March 31, 2020

iCE Neurosystems, Inc.
% Allison Komiyama, Ph.D., R.A.C.
Principal Consultant
EAS Consulting Group, LLC
33 Golden Eagle Lane
Littleton, Colorado 80127

Re: K191868
Trade/Device Name: iCEWav Neuromonitoring Platform
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, OLT
Dated: January 20, 2020
Received: January 21, 2020

Dear Dr. Komiyama:

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,

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)*
K191868

Device Name
iCEWav Neuromonitoring Platform

Indications for Use *(Describe)*
The iCEWav Neuromonitoring Platform (iCEWav) is intended to monitor the state of the brain by recording and displaying EEG signals and can also receive and display a variety of vital signs and other measurements from third-party devices.

The iCEWav Neuromonitoring Platform is intended for use by a physician or other qualified medical personnel. It is intended for use on patients of all ages within a hospital or medical environment including the intensive care unit, operating room, emergency room, and other clinical settings where brain monitoring may be indicated. The system provides no function that will directly prevent, mitigate, screen, treat or diagnose a specific disease or condition.

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 - K191868

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Device Trade Name:	iCEWav Neuromonitoring Platform
Common Name:	Electroencephalograph
Classification Name:	Electroencephalograph (21CFR882.1400, Product Code GWQ, OLT)
Date of Preparation:	January 20, 2020

Substantially equivalent devices:

The iCEWav Neuromonitoring Platform is being compared to the software applications in the predicate Component Neuromonitoring System, manufactured by Moberg Research, Inc. (K080217) and Persyst 13 manufactured by Persyst Development Corporation (K151929). The Moberg software application acquires, displays, stores and archives electroencephalographic signals from the brain in addition to allowing the user to configure the EEG recording montage and providing real-time feedback on electrode impedance. The Moberg application also collects data from bedside systemic physiological monitors for display and storage in parallel to collected EEG data. The Persyst software application offers offline quantitative EEG analytical processes for a range of derivatives from raw EEG data.

1.1 Device Description

The iCEWav Neuromonitoring Platform (iCEWav) is a clinical neuromonitoring system designed to streamline the collection and integration of high-fidelity electroencephalographic (EEG) data and matched systemic physiological data to assist clinicians caring for patients with brain injury.

The iCEWav Neuromonitoring Platform includes a computer hardware element and associated touchscreen monitor that are affixed to a wheeled cart approved for use in the clinical environment. The computer hardware system is attached via USB connection to a third-party EEG amplifier system. A separate storage basket is included on the cart for storage of the EEG amplifier when not in use. The computer hardware element includes a range of standard USB, Ethernet and serial ports to allow for connection with a range of third-party physiological monitoring systems found in the clinical environment.

The iCEWav Neuromonitoring Platform encompasses in-house iCEWav software that serves to gather EEG and systemic data, automate functions of device performance to allow ease-of-use by clinicians, combine data in a format that allows for seamless real-time and retrospective evaluation, and provide a Graphical User Interface that allows a clinician to evaluate data according to preferences of the clinician.

EEG data collection utilizes disposable third-party clinical EEG electrodes connected to a third-party clinical EEG amplifier, with resulting digital signals transmitted to the iCEWav computer hardware element. In parallel, correlative physiological data (heart rate, blood pressure, etc.) from third-party monitors are transferred into the system using standard data connections (serial, Ethernet or USB). Time-locked EEG and systemic physiological data are made available for real-time display as well as local hardware-based storage. Using iCEWav, a clinician can simultaneously monitor aspects of systemic physiology and brain electrical activity to help identify and interpret ongoing clinical developments which may have negative effects on brain health.

EEG data can be displayed as raw waveforms or can be displayed using a range of quantitative measures including Compressed Spectral Array (CSA), Total Power, Alpha/Delta Ratio, Burst Suppression Ratio, and Asymmetry Index. Data can be viewed as it is collected in real time; alternatively, stored data can be reviewed retrospectively. EEG and physiological data can be viewed in parallel fashion. Scaling parameters for each data variable as well as the time window to be reviewed can be controlled by a clinical user.

