June 30, 2026

Universal Brain
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market St., Floor 23
Philadelphia, Pennsylvania 19103

Re: K253767
Trade/Device Name: UB ERP System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLT, GWQ, GWJ
Dated: November 25, 2025
Received: November 25, 2025

Dear Janice Hogan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Patrick Antkowiak -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253767

Please provide the device trade name(s).

UB ERP System

Please provide your Indications for Use below.

The UB ERP System is intended for the acquisition, display, analysis, storage and reporting of electrical activity of a patient's brain, including electroencephalography (EEG) signals and event-related potentials (ERPs), obtained by placing two or more electrodes on the head of adults and adolescent patients to aid in diagnosis. The EEG signals are time-stamped. It is used with an UB EEG Cap loaded with appropriate software and connected to a Windows PC using a USB cable.

The UB ERP system is to be used in a health care facility or a clinic under the direction of a healthcare professional.

The UB ERP System does not draw any diagnostic conclusion. A clinical expert must interpret recorded EEG signals. The results of such interpretation should be considered only in conjunction with other clinical findings.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY

Universal Brain's UB ERP System
K253767

Submitter's Name, Address, Telephone Number, Contact Person, and Date Prepared

Universal Brain, Inc.
212-214 Homer Avenue
Palo Alto, CA 94301
Contact: Kazutaka Okuda

Submission Correspondent:

Janice M. Hogan
Hogan Lovells US LLP
janice.hogan@hoganlovells.com
(267) 675-4611

Date Prepared: May 29, 2026

Name of Device: UB ERP System

Common or Usual Name: EEG/EP System, EEG Amplifier, and ERP Measurement System

Classification Name: Electroencephalograph

Regulatory Class: Class II

Regulation Number: 21 CFR 882.1400

Product Code: OLT, GWJ, GWQ

Primary Predicate Device

NeuralScan System, Medeia, Inc., NeuralScan System, K192753

Secondary Predicate Device

Cumulus Functional Neurophysiology Platform, Cumulus Neuroscience Limited, K221963

Device Description

The UB ERP System is an electroencephalography (EEG)-based device used to record, store and report electrical activity in the brain and measure event-related potentials (ERPs) by placing two or more electrodes on the head of adults and adolescent patients to aid in diagnosis.

The UB ERP System hardware consists of an UB EEG device with electrodes, amplifier and electronics in the form factor of a Cap. The Cap has a modular design with an Inner Cap and Outer Cap. The Inner Cap is integrated with EEG electrodes and the Outer Cap holds the electronic module with firmware and covers the Inner Cap with an adjustable strap for a snug fit.

The UB ERP System package consists of the following components:

1. Outer Cap with Electronics Module
2. Inner Cap with Electrodes
3. Dry Electrode Kit- Medium, Flat
4. Disposable Electrodes
5. Ear Clip with Reference Cable
6. Electro-oculography (EOG) Cable
7. Photodiode Cable

The UB ERP System software consists of firmware (embedded in the Cap's electronic module) and Neurotique-2 software application (or App) for presenting stimuli and measuring ERPs based on the participant's response to these stimuli. The App software is installed and runs from the user's Windows personal computer (PC, not provided).

The Neurotique-2 App software is run on the PC by a healthcare professional. After successful authentication, the App runs and enables the Operator Window (OW, on the Operator PC display) to set up the system, create participants, configure settings, and manage EEG recording sessions (e.g. task selection, data quality review, calibration completion, etc.). After a session starts, the Participant Window (PW, shown on the Participant Display) is opened and the App presents stimuli related to various tasks and collects EEG signals. Raw EEG and participant response data are stored in the Windows filesystem after each task is completed. After a recording session is completed, all data are analyzed and output as an ERP report in PDF format using the Reporting Service.

Intended Use / Indications for Use

The UB ERP System is intended for the acquisition, display, analysis, storage and reporting of electrical activity of a patient's brain, including electroencephalography (EEG) signals and event-related potentials (ERPs), obtained by placing two or more electrodes on the head of adults and adolescent patients to aid in diagnosis. The EEG signals are time-stamped. It is used with an UB EEG Cap loaded with appropriate software and connected to a Windows PC using a USB cable.

