May 11, 2022

Pascall Systems, Inc.
% Robert Steurer
Consultant
Steurer Consulting Group
800 Blue Quail Rd.
Keller, Texas 76248

Re: K213299
Trade/Device Name: Wireless EEG System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLT, OMC, ORT, GXY
Dated: September 29, 2021
Received: October 1, 2021

Dear Robert Steurer:

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,

for
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213299

Device Name
Wireless EEG System

Indications for Use *(Describe)*
The Pascall Systems, Inc. Wireless EEG System, is intended to be used for measuring and recording the electrical activity of a patient's brain, obtained by placing electrodes on the forehead and wirelessly transmitting the electroencephalographic (EEG) signals for storage and display. The Pascall Systems, Inc. Wireless EEG System, is intended for use in the acquisition of EEG signals, displaying them in real time and storing them for later review and analysis. The Pascall Systems, Inc. Wireless EEG System, is intended for use in a hospital Operating Room, Post Anesthesia Care Unit, Intensive Care Unit, Emergency Department, or in other medical facilities such as inpatient and outpatient (ambulatory) surgery settings.
The Pascall Systems, Inc. Wireless EEG System is indicated for use on patients 18 years of age or older and is to be used by licensed medical professionals that have been adequately trained in the use and interpretation of raw EEG data for determination of brain state during anesthesia. The Pascall Systems, Inc. Wireless EEG System does not provide any diagnostic conclusion about the patient's condition.

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

Date Prepared:	May 7, 2022
Submitter:	Pascall Systems, Inc. 200 Portland St. Boston, MA 02114
Submitter Contact:	Pascall Systems, Inc. 200 Portland St. Boston, MA 02114 Tuan Le Mau Pascall Systems, Inc. Phone: 857-225-4138 Email: tuan@pascallsystems.com
Application Correspondent:	Bob Steurer Principal Consultant Steurer Consulting Group 800 Blue Quail Rd. Keller, TX 76248 steurerbob@gmail.com +1 (425) 358-1072
Manufacturing Site:	Pascall Systems, Inc. 200 Portland St. Boston, MA 02114
Trade/Proprietary Name:	Wireless EEG System
Common/Usual Name:	Electroencephalograph
Classification Name:	Reduced-Montage Standard Electroencephalograph
Device Class:	Class II
Primary Classification Regulation:	21 CFR §882.1400
Primary Product Code:	OLT
Secondary Product Codes:	OMC, ORT, GXY

Substantially Equivalent Devices:

Company	***Predicate 510(k) Number***	***Predicate Manufacturer / Model***
NeuroWave Systems	*K142834*	*DiscoverEEG Model DE-401*
Nihon Kohden	*K120485*	*QP-160AK EEG Trend Program*

Primary Predicate

Secondary Predicate

Device Description:

The Pascall Systems Wireless EEG system is a brain monitoring or Electroencephalographic (EEG) device. The system is designed to record and display four channels of electroencephalograms (EEGs) obtained from noninvasive electrodes placed on a patient's head. The acquired EEG waveforms (4 channels) and processed EEG variables which include a Spectrogram, Artifact index, electromyography (EMG) index, burst-suppression probability, and phase-amplitude modulogram are continuously displayed by the system.

Licensed medical professionals which include anesthesiologists, nurse anesthetists, etc. combine and interpret the data presented by the Pascall Systems Wireless EEG with information provided by other instruments in the operating room.

The primary purpose of the Pascall Systems Wireless EEG is in the acquisition of electroencephalographic (EEG) signals, displaying them along with the processed variables in real time and storing them for later review and analysis. The Wireless EEG system is intended for use in a hospital Operating Room, Post Anesthesia Care Unit, Intensive Unit, Emergency Department, or in other medical facilities such as inpatient and outpatient (ambulatory) surgery settings.

