August 23, 2024

NeuroServo Inc.
Nicolas Tremblay
CEO
2065 Parthenais, Suite 416
Montreal, QC H2K3T1
Canada

Re: K240593
Trade/Device Name: VEEGix EEG System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLT, OMC, ORT, GXY
Dated: March 1, 2024
Received: March 1, 2024

Dear Nicolas Tremblay:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

FDA 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240593

Device Name

VEEGix EEG System

Indications for Use *(Describe)*

The VEEGix 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 VEEGix 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 VEEGix 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 VEEGix EEG System is indicated for use on patients 18 years of age or older and is to be used by licensed medical professionals who have been adequately trained in the use and interpretation of EEG data for determination of brain state.

The VEEGix EEG System does not provide any diagnostic conclusion about the patient's condition.

The VEEGix EEG System is not to be used as a stand-alone in the evaluation or diagnosis of a disease or other condition.

The VEEGix EEG System is not intended for use in life support systems.

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.

VEEGix™ EEG System
Traditional 510(k) Summary
K240593

510(k) Summary:

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92

Applicant Information:

NeuroServo Inc.
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Suite 416
Montréal, Québec
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Contact Information:

Nicolas Tremblay
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Date Prepared:

June 27, 2024, updated: August 22, 2024

Subject Device Information:

510(k) Number:	K240593 (Pre-Market)
Trade Name:	VEEGix EEG System
Manufacturer:	NeuroServo, Inc.
Classification Name:	Electroencephalograph, 21 CFR 882.1400
Device Class:	Class II
Product Code:	OLT – Sec. OMC, ORT, GXY

Primary Predicate Device Information:

510(k) Number:	K213299
Trade Name:	Wireless EEG System
Manufacturer:	Pascall Systems, Inc.
Classification Name:	Electroencephalograph, 21 CFR 882.1400
Device Class:	Class II
Product Code:	OLT – Sec. OMC, ORT, GXY

Secondary Predicate Device Information:

510(k) Number:	K221563
Trade Name:	Neurosteer EEG Recorder
Manufacturer:	Neurosteer Inc.
Classification Name:	Electroencephalograph, 21 CFR 882.1400
Device Class:	Class II
Product Code:	OMC, GXY

Device Description:

The VEEGix™ EEG system (subject device) is a Electrocochleographic (EEG) device to allow healthcare practitioners, nurses, neurologists and qualified technicians working in 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 to observe a patient's EEG signals and its derivatives.

The use of the subject device is a straight-forward procedure of applying the VEEGix Electrode, which is a lightweight band, onto the patient's scalp in which the electrodes acquire the patient's EEG signals. Those signals are transmitted via the VEEGix EEG module (module) to the VEEGix iOS app (application) which display the patient's EEG measurements in real-time to allow healthcare practitioners, nurses, neurologists and qualified technicians to monitor and record those EEG measurements.

Indications for Use:

The VEEGix 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 VEEGix 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 VEEGix 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 VEEGix EEG System is indicated for use on patients 18 years of age or older and is to be used by licensed medical professionals who have been adequately trained in the use and interpretation of EEG data for the determination of brain state.

The VEEGix EEG System does not provide any diagnostic conclusion about the patient's condition.

The VEEGix EEG System is not to be used as a stand-alone in the evaluation or diagnosis of a disease or other condition.

The VEEGix EEG System is not intended for use in life support systems.

Summary of substantial equivalence

The primary predicate device is Wireless EEG System, manufactured by Pascall Systems, and cleared under K213299. The secondary predicate device, Neurosteer EEG Recorder System by Neurosteer Inc., cleared under K221563 is cited for the intent for use and same number of electrodes.

The indications for use of the subject device are a subset of (narrower than and encompassed by) the primary (Wireless EEG System by Pascall Systems, Inc) predicate device's indications and falls within the same intended use as that of the secondary predicate device (Neurosteer EEG Recorder). All three devices

are intended to monitor the brain by real-time data acquisition and processing of electroencephalograph signals.

Same as for the primary predicate, the subject device is intended to be used with adult patients 18 years of age or older. Both the subject and primary predicate devices are intended to be used 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.

Neither devices provide any diagnostic conclusion about the patient's condition. However, the indication for use of VEEGix EEG System explicitly prohibits the use of device in life support systems and its stand-alone use in the evaluation or diagnosis of diseases or other conditions.