The UB ERP System is to be used in a health care facility or a clinic under the direction of a healthcare professional.

The UB ERP System does not draw any diagnostic conclusion. A clinical expert must interpret recorded EEG signals and ERPs. The results of such interpretation should be considered only in conjunction with other clinical findings.

The indications for use of the subject device are substantially equivalent to those of

the predicate. The UB ERP indications for use include additional language clarifying the use environment for the device and its limitations, as it is not a standalone diagnostic. These additions do not raise different questions of safety and effectiveness, nor alter the intended use of the proposed device. Thus, the UB ERP System satisfies the first criterion for a finding of substantial equivalence.

Summary of Technological Characteristics / Principle of Operation

Both the UB ERP System and the NeuralScan System (predicate) use an EEG system for acquisition of physiological signals from the brain using two or more channels or electrodes. Both devices consist of an EEG device with an amplifier (electronics and embedded firmware) to record EEG data, recording electrodes, cables, a personal computer (base station), application software and subject response buttons to measure ERPs.

At a high level, the subject and predicate devices are based on the same technological elements: using an EEG device and collecting EEG data to measure ERPs.

The following technological differences exist between the subject and predicate device:

- The UB ERP System utilizes dry electrodes to record EEG data.
- The UB ERP system utilizes seven (7) EEG channels and nine (9) total channels to collect data vs. 21 EEG channels and 23 total channels for the predicate.
- The UB ERP System measures blinks using an EOG cable that is connected to disposable gel electrodes, to monitor and correct EEG signals for artifacts from eye blinks. Similarly, the predicate device has 2 bio-channels for measuring electrocardiogram / electromyography (ECG/EMG) and peripheral capillary oxygen saturation (SpO2) physiological signals during EEG/ERP measurement.
- The UB ERP System has a photodiode and cable to improve the accuracy of ERP measurement.
- The UB ERP System utilizes only visual stimuli, whereas the predicate device utilizes audio and visual stimuli.
- The predicate device utilizes only the Oddball task for measuring P300 ERPs, whereas the UB ERP System utilizes Oddball, Flankers and Doors tasks to measure P300 ERPs.
- The UB ERP System is able to generate an ERP report.

The technological differences of the device hardware do not raise new questions of safety or effectiveness because they are design modifications intended to enhance signal quality and workflow and fall within the range of product features for similar, FDA-cleared devices in product code GWQ (which include multiple bio-channels and gel electrodes). Specifically:

- The dry electrodes met performance specifications and measured EEG signals with good quality. FDA has cleared dry electrodes in similar devices in product

code GWQ (e.g., Cumulus Functional Neurophysiology Platform (K221963). The substantial equivalence (SE) chart includes Cumulus Functional Neurophysiology Platform as a secondary predicate.

- The reduced channel count does not affect device functionality, ERP measurement accuracy or clinical utility. Specifically, seven (7) EEG channels were sufficient for recording good EEG data and measuring ERPs as evidenced via device testing.
- The blink detection or EOG capability is within the range of its predicates' features. The NeuralScan System has 2 bio-channels for measuring electrocardiogram / electromyography (ECG/EMG) and peripheral capillary oxygen saturation (SpO2) signals during ERP measurement. Thus, other cleared devices also collect various biosignals or physiological information during ERP measurement.

Bench and clinical testing confirm the UB ERP System, with these technological differences, performs in accordance with its specifications and is as safe and effective as the predicate devices.

The differences in stimuli type and number of tasks used to measure ERPs do not raise new questions because both provide similar ERP information using well-known tasks, and bench and clinical testing confirmed performance to specifications. Both systems use software to acquire EEG data and analyze ERPs; the UB ERP System's report simply automates the manual workflow for physicians, presenting amplitude and latency data derived from raw EEG signals. It does not change the underlying data, is provided as a convenience, and does not affect device performance or introduce new risks based on clinical assessment and physician feedback.

Therefore, as none of the differences raise new questions of safety or effectiveness, the UB ERP System is substantially equivalent to the predicate device.

