December 13, 2017

Evoke Neuroscience, Inc.
% Marinela Gombosev
Executive VP Operations and Marketing
Evoke Neuroscience
200 Valencia Dr. Suite 109
Jacksonville, North Carolina 28546

Re: K171781
Trade/Device Name: eVox System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, GWJ
Dated: November 10, 2017
Received: November 13, 2017

Dear Ms. Gombosev:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171781

Device Name
eVox System

Indications for Use *(Describe)*
The eVox System is intended for the acquisition, display, and storage, of electrical activity of a patient's brain including electroencephalograph (EEG) and event-related potentials (ERP) obtained by placing two or more electrodes on the head to aid in diagnosis.

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

I. SUBMITTER

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DATE PREPARED

June 6, 2017

II. DEVICE

Trade/Proprietary Name: eVox System
Common/Usual Name: EEG System, EEG Amplifier
Classification Name: Electroencephalograph
Classification Regulation: 882.1400
Product Code: GWQ, GWJ
Device Class: Class 2

Classification Panel: Neurology

III. PREDICATE DEVICES

Legally Marketed Device(s)	510(k) #	Clearance Date
Mitsar-EEG	K143233	8-13-2015
COGNISION EEG	K141316	2-13-2015
Nicolet EDX System	K112052	3-15-2012

IV. DEVICE DESCRIPTION

The eVox System is intended for the acquisition, display, and storage, of electrical activity of a patient's brain including electroencephalograph (EEG) and event-related potentials (ERP) obtained by placing two or more electrodes on the head to aid in diagnosis

The medical system includes the "eVox System" amplifier device, accessories, and a computer (laptop computer or tablet device with internal battery and power cord).

The hardware and ancillary components used in conjunction with the eVox System include an EEG cap, the eVox Amplifier, a charging kit (that consists of a USB cable, clip kit, and wall adapter), a Subject Response Device and a Base Station laptop computer. The software on the Base Station laptop computer is intended for device functioning.

The eVox System consists of two software components:

- Base Station laptop computer software: pre-loaded Evoke software EVO-002-400-BIATS.
- Firmware running on the eVox Amplifier PN SW-MSP430.

The Base Station laptop is running on a Windows Operating System and is paired with the eVox Amplifier with Bluetooth wireless technology. The Evoke software runs on the Base Station computer and has a graphic user interface that allows the clinician to set up a patient and create a new patient record, conduct a study to collect EEG and ERP data, view live EEG and ERP data on the Base Station monitor, and export recorded data to a file.

Firmware for the eVox System resides on the eVox Amplifier. The purpose of the eVox amplifier firmware is to acquire electrophysiology data from the patient and transmit it to the Base Station.

The Amplifier operational mode is controlled wirelessly via the Evoke software. In addition to 19 channels of EEG recording the device includes a mode to measure the cap electrode impedances. This is useful for determining if the electrodes are making a good electrical connection with the scalp at each electrode location.

The primary software outputs are EEG and ERP data files. These data files are written as floating point numbers in binary format, which represent the electrical potential on each of the 19 EEG channels in microvolts.

The eVox System amplifier device does not come in direct contact with patients. Accessories that contact patients, such as the EEG electrode cap, are the same as used with legally marketed devices or are comprised of the same materials as legally marketed accessories.

The eVox System is intended for prescription use in any healthcare, medical, or athletic or sports clinics, or outside of medical facilities such as in the sports arena under the supervision of a physician. Also, investigations can be performed outside of healthcare facilities, as long as they are led by qualified medical personnel.

The device is not sterile. The device is intended for use by qualified medical personnel only and qualifies for exemption per 21 CFR 801 Subpart D «Prescription devices».

V. INDICATIONS FOR USE

The eVox System is intended for the acquisition, display, and storage, of electrical activity of a patient's brain including electroencephalograph (EEG) and event-related potentials (ERP) obtained by placing two or more electrodes on the head to aid in diagnosis.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The following table compares the technological characteristics of the eVox System to those of the predicate devices in order to demonstrate substantial equivalence.

