November 30, 2022

Neurosoft Ltd.
℅ Vicki Chester
Manager, Regulatory Affairs and Quality Assurance
CortiCare, Inc.
5950 La Place Court, Ste. 160
Carlsbad, California 92008

Re: K220254
Trade/Device Name: Neuron-Spectrum-AM with Neuron-Spectrum.NET Software
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLT, OLV, GWQ
Dated: March 4, 2022
Received: March 4, 2022

Dear Vicki Chester:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220254

Device Name
Neuron-Spectrum-AM System with Neuron-Spectrum.NET

Indications for Use *(Describe)*

The Neuron-Spectrum-AM system with Neuron-Spectrum.NET software is intended for use as a digital neurophysiological system for recording, processing, and displaying biopotential signals such as Electroencephalography (EEG) and Polysomnography (PSG) derived from Electroencephalography (EEG) by the means of a dedicated software module and dedicated electrodes.

The device is portable and can register up to 21 EEG channels, 4 polygraphic channels, 1 breath channel, and 1 direct current channel.

The device does not provide alarms, does not provide automated event marking and does not provide to the user any diagnostic conclusion about the patient's condition. They are intended for use in patient care institutions, diagnostics centers, neurosurgical hospitals, experimental laboratories, and sleep laboratories. The device can also be used as a home use device under supervision of qualified personnel. The patient group includes all ages and sexes.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements established by 21 CFR 807.92.

1. Submitter Information

Submitter:	Neurosoft Ltd.
Address:	5, Voronin str. 153032, Ivanovo Russia Federation
Contact Person:	Michael Durdin Chief Development Officer Phone: +7 (4932) 24-04-34 Fax: +7 (4932) 24-04-35
Date Prepared:	November 29, 2022

2. Subject Device

Common Name:	Neuron-Spectrum-AM with Neuron-Spectrum.NET Software
Trade Name:	Neuron-Spectrum-AM with Neuron-Spectrum.NET Software
Regulation:	21 CFR 882.1400
Classification Name:	Electroencephalograph
Product Codes:	OLT (primary), OLV (secondary), GWQ
FDA Panel:	84 - Neurology
Class:	II

3. Predicate Device

510(k) Number:	K133995
Manufacturer:	Neurosoft Ltd.
Trade Name:	Neuron-Spectrum-4/P with Neuron-Spectrum.NET
Regulation:	21 CFR 882.1400
Classification Name:	Electroencephalograph
Product Code:	OLT, OLV, GWQ
FDA Panel:	84 - Neurology
Class:	II

4. Device Description

The Neuron-Spectrum-AM with Neuron-Spectrum.NET Software (Subject device) is an ambulatory wireless digital neurophysiological device capable of recording, processing, and displaying electroencephalography (EEG), video EEG, long-term monitoring (LTM), and polysomnography (PSG) biopotential signals.

As listed in Table 1, The NS-AM device comprises an Electronic Unit, a Battery Adaptor, an External Rechargeable Battery Bank, a Carrying Pouch and the Neuron-Spectrum.NET desktop application software. The Neuron-Spectrum.NET Software application was cleared in the Predicate's 510(k) submission (K133995).

The Subject device supports up to 21 EEG channels, 4 wide-band polygraphic channels, 1 breath channel, and 1 direct current channel for a total of 27 analog input channels.

The Electronic Unit acquires, records and transmits biopotential signals such electroencephalography (EEG) and polysomnography (PSG). The built-in 2.4GHz Wi-Fi radio allows real-time transfer of the collected biopotential signals to the computer running the Neuron-Spectrum.NET software. The biopotential signals are also recorded onto a removable SD memory card as back up for later post analysis.

The Electronic Unit includes a front panel ON/OFF power button, a light sensor and a User Interface (UI). The UI consist of a liquid crystal display and three menu navigation buttons. Figure 4 shows the UI main functions. The Electronic Unit can be powered by replaceable internal AA batteries or by the External Rechargeable Battery Bank.

The Electronic Unit and the External Rechargeable Battery Bank reside side-by-side inside the Carrying Pouch. The pouch is strapped and worn over the patient clothing while in use.

The Neuron-Spectrum.NET software is a computer application that receives, records, processes, and displays the biopotential signals collected by the electronic unit on the PC display. The main operations provided by the Neuron-Spectrum.NET software are:

- EEG Acquisition
- EEG Review, Editing, Storing, Exporting.
- EEG Analysis
- Creation of Exam Reports
- Program Setup

The electronic unit measures (141 H x 96 W x 36 D) mm and weighs about 270 grams. The External Rechargeable Battery Bank unit measures (165 H x 106 W x 25 D) mm and weighs about 570 grams. The combined weight for the electronic unit, the battery adaptor and the External Rechargeable Battery Bank is approximately 880 grams.