Indications for Use:

The Pascall Systems, Inc. Wireless EEG System, is intended to be used for measuring and recording the electrical activity of a patient's brain, obtained by placing electrodes on the forehead and wirelessly transmitting the electroencephalographic (EEG) signals for storage and display. The Pascall Systems, Inc. Wireless EEG System, is intended for use in the acquisition of EEG signals, displaying them in real time and storing them for later review and analysis. The Pascall Systems, Inc. Wireless EEG System, is intended for use in a hospital Operating Room, Post Anesthesia Care Unit, Intensive Care Unit, Emergency Department, or in other medical facilities such as inpatient and outpatient (ambulatory) surgery settings.

The Pascall Systems, Inc. Wireless EEG System is indicated for use on patients 18 years of age or older and is to be used by licensed medical professionals that have been adequately trained in the use and interpretation of raw EEG data for determination of brain state during anesthesia. The Pascall Systems, Inc. Wireless EEG System does not provide any diagnostic conclusion about the patient's condition.

Summary of Substantial Equivalence:

The intended use of the primary predicate device and the Pascall Systems, Inc. Wireless EEG are substantially equivalent. Both systems are intended to monitor the brain by real-time data acquisition and processing of electroencephalograph signals in adult patients 18 years of age or older. Both systems are intended to be used in the operating room, post-anesthesia recovery unit, intensive/critical care unit. The primary predicate device includes use in clinical settings, at home and for clinical research. The subject device does not claim use in these areas but does specify inpatient and outpatient surgery settings. This difference in the environment of use is not considered significant and do not affect safety or effectiveness.

Both systems use an electrode array and sensor/amplifier to detect and communicate the electroencephalograph to a PC display unit that provides raw EEG waveforms and a digital spectral analysis presentation to a clinical user. Both systems use a reduced montage of 4 electrodes to obtain 4 EEG channels. The Pascall Systems, Inc. includes a reference electrode and ground electrode (total of 6 electrodes) while the primary predicate device uses a 5^{th} electrode as a reference.

Both systems provide signal quality indications including electrode impedance measurements to alert the user of poor electrode contact for each EEG channel which can indicate the signal is suspect. Both systems measure and display artifact. The primary predicate device displays Artifact Detection Flags and Noise Level. The subject device displays an Artifact Index that is intended to represent noise associated with the use of an electrosurgical unit. The primary predicate device performs a pre-processing on the EEG that includes artifact removal. The subject device performs band-pass filtering pre-processing but does not perform further artifact filtering and displays the artifact index based on the raw signal that is contained within the band-pass of the system. The difference in these data presentations does not affect safety and effectiveness as both devices provide an equivalent display of signal quality to alert the user.

Both systems are not intended to be the sole basis for diagnosis or therapy decisions but are used in conjunction with other clinical signs, data, and symptoms. Both systems display the raw EEG waveforms. The primary predicate device requires a wireless option to transmit the data for display on the Data Viewer while the subject device uses wireless functionality to transmit this data on a continuous basis to a tablet for display.

Both systems display a spectrogram and indicate spectral edge frequency along with the display of the quality indicators for artifact, electrode impedance, and EMG. The primary predicate device presents the spectral edge frequency as 50% Median Edge Frequency and 95% Spectral Edge Frequency (SEF) while the subject device displays Spectral Edge Frequency of 95% and a marker at 10 and 20 Hz on the 0 - 30 Hz scale provided as an aid to help identify the frequency components of the spectrogram.

The subject device and the secondary predicate device both display a presentation of burst suppression. The secondary predicate device displays the data as a burst suppression ratio over a given time period. This is the ratio of measurable EEG signal above a stated threshold, and the suppressed EEG signal that is below the stated threshold. The subject device displays burst suppression probability which is the probability that suppression varies smoothly in time and measures only those frequencies that are within a certain range. These differences are not significant and do

not affect safety and efficacy as both devices present a means of determining suppression percentage.

The subject device also displays phase-amplitude modulogram which is not displayed by either of the predicate devices. The phase-amplitude modulogram is a color-intensity display that help visualize the relationship between the amplitude of the high-frequency components of the EEG and the phase of the low-frequency components in the EEG signal. This display provides an additional tool for the medical professional and does not affect safety and effectiveness of the subject device.

