DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 13, 2015

Neuronetrix Solutions
% Cheryl Fisher
Senior Consultant QA
Emergo Group
816 Congress Ave, Suite 1400
Austin TX 78701

Re: K141316
Trade/Device Name: COGNISION™ EEG/EP SYSTEM
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLT, GWJ, OMC
Dated: January 12, 2015
Received: January 13, 2015.

Dear Ms. Fisher,

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 yours,

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)*
K141316

Device Name
COGNISION™ EEG/EP SYSTEM

Indications for Use *(Describe)*
The COGNISION System is for use by qualified clinical professionals 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.

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

for

COGNISION™ EEG/ERP SYSTEM

1. Submission Sponsor

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3. Date Prepared

1/12/2015

4. Device Identification

Trade/Proprietary Name:	COGNISION™ EEG/ERP SYSTEM
Common/Usual Name:	EEG/EP System, EEG Telemetry System
Classification Name:	Multiple: Electroencephalograph, Evoked Response Auditory Stimulator
Classification Regulation:	Multiple: 882.1400 882.1900
Product Code:	Multiple: OMC, Reduced Montage Electroencephalograph OLT, Non-Normalizing Quantitative Electroencephalograph Software GWJ, Stimulator, Auditory, Evoked Response
Device Class:	All product codes utilized are considered Class II
Classification Panel:	Neurology

5. Legally Marketed Predicate Device(s)

K131383	Advanced Brain Monitoring X-10/X-24 family
K112052	CareFusion Nicolet EDX 2/ Viking Software
K962447	Physiometrix Equinox Digital EEG System

6. Device Description

The COGNISION™ EEG/EP System is a combination device for reduced montage recording and display of electroencephalographic (EEG) and evoked potentials (EP) test data.

The system uses elastic bands to accurately position 10 electrode pods around the head (7 recording channels, 2 linked mastoids, and 1 common).

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). A lithium-ion battery in the HCU is used to power the system. The HCU communicates via a wireless data link to a Windows PC to stream EEG data.

HydroDot® Biosensors (from HydroDot Inc., and not included as part of this submission) are inserted into each electrode pod to electrically couple the electrode pods to the subjects scalp.

Software on the PC is used to setup the tests and view and evaluate the resultant test data using standard EEG/EP display methods.

Calibrated audiometric earphones (from E-A-R Auditory Systems) can be plugged in to the amplifier A/D converter box to deliver various auditory stimuli to produce evoked potential EEG responses.

7. Indication for Use Statement

The COGNISION System is for use by qualified clinical professionals 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.

8. Substantial Equivalence Discussion

The following table compares the COGNISION™ EEG/EP Systems to the predicate device(s) with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Manufacturer	Neuronetrix Solutions	Advanced Brain Monitoring	CareFusion	Physiometrix Inc.	SIGNIFICANT DIFFERENCES
Trade Name	COGNISION™ EEG/ERP SYSTEM	X10	Nicolet EDX 2/Viking Software	Equinox™ Digital EEG System	
510(k) Number	K141316	K131383	K112052	K962447	None
Regulation Number	882.1400, 882.1900	882.1400	882.1400, 882.1900 Additional: 882.1870, 890.1375, 882.1550, 882.1890, 882.1880	882.1400 882.1320 882.1835	Between the three predicates all regulations are commensurate with the COGNISION™ EEG/ERP System
Regulation Name	Electroencephalograph, Evoked response auditory stimulator	Electroencephalograph	Electroencephalograph, Evoked response auditory stimulator Additional: Evoked Response Electrical Stimulator Diagnostic Electromyopraph Nerve Conduction Velocity Measurement Device Evoked Response Photic stimulator Evoked Response Mechanical Stimulator	Electroencephalograph Cutaneous Electrodes Physiological Amplifier	Between the three predicates all the regulations associated with the COGNISION™ EEG/ERP System are commensurate. The primary regulation for all three devices is the same while the The Equinox System and the X-10 System do not perform EP. The Nicolet EDX 2/Viking Software performs EP with additional stimulus types
Product Code	OMC, OLT, GWJ	OMC	OLT, GWJ Additional: GWF, GWE,GZP,IKN,JXE	GXY	Products of this type typically contain multiple product codes which are generally required for a complete system The X-10 System and COGNISION™ EEG/ERP System share the product code: • OMC Reduced Montage System