A table comparing the subject and predicate devices is provided at the end of this 510(k) summary.

Performance Data

The following non-clinical tests were conducted on the UB ERP System.

Test	Applicable Standard	Test Result
Electrical Safety	IEC 60601-1:2005+AMD1:2012 (ed 3.1) Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance.	Pass
Electromagnetic Compatibility (EMC) and Electro-Static Discharge (ESD)	IEC 60601-1-2:2015 Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.	Pass

Test	Applicable Standard	Test Result
Electroencephalographs	IEC 60601-2-26:2019 Medical Electrical Equipment Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs.	Pass
Software Verification Testing	IEC 62304 Edition 1.1 2015 -06 Consolidated Version Medical device software – Software life cycle processes	Pass
Transit Testing	ISTA 3A 2018 Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less.	Pass
Design Verification Testing	Testing per product specifications.	Pass

In all instances, the UB ERP System functioned as intended and results obtained were as expected.

Blink detection validation testing was conducted to demonstrate the system accurately detects and adjusts for blinks.

A clinical study was conducted to assess the measurement of brain activity using electroencephalography (EEG) and event-related potentials (ERPs) with the UB ERP System and Neurotique-2 App software. Usability data were collected from representative users of the system as part of the clinical study. EEG data were collected using the UB Cap while the participants viewed stimuli and performed tasks presented by Neurotique-2 App software. P300 (a positive deflection in the EEG signal 300 milliseconds (ms) after stimulus presentation) ERPs were measured for a range of Oddball tasks (e.g., active, passive, and novel); a Flankers task (speeded response task) and a Doors guessing task. The safety endpoints were the frequency of device and data-collection related serious adverse events and adverse events. The device effectiveness endpoint was the successful measurement of P300 in 80% of the participants. At a minimum, the P300 success criteria were defined by: (a) large and transient positive voltage deflection in the ERP at Cz that peaks 300–600 ms following stimulus presentation; (b) lower amplitude activity in the baseline period ((i.e., -200 to 0 ms) than in the post-stimulus ERP period; and (c) P300 Peak Amplitude > 5µV. Additional criteria were used for P300 measurement using variations of these tasks.

Results from the clinical study demonstrated that the UB ERP System is safe with no adverse events and able to successfully measure the P300 ERPs across three Oddball tasks utilized by the predicate device. In addition, robust P300s were obtained utilizing the Flankers and Doors tasks of the Neurotique-2 software. The study concluded that the UB ERP System is safe and effective for EEG and ERP measurements using the Oddball, Doors and Flankers tasks. The usability assessment confirmed that the user interface, labeling, and instructions for use are clear and effective.

Conclusion

The UB ERP System is substantially equivalent to the NeuralScan System predicate device, as well as the Cumulus Functional Neurophysiology Platform. The UB ERP System has the same intended uses and similar indications for use, technological characteristics, and principles of operation as its primary predicate device. The minor

technological differences between the UB ERP System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the UB ERP System is as safe and effective as the NeuralScan System. Thus, the UB ERP System is substantially equivalent to the predicate devices.

UNIVERSAL BRAIN, INC.

UB ERP SYSTEM

SUBSTANTIAL EQUIVALENCE COMPARISON TABLE

Feature	UB ERP System	NeuralScan System	Cumulus Functional Neurophysiology Platform	Comparison to NeuralScan
510(k) Number	N/A	K192753	K221963	
Product Codes	OLT, GWQ, GWJ	OLT, GWQ, GWJ	GWQ	Same
Indications for Use	The UB ERP System is intended for the acquisition, display, analysis, storage and reporting of electrical activity of a patient's brain, including electroencephalography (EEG) signals and event-related potentials (ERPs), obtained by placing two or more electrodes on the head of adults and adolescent patients to aid in diagnosis. The EEG signals are time-stamped. It is used with an UB EEG Cap loaded with appropriate software and connected to a Windows PC using a USB cable. The UB ERP system is to be used in a health care facility or a clinic under the direction of a healthcare professional. The UB ERP System does not draw any diagnostic conclusion. A clinical expert must interpret recorded EEG signals and ERPs. The results of such interpretation should be considered only in conjunction with other clinical findings.	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 Cumulus Functional Neurophysiology Platform is intended for the acquisition, display and storage of electroencephalograph (EEG) obtained by placing electrodes on the head of adults and adolescent patients. The EEG signals are time-stamped. The system can be used in the patient's home or a health care facility.	Substantially Equivalent (SE)

