529	NEBA CEEG 2R mobile Headset K223628	Discussion
sizes and dimensions	Epilog comes in one size: 27 mm x 27 mm x 7 mm	AE-120A EEG Head Set has flexible arms that are adjusted to fit different adult patient head sizes along with adjustments from the belts/ straps (chin).	Width, height, and anatomically conforming curvature of The CEEG2 Headset were selected for compatibility over a head size range that spans two standard deviations below an age six mean head size to two standard deviations above an adult mean head size. The Support Subassemblies measure, inside view, approximately 107 mm in width and 70 mm in height.	Same. Like the Nihon Kohden headset, the NEBA Headset is adjustable to accommodate a range or head sizes.
conductive gel	Conductive electrolyte is in the form of a hydrogel converted in a one-piece adhesive sticker as an accessory to Epilog-Disposable. The sticker is replaceable and onetime use	Conductive electrolyte paste is included in a packet gel reservoir integrated into each electrode. User inserts electrode into the electrode attachment position in Head Set with paste	Conductive electrolyte gel is integrated into each electrode.	Same. The NEBA Headset uses electrodes with integrated conductive gel like the Nihon Khoden Device.
Biocompatibility	Biocompatibility of patient contacting components verified with Irritation, Sensitization, and Cytotoxicity testing per ISO 10993- 5:2009 and ISO 10993-10:2010	Biocompatibility of patient contacting components verified with Cytotoxicity, Sensitization, and Irritation per ISO 10993-S and ISO-10993-10	Biocompatibility of patient contacting components verified with Cytotoxicity, Sensitization, and Irritation per ISO 10993-S and ISO-10993-10	ISO 10993-1:2009 was used to evaluate the materials. ISO 10993-5:2009 was used to test for Cytotoxicity. Material risk analysis indicated materials did not put patient or operator at risk. Sensitization, and Irritation were ruled out.

Performance data

Table 5b summarizes the efforts to validate and verify the performance of the CEEG2R device.

Table 5b - Performance Testing Summary

Description	Industry Standard	FDA Recognition Number	Testing Lab	Complete Date
CEEG2 Headset Assembly Verification	IEC 60601-1-6:2006	N/A	Evergreen Research Inc	02/25/2020
CEEG2 Headset Assembly Verification	IEC 60601-1:2005/A1:2012 IEC 60601-2-26:2012 ISO 14971:2007	N/A N/A 5-40	MECA / Evergreen Research Inc	10/28/2020
CEEG2 Headset Assembly Verification	N/A	N/A	Evergreen Research Inc	11/03/2021
CEEG2R Mobile Software Verification	IEC 60601-1-6:2006	N/A	Evergreen Research Inc	03/02/2020
CEEG2R Mobile Software Verification	N/A	N/A	Evergreen Research Inc	05/05/2020
CEEG2R Mobile Software Verification	IEC 60601-1-8:2006/A1:2012 IEC 62304:2006/A1:2016	5-76 13-79	MECA / Evergreen Research Inc	10/21/2020
CEEG2R Electromagnetic Disturbance	IEC 60601-1-2:2015	N/A	CCIC Southern Testing Co., Ltd.	11/20/2020
CEEG2R Wireless Headset Emission and Exposure 47 CFFR Part 15 Subpart B	ANSI C63.4:2014	N/A	CCIC Southern Testing Co., Ltd.	11/20/2020
CEEG2R Wireless Charger RF Exposure	KDB 680106 D01 V03	N/A	Waltek Testing Group	08/19/2021
CEEG2R Wireless Charger 47 CFR Part 15 Subpart C	ANSI C63.10-2013	N/A	Waltek Testing Group	08/19/2021
Cytotoxicity	ISO 10993-5:2009	2-245	Nelson Labs	12/13/2019

The NEBA® Compact EEG2R Mobile Headset was evaluated for basic electrical safety and essential performance to IEC 60601-1, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

The NEBA® Compact EEG2R Mobile Headset was evaluated for electromagnetic compatibility in accordance with IEC 60601-1-2, Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.

The NEBA® Compact EEG2R Mobile Headset was evaluated for compliance with IEC 60601-1-26, Particular requirements for the safety of electroencephalographs.

The NEBA® Compact EEG2R Mobile also demonstrated compliance with 47 CFR Part 15 Subpart B and Subpart C for emissions and exposure.

Biocompatibility

NEBA Health used ISO 10993-1:2018 and the FDA guidance "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" to plan biological evaluation and select tests to evaluate the biological response of the CEEG2R device. NEBA Health captured the biological analysis in a document named, "CEEG2 Regulatory (CEEG2R) Mobile Headset -Materials Specification and Biocompatibility Assessment."

NEBA Health used ISO 14971:2007 to determine Risks associated with materials used in the device and their biological hazards. Each material identified as needing a biological review was evaluated. Certain materials required cytotoxicity testing.

Clinical testing

Clinical testing was not performed to demonstrate substantial equivalence.