Technological Comparison

Trade Name	eVox System	MITSAR-EEG	COGNISION™	Nicolet EDX 2 Viking Software	Comments
510 (k) Number	K171781	K143233	K141316	K112052	
Product codes	GWQ, GWJ,	GWQ	GWJ Additional: OMC, OLT,	GWJ Additional: OLT, GWF, GZP, IKN, JXE, GWE	Product contains multiple product codes which are generally required for a complete system. The eVox System and the Mitsar – EEG device share the product code: GWQ: Full Montage System The eVox System, the COGNISION system and Nicolet EDX system share the product code: GWJ: Evoked response auditory stimulator
Indications for Use	The eVox System is intended for the acquisition, display, and storage, of electrical activity of a patient's brain including electroencephalograph (EEG) and Event-related Potentials (ERP) obtained by placing two or more electrodes on the head to aid in diagnosis.	The device Mitsar-EEG is intended to acquire, display and store the electrical activity of a patient's brain obtained by placing two or more electrodes on the head to aid in diagnosis.	The COGNISION system is for use by qualified clinical professional in private practice offices or small clinical settings for the acquisition, display, analysis, storage, reporting and management of electroencephalograph (EEG) and auditory evoked potentials (AEP) information.	The Nicolet EDX is intended for the acquisition, display, analysis, reporting and management of electrophysiological information from the human nervous and muscular system including Nerve Conduction (NCS). Electromyography (EMG), Evoked Potentials (VEP), Auditory (AEP) Somatosensory Evoked Potentials (SEP), Electroretinography (ERG) Electrooculography (EOG), P300, Motor Evoked Potential (MEP). The	

Trade Name	eVox System	MITSAR-EEG	COGNISION™	Nicolet EDX 2 Viking Software	Comments
				Nicolet EDX with Viking Software may be used to determine automatics responses to physiologic stimuli by measuring the change in electrical resistance between two electrodes (Galvanic Skin Response and Sympathetic Skin Response). Autonomic testing also includes assessments of RR interval variability. The Nicolet EDX with Viking Software is used to detect the physiologic function of the nervous system, for the location of neural structures during surgery and to support the diagnosis of neuromuscular disease or condition. The listed modalities do not include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the nerve; Electromyography measures the electrical activity of the muscle and Evoked Potential measure electrical activity from the Central Nervous System. The Nicolet EDX with Viking Software is intended to be used by a qualified healthcare provider.	
Principle of Operation	The eVox System device is used for acquisition of physiological signals using two or more channels of electroencephalography	The Mitsar EEG consists of biosignal amplifier, USB cable, USB dongle and software. The medical system includes	The COGNISION EEG/EP System is a combination device for reduced montage recording and display of electroencephalographic (EEG)	The Nicolet EDX system with Viking Software (Viking EDX) is designed for the acquisition, display, analysis, reporting and management of electrophysiological information	The eVox System has a principle of operation that closely matches that of its predicates. All devices use skin coupling methods, either through electrodes or sensors

Trade Name	eVox System	MITSAR-EEG	COGNISION™	Nicolet EDX 2 Viking Software	Comments
	(EEG) from the scalp. It consists of an eVox amplifier, a laptop computer (base station), a patient EEG cap, subject response button, ear buds, and a charging cord. The eVox amplifier and software provide a means to: a) initiate a study, track user EEG and ERP data and enter text or questionnaire information, b) acquire and save signals to the memory of the device, c) transmit signal data from the device, d) Visually inspect the acquired signal. e)Manage Event-related Potentials	"Mitsar EEG" device and computer (stationary PC with uninterruptible power supply (UPS) or laptop with internal battery). The Mitsar EEG device is an amplifier which receives patient EEG data from a patient EEG cap or EEG electrodes.	and evoked potentials (EP) test data. The system uses elastic bands to accurately position 10 electrode pods around the head. EEG signal amplification, conditioning, and A/D conversion is performed by electronic circuits closely coupled to the electrode pods through short flexible printed wires. The headset is connected by a cable to a handheld control unit and data acquisition box (HCU). The HCU communicates via a wireless data link to a Windows PC to stream EEG data. Software on the PC is used to setup the tests and view and evaluate the resultant test data using standard EEG/EP display methods.	from the human nervous and muscular systems. The system is designed to perform nerve conduction studies (NCS), needle electromyography (EMG) testing, evoked potential (EP) testing, and intra-operative monitoring (IOM). The system can also perform multi-modality recording through Multi-mode programs (MMP). Viking EDX provides a variety of tests spanning the various modalities.	which transmits patient EEG and ERP from the surface of the scalp to an amplifier. The connection between the amplifier and electrodes is a wired connection for the devices. All devices convert the analog data into digital data which is then transmitted to a base station or computer. Once transmitted to the base station, the devices display and store the data on the base station and allow the user to export the data to a file.
Patient population	All age groups	All age groups	Adults	Unknown	
Use environment	Intended for use in any healthcare, medical, or athletic or sports clinics, or outside of medical facilities such as in the sports arena under the supervision of a physician. Also, investigations can be	Intended for use in functional diagnostics wards and departments at out-patient clinics, hospitals, health research institutes, health centers and other medical institutions.	Physicians' Offices	Physicians' Offices	