The iCEWav system has several features to optimize ease of use. The patient Admission procedure includes a step-by-step walkthrough process to assist the user in configuring the EEG system and perform initial electrode impedance testing to ensure correct connection to the third-party EEG amplifier. The system provides several options for baseline EEG recording montages that the user can select to streamline the initiation of EEG recording. The user can also easily customize the recording montage. The system automatically detects availability of data inputs from other third-party physiological monitors that are connected to the system hardware and offers the user the list of the available inputs to be selected or deselected for display. The system offers the option for continuous impedance checking of connected electrodes through the third-party EEG amplifier, and for convenience the user may select to remove channels demonstrating poor impedance from the raw and quantitative EEG displays.

During or following a period of recording, patient data may be accessed and reviewed from local storage.

1.2 Indications for Use

The iCEWav Neuromonitoring Platform (iCEWav) is intended to monitor the state of the brain by recording and displaying EEG signals and can also receive and display a variety of vital signs and other measurements from third-party devices.

The iCEWav Neuromonitoring Platform is intended for use by a physician or other qualified medical personnel. It is intended for use on patients of all ages within a hospital or medical environment including the intensive care unit, operating room, emergency room, and other clinical settings where brain monitoring may be indicated. The system provides no function that will directly prevent, mitigate, screen, treat or diagnose a specific disease or condition.

1.3 Summary of Technological Characteristics and Substantial Equivalence

The iCEWav Neuromonitoring Platform has the combined technical characteristics of the specified Predicate Devices. The system can record, store, process, and display EEG from an EEG amplifier and/or physiological data from other physiological monitoring devices. Quantitative EEG parameters can be generated and displayed in parallel with systemic physiological data. Impedance data from the third-party EEG amplifier can be used to evaluate recording quality from individual EEG electrodes.

The following table provides a substantial equivalence comparison of the iCEWav Neuromonitoring Platform under review to the two predicate devices.

Table 1: Substantial Equivalence Technical Characteristics - Overview

SYSTEM FEATURE	iCEWav Neuromonitoring Platform	Component Neuromonitoring System – Moberg Research	Persyst 13	Comment
510(k) Number	Pending	K080217	K151929	Equivalent
Device Class	Class II	Same	Same	Equivalent
Class Name	Electroencephalograph (EEG)	Electroencephalograph (EEG)	Electroencephalograph (EEG)	Equivalent
Product Code	GWQ, OLT	OMA, GWQ, OLT, MUD, MHX, ORT	OMB, OLT, OMA	Equivalent
Classifying Regulation (primary)	882.1400	882.1400	882.1400	Equivalent
Intended User	Qualified medical practitioners	Qualified medical practitioners	Qualified medical practitioners	Equivalent
Indications for Use	The iCEWav Neuromonitoring Platform (iCEWav) is intended to monitor the state of the brain by recording and displaying EEG signals and can also receive and display a variety of vital signs and other	The Component Neuromonitoring System is intended to monitor the state of the brain by recording and displaying EEG signals, and can also receive and display a variety of vital signs and other measurements from third-party monitoring	Persyst 13 EEG review and analysis software is intended for the review, monitoring and analysis of EEG recordings made by EEG devices and to aid in the assessment of EEG.	Equivalent