All three devices use an electrode array and sensor/amplifier to detect and communicate the electroencephalograph signals wirelessly to a display unit that provides raw EEG waveforms and a digital spectral analysis presentation to a clinical user.

All three devices use a reduced montage of disposable EEG Electrode to archive the indication for use. The primary predicate device uses 6 electrodes. The secondary predicate device uses 3 electrodes, same as the VEEGix EEG system. This difference does not affect the indication for use and do not affect safety nor effectiveness as all three devices has been successfully tested for essential performances of Electroencephalograph as per requirements defined in clause 201.4.3.101 in the IEC 80601-2-26 Standard.

The subject and the primary predicate devices both provide signal quality indications including electrode impedance alert in the case of poor electrode contact, noise (EMG) indicator and automatic artifact detection/marker.

The Processed EEG Bandwidth, common mode rejection, and amplifier input impedance of the VEEGix EEG System is substantially equivalent to the primary predicate device since the performance of the VEEGix EEG System on these technical characteristics points is better so it does not affect the safety or effectiveness of the device.

Like primary predicate device, the subject device displays a spectrogram and indicate 95% Spectral Edge Frequency (SEF) along with the quality indicators for artifact, electrode impedance, and EMG. The primary predicate device presents markers at 10 and 20 Hz on the 0 - 30 Hz scale as aids to identify the frequency components of the spectrogram while the VEEGix EEG System does not include these markers. Those markers were provided as aids by the predicate device while the VEEGix EEG System present 2 spectrograms with different time spans to help with identifying current frequency components. The difference in these data presentations does not affect safety and effectiveness as both of these devices provide an equivalent way to display frequency component.

Both the subject device and the primary predicate device display a presentation of burst suppression. The primary predicate 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. The VEEGix EEG System displays suppression ratio in % which is in accordance with the definition of the 2021 definition of the American Clinical Neurophysiology Society. These differences are not significant and do not affect safety and efficacy as both devices present a means of determining suppression percentage.

Overall, all the three devices display additional tools for the medical professional. Those additional tools are aimed to help the medical professional in their overall appreciation of patient brain state. The primary predicate device adds a phase-amplitude modulogram who is a color-intensity display that promoted to 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. The VEEGix EEG System, on its side, incorporates an amplitude-integrated EEG, which have undergone bench testing against gold standards for the purpose. The differences in additional tools do not affect the indication for use or the safety and effectiveness of the subject device.

The skin-contacting components of all the three devices underwent evaluation according to the requirements outlined in ISO 10993 standards for cytotoxicity, skin irritation, and skin sensitization.

Technology Comparison:

Attributes	Primary Predicate Pascall Systems, Inc. Wireless EEG System (K213299)	Secondary Predicate Neurosteer EEG Recorder (K221563)	Subject Device VEEGix EEG System	Comments
Classification Regulation	Class II per 882.1400	Class II per 882.1400	Class II per 882.1400	Same as primary predicate
Product Code(s)	OLT, OMC, ORT, GXY	OMC, GXY	OLT, OMC, ORT, GXY	Same as primary predicate
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.	The Neurosteer EEG Recorder is intended to record and store EEG signals, and to present the EEG signals in visual formats in real time. The visual signals assist trained medical staff to make neurological diagnoses. The EEG Recorder does not provide any diagnostic conclusion about the subject's condition and does not provide any automated alerts of an adverse clinical event. The EEG Recorder is intended to be used in a professional healthcare facility environment	The VEEGix 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 VEEGix 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 VEEGix 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 VEEGix 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 EEG data for determination of brain state. The VEEGix EEG System does not provide any diagnostic conclusion about the patient's condition. The VEEGix EEG System is not to be used as a stand-alone in the evaluation	The indications for use of the subject device are a subset of (narrower than and encompassed by) the primary predicate device's indications and falls within the same intended use as that of the secondary predicate. Thus, no new or different questions of safety or effectiveness arise for the subject device when used as labelled.