Trade Name	eVox System	MITSAR-EEG	COGNISION™	Nicolet EDX 2 Viking Software	Comments
	performed outside of healthcare facilities, as long as they are led by qualified medical personnel.	Also, investigations can be performed outside of healthcare facilities, as long as they are led by qualified medical personnel.			
Safety class	Class II	Class II	Class II	Class II	
Biocompatibility	Per ISO 10993-1	Per ISO 10993-1	Per ISO 10993-1	Per ISO 10993-1	
Intended Use	The eVox System is intended for the acquisition, display, and storage, of electrical activity of a patient's brain including electroencephalograph (EEG) and Event-related Potentials (ERP) obtained by placing two or more electrodes on the head to aid in diagnosis.	The Mitsar-EEG is intended to acquire, display and store the electrical activity of a patient's brain by placing two or more electrodes on the head to aid in diagnosis.	The COGNISION system is a combination device for reduced montage recording and display of electroencephalograph (EEG) and evoked potentials (EP) test data.	The Nicolet EDX with Viking Software (Viking EDX) is intended for the acquisition, display, analysis, reporting and management of electrophysiological information from the human nervous and muscular systems. The system is designed to perform nerve conduction studies (NCS), needle electromyography (EMG) testing, evoked potential (EP) testing, and intra-operative monitoring (IOM). The system can also perform multi-modality recording through Multi-mode programs (MMP).Viking EDX provides a variety of tests spanning the various modalities.	
ERP Stimulus Modality	Auditory; Visual	None	Auditory	Auditory; Visual	
System Components	eVox System consists of :	"Mitsar EEG" consists of	COGNISION™ consists of: • Head Set	CareFusion Nicolet EDX 2 Viking Software consists of:	

Trade Name	eVox System	MITSAR-EEG	COGNISION™	Nicolet EDX 2 Viking Software	Comments
	• an eVox amplifier, • a laptop computer (base station), • a patient EEG cap, • subject response button, ear buds, • and a charging cord.	• biosignal amplifier, • computer (stationary PC with uninterruptible power supply (UPS) • or laptop with internal battery) • USB cable, • USB dongle • and software.	• Auditory stimulator • Handheld Control Unit (HCU) including Interface Software • Connecting Headset cable between the headset and the handheld control unit	• EDX Console • Electrical stimulators • Auditory Stimulator • Trigger input/output • LED google interface Control Panel • Amplifier • Computer Monitor • Keyboard, Mouse • Printer	
ERP Paradigm **(Auditory and Visual Stimuli)**	P300 Oddball - Single Stimulus - Single Deviant - 2 Deviant - Active and Passive	None	P300 Oddball - Single Stimulus - Single Deviant - 2 Deviant - Active and Passive	P300 Oddball - Single Stimulus - Single Deviant - 2 Deviant - Active and Passive	
ERP Task Response	User Buttons	User Buttons	User Buttons	User Buttons	
Skin Coupling	Custom Electrode Band and Gel	Custom Electrode Band and Gel	HydroDot Biosensor	Discrete Electrode Wires	The eVox system, Mitsar EEG, and Nicolet EDX use the same method of utilizing a conductive gel between electrode and the skin The COGNISION system uses HydroDot Biosensor.

