K131944

APR 10 2014

4. 510(k) Summary

Summary Date: November 4, 2013

Submitter Data: Jordan NeuroScience, Inc.
1660 Plum Lane
Redlands, CA 92374
909-881-2694

Primary Contact: Anne Perry
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Device Name: iEEG (Intelligent Electroencephalograph)

Common Name: electroencephalograph

Device Classification Name: Electroencephalograph

Regulation: 882.1400 – Electroencephalograph

Regulatory Class: Class II

Primary Product Code(s):
OMC - **Reduced**- Montage Standard Electroencephalograph

Predicate Information
BrainScope Zoom-100 (K082886 cleared on 8/10/2009) Lifelines Trackit Recorder (K010460 cleared on 05/14/2001).

Device Description
The Intelligent Electroencephalogram (iEEG) device acquires and stores electrical activity of the brain and patient data. The iEEG can be used with other FDA cleared devices such as the BraiNet Kit (K043009) and Ives EEG electrode (K062880). The BraiNet Kit consists of the BraiNet Template (electrode cap), and Sub-dermal EEG Needle Electrodes and Cutaneous EEG Electrodes.

The iEEG consists of an iEEG transmitter module, a medical grade AC charging adapter/charging cable and an iEEG viewer/recorder software.

The wireless iEEG transmitter module provides an EEG electrode connection, electrode impedance (connection) status indicator(s), a single-user multi-function push button switch that provides power on/off, electrode impedance check. The wireless module is powered by an internal rechargeable energy source.

The AC charger module provides a convenient means to recharge the wireless module's internal energy source when not in use. The device is not intended to be charged when attached to the patient.

The iEEG viewer/recorder software provides, with the aid of host computer hardware and operating system, the ability to collect EEG electrode data from the wireless iEEG transmitter module, view EEG data, and record data to digital file. The iEEG viewer/recorder provides eight signal graphic display of selectable EEG montages (lead/electrode combinations). It also enables subject data entry (Name, DOB, ID number etc.) and control of EEG data recording to digital file.

The Intelligent Electroencephalogram (iEEG) is designed to be capable of usage and storage in hospital, clinic, and emergency room environments. The iEEG transmitter modules communicate with the computer by using Bluetooth wireless technology.

Intended Use

The iEEG device is intended to acquire and store electrical activity of the brain and patient data for review by a medical professional using a legally marketed digital EEG system to assist in the diagnosis of neurological disorders. The device is intended for use by medical personnel in any location within a medical facility, physician's office, laboratory, and clinic or outside of a medical facility under the supervision of a medical professional. The device is intended for use on all patient populations including pediatric.

Technological Characteristics

The proposed iEEG and both predicate devices are battery operated reusable electro-medical devices used to acquire and store electrical activity of the brain within a medical facility. The proposed iEEG and the predicate devices are also used outside of a medical facility under the supervision of a medical professional. The proposed iEEG and the predicate devices have the added capability to export data via wireless Bluetooth technology. The different technological characteristics are included in the risk assessment and testing (see section 16, 17, and 18). No new questions of safety and effectiveness were introduced. Refer to the following Table of Technological Characteristics for a summary.

Performance Data

The device was tested to IEC 60601-1-1 for safety and IEC 60601-2 Electromagnetic Compatibility. The device was also evaluated to standard IEC 60601-2-26 for essential EEG performance specifications. The device with a suitable battery charger was evaluated to IEC 60601-1/A2:1995, IEC 60601-2-26 and applicable national requirements. All applicable tests according to the specified standards were completed and passed. Bench testing was performed and confirms that the device meets design requirements and specifications.

Substantial Equivalence

The proposed iEEG device is substantially equivalent in both function and use to the predicate device, BrainScope Zoom-100 (K082886 cleared on 8/10/2009). The iEEG device is substantially equivalent in EEG function and use of the reference device, Lifelines Trackit Recorder (K010460 cleared on 05/14/2001).
The iEEG device is not used for a polysomnographs (sleep studies). Therefore the product code OLV of the device (Lifelines Trackit Recorder) does not apply.