Feature	UB ERP System	NeuralScan System	Cumulus Functional Neurophysiology Platform	Comparison to NeuralScan
Principle of Operation	The UB ERP System is an EEG-based device used to monitor and report electrical activity in the brain by placing two or more electrodes on the head. It consists of hardware and software for measuring EEG signals and event-related potentials (ERPs) from the brain. The UB ERP System hardware consists an inner cap with electrodes, outer cap with an electronic module (amplifier and electronics), USB-C cable, dry (medium and flat) electrodes, disposable gel electrodes, ear clip with reference cable, electro-oculography (EOG) cable and photodiode cable. The UB ERP System software consists of firmware (embedded in the Cap's electronic module) and Neurotique-2 software application (or App). The App software is installed and runs from the user's Windows personal computer (PC, not provided). The UB ERP system provides a means to: - Initiate a study, monitor participant EEG signals by presenting stimuli and collect user response to these stimuli - acquire and save signals to the memory of the device, - transmit signal data from the device, - analyze signals and measure ERPs, and - generate ERP reports	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 Cumulus Functional Neurophysiology Platform is used for acquisition of physiological signals using 2 or more channels of EEG from the scalp. It consists of a mobile device with mobile app software, a patient EEG Headset, earphones, and charging cord for EEG Headset and mobile device. The technology provides a means to: - Initiate a study, track user EEG data - Acquire and save signals to memory of the device - Transmit signal data from device, - Visually inspect acquired signal	SE

Feature	UB ERP System	NeuralScan System	Cumulus Functional Neurophysiology Platform	Comparison to NeuralScan
Patient Population	Adults and adolescents	Adults and adolescents	Adults and adolescents	SE
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 facility, medical facility, athletic or sports clinics, or outside of medical facilities provided they are led by qualified medical personnel.	Intended for healthcare and medical facilities, athletic and sports clinics, or outside facilities if led by qualified medical personnel. In addition, it may be used in the home.	Same
Device Class	Class II	Class II	Class II	Same
System Components	The UB ERP System consists of: - Outer Cap with Electronics Module - Inner Cap with Electrodes - USB-C cable - Dry Electrode Kit-Medium, Flat - Disposable Electrodes - Ear Clip with Reference Cable - Electro-oculography (EOG) Cable - Photodiode Cable - EEG firmware - Neurotique-2 ERP Application (App) software	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.	Cumulus functional neurophysiology platform consists of: - Patient EEG Headset - Mobile device with mobile app software - Earphones - Web dashboard software Charging cords for EEG	SE
Interface with Amplifier	USB	USB or WiFi to PC	Bluetooth (EEG to mobile device) and WiFi (mobile device to cloud)	Same
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, with USB cable for charging the battery	Same
Rx Use or OTC	Rx Use	Rx Use	Rx Use	Same
Typical Biopotential Signals Recorded	Electroencephalography (EEG), EP/ERP	Electroencephalography (EEG), EP/ERP	Electroencephalography (EEG)	Same
Electroencephalography (EEG), EP/ERP				
ERP Stimulus Modality	Visual	Auditory; Visual	NA	SE

