March 17, 2020

Medeia, Inc.
% Daniel Lehtonen
Regulatory Consultant
Compliance and Regulatory Services LLC
3771 Southbrook Dr
Dayton, Ohio 45430

Re: K192753
Trade/Device Name: NeuralScan System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLT, GWJ, GWQ
Dated: February 19, 2020
Received: February 20, 2020

Dear Daniel Lehtonen:

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)*
K192753

Device Name

NeuralScan System

Indications for Use *(Describe)*

The NeuralScan System is intended for the acquisition, display, analysis, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the Requirements of Safe Medical Device Systems Act 1990 and 21 CFR Sec. 807.92

510(k) Number: **K192753**

a1 APPLICANT INFORMATION:

Date Prepared:	26 September 2019
Name:	Medeia, Inc.
Address:	7 W. Figueroa Street Suite 300 Santa Barbara, CA, 93101
Contact Person:	Slav Danev
Phone Number:	+1 800 433 4609
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a2 NAME OF DEVICE:

Trade Name:	NeuralScan System
Common Name:	EEG/EP System, EEG Amplifier
Classification Name:	Non-normalizing quantitative electroencephalograph software 21 CFR 882.1400 (OLT); Full-montage standard electroencephalograph 21 CFR 882.1400 (GWQ); Stimulator, auditory, evoked response 21 CFR 882.1900 (GWJ)
Classification Panel:	Neurology

a3 PREDICATE DEVICES:

Predicate Device:	K171781; eVox System
Predicate Device:	K141316; Cognision™

The FDA database for recalls was searched on 15 Aug 2019 during the preparation of the 510(k) submission and no recalls for the devices noted above were found.

a4 STATEMENT OF INTENDED USE:

The NeuralScan System is intended for the acquisition, display, analysis, 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.

a5 DESCRIPTION OF THE DEVICE:

The NeuralScan System is comprised of the NeuralScan Amplifier with embedded firmware for acquisition and transmission of physiological signals, an EEG cap, a Subject Response Device, a laptop computer preloaded with the NeuralScan Evoke software, and a charging kit (that consists of a USB cable, clip kit, and wall adapter).

The NeuralScan Evoke software runs in a Windows Operating System environment and controls the 23 channel (21 EEG and 2 bio channels) NeuralScan EEG amplifier via a USB cable or Wi-Fi connection. The software has a graphical user interface that allows the user to input patient information, create new records, conduct studies to collect EEG and ERP data, view live data streams of the laptop display, record data to a file, analyze resultant test data using standard Frequency EEG analysis and EP display methods and print the results. The software includes a mode to measure the cap electrode impedances which is useful for determining if the electrodes are making a good electrical connection with the scalp at each electrode location. Interpretation of the data is the responsibility of the physician as the software does not provide any diagnosis based on the data.

The patient contacting accessories are commercially sourced and used without modification. The device and the accessories are not sterile and are not intended to be sterilized.

The NeuralScan System is intended for prescription use in any healthcare, medical, athletic or sports clinic, or outside of medical facilities provided they are led by qualified medical personnel.

The device is intended for use by qualified medical personnel only and qualifies for exemption per 21 CFR 801 Subpart D Prescription devices.

a6 TECHNOLOGICAL CHARACTERISTIC COMPARISON:

NeuralScan product share similar device characteristics, intended use, performance, specifications, sensors and is the same in design, function, and application to the predicate devices.

The comparison table, beginning on page 5, demonstrates that the NeuralScan device is substantially equivalent to the predicate devices. The nonclinical data support the safety of the device and the hardware and software verification and validation demonstrate that the NeuralScan device should perform as intended in the specified use conditions.

Based on comparisons of device technological characteristics, features, materials, intended use and performance the NeuralScan has been shown to be substantially equivalent to the commercially available predicate devices.

b1 NON-CLINICAL TESTING:

Bench testing was carried out on the following characteristics:

- Electroencephalograph (EEG)
- Measurement accuracy
- Communication, data transmission and storage
- Reliability (QoS) Wireless Quality of Service
- Electromagnetic compatibility (EMC)
- Electrical safety testing
- Wireless Coexistence Wi-Fi testing
- Software verification and validation testing
- Biocompatibility verification

In addition to the above, usability testing was also conducted.