Trade Name	eVox System	MITSAR-EEG	COGNISION™	Nicolet EDX 2 Viking Software	Comments
Sterile	No	No	No	No	
Single Use	No	No	No	No	
Shelf life	Durable good	Durable good	Durable good	Durable good	
Typical Biopotential Signals Recorded	Electroencephalography (EEG), EP/ERP	Electroencephalography (EEG)	Electroencephalography (EEG), EP/ERP	Electroencephalography (EEG), EP/ERP	The eVox System, the COGNISION system and the Nicolet EDX record EEG and EP/ERP. TheMitsar-EEG device does nothave EP/ERP modality.
Number of Signal Recording Channels	Up to 21	Up to 21	Up to 10	7	
Recording Channels Location and Positioning Systems	Fz,Cz,Pz,F3,P3,F4,P4 Utilizing elastic bands using distance ratios consistent with the 10-20 System	Fz,Cz,Pz,F3,P3,F4,P4 Utilizing elastic bands using distance ratios consistent with the 10-20 System	Fz,Cz,Pz,F3,P3,F4,P4 Utilizing elastic bands using distance ratios consistent with the 10-20 System	Variable Discrete electrode wires	The eVox system, the Mitsar system and the COGNISION system use the same exact electrode placement configuration and a similar method position of electrodes. The Nicolet EDX system has a variable electrode configuration that may be configured in similar manner.
Impedance Test	Yes	Yes	Yes	Yes	
Amplifier Input Impedance	> 10 MΩ	> 200 MΩ	> 60 MΩ	> 1000 MΩ	Performance testing per IEC 60601-2-26:2012 confirmed 10 MΩ is sufficient to eliminate distortion in the measured signal.

Trade Name	eVox System	MITSAR-EEG	COGNISION™	Nicolet EDX 2 Viking Software	Comments
Analog to Digital Conversion	24 Bit	16 Bit	16 Bit	24 Bit	
Sampling Rate	250 Hz	500 Hz	125/250 Hz	384 KHz	Clinically relevant human electrophysiology does not exceed 100 Hz and therefore there is no technical need to sample above 250 Hz.
Common mode rejection	>110 dB	>100 dB	>90dB	>110dB	
Analysis Software	Embedded, commercially available, and user defined.	Embedded, commercially available and user defined.	Embedded, commercially available, and user defined.	Embedded, commercially available and user defined.	
Interface with Amplifier	Class 2 Bluetooth® version 2.0 to PC	USB cable to PC	Bluetooth 2.0/4.0	USB cable to PC	
Power Supply	Li-Ion Battery, with USB cable for charging the battery.	USB cable	Li Ion Battery	Mains (100-240 VAC)	
EEG input terminals	up to 19 channels	up to 21 channels	Up to 7 channels	2-8 channels	
Resolution	24 bits	16 bits	16 bits	24 bits	

Trade Name	eVox System	MITSAR-EEG	COGNISION™	Nicolet EDX 2 Viking Software	Comments
Band Pass	0.1 to 50 Hz	0.162-70 Hz	0.4 to 40 Hz	Unknown	The Band pass is the subset of the Cognition System. The eVox system meets the frequency requirements of IEC 60601-2-26 (0.5Hz-50 Hz)
Noise	2-3 uVp-p	< 1.5µVp-p	≤1µV RMS	<0.6µV RMS	The measured noise of 2-3uVp-p for the eVox System is well within the IEC 60601-2-26:2012 requirement of 6 uVp-p.
Type	Burst (White Noise)	None	Unknown	Click, Pip, Burst	The eVox system uses a burst type noise stimulus to evoke an ERP.
Duration	100ms	None	50ms	0.05 to 1 ms	100ms is a typical length for evoking an ERP.
Side	Both	None	Unknown	Left, Right, Both	
Frequency Range	440 Hz-16kHz	None	Unknown	250Hz-8kHz	The eVox system generates a sound with a frequency range of 440Hz-16kHz which is a sufficiently wide enough band for human hearing.
Intensity	0 to 85dB	None	Unknown	0 to 139dB pSBL	The sound emitted by the eVox system is a flat white noise burst, therefore the peak and average is the same. Maximum decibel level is 85dB, well below 125dB (no risk to user).
Noise Patterns	12.5% occurrence randomly distributed over	None	10 % occurrence within 10-60 minutes	Unknown	The balance of this pattern is best to elicit the desired ERPs.

Trade Name	eVox System	MITSAR-EEG	COGNISION™	Nicolet EDX 2 Viking Software	Comments
	10 minutes				
Input Voltage Range	+/-150 mV	5 mV	Not Stated	Not Stated	Due to the 24x gain that is applied to the A/D channels by the eVox firmware the dynamic range is +/-150 mV for the eVox System which is sufficient for its use environment.
Safety Standards Compliance	IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint) EN 60601-1-2:2012 IEC 60601-2-26:2012	EN 60601-1:2005 EN 60601-1-2:2005 EN 60601-2-26	UL 60601-1:2003 EN60601-1-2/A1:2007 EN60601-1-2/A1:2007 EN 60601-2-26 IEC 60601-2-40	EN / IEC 60601-1:1998 +A1:1991+A2:1995 IEC 60601-1-1:2000 EN/IEC 60601-1-2: Ed 2.0+A1:2004 IEC 60601-2-40: 1998, Ed 1, UL60601-1:2003-04-25 Ed1, Rev 2003/06/30	
Operating Environment	0 to +45 °C, Relative humidity, 5% to 95% non-condensing	Not Published	60-90 °F	Not Published	
Storage Environment	−20° to 45° C , Relative humidity, 5% to 95% non-condensing	Not Published	Not Published	Not Published	