Feature	UB ERP System	NeuralScan System	Cumulus Functional Neurophysiology Platform	Comparison to NeuralScan
ERP Paradigm (Auditory and Visual Stimuli)	**P300 Oddball** - Single Deviant (Active - Standard and Target) - Single Deviant (Passive - Standard and Target) - 2 Deviant (Active Novel - Standard, Target and Novel) **Flankers** - Compatible and Incompatible **Doors** - Gain and Loss Outcomes	**P300 Oddball** - Single Stimulus - Single Deviant - 2 Deviant - Active and Passive	NA	SE
ERP Task Response	User Buttons	User Buttons	NA	Same
Skin Coupling	Dry electrodes	Custom Electrode Band and Gel	Dry electrodes	SE
Number of Signal Recording Channels	9 Channels (7 EEG channels + VBIAS (GND) + Reference (Earlobe))	Up to 23 channels NeuralScan system has 2 bio-channels	16 channels	SE
EEG Input Terminals	up to 7 channels	Up to 21 channels	16 channels	SE
EEG Recording Channels Location and Positioning Systems	Electrode positions shall be in the Fp1, Fp2, F3, F4, Fz, Cz, Pz, per International 10-20 system.	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	Not reported	SE
Impedance Test	Yes	Yes	Not reported	Same
Amplifier Input Impedance	> 1 GΩ	> 200 MΩ	Not reported	SE
Analog to Digital Conversion	24 Bit	24 Bit	24 Bit	Same
Sampling Rate	250 and 500 Hz	200, 500, 1000 Hz	250 and 500 Hz	SE
Common mode rejection	> 110 dB	>110 dB	> 110 dB	Same

Feature	UB ERP System	NeuralScan System	Cumulus Functional Neurophysiology Platform	Comparison to NeuralScan
Analysis Software	Embedded, commercially available, and user defined.	Embedded, commercially available, and user defined.	Embedded and user defined	Same
Resolution	24 bits	24 bits	24 bits	Same
Band Pass	0.1 to 50 Hz	0.1 to 50 Hz	0.5 to 50 Hz	Same
Noise	< 1 uV peak-to-peak	2-3 uVp-p	1.6 µV p-p	SE
Audio Type	Not Applicable (NA)	Burst (White Noise)	Not reported	NA
Input Voltage Range	± 400mV Due to the 24x gain that is applied to A/D channels, the dynamic range is ±400 mV for the UB ERP System, which is sufficient for its use environment.	±400 mV	±200 mV	SE
General Specifications				
Safety Standards Compliance	• IEC 60601-1:2005+AMD1:2012 (ed 3.1) Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance. • IEC 60601-1-2:2015 Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests. • IEC 60601-2-26:2019 Medical Electrical Equipment Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs. • IEC 62304 Edition 1.1 2015 -06 Consolidated Version Medical device software – Software life cycle processes • ISTA 3A 2018 Packaged-Products for	• 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	• DIN EN ISO 10993-1:2018: Biological Evaluation of Medical Devices, Part 1: Evaluation and testing within a risk management system. • DIN EN ISO 10993-5:2009: Biological Evaluation of Medical Devices, Part 5: In vitro cytotoxicity • ISO 10993-10:2021: Biological evaluation of medical devices - Part 10: Tests for skin sensitization • ISO 10993-12:2021: Biological evaluation of medical devices - Part 12: Sample preparation and reference materials • ISO 10993-23:2021: Biological evaluation of medical devices - Part 23: Tests for irritation • IEC 60601-1:2005+AMD1:2012 (ed 3.1) Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance.	SE

Feature	UB ERP System	NeuralScan System	Cumulus Functional Neurophysiology Platform	Comparison to NeuralScan
	Parcel Delivery System Shipment 70 kg (150 lb) or Less.		• IEC 60601-1-2:2015 Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests. • IEC 60601-1-11:2015 Medical Electrical Equipment - Part 1-11: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment. • IEC 80601-2-26:2019 Medical Electrical Equipment Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs. • ANSI C63.10 2013 American National Standard of Procedures for Compliance Testing of Unlicensed Wireless Devices • ANSI 63.4 2014 American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz • IEC 62304 Edition 1.1 2015 -06 Consolidated Version Medical device software – Software life cycle processes • ISTA 3A 2018 Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less.	

Feature	UB ERP System	NeuralScan System	Cumulus Functional Neurophysiology Platform	Comparison to NeuralScan
Operating Environment	Temperature: 5 to +40 °C; Relative humidity, 15% to 90% non- condensing	10 to +45 °C, Relative humidity, 30% to 70% non-condensing	Not reported	SE
Storage Environment	Temperature: -20 to +60 °C; Relative humidity, 10% to 95% non- condensing	-40° to 70° C, Relative humidity, 5% to 95% non-condensing	Not reported	SE