					The X10 system is a reduced montage EEG device equivalent to the EEG functionality of the COGNISION™EEG/ERP SYSTEM However it does not include GWJ EP Functionality as the COGNISION™EEG/ERP SYSTEM does. ***T***he Nicolet EDX 2 ***and*** COGNISION™ EEG/ERP System share two main product codes: 1. OLT- Non-Normalizing Quantitative Electroencephalograph Software 2. GWJ-Stimulator Auditory Evoked Response The COGNISION™ EEG/ERP System utilizes a reduced montage headset of less than 16 electrodes. The Nicolet EDX 2 System can utilize either a reduced or full montage array. Additionally the Nicolet EDX 2 system has additional modalities associated with other Evoked Potentials such as visual and muscular as well as the auditory evoked potential modality. Wherein the COGNISION™ EEG/ERP System has only Auditory Evoked Potential capability.

					The Equinox System performs full montage EEG. The Physiometrix Equinox does not have Evoked Potential capability.
Indications for Use	The COGNISION™ EEG/ERP System is for use by qualified clinical professionals 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 X-Series System is intended for prescription use in the home, healthcare facility or clinical research environment to acquire, transmit and display and store physiological signals from patients 6 and older. The X-Series system requires operation by a trained technician. The x-Series System acquires, transmits, displays and stores electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG) and /or electromyogram (EMG, and accelerometer signals. The X-Series system only acquires and displays physiological signals, no claims are being made for analysis of the acquired signals with respect to the	The Nicolet EDX 2 is intended for the acquisition, display, analysis, storage, reporting, and management of electrophysiological information from the human nervous and muscular systems including Nerve Conduction (NCS), Electromyography (EMG), Evoked Potentials (EP), Autonomic responses and Intra-Operative Monitoring including Electroencephalography (EEG).	The Equinox system is indicated for preserving the full fidelity of the EEG waveform data in the patient population while providing tools for displaying and printing the waveforms for analysis and interpretation by trained healthcare professionals Intended use is defined as The Equinox Digital EEG System records and digitizes EEG data and automatically stores it on optical disk. Post-processing options include display on paper or computer monitor	All products are intended for use by qualified clinical professionals. All products are used for acquisition and display of EEG data. The Nicolet EDX 2 and the COGNISION systems have the added capability of recording Auditory Evoked Potential. The Nicolet EDX 2 system provides the following capabilities above the COGNISION™ EEG/ERP System Nerve Conduction and Electromyography. The X-10 Systemcontains the following capabilities above the COGNISION™ EEG/ERP SYSTEM, EOG electrooculogram, ECG electrocardiogram, and EMG electromyogram The Equinox System only contains EEG capability and does have auditory evoked potential capability.

		accuracy, precision and reliability			
Anatomical contact sites	Patient's skin (scalp) (auditory stimulators/earphones)	Patient's skin (scalp) and chest	Patient's head (auditory stimulators) , skin with electrical stimulator probes	Patient's skin (scalp)	The COGNISION™ EEG/ERP System and the other predicates all use electrodes which contact specific locations on the scalp for EEG recording. The COGNISION™ EEG/ERP System and the Nicolet system also use earphones for auditory evoked potentials testing. The X10 and Nicolet also have functionality for recording electrophysiological data from the chest.
EP Stimulus Modality	Auditory	NA	Auditory	NA	Both the Nicolet EDX 2/Viking and the COGNISION™EEG/ERP SYSTEM contain an auditory evoked potential modality. The X-10 Systemand Equinox System s. do not have an auditory evoked potential modality
EP Paradigm (Auditory Stimulus)	P300 Oddball -Single Stimulus -Single Deviant -2 Deviant -Active and Passive	N/A	P300 Oddball -Single Stimulus -Single Deviant -2 Deviant -Active and Passive	N/A	Both the Nicolet EDX 2/Viking and the COGNISION™EEG/ERP SYSTEM utilize the same EP Paradigms. The X-10 and Equinox systems do not have this functionality.
EP Task Response	User Buttons	N/A	User Buttons	N/A	Both the Nicolet EDX 2/Viking system and the COGNISION™EEG/ERP SYSTEM utilize user buttons to respond to the auditory evoked Potential. The X-10 and Equinox systems do not have