The skin contacting components of both the primary predicate device and the subject device are made of materials that meet the ISO 10993 standards for cytotoxicity, skin irritation, and skin sensitization.

Technology Comparison:

The Pascall Systems, Inc. Wireless EEG System employs similar technological characteristics to the predicate devices.

Performance Characteristic	**Primary Predicate Device NeuroWave Systems Inc. DiscoverEEG Model DE-401 (K142834)**	**Secondary Predicate Device QP-160AK Trend Program (K120485)**	**Pascall Systems, Inc. Wireless EEG System (K213299)**
Modalities	EEG	EEG	EEG
Environment of Use	Operating room, intensive care unit, emergency room, clinical settings and at home where EEG monitoring is used.	Medical facility, laboratory, clinic or nursing home, or outside of a medical facility under supervision of a medical professional	Operating Room, Post Anesthesia Care Unit, Intensive Care Unit, Emergency Department, or in other medical facilities such as inpatient and outpatient (ambulatory) surgery settings
Number of EEG channels	4 (2 frontotemporal channels, and 2 temporal channels)	Up to 32/64	4 (2 frontotemporal channels, and 2 temporal channels)
Number of electrodes	5 (4 measurement electrodes)	N/A; software only	6 (4 measurement, 1 reference, 1 ground), single use
Sensing Electrodes	Silver/Silver chloride, disposable	N/A; software only	Silver/Silver chloride, disposable
Power Source	Battery	N/A; software only	Battery
System Components	Electrode (Sensor) Array, Acquisition and Memory Modules, Data Viewer Software	Trend program software only	Electrode Array (disposable patch), Sensor module, acquisition, Tablet for memory and data viewing
Screen Display Details	• 4 Raw EEG Waveforms • Signal Quality information: Channel Connection flags, Impedance values, Artifact Detection flags, Noise Level • Spectral Parameters: EEG power spectrum and frequency bands including: 50% Median Edge Frequency (MEF), and 95% Spectral Edge Frequency (SEF). Power spectrum displayed as Density Spectral Array (DSA) Spectral	• Up to 64 channels Raw EEG • Signal Quality information: Unknown • Spectral Parameters: EEG power spectrum including power asymmetry trends and power ratio. Frequency bands: including Spectral Edge Frequency (SEF); Power spectrum displayed as	• 4 Raw EEG Waveforms • Signal Quality information: Channel Connection flags, Impedance values(electrode contact signal strength), Artifact (ART),Noise Level (EMG) • Spectral Parameters: EEG power spectrum and frequency bands including: Two horizontal lines at 10 and 20 Hz provided as an aid to help identify the

	Powers in EEG frequency bands traditionally used to quantify EEG signals (α, β1, β2, δ, θ and γ)	Density Spectral Array (DSA) w/ DSA Asymmetry	frequency components of the spectrogram, SEF 95% Power spectrum displayed as Density Spectral Array (DSA) Spectral Powers in EEG frequency bands traditionally used to quantify EEG signals (α, β1, β2, δ, θ and γ)
Storage for offline recording	Yes, on SD Card	Unknown	Yes, in the tablet display
Electrode Impedance	Yes	Unknown	Yes
Detection for Leads Off	Yes	Unknown	Yes
File output capability	Yes	Unknown	Yes
Real time EEG Display	Yes, if wireless option is present	Unknown	Yes, wireless to tablet
Processed EEG Bandwidth	User Selectable in Data Viewer software Low Filter: 0.125 or 0.5 Hz High Filter: 30 or 70 Hz	Unknown	0.5 Hz to 45 Hz
Automatic Artifact Identification	Yes	Unknown	Yes
Common Mode Rejection	$\geq$ 110 dB	N/A; software only	$\geq$ 90 dB
Amplifier Input Impedance	$\geq$ 100 M Ohm	N/A; software only	$\geq$ 500 M Ohm
Electrode Impedance Test	Yes	Unknown	Yes
Contains Patient Isolation	Battery powered, thus no connection between patients and mains power	N/A; software only	Battery powered, thus no connection between patients and mains power
Event Markers	Yes, artifact detection and signal quality events, user selectable events included in Data Viewer Software	Yes, user annotation; others unknown	Yes, artifact detection
Burst Suppression Display	No	Yes, Burst Suppression Ratio w/ calculation of inter-burst interval (IBI) and burst per minute (BPM) trends	Yes, Burst Suppression Probability
Display Interface	LEDs to ensure proper system connection and operation	Displayed on EEG device on which it is installed	Tablet display indicates connection and operation
Biocompatibility	The Electrode Array is made of the materials that have been shown to pass cytotoxicity, primary skin irritation and sensitization as required.	N/A; software only	The Electrode Array patient contact materials have been tested and passed the tests per ISO 10993 for cytotoxicity, primary skin irritation and sensitization as required for patient contact $\leq$ 24 hours duration.