			or diagnosis of a disease or other condition. The VEEGix EEG System is not intended for use in life support systems.	
Modalities	EEG	EEG	EEG	Same
Environment of Use	Operating Room, Post Anesthesia Care Unit, Intensive Care Unit, Emergency Department, or in other medical facilities such as inpatient and outpatient (ambulatory) surgery settings	Professional healthcare facility environment settings	Operating Room, Post Anesthesia Care Unit, Intensive Care Unit, Emergency Department, or in other medical facilities such as inpatient and outpatient (ambulatory) surgery settings	Same as primary predicate and included in the environment of the secondary predicate
Number of EEG channels	4 (2 frontotemporal channels, and 2 temporal channels)	1 bipolar	1 bipolar	Same as the secondary predicate and substantially equivalent as the primary predicate
Number of electrodes	6 (4 measurement, 1 reference, 1 ground), single use	3 (Locations: Fp1, Fpz, Fp2)	3 (Locations: Fp1, Fpz, Fp2)	Same as the secondary predicate and substantially equivalent as the primary predicate
Sensing Electrodes	Silver/Silver chloride, disposable	Silver/Silver chloride, disposable	Silver, disposable	Substantially equivalent
Power Source	Battery	Battery	Battery	Same
System Components	Electrode Array (disposable patch), Sensor module, acquisition, Tablet for memory and data viewing	Electrode Array (disposable patch), Sensor module, acquisition, Tablet for data viewing, and cloud platform for data storage	Electrode Array (disposable patch), Sensor module, acquisition, Tablet for memory and data viewing	Same as primary predicate and similar as the secondary predicate
Screen Display Details	• 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 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)	• Raw EEG Waveforms • Spectrogram • Metrics and bar graph views	• Raw EEG Waveforms • Signal Quality information: Channel Connection flags, Artifact (ART), Noise Level (EMG) and Interference Level • Spectral Parameters: EEG power spectrum and SEF 95%. Power spectrum displayed as Density Spectral Array (DSA) Spectral Powers in EEG frequency bands traditionally used to quantify EEG signals (α, B, δ, θ and γ)	Substantially equivalent to the primary predicate, the missing two horizontal lines at 10 and 20 Hz in the subject device, which serve as aids to identify the frequency components of the spectrogram and division of B Band into β1 and β2, does not raise any new questions of safety or effectiveness. Secondary predicate display capabilities included in the subject device.

Storage for offline recording	Yes, in the tablet display	Cloud storage	Yes, in the tablet display	Same as primary predicate
Electrode Impedance	Yes	Unknown	Yes	Same as primary predicate
Detection for Leads Off	Yes	Yes	Yes	Same
File output capability	Yes	Yes	Yes	Same
Real time EEG Display	Yes, wireless to tablet	Yes, wireless	Yes, wireless to tablet	Same
Processed EEG Bandwidth	0.5 Hz to 45 Hz	Unknown	0.5 Hz to 80 Hz	Substantially equivalent as primary predicate
Automatic Artifact Identification	Yes	Unknown	Yes	Same as primary predicate
Common Mode Rejection	> 90 dB	Unknown	> 100 dB	Substantially equivalent as primary predicate
Amplifier Input Impedance	> 500 M Ohm	Unknown	200 GΩ	Substantially equivalent as primary predicate
Electrode Impedance Test	Yes	Unknown	Yes	Same as primary predicate
Contains Patient Isolation	Battery powered, thus no connection between patients and mains power	Battery powered, thus no connection between patients and mains power	Yes, the subject device has been designed with reinforced Insulation (2 MOPP) and this isolation has been validated by external agency testing. The subject device is battery powered and can also be used while charging.	Substantially equivalent as primary predicate
Event Markers	Yes, artifact detection	Unknown	Yes, artifact detection	Same as primary predicate
Burst Suppression Display	Yes, Burst Suppression Probability	N/A	Yes, Suppression Ratio (%)	Substantially equivalent as primary predicate
Display Interface	Tablet display indicates connection and operation	Portable display monitor	Tablet display indicates connection and operation.	Same as primary predicate
Biocompatibility	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 < 24 hours duration.	The Electrode Strip was assessed in accordance with ISO 10993-1 and was tested in its final finished form for the following endpoints: - Cytotoxicity (ISO MEM elution method per ISO 10993-5:2009); - Irritation (rabbit irritation test per ISO 10993-10:2010); - Sensitization (guinea pig maximization per ISO 10993-10:2010)	The Electrode Array patient contact materials have been tested per ISO 10993 for cytotoxicity, primary skin irritation and sensitization as required for patient contact < 24 hours duration.	Substantially equivalent

Each line from the above Technological Comparison table, the subject device has demonstrated substantially equivalent performance in comparison to the predicate device.