					this functionality.
General Display Functionality	Channel Selection X/Y Windowing Color Selection Grid Display	Channel Selection X/Y Windowing Color Selection Grid Display	Channel Selection X/Y Windowing Color Selection Grid Display	Channel Selection X/Y Windowing Color Selection Grid Display	All systems share similar display functionality with minor UI differences that do not effect performance.
EP Display Functionality	Average Waves Difference Waves Stimulus Onset Button Press	N/A	Average Waves Difference Waves Stimulus Onset Button Press	N/A	Both the Nicolet EDX 2/Viking and the COGNISION™EEG/ERP SYSTEM utilize the same EP Display functionality. The X-10 and Equinox systems do not have this functionality.
Skin Coupling	HydroDot® Biosensor	Custom Electrode Band and Gel	Discrete Electrode Wires	HydroDot® Biosensor	The COGNISION™ EEG/ERP System and the Equinox system both use HydroDot Biosensors (commercially available from HydroDot, Inc.) to couple the Ag-Ag/Cl electrodes to the skin. The other predicates use similar methods utilizing a conductive gel between an Ag-Ag/Cl electrode and the skin. .
Target Population	Adults	Ages 6 and older	Unknown	Adults	The target population is the same for the COGNISION™ EEG/ERP System and the Equinox System. The target population for the Nicolet EDX 2 system is unknown. The Advanced Brain Monitoring Inc. X-10 system is utilized for a population of 6 and older. It is important to note the ***COGNISION™ EEG/ERP System*** is only for use on adults.
Environment of use	Physician Offices	Home, Healthcare Facility and Clinical Research	Physician offices	Unknown	The environment of use is similar for the COGNISION™ EEG/ERP SYSTEM, and the Nicolet EDX 2 systems as they

					are both used in a Physician office environment. It is unknown in what environment the Equinox system is utilized. The X-10 system is utilized in the Home, Healthcare Facility and Clinical Research Environments and have testing to support these indications whereas the COGNISION™ EEG/ERP System was tested to support its intended environment of use.
Design	The COGNISION™ EEG/EP System is a combination device for reduced montage recording and display of electroencephalographic (EEG) 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). A lithium-ion battery in the HCU is used to power the	The X10 System is comprised of a Headset and accessories, Synapse Crème, X-Series Basic Software and BT receiving unit. The system combines hardware, firmware and software to acquire physiological signals. It acquires physiological data through a battery powered headset worn by the patient and provides a flexible platform for applying sensors using synapse cream and acquiring signals from multiple locations on the head or body, transmitting and recording the signals and providing visual indications to	The Nicolet EDX 2 System consists of a base unit console containing 2 electrical stimulators, and an auditory and visual stimulator. The base unit also has two trigger inputs and two trigger outputs for connections to external devices. The base unit has up to 12 switchable output sites, and is connected through a single USB (2.0) connection to the computer on the control panel. The control panel houses the computer and amplifiers for signal processing through a 24-bit A/D converter. Digital Signal	The patient module is a small battery powered unit attached to the patient. It transmits EEG data from the patient to the DSP card via fiber optic cable which also acts as isolation for the patient module. The data are conditioned and digitized at the DSP Card and then transmitted to a host PC (Digital EEG machine)	The COGNISION™ EEG/EP System and its predicate devices share a similar configuration including a headset in either reduced or full montage configurations, and a combination of software and hardware that in conjunction with electrodes either cleared with the system or independently appropriately sense brain wave data and transmit the raw data to hardware/software mechanisms that transmit and display the electrical brain wave data. The COGNISION™ EEG/EP System, Nicolet EDX 2/Viking Software system, and Advanced Brain Monitoring Inc. X-10 system have additional accessories to support additional modalities commensurate with their indications for use.

	system. 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.	ensure high quality data are obtained. The basic software provides a means to: a. Initiate a study and track patient information b. Acquired and wirelessly transmit signals from the device. c. Visually inspect the signal quality	Processing provides advanced signal processing such as filtering, sound optimization. The base unit firmware and DSP are run from this computer, where data can be acquired and displayed simultaneously		
Sterile	No	No	No	No	Same
Single Use	No	No	No	No	Same
Shelf Life	Durable good	Durable good	Durable good	Durable good	Same
Power Source	Li Ion Battery	Li Ion Battery	Mains (100-240 VAC)	Mains (100-240 VAC)	The COGNISION™ EEG/ERP System and the X-10 system use similar lithium ion batteries while the Nicolet EDX 2/Viking Software system and Equinox system is powered via a standard wall plug. X-10 Systemuses a Li Ion Batteries as does the COGNISION™ EEG/ERP SYSTEM.
Recording Channels Location and Positioning 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 plastic bands using distance ratios consistent with the 10-20 System	Variable Discrete electrode wires	10-20 System Utilizing elastic bands using distance ratios consistent with the 10-20 System	Both the COGNISION™ EEG/ERP System and the X-10 System use the exact same electrode placement configurations of Fz,Cz,Pz,F3,P3,F4,P4 and a