Trackit, Zoom-100 and Insight are Class II legally marketed devices.

BrainScope Zoom-100 (K082886 cleared on 8/10/2009) is the predicate. The proposed device has equivalent intended use and has equivalent technology to the BrainScope Zoom-100 as indicated in the table below. Lifelines Trackit Recorder (K010460 cleared on 05/14/2001) is included as a reference device for the added technology of the Bluetooth wireless transmission of recorded data and for the additional application environment of outside of a medical facility under the supervision of a medical professional.

		Device				Explanation of Variation
		iEEG (Subject)	BrainScope Z-100 (Predicate)	Trackit EEG (Predicate) The information is based on use of the device with Persyst software	Persyst Insight	
Regulatory Information	510(k)#	K082886	K082886	K010460	K011397	N/A
	Class	Class II	Class II	Class II	Class II	Same
	Product code	OMC	OMC	GWQ	GWQ/OMB	The two product codes OMC and GWQ have exactly the same definition except GWQ has 16 channels and above, OMC has less than 16. The number of channels does not affect the fundamental scientific technology of the device. The Trackit EEG device allows for both full and reduced channel configurations.
	Regulation number	882.1400	882.1400	882.1400	882.1400	Same
	Indications for Use	The iEEG device is intended to acquire and store electrical activity of the brain and patient data for review by a medical professional using a digital EEG system to monitor the state of the brain.	The ZOOM-100DC is used to measure and record the electrical activity of a patient's brain. The ZOOM-100DC is intended to monitor the state of the brain by acquisition and display of EEG signals and by the calculation of standard quantitative EEG parameters.	The Lifelines Trackit is a 10 to 36 channel ambulatory electroencephalo -graph that is designed for use in a variety of monitoring applications to record physiological data for EEG and Sleep Studies.	Persyt Insight (Reveal) software is universal EEG software for display of EEG data to be interpreted by a medical professional.	Equivalent. The Zoom-100 and Trackit devices are used to acquire and store electrical activity of the brain. Persyst only displays acquired data.

	Clinical Application environment	The device is intended for use in a healthcare facility, clinical research environment, or in the home under the supervision of a qualified healthcare professional	Hospitals and clinics	For use in any location within a medical facility or outside of a medical facility under the supervision of a medical professional	The software is intended for use by a trained EEG technologist or physician.	Equivalent. All devices are usable within a medical facility. The iEEG and Trackit have the similar application in environment outside of a medical facility under the supervision of a medical professional.
Specifications	Modalities	EEG	EEG	EEG/PSG	EEG	Equivalent for EEG. The iEEG does not have the modality option of PSG. The PGS is used for monitoring sleep studies. The product code OLV does not apply as iEEG is not used for a polysomnographs (PSG).
	EEG Channels	8	8	10 to 32	4 to 64	Equivalent. Reduced montage is the same for iEEG and Zoom-100. The Trackit EEG reference device allows for both full and reduced montage. The number of electrodes does not affect the fundamental scientific technology of the device.
	Montage	10/20 system	10/20 system	10/20 system	10/20 system	Same
	Sample Rate	250 Hz	200 Hz	256 Hz	NA	Equivalent, sampling rate defines the number of samples per second taken to create a digital representation of the EEG waveforms. All devices provide a sampling rate well above the upper frequency content

						of the EEG waveforms to provide comparable and high fidelity representation of the EEG waveforms.
	ADC Resolution	16 bit	16 bit	16 bit	NA	Same
	ADC CMRR	> 115dB	>100dB	>100dB	NA	Equivalent, Common Mode Rejection Ratio (CMRR) is the measure of a system's ability to ignore or reject common background electrical noise from the EEG signals to be recorded (60 Hz line power noise for example) The greater the CMRR value the better the rejection of common noise sources. The iEEG device is slightly better than the predicate or reference device and would provide comparable performance
	Input Impedance	10MOhm	10MOhm	1MOhm	NA	Equivalent, Same as The primary predicate (Zoom 100) (Trackit EEG) is lower in impedance, subject to a loss in EEG signal level.
	Electrode Impedance	Yes	Yes	Yes	NA	Same
	Wireless Output	Bluetooth 2.4 GHz	Bluetooth 2.4 GHz	Class 1 Bluetooth Connection	NA	Same
	Data Format	edf	Unknown	edf	NA	Equivalent to Trackit device.
	Electrode Material	Standard off shelf electrodes	Standard off shelf electrodes	Standard off shelf electrodes	NA	Same
	Battery	Rechargeable Lithium-Polymer	Rechargeable Lithium Ion	Disposable Batteries or Rechargeable Lithium Ion (Optional)	NA	Equivalent, Lithium Polymer and Lithium Ion use the same chemistries. Lithium Polymer