Performance Testing Summary

Tests were performed and verified with the VEEGix™ EEG system in accordance with performance standards for EGG devices for the environment use and the based on the subject device's indications of use and those of the predicate device. Those test methods along with the verification results are detailed in the following table.

Non-clinical performance testing

Medical devices, Electrical Safety, Electromagnetic:

Applicable standards were used:

- 13485:2016 MDSAP Medical devices - Quality Management Systems - Requirements for regulatory purposes
- ANSI AAMI ES60601-1: Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD) (Consolidated Text) (Includes ANSI/AAMI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012)
- ANSI AAMI IEC 60601-1-2:2014 - Risk Management of Medical Electrical Equipment Package
- IEC 80601-2-26:2019 Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
- IEC 62133-2 Edition1.0 2017-02
  Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells and for batteries made from them for use in portable applications - Part 2: Lithium systems
- IEC 60529 Edition 2.2 2013-08 DEGREES OF PROTECTION PROVIDED BY ENCLOSURES (IP Code)
- ANSI/AAMI/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
- AMMI TIR57:2019/(R) 2023 Principles For Medical Device Security Package

Wireless Coexistence:

Applicable standards were used:

- AAMI TIR69:2017/(R)2020 Risk management of radio-frequency wireless coexistence for medical devices and systems
- IEEE ANSI USEMCSC C63.27-2021 American National Standard for Evaluation of Wireless Coexistence
- IEC 80001-1:2021 Application Of Risk Management For IT-Networks Incorporating Medical Devices - Part 1: Safety, Effectiveness And Security In The Implementation And Use Of Connected Medical Devices Or Connected Health Software

Verifications includes that wireless connectivity between the VEEGix module and the VEEGix iOS app as to support a continuous feed of EEG signals as to maintain a stable connectivity without loss of the EEG signal for a period of a 7 days.

Shelf Life:

The electrode component has a shelf life of 2 years. This is based on the shelf life of the tape adhesive manufacturer and the conductive fabric characteristic.

Whereas the rest of the subject device, excluding the electrode component, has a shelf life of 5 years. This is based on the following:

- MTBF Analysis for components involved in essential performance and safety.
- Enclosure IP67 Rating.
- Quality and intended use of the internal battery.
- Gold contact plating for all connections in the system.

Reference: "Estimated Useful Lives of Depreciable Hospital Assets," American Hospital Association

Biocompatibility:

Applicable standards were used:

- ISO 10993-1 Fifth edition 2018-08 Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process (ISO 10993-1:2018, Including Corrected Version 2018-10)
- ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-23 First edition 2021-01 Biological Evaluation Of Medical Devices Tests For Irritation
- ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization

Based on all the information evaluated as part of this submission, it is concluded that patient risk is negligible.

Usability/ Human Factors:

Applicable standards were used:

- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION Medical devices - Part 1: Application of usability engineering to medical devices

Clinical performance testing

Bench testing:

Bench testing was performed in hospital to compare the quality and medical EEG feature similarity of electroencephalography (EEG) signals obtained by the NeuroServo (NS) device and those recorded with a conventional clinical EEG system (N1) (NicoletOne, Natus Medical Inc., Pleasanton, CA) in an ICU setting.

To investigate the equivalency of the EEG signals acquired by NS and N1 systems, we conducted a visual comparison of the signals in the time domain. A point-by-point comparison of the amplitude of the waveforms requires precise temporal alignment of the signals. The signals obtained from NS and N1 systems were initially sampled in 2048 and 512 samples per second, respectively. Therefore, we downsampled the NS signal by decimation with a factor of 4 to ensure a point-by-point comparison. The signal then was band-pass filtered at corner frequencies at 0.5 and 40 Hz, and notch filtered at 58-62 Hz. Next, we used the prominent artifacts present in the data to roughly align the signals in the time domain. For precise alignment, we segmented the data int nonoverlapping 10-second epochs and used the cross-correlation function “xcorr” in MATLAB (Mathworks, Natick, MA) to find the time lag (often less than 100 ms) with the highest correlation which then was used to realign the signals in time-domain. We used 10-second epochs as this is a common temporal range used by experts for the offline or online visualization of data. Next, we repeated the same process for all segments to compensate for the occasional sample drifts in the data which could occur due to independent sampling clocks. An exemplar snippet of time-aligned EEG signals obtained by N1 and NS systems is shown in Fig. 1A in blue and red traces, respectively. This example demonstrates a substantial overlap between the waveforms. To quantify the similarity, we computed Pearson’s correlation coefficient between the two waveforms which demonstrated a high correlation coefficient between the two waveforms (Fig. 1B; r=0.84, p<0.0001).