					similar method of electrode positioning. The Equinox system uses a similar method of electrode positioning but includes additional electrodes for a full montage. The electrode placement in each system is not configurable by the user or patient. The Nicolet EDX 2/Viking Software system has a variable electrode configuration that may be configured in a similar manner but it is not fixed as the X-10, Equinox and the COGNISION™ EEG/ERP System are.
Performance **1. Channels**	1. 7	1. 7	1. 2-8	1. 16	1. It is the same as the X-10 system and/or a subset of the other two.
2. Gain	2. 550	2. 1000	2. **User Adjustable**	2. Unknown	2. The COGNISION™ system gain is fixed by design to ensure an accurate EEG measurement over each channel. The Advanced Brain Monitoring Inc. X-10 system is also fixed. The Nicolet EDX 2 with Viking Software system has an adjustable gain which allows it to accurately measure and record additional

					electrophysiological signals (Nerve Conduction and Electromyography) as well as evoked potential information.
3. Sampling Rate	3. 125/250Hz	3. 256Hz	3. 384KHz	3. Unknown	3. The COGNISION™ System sampling rate was selected to be ~ 3x greater than the highest pass band frequency to prevent aliasing during signal processing. The sampling rate is closely aligned with both the X-10 system and the Nicolet EDX 22 with Viking Software System
4. A/D Bits	4. 16	4. 16	4. 24	4. Unknown	4. Same as X-10 System
5. Noise	5. ≤ 1µV RMS	5. ≤ 1.5µV RMS	5. <0.6 µV RMS	5. Unknown	5. The noise of the COGNISION™ EEG/ERP System is in between the noise range associated with the X-10 Systemand the Nicolet EDX 2 with Viking Software system
					6. The COGNISION™ EEG/ERP System is within the range of the Advanced Brain

6. Pass Band	6. 0.4-40Hz	6. 0.1-65Hz	6. 0.05 to 5KHz	6. Unknown	Monitoring Inc. X-10 system and at 0.4Hz the device functions as intended 7. The COGNISION™ EEG/ERP System has an appropriately high CMRR consistent with the predicates. 8. Same as the X-10 and Nicolet EDX 2 with Viking Software system 9. The COGNISION™ EEG/ERP System 's input impedance is appropriately high for use with the electronic circuits employed in the design. This value can vary substantially between systems depending on the electronic components used without affecting performance between systems. Anything above 50MΩ input impedance is a realistic performance specification with modern integrated circuits like those used in the COGNISION™ EEG/ERP System .
7. CMRR	7. ≥ 90dB	7. 105 dB	7. >110dB at 50/60 Hz	7. Unknown	
8. Impedance Test	8. Yes	8. Yes	8. Yes	8. Unknown	
9. Input Impedance	9. > 60 MΩ	9. > 100 GΩ	9. >1000 MΩ	9. Unknown	

10. Non-Clinical Performance Data

The COGNISION™ EEG/EP System is tested using an automated test set to perform all necessary electrical and audio tests.

The test set includes an electronic fixture, integrated biosignal generator, electronic sensors, and an oscilloscope output to produce all required inputs and measure all necessary electronic performance parameters.

The testing protocols are controlled with a LabView application running on a Windows-based PC.

All testing parameters are automatically recorded in a validation report. The validation report lists the parameters tested and results. The tests which are performed are shown in the Table below. In addition a user can test system functionality by cycling through a self test (parameters for this listed below).

