DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 2, 2017

Neuroelectrics Barcelona S.L.U.
% Deirdre Barrow
Senior Consultant, Regulatory
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2500 Bee Cave Road Building 1, Suite 300
Austin, Texas 78746

Re: K162681
Trade/Device Name: Enobio Wireless EEG
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, GWL
Dated: April 21, 2017
Received: April 27, 2017

Dear Deirdre Barrow:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162681

Device Name
Enobio Wireless EEG

Indications for Use *(Describe)*
ENOBIO is an EEG portable monitoring device of 8, 20, 32 channels intended for the use in clinical patient monitoring for use in hospitals and other medical environments.

The Enobio is intended to acquire, store, transmit and display electrophysiological signals in wireless mode as an aid in diagnostics. The system digitizes analogue EEG signals collected by a cap with electrodes, amplifies them, and uses WiFi connectivity to transmit the EEG data to a dedicated host computer with the software.

This device is intended to be used by trained health-care personnel. It is restricted to sale by or on order of a physician.

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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510(k) Summary

K162681

1. Submission Sponsor

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3. Date Prepared

September 21, 2016

4. Device Identification

Trade/Proprietary Name: ENOBIO WIRELESS EEG

Common/Usual Name: Electroencephalograph

Classification Name: Full-Montage Standard Electroencephalograph

Regulation Number: 882.1400 & 882.1835

Product Code: GWQ, Full-Montage Standard Electroencephalograph &

GWL, Amplifier, Physiological Signal

Device Class: Class II

Classification Panel: Neurology

5. Legally Marketed Predicate Device

Device Name	510(k) No.	Product Code	Classification Regulation	Sponsor
Nicolet Wireless EEG	K103140	GWL & GWQ	21 CFR 882.1835 & 21 CFR 882.1400	Carefusion 209, Inc.

6. Indication for Use Statement

ENOBIO is an EEG portable monitoring device of 8, 20, 32 channels intended for the use in clinical patient monitoring for use in hospitals and other medical environments.

The Enobio is intended to acquire, store, transmit and display electrophysiological signals in wireless mode as an aid in diagnostics. The system digitizes analogue EEG signals collected by a cap with electrodes, amplifies them, and uses WiFi connectivity to transmit the EEG data to a dedicated host computer with the software.

This device is intended to be used by trained health-care personnel. It is restricted to sale by or on order of a physician.

7. Device Description

The Neuroelectrics device, Enobio Wireless EEG, performs electroencephalographic measurements with non-invasive technology.

Enobio is a wireless, battery-operated and portable electrophysiology sensor system for the recording of the electroencephalogram (EEG). It has been designed for use in a clinical environment or hospital.. Enobio use must be controlled by specialized medical personnel able to guarantee the correct recording.

ENOBIO WIRELESS EEG, consists of three models designated as the 8, 20 and 32 channels. ENOBIO WIRELESS EEG has a sampling rate of 500 SPS, it works in a bandwidth from 0 to 125Hz (DC coupled) and it provides a resolution of 24 bits – 0.05µV. Enobio is capable of acquiring a variety of electrophysiological signals. These signals include EEG, EOG, ECG and EMG.

The Enobio system is primarily made up of the following three items:

- Necbox (amplifier, transmitter and control box),
- the neoprene cap with the electrodes and
- the NIC software.

The Necbox, which has a data amplifier, connects directly via Wi-Fi to the Neuroelectrics Instrument Controller (NIC) software running on a computer. The EEG data is streamed through the standard Wi-Fi band, and the standard Wi-Fi operating distance range is 10 meters. In all situations the amplifiers store a copy of the data locally to allow for data back-up. This amplifier provides storage and subsequent transmission of data that is not transferred live when the amplifier is in out of range situations.

8. Substantial Equivalence Discussion

The following table compares the ENOBIO WIRELESS EEG to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Comparison of Characteristics

Manufacturer	**Neuroelectrics**	**Carefusion**	**Significant Differences**
Trade Name	ENOBIO WIRELESS EEG	Nicolet Wireless EEG	
510(k) Number	K162681	K103140 (predicate)	n/a
Product Code	GWL & GWQ	GWL & GWQ	Same
Regulation Number	882.1835 & 882.1400	882.1835 & 882.1400	Same
Regulation Name	Amplifier, Physiological Signal & Full-Montage Standard Electroencephalograph	Amplifier, Physiological Signal & Full-Montage Standard Electroencephalograph	Same
Indications for Use	ENOBIO is an EEG portable monitoring device of 8, 20, 32 channels intended for the use in clinical patient monitoring for use in hospitals and other medical environments. The Enobio is intended to acquire, store, transmit	The Nicolet Wireless EEG Amplifier is intended to be used as a front end amplifier to acquire, store, and transmit electrophysiological signals in a wired or wireless mode for the Nicolet Neurodiagnostic	No significant difference as each device acquires, stores, amplifies and transmits EEG signals to host software for neurological applications.