Performance Testing Summary

Non-Clinical Bench Performance Testing:

1. Tests Performed

The Pascall Systems, Inc. Wireless EEG System was tested in accordance with performance standards for electroencephalographic devices. The following test information is in the submittal:

- Verification and Validation (planning and test protocols)
- Electrical Safety
- Electromagnetic Compatibility
- Wireless Coexistence
- Non-Clinical Performance Testing and Reports

The following standards, or applicable sections were used:

- IEC 60601-1:2005 MOD Medical Electrical Equipment – Part 1: General Requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 80601-2-26 Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
- ISO 10993 Biological evaluation of medical devices, Parts 5 and 10, Tests for in vitro cytotoxicity, and Tests for irritation and skin sensitivity

2. Test Objectives

To test the claimed ranges of measurement provided in the device specification and labeling that support the intended use and essential principles including the following additional essential performance requirements defined in clause 201.4.3.101 in the IEC 80501-2-26 Standard:

a) Measurement accuracy of amplitude and rate of variation
b) Input dynamic range and differential offset voltage
c) Input noise
d) Frequency response
e) Common mode rejection

3. Test Methods

Testing was performed per the applicable standards on production equivalent units. Bench testing was performed on an end-to-end system using simulated input.

We performed testing to establish substantial equivalence of the BSR by repeatedly inputting 49 segments of EEG signals from 10 patients and comparing the output to the burst suppression ratio determined using manual review of the raw EEG timeseries. The testing demonstrated that all runs of the 49 segments passed the acceptance criteria (<5% difference from manual review) for a 100% level of agreement.

The real-time Spectrogram, Phase-Amplitude display, EMG Index, ARTF Index, outputs were validated by applying known simulated input signals, including relevant corner case signals, and verifying that the CM0D device display produced expected outputs.

4. Pass/Fail Criteria

Pass criteria is compliance with the claimed range and precision provided in the labeling for the Pascall Systems, Inc. Wireless EEG System. Deviation from standards criteria is identified in the applicable test report.

5. Results Summary

The results of performance testing showed the Pascall Systems, Inc. Wireless EEG System met all applicable specifications.

Sterilization and Shelf Life: The Pascall Systems, Inc. Wireless EEG System is not provided sterile. The Pascall Systems, Inc. Wireless EEG System components have a shelf life as follows:

a) M0 Patch (M0P) is the component that contains the electrodes, battery, and adhesive to attach to the patient skin and has a storage shelf life of 6 months.
b) M0 Sensor (M0S) is the sensor component that contains the electronics and has a shelf life of 2 years
c) Clinician M0 display (CM0D) has no stated shelf life

Biocompatibility: The Pascall Systems, Inc. Wireless EEG System uses an adhesive, reduced montage electrode array to contact the patient. All component materials that are patient contacting have been tested per ISO 10993 third edition for cytotoxicity, skin sensitization, and skin irritation and found to be within acceptable limits. The complete manufactured assembly has been tested to the ISO 10933 third edition for cytotoxicity, skin sensitization, and skin irritation and found to be within acceptable limits.

Discussion/Conclusion

Based on a review of the test results and comparison to the predicate device characteristics and known specifications, the results show that the Pascall Systems, Inc. Wireless EEG System is substantially equivalent to the predicate device.