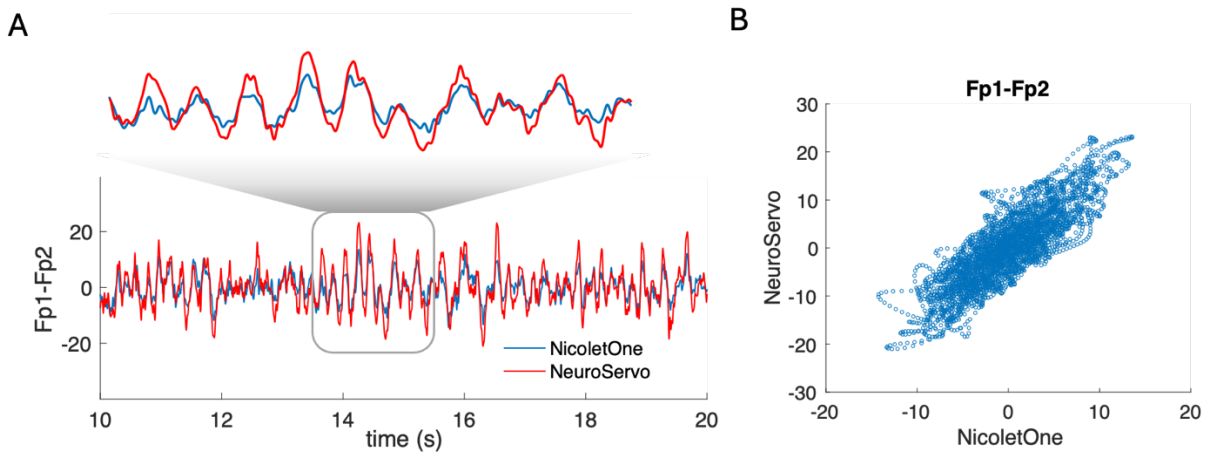

Figure 1. Visual comparison of waveforms obtained by NeuroServo (NS) and NicoletOne (N1) systems. (A) The signals were time-aligned and overlayed for visual comparison. The bottom panel demonstrates a 10-second snippet of the waveform. A 2-second segment is selected (grey box) and expanded in the panel above. (B) The Pearson’s correlation coefficient between the time-aligned signals is r=0.84 (p<0.0001)

Based on the clinical performance testing, our findings suggest that both the NS and N1 devices exhibit comparable EEG signal quality, indicating equivalence between the EEG signals recorded by the NS and N1 devices.

Conclusions:

Based on the test results provided above, and comparison to the predicate devices characteristics, the results show that the subject device is substantially equivalent to the predicate devices.

Based on the Performance Testing table, the subject device met all predetermined acceptance criteria. The conclusion from those verifications determines that its safe and effective use for the intended population and use environments.

Based on the clinical performance testing, our findings suggest that both the NS and N1 devices exhibit comparable EEG signal quality, indicating equivalence between the EEG signals recorded by the NS and N1 devices. These results are promising, as they suggest that the decision between the NS and N1 devices may depend on factors other than their core performance differences. Considerations such as cost, ease of use, and specific features could play a significant role in selecting the most suitable monitoring system for a particular clinical context. Importantly, the NS system emerges as a potentially more cost-effective and user-friendly option compared to the traditional EEG devices, which could make it preferable in certain scenarios.

The indications for use of the subject device are a subset of (narrower than and encompassed by) the primary predicate device's indications and falls within the same intended use as that of the secondary predicate. Thus, no new or different questions of safety or effectiveness arise for the subject device when used as labelled.

The minor technological differences between the subject device and its predicate devices raise no new or different questions of safety or effectiveness. Consequently, the subject device is substantially equivalent.