Neuronetrix Solutions utilized the following FDA Guidance documents in the preparation and testing of the COGNISION™ EEG/EP System:

- Electroencephalograph Devices Guidance for 510(k) Content Draft Document Version 1.0, November 3, 1997".
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices May 29, 1998
- Guidelines for Reviewing Premarket Notifications that Claim Substantial Equivalence to Evoked Response Stimulators

Test	*Test Description*	*Acceptance Criteria*
Current Draw	Measures current draw for nominal values, tests for shorts and abnormal functionality	-420 to -525mA
Cal Tones	Determines internal continuity and functioning CAL Tones	Low Cal Frequency: 13.50 - 14.50 Hz Low Cal Power: 31.5 - 33.5 dB µV High Cal Frequency: 27.00 - 28.00 Hz High Cal Power: 31.5 - 33.5 dB µV
Baseline Noise	Measures internal "baseline" noise from Uberyoke and Electrode Strings by shorting amplifiers to ground	Noise V_{RMS}: < 1 µV
Crosstalk	Measures channel to channel crosstalk by injecting a large known signal into a channel and monitoring its effects on other channels outputs	Minimum Crosstalk >60 dB @ 10 Hz, 730 mv pk-pk input on driven CH
CMMR	Inject a known signal into all electrodes then evaluate the EEG signal to establish the CMRR	Min Attenuation : < 90 dB CMRR @ 60 HZ : <100 dB CMRR @ 50 HZ : < 100 dB
Gain Linearity	To validate gain and gain linearity by injecting a spectrum of EEG voltages at a given frequency and record the output voltage. Enter gain offset into COGNISION™	Maximum deviation from linearity : < 0.1
Frequency Response	To validate gain across a spectrum of frequencies by injecting a spectrum of EEG frequencies at a given voltage and recording the voltage attenuation	Max Deviation: < 0.2*x+0.45 dB @ 0.2-0.4 Hz Max Deviation: < 0.45 dB @ 0.3-32 Hz Max Deviation: < 0.15*x+0.45 dB @ 33-50 Hz Gain @ 33 Hz: -3.418 < x < -2.218 dB Gain @ 10 Hz: -0.38 < x < 0.52 dB Gain @ 0.4 Hz: -3.90 < x < -2.70 dB Gain Pass band Values: Variance 1-20 Hz : < 1 dB
CAL Tone loopback	Determines Uberyoke internal continuity and basic functionality using CAL Tones	CAL Tones power spectrum should contain three peaks at 13.9, 28.8 and a third around 45 Hz. CAL Tones Time Domain should have two signals 180 degrees out of phase with each other

Self-Test

In the field, the user can perform a self-test by pressing the key combination O-*. This will cycle the system through the following tests to ensure that the system is operating properly (see HCU SELF TEST LOGIC SCHEMA, IN-1706, for detailed description of the self-test)

Test	*Test Description*	*Acceptance Criteria*
Keypad Test	To ensure all buttons on the keypad work	**PASS**/FAIL
Button Test	To validate user button functionality.	**PASS**/FAIL
LED Test	To ensure the LEDX visibly turn on and off.	**PASS**/FAIL
Power on	To ensure that the unit will power ON.	**PASS**/FAIL
Power off	To ensure that the unit will power OFF.	**PASS**/FAIL
HCU USB Charge	To ensure the HCU can charge via USB	State is 20-90% : Current 350-460mA
Buzzer Test	To ensure that the buzzer is working properly	**PASS**/FAIL
Bluetooth Test	To ensure that Bluetooth is working properly	**PASS**/FAIL
Data Flash Test	To ensure that data is written to Flash properly	**PASS**/FAIL
Audio DAC Test	To ensure that the Audio DAC is working properly	**PASS**/FAIL
Audio Flash Test	To ensure that data is written to Audio Flash properly	**PASS**/FAIL

Conclusions: The COGNISION™ EEG/EP System passed the testing according to the established specifications and the COGNISION™ EEG/EP System is consistent with that of the predicate devices in terms of EEG/EP recording performance. The

As part of demonstrating safety and effectiveness of COGNISION™ EEG/ERP System and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, NeuroNetrix Solutions completed a number of tests. The COGNISION™ EEG/ERP System meets all the requirements for overall design, biocompatibility, and electrical safety confirms that the design output meets the design inputs and specifications. The COGNISION™ EEG/ERP System passed all testing stated above as shown by the acceptable results obtained.

The COGNISION™ EEG/ERP 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.

11. Clinical Performance Data

The COGNISION™ System was validated in actual use conditions on initial production units or their equivalents. Patients with a neurological condition were observed in an environment consistent with the intended use and the design validation met all acceptance criteria.

12. 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 different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the difference between the COGNISION™ EEG/EP System and the predicate devices do not raise any questions regarding its safety and effectiveness. The COGNISION™ EEG/EP System, as designed and manufactured, is det ermined to be substantially equivalent to the referenced predicate devices.