	measurements from third-party devices. The iCEWav Neuromonitoring Platform is intended for use by a physician or other qualified medical personnel. It is intended for use on patients of all ages within a hospital or medical environment including the intensive care unit, operating room, emergency room, and other clinical settings where brain monitoring may be indicated. The system provides no function that will directly prevent, mitigate, screen, treat or diagnose a specific disease or condition.	devices (such as ICP, ECG, SpO_2, and others). It also has the optional capability to record and display patient video. The Component Neuromonitoring System is intended for use by a physician or other qualified medical personnel. It is intended for use on patients of all ages within a hospital or medical environment, including the operating room, intensive care unit, emergency room, and clinical research settings.		
Clinical Application	Intended for use in patients of all ages who require brain physiological monitoring	Intended for use in patients of all ages who require brain physiological monitoring	Intended for use in adults (greater than or equal to 18 years)	Equivalent
Contraindica-tions	None	None	None	Equivalent
Environment of use	Clinical settings in which patients requiring physiological monitoring of the brain are encountered	Same	Same	Equivalent
Duration of use	Per the requirements of the clinician-user.	Same	Same	Equivalent
Hardware components of system	Integrated computer system, flat panel touch screen display, third-party clinical EEG amplifier system, wheeled cart with associated power supply, and cabling necessary for connection to external	Brand-specific EEG amplifier system; otherwise the same	None – software only.	Equivalent

	monitors via USB, serial or Ethernet connection.			
Device materials	N/A – there are no implants or other elements that come into patient contact.	Same	Same	Equivalent
User input	Touchscreen monitor	Touchscreen monitor	Mouse/keyboard associated with host computer	Equivalent
Third party device inputs	Separate third-party EEG amplifier via USB; systemic data from bedside physiological monitor via standard USB to serial port cabling (see below)	Product-specific EEG amplifier via USB; systemic data from bedside physiological monitor via standard USB to serial port cabling (see below)	(n/a)	Equivalent

Table 2: Substantial Equivalence Technical Characteristics – Data input and display

SYSTEM CHARACTER-ISTIC	iCEWav Neuromonitoring Platform	Component Neuromonitoring System – Moberg Research	Persyst 13	Comment
Records and displays raw EEG data from amplifier, performs gain and filtering functions that may be modified by the user	Raw digitized EEG signals recorded directly from the amplifier at hardware-specified sampling rate; 50/60Hz notch filter may be activated/deactivated by User; hi-pass and low-pass filters may be set by User; gain and other display specifications (time interval displayed, time between intervals, etc); user may select from preset electrode montage or modify montage according to user specifications.	Same	Same	Equivalent
Records and displays data from bedside physiological monitors	System is connected to bedside monitors using USB, serial or Ethernet connection; device-specific data integration; detection of external device-specific data labeling; user-controlled selection for display of subsets of available data; data displayed in traditional two-dimensional line graph format; user can modify scaling of individual graphs for each data input.	Same	(n/a)	Equivalent
Continuously monitors impedance of recording electrodes	Continuous impedance data available for user review; continuous impedance review may be turned off by User; system provides User with information regarding signal quality based on impedance that can be used to disable channels demonstrating poor	Same	(n/a)	Equivalent

	impedance; User may disable impedance-based signal quality monitoring			

Table 3: Patient admission process and data storage

SYSTEM FEATURE	iCEWav Neuromonitoring Platform	Component Neuromonitoring System – Moberg Research	Persyst 13	Comment
Patient identification	User can input patient name, date of birth and medical record number for subsequent file identification; data files can be searched for recall of previously recorded data or to add files to previously monitored patients	Same	(n/a)	Equivalent
Data storage	Time-locked EEG and systemic physiological data are stored locally on system hardware; user may load previously recorded data for retrospective review	Same	(n/a)	Equivalent

Table 4: Quantitative EEG parameter calculation and display

SYSTEM FEATURE	iCEWav Neuromonitoring Platform	Component Neuromonitoring System – Moberg Research	Persyst 13	Comment
System generates and makes available for display quantitative EEG (qEEG) parameters	System utilizes Fast Fourier Transform processes to generate Compressed Spectral Array (CSA) data; additional parameters available include Total Power, Alpha/Delta ratio and Burst Suppression Ratio; qEEG parameters can be individually selected/displayed per user specifications; gain function for CSA can be set by User; scaling for graphs of qEEG outputs can be manipulated per user specifications	(n/a)	Same	Equivalent