						utilizes a micro pore polymer material as the battery plate separator.
	Charger	Yes	Yes	Yes	NA	Same
Waveform Review		iEEG	Zoom-100	Trackit		
	Data format	edf	unknown	edf	edf	edf is a universal data format for EEG
	Data Review	Persyst Insight, or JNS Viewer or legally marketed edf reader	unknown	Persyst Insight or legally marketed edf reader	edf and various proprietary data formats	Same
	Display Channels	8 to 24	unknown	NA	4 to 64	
	Hi Filter Settings	off 10 Hz 13 HZ 15 Hz 20 Hz 25 Hz 35 HZ 50 Hz 70 Hz	NA	NA	off 1Hz 5Hz 10 Hz 15 Hz 20 Hz 25 Hz 35 HZ 40 Hz 80 Hz	Same or clinically insignificant differences
	Low filter settings	off 0.3 Hz 0.5 Hz 1 Hz 2 Hz 3 Hz 10 Hz 15 Hz 20 Hz	NA	NA	off 0.3 Hz 0.5 Hz 1 Hz 2 Hz 3 Hz 10 Hz 15 Hz 20 Hz	Same
	60 Hz filter	yes	NA	NA	yes	Same
	Gain	1 uv/mm 1.5 uv/mm 3 uv/mm 5 uv/mm 7 uv/mm 10 uv/mm 15 uv/mm 20 uv/mm 25 uv/mm 35 uv/mm 50 uv/mm 125 uv/mm 250 uv/mm	NA	NA	1 uv/mm 1.5 uv/mm 3 uv/mm 5 uv/mm 7 uv/mm 10 uv/mm 15 uv/mm 20 uv/mm 30 uv/mm 35 uv/mm 50 uv/mm 125 uv/mm 250 uv/mm 500 uv/mm	Same or clinically insignificant differences
	Time Base	1 Sec 2 Sec 5 Sec 10 Sec 20 Sec	NA	NA	1 Sec 2 Sec 5 Sec 10 Sec 15 Sec	Same or clinically insignificant differences

		30 Sec 60 Sec 120 Sec			20 Sec 30 Sec 60 Sec 120 Sec 240 Sec	
	Display Montage	User selectable Transverse-AP Hatband Plus Hatband Double diamond Common Ave Ref Referential D-Banana	NA	NA	User selectable User definable Transverse Transverse-AP Common Ave Referential Referential Laplacian Double Banana BiPolar Double Diamond	Same or clinically insignificant differences

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 10, 2014

Jordan Neuroscience Inc.
Ms. Anne Perry
VP Finance and Administration
1660 Plum Lane
Redlands, CA 92374

Re: K131944
Trade/Device Name: iEEG
Regulation Number: 21 CFR 882.1400
Regulation Name: Reduced- montage Standard Electroencephalograph
Regulatory Class: Class II
Product Code: OMC
Dated: March 12, 2014
Received: March 13, 2014

Dear Ms. Perry:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 yours,

Felipe Aguel -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 on last page.

510(k) Number *(if known)*
K131944

Device Name
iEEG

Indications for Use *(Describe)*
The iEEG device is intended to acquire and store electrical activity of the brain and patient data for review by a medical professional using a digital EEG system to monitor the state of the brain. The device is intended for use in a healthcare facility, clinical research environment, or in the home under the supervision of a qualified healthcare professional. The device is intended for use on all patient populations including pediatric.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.04.10 17:46:16 -04'00'

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