VII. PERFORMANCE DATA

a. Verification and Validation Testing

Verification and validation testing was performed for the eVox System and the required documentation was provided with the 510k application per the FDA's Guidance for Industry and FDA Staff, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices and General Principles of Software Validation.

b. Performance Testing

Extensive functional device testing and user testing has been performed with satisfactory results.

Additionally, tests have been performed by the accredited laboratories and show full compliance with standards below with the exception of DC offset, which passed under a relaxed condition. This deviation is acceptable for the intended use of the device.

IEC 60601 - 2 - 26:2012 Medical electrical equipment - Part 2: Particular requirements for the safety of electroencephalographs.

Test	Test Method Summary	Results / P or F (per IEC 60601-2-26 performance limits)
Accuracy of signal reproduction Purpose: verify signal is accurately reproduced over a range of amplitudes.	Test circuit and method per IEC 60601-2-26 clause 201.12.1.101.1. Amplitude of 2Hz Triangle wave varied from 50uV to 500uV. IEC 60601-2-26 Pass-Fail Limit: error < 20%	Pass Test shows that Evoke system accurately reproduces EEG signals over the specified range
Input dynamic range and differential offset voltage Purpose: verify signal accuracy in presence of dc offset voltages.	Test circuit and method per IEC 60601-2-26 clause 201.12.1.101.2. 1mV 6Hz Triangle wave with 300mV offset added. IEC 60601-2-26 Pass-Fail Limit: amplitude error < 10%	300mV Offset: 100% error: Fail 187mV Offset: 1.5% error: Pass

Test	Test Method Summary	Results / P or F (per IEC 60601-2-26 performance limits)
Input Noise Purpose: verify that the signal noise caused by amplifier does not exceed max 6 μ V peak-to-valley	Test circuit and method per IEC 60601-2-26 clause 201.12.1.101.3. Inputs shorted together. IEC 60601-2-26 Pass-Fail Limit: max 6 μ V peak-to-valley	Maximum noise: 3.4 uV: Pass
Frequency Response Purpose: verify signal is accurately reproduced over a range of frequencies	Test circuit and method per IEC 60601-2-26 clause 201.12.1.101.4. Triangle wave Amplitude established at 5Hz, is then adjusted to 0.5 Hz and 50Hz. IEC 60601-2-26 Pass-Fail Limit: output amplitude > 71%, < 110%	0.5 Hz: 100%: Pass 5 Hz: 105%: Pass 50 Hz: 76%: Pass
Common mode rejection Purpose: verify amplifier rejects common mode noise	Test circuit and method per IEC 60601-2-26 clause 201.12.1.101.5. Apply 1Vrms at 60Hz to all inputs tied together. IEC 60601-2-26 Pass-Fail Limit: output amplitude < 10mm (= 100uVpp)	With 0 DC Offset: 67.3uVpp: Pass With 187mV dc Offset: output is saturated: Fail

c. Safety Testing

The tests have been performed by the accredited laboratories and show full compliance with standards below:

IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 plus US Differences to: US National standard ANSI/AAMI ES60601-1: 2005 / A2:2010 (FDA recognition # 19-4).

d. Electrical Safety and Electromagnetic Compatibility (EMC)

The tests have been performed by the accredited laboratories and show full compliance with standards below. The device under consideration has passed the tests according to IEC 60601-1-2:2007.

IEC 60601-1-2 Edition 3: 2007-03, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility

(FDA recognition # 19-1)

VIII. CONCLUSIONS

The eVox System passed the testing according to the established specifications and the eVox System is consistent with that of the predicate devices in terms of EEG and ERP recording performance.

As part of showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, Evoke Neuroscience completed a number of tests. The eVox System meets all the requirements for overall design, biocompatibility, and electrical safety confirms that the design output meets the design inputs and specifications.

The eVox System passed all testing stated above as shown by the acceptable results obtained.

The eVox System complies with the applicable voluntary standards for biocompatibility and electrical safety. The device passed all the testing in accordance with national and international standards.