Referenced Standards and Performance Testing:
The NeuralScan device was tested and meets the requirements of following

- IEC 60601-1- Medical Electrical Equipment - Part 1: Basic safety and essential performance Ed3.1 2005+A1:2012
- IEC 60601-1-2:2014 - Medical electrical equipment-basic safety and essential performance-EMC
- IEC 60601-2-26:2012 Medical electrical equipment - Part 2-26: Basic safety and essential performance of electroencephalographs
- ISO 15223-1:2012 Medical devices - symbols to be used with medical device labels, labelling, and information to be supplied - part 1: general requirements

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 50µV to 500µV. IEC 60601-2-26 Pass-Fail Limit: error < 20%	Pass Test shows that NeuroScan 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: 1.5% error: Pass 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 6µV 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 6µV peak-to-valley	Maximum noise: 3.4 µV: 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 (= 100µVpp)	With 0 DC Offset: 67.3µVpp: Pass With 187mV dc Offset: 68µVpp: Pass

Software Verification and Validation Testing

Software verification and validation testing were conducted following the FDA guidance document for software contained in medical devices. The software was considered to be a "moderate" level of concern since a failure or latent flaw could indirectly result in a minor injury to the patient through incorrect or delayed information or through action of the operator.

b2 CLINICAL TESTING:

No Clinical testing was necessary to determine substantial equivalence.

b3 CONCLUSIONS DRAWN FROM TESTING:

Based on information obtained on the predicate device with reference to the design specification, electrical safety / EMC testing and intended use, the NeuralScan device was subjected to the same type of testing. The results support the conclusion that the NeuralScan device is substantially equivalent to the Predicate devices.

Substantial Equivalence Comparison Table

Trade Name	NeuralScan System	eVox System	Cognision™	Comments
510 (k) Number		K171781	K141316	
Product codes	OLT, GWQ, GWJ	GWQ, GWJ	OLT, GWJ, OMC	
Indications for Use	The NeuralScan System is intended for the acquisition, display, analysis, 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 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 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.	Product contains multiple product codes which are generally required for a complete system. The NeuralScan System and the eVox device share the product codes: **GWQ**: Full Montage System **GWJ**: Evoked response auditory stimulator The NeuralScan System, the COGNISION system share the product code: **OLT:** Non-normalizing quantitative electroencephalograph software and **GWJ**: Evoked response auditory stimulator

Trade Name	NeuralScan System	eVox System	Cognision™	Comments
Principle of Operation	The NeuralScan System device is used for acquisition of physiological signals using two or more channels of Electroencephalography (EEG) from the scalp. It consists of a NeuralScan amplifier, a laptop computer (base station), a patient EEG cap, subject response button, ear buds, and a charging cord. The NeuralScan amplifier and software provide a means to: - Initiate a study, track user EEG and ERP data and enter text or questionnaire information - acquire and save signals to the memory of the device, - transmit signal data from the device, - visually inspect the acquired signal. - manage event- related Potentials	The eVox System device is used for acquisition of physiological signals using two or more channels of electroencephalography (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: - initiate a study, track user EEG and ERP data and enter text or questionnaire information, - acquire and save signals to the memory of the device, - transmit signal data from the device, - visually inspect the acquired signal. - manage event- related Potentials	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). 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.	The NeuralScan System has a principle of operation that closely matches that of its predicates. All devices use skin coupling methods, either through electrodes or sensors 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	Adult Population	
Use environment	Intended for use in any healthcare facility, medical facility, athletic or sports clinics, or outside of medical facilities provided they are led by qualified medical personnel.	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 performed outside of healthcare facilities, as long as they are led by qualified medical personnel.	Physicians' Offices	
FDA Device Class	Class II	Class II	Class II	

Trade Name	NeuralScan System	eVox System	Cognision™	Comments
Biocompatibility	Per ISO 10993-1	Per ISO 10993-1	Per ISO 10993-1	
System Components	NeuralScan System consists of: - a NeuralScan amplifier, - a laptop computer (base station), - a patient EEG cap, - subject response button, ear buds, - and a charging cord.	eVox System consists of: - an eVox amplifier, - a laptop computer (base station), - a patient EEG cap, - subject response button, ear buds, - and a charging cord.	COGNISIONTM consists of: - Head Set - Auditory stimulator - Handheld Control Unit (HCU) including Interface Software - Connecting Headset cable between the headset and the handheld control unit	
Sterile	No	No	No	
Single Use	No	No	No	
Shelf life	Durable good	Durable good	Durable good	
Interface with Amplifier	USB or WiFi to PC	Class 2 Bluetooth version 2.0 to PC	Bluetooth 2.0/4.0	
Power Supply	Li-Ion Battery, with USB cable for charging the battery.	Li-Ion Battery, with USB cable for charging the battery.	Li-Ion Battery	
Typical Biopotential Signals Recorded	Electroencephalography (EEG), EP/ERP	Electroencephalography (EEG), EP/ERP	Electroencephalography (EEG), EP/ERP	
Electroencephalography (EEG), ERP				
ERP Stimulus Modality	Auditory; Visual	Auditory; Visual	Auditory	
ERP Paradigm (Auditory and Visual Stimuli)	P300 Oddball - Single Stimulus - Single Deviant - 2 Deviant - Active and Passive	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	
Skin Coupling	Custom Electrode Band and Gel	Custom Electrode Band and Gel	Discrete Electrode Wires	The NeuralScan, and eVox use the same method of utilizing a conductive gel between electrode and the skin. The COGNISION system uses HydroDot Biosensor.