Manufacturer	Neuroelectrics	Carefusion	Significant Differences
Trade Name	ENOBIO WIRELESS EEG	Nicolet Wireless EEG	
	and display electrophysiological signals in wireless mode as an aid in diagnostics. The system digitizes analogue EEG signals collected by a cap with electrodes, amplifies them, and uses WiFi connectivity to transmit the EEG data to a dedicated host computer with the software. This device is intended to be used by trained health-care personnel. It is restricted to sale by or on order of a physician	system.	
Mechanism of Action	The Enobio Wireless EEG is a wireless and wearable electrophysiology sensor system for the recording of electroencephalogram (EEG) measurements	The device is intended to be used as a front end Nicolet EEGwireless32/64 amplifier with the Nicolet Neurodiagnostic system to record, measure, store, analyze and display cerebral and extra cerebral physiologic data for EEG and Sleep studies with or without synchronous digital video. The device is wearable on the torso or head	No Significant Difference; the differences between them are: • The Enobio Wireless EEG is only available in a wireless assembly whilst the Nicolet Wireless EEG is available in a wired and wireless assembly. • The associated software systems are obviously proprietary and are therefore different but the fundamental technology of acquiring, storing, amplifying and transmitting EEG signals to host software is very similar between the two

Manufacturer	Neuroelectrics	Carefusion	Significant Differences
Trade Name	ENOBIO WIRELESS EEG	Nicolet Wireless EEG	
			devices • The Enobio Wireless EEG is only available in a battery operated configuration whereas the predicate device, Nicolet Wireless EEG, can be battery or AC powered.
Technology Overview	**System components:** • cap with electrodes • control box (amplifier, transmitter) • software for PC	**System components:** • patient cable • amplifier, CPU and display monitor, telemetry unit • access point	No significant difference as each device consists of a method of capturing the signal, storing, amplifying and transmitting the signal
	Interface to amplifier: Wireless Ethernet	**Interface to amplifier:** Wired Ethernet (10/100baseT)or Wireless Ethernet (802.11b/g)	No significant difference as the predicate device, Nicolet Wireless EEG offers wired or wireless signal transmission to the host computer used to display and manage acquired data. The proposed device, Enobio Wireless EEG, offers wireless signal transmission only.
	A/D conversion: 24 bits	**A/D conversion:** 24 bits	Same
	Sampling rate: 500 Hz	**Sampling rate:** 125, 250, 500, ... 48000 Hz	No significant difference as the predicate device, Nicolet Wireless EEG offers the user a choice of sampling rates that the user may select. The proposed device, Enobio Wireless

Manufacturer	Neuroelectrics	Carefusion	Significant Differences
Trade Name	ENOBIO WIRELESS EEG	Nicolet Wireless EEG	
			EEG, provides a fixed sampling rate of 500 Hz included within the range offered by the predicate device.
Anatomical Location	Worn on the head via a headcap or headband	Worn on the torso and/or via a headcap	No significant difference as the only option available for the proposed device, Enobio Wireless EEG, is a headcap or headband which is included with the options available with the Nicolet Wireless EEG
Material	ABS 40%c, ABS, gel , neoprene	Not specified	No significant difference as while a potential difference exists between the devices in terms of patient contacting materials, appropriate biocompatibility testing has been conducted on the proposed device.
Number of Channels	8, 20, 32 channels	32 or 64 channel	No significant difference as the number of channels reflects the simpler nature of the Enobio device. Testing has been conducted to ensure each model performs in accordance with the intended use.
Temperature Control Range	Use Temperature Range: +5 to 45 °C Storage in Box Temperature Range: -25 to +70 °C	Not defined but as the use has been confined to research institutions, clinic, hospital, operating room and epilepsy evaluation	No significant difference as the operating environment is very similar to that of the proposed device therefore the operating range in

Manufacturer	Neuroelectrics	Carefusion	Significant Differences
Trade Name	ENOBIO WIRELESS EEG	Nicolet Wireless EEG	
Pressure Range	Atmospheric Pressure: 700 - 1.000 hPa	environments it would be expected to be within the same range as that of the proposed device	terms of temperature, pressure and humidity would be expected to have similar parameters.
Humidity Range	15 - 93 %		
Sterile	no	no	Same
Single-Use	no	no	Same
Shelf Life	5 years	Unknown	Unknown; predicate device shelf life is not available
Software Microprocessor	ATSAM4SD32CGWL	Unknown	N/A
Battery Operated	yes	yes	Same
AC Powered	no	yes	No significant difference: The Enobio Wireless EEG is only available in a battery operated configuration whereas the predicate device, Nicolet Wireless EEG, can be battery or AC powered
Complies with ISO 10993-1	yes	yes	Same
Electrical Safety Testing Passed	yes	yes	Same

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of Enobio Wireless EEG and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, Neuroelectrics completed a number of non-clinical performance tests. The Enobio Wireless EEG meets all the requirements for overall design, biocompatibility, and electrical safety, confirming that the design output meets the design inputs and specifications for the device.

The Enobio Wireless EEG passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Biocompatibility;
    - ISO 10993-1: 2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing
    - ISO 10993-5: 2009, Biological Evaluation of Medical Devices - Part 5: Test for In Vitro Cytotoxicity
    - ISO 10993-10: 2010, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type Hypersensitivity
- Electrical Performance;
    - IEC 60601-1: 2005 + CORR. 1 (2006) + CORR 2 (2007), Medical Electrical Equipment - Part 1 General Requirements for Basic Safety and Essential Performance
    - IEC 60601-1-2:2007 (Third Edition), Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests. (General II (ES/EMC))
    - IEC 60601-2-26:2012, Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
    - IEC 60601-1-11: 2010, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests; all applicable requirements were met
    - IEC 61000-4-3, Radiated, radio-frequency, electromagnetic field immunity test
- Software verification and validation testing per IEC 62304 and FDA Guidance
- Disinfection testing
- Compatibility of electrodes with Enobio Wireless EEG
- Product specification compliance tests:
    - Bandwidth
    - Sampling Rate
    - Input Referred Noise
    - Dynamic Range
    - Operating Hours
    - Resolution
    - Input Impedance

10. Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate device, have been on the market for many years with proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be

demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device.

The Enobio Wireless EEG, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device, Nicolet Wireless EEG.