Trade Name	NeuralScan System	eVox System	Cognision™	Comments
Number of Signal Recording Channels	Up to 23	Up to 21	Up to 10	Both the NeuralScan and Evox systems have 2 bio-channels
EEG input terminals	up to 21 channels	up to 19 channels	Up to 7 channels	Full montage for 10-20 system has 21 channels
EEG Recording Channels Location and Positioning Systems	Any of the 21 EEG Channels including: Fz, Cz, Pz, F3, P3, F4, P4 Utilizing elastic bands using distance ratios consistent with the 10-20 System	Any of the 19 EEG Channels including: 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	Same – full and reduced montage recording capabilities
Impedance Test	Yes	Yes	Yes	
Amplifier Input Impedance	> 200 MΩ	> 10 MΩ	> 60 MΩ	Performance testing per IEC 60601-2-26:2012 confirmed 10 MΩ is sufficient to eliminate distortion in the measured signal.
Analog to Digital Conversion	24 Bit	24 Bit	16 Bit	
Sampling Rate	200, 500, 1000 Hz	250 Hz	125/250 Hz	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	>110 dB	>90dB	
Analysis Software	Embedded, commercially available, and user defined.	Embedded, commercially available, and user defined.	Embedded, commercially available, and user defined.	
Resolution	24 bits	24 bits	16 bits	
Band Pass	0.1 to 50 Hz	0.1 to 50 Hz	0.4 to 40 Hz	
Noise	2-3 µVp-p	2-3 µVp-p	≤1µV RMS	
Audio Type	Burst (White Noise)	Burst (White Noise)	Unknown	The NeuroScan system uses a burst type noise stimulus to evoke and ERP
Audio Duration	100ms	100ms	50ms	
Audio Side	Both	Both	Unknown	

Trade Name	NeuralScan System	eVox System	Cognision™	Comments
Audio Frequency Range	440Hz-16kHz	440 Hz-16kHz	Unknown	The NeuralScan 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	0 to 85dB	Unknown	The sound emitted by the NeuralScan system is a flat white noise burst, therefore the peak and average are the same. Maximum decibel level is 85dB, well below 125dB (no risk to user).
Audio Noise Patterns	12.5% occurrence randomly distributed over 10 minutes	12.5% occurrence randomly distributed over 10 minutes	10% occurrence within 10-60 minutes	The balance of this pattern is best to elicit the desired ERPs.
Input Voltage Range	± 400 mV	± 150 mV	Not Stated	Due to the 24x gain that is applied to the A/D channels by the NeuralScan the dynamic range is ± 400 mV for the NeuralScan System which is sufficient for its use environment.
General Specifications				
Safety Standards Compliance	- IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint) - EN 60601-1-2:2014 - IEC 60601-2-26:2012	- 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	- UL 60601-1:2003 - EN60601-1-2/A1:2007 - EN60601-1-2/A1:2007 - EN 60601-2-26 - IEC 60601-2-40	
Operating Environment	10 to +45 °C, Relative humidity, 30% to 70% non- condensing	0 to +45 °C, Relative humidity, 5% to 95% non- condensing	60-90 °F	
Storage Environment	−40° to 70° C, Relative humidity, 5% to 95% non- condensing	−20° to 45° C, Relative humidity, 5% to 95% non- condensing	Not Published	

Conclusion	The comparison tabulated above demonstrates that the NeuralScan device is substantially equivalent to the predicate devices. The nonclinical data support the safety of the device and the hardware and software verification and validation demonstrate that the NeuralScan device should perform as intended in the specified use conditions.
Declarations	• This summary includes only information that is also covered in the body of the 510(k). • This summary does not contain any puffery or unsubstantiated labeling claims. • This summary does not contain any raw data, i.e., contains only summary data. • This summary does not contain any trade secret or confidential commercial information. • This summary does not contain any patient identification information.