Table 1: Neuron-Spectrum-AM with Neuron-Spectrum.NET Software Components

#	Description	Note
1	Electronic Unit (2.4GHz Wi-Fi Radio / 32MB SD Mem Card)	Main Data Collection Device
2	Battery Adaptor (Electromechanical Interface to External Battery)	Component
3	External Rechargeable Battery Bank (w/ Power Supply Adaptor)	Component
4	Neuron-Spectrum.NET Software Application	Application

5. Intended Use/Indications for Use

5.1. Neuron-Spectrum-AM system Intended Use

The Neuron-Spectrum-AM system with Neuron-Spectrum.NET software is intended for use as a digital neurophysiological system intended for recording, processing, and displaying biopotential signals such as Electroencephalography (EEG). Polysomnography (PSG) derives from Electroencephalography (EEG) by the means of a dedicated software module and dedicated electrodes.

The device is portable and can register up to 21 EEG channels, 4 polygraphic channels, 1 breath channel, and 1 direct current channel.

The device does not provide alarms, does not provide automated event marking and does not provide to the user any diagnostic conclusion about the patient's condition. They are intended for use in the patient care institutions, diagnostics centers, neurosurgical hospitals, experimental laboratories, and sleep laboratories. The device can also be used as a home use device under supervision of qualified personnel. The patient group includes all ages and sexes.

5.2. Explanation of Differences

The Intended Use of the Neuron-Spectrum-AM system is nearly identical to that of the Predicate device. The (3) key differences between the Intended Use of the Neuron-Spectrum-AM system and the Intended Use of the Predicate device are:

a. The Neuron-Spectrum-AM Electronic Unit is portable and communicates with the PC running the Neuron-Spectrum.NET software via a wireless link versus a USB link in the Predicate device;

b. The Neuron-Spectrum-AM system can also be used in a Home Healthcare environment under supervision of qualified personnel; and

c. There are minor differences in the number of channels that can be monitored.

The use of wireless communications versus USB has the same operation and functionality as the Predicate device between the Electronic Unit and the computer running the NS.NET software. Technology for wireless communications and Cybersecurity are implemented in the Neuron-Spectrum-AM system to ensure correctness and security of the wireless data transmission.

The use of the Neuron-Spectrum-AM system in a Home Healthcare environment is under the supervision of qualified healthcare monitoring personnel, the same as in patient care institutions, diagnostics centers, neurosurgical hospitals, experimental laboratories, and sleep laboratories for the Neuron-Spectrum-AM system and the Predicate device. The Neuron-Spectrum-AM system conforms with International Standard IEC 60601-1-11 for medical electrical systems used in the home healthcare environment.

The minor differences in the number of channels that can be monitored are not critical to the intended diagnostic use of the device. Moreover, this number of channels allows recording the high-quality EEG that complies with the American Clinical Neurophysiology Society Guidelines (https://journals.lww.com/clinicalneurophys/Fulltext/2016/08000/American_Clinical_Neurophysiology_Society.3.aspx).

Overall, these differences are not critical to the intended diagnostic use of the device, and do not affect the safety and effectiveness of the device when used as labeled.

6. Comparison of Technological Characteristics to Predicate

Table 2 provides a comparison of the technological characteristics between the Subject device and the Predicate device.

Subject Device: Neuron-Spectrum-AM with Neuron-Spectrum.NET Software

Predicate Device: Neuron-Spectrum- 4/P with Neuron- Spectrum.NET Software (K133995)

Table 2: Comparison of Technological Characteristics

Characteristic	Subject Device	Predicate Device	Same / Different
Biopotential Signals Recorded	• Electroencephalography (EEG) • Electrocardiography (ECG) • Electrooculography (EOG) • Video EEG, PSG • Respiration	• Electroencephalography (EEG) • Electrocardiography (ECG) • Electrooculography (EOG) • Video EEG, PSG • Respiration • Evoked potential (EP)	Similar
Number of Signal Recording Channels	• Up to 21 EEG channels • 1 Breath channel • 1 Direct current channel	• Up to 21 EEG channels • 1 Breath channel • 2 Direct current channels	Same
Analog Input Channels (per unit)	• 27	• 28	Different
Sampling rate	• 100, 200, 500, 1000, 2000, 5000 Hz	• 100, 200, 500, 1000, 2000, 5000 Hz	Same
Electronic Unit Power Source	• Battery Power	• Computer USB Port Power	Different
Application Software	• Neuron-Spectrum.NET Software	• Neuron-Spectrum.NET Software	Same
Video Camera Support	• Available	• Available	Same
Alarms	• None	• None	Same
Digital Resolution	• 32/64 bits	• 32/64 bits	Same
Input noise EEG (rms value)	• Within 0.5-200 Hz not more than 2 μV (not more than 0.3 μV)	• Within 0.5-200 Hz not more than 2 μV (not more than 0.3 μV)	Same
Input impedance EEG	• Not less than 400 MΩ	• Not less than 400 MΩ	Same

Characteristic	Subject Device	Predicate Device	Same / Different
Low Pass Filter	• -12dB/octave • 5–200 Hz (step 0.1 Hz)	• 5–200 Hz (step 0.1 Hz)	Same
High Pass Filter	• -12dB/octave • 0.05–10 Hz (step 0.01 Hz)	• 0.05–10 Hz (step 0.01 Hz)	Same
Connection to Patient	• By means of EEG, ECG, EOG, PSG electrodes and sensors (respiratory sensors, snoring sensor, body position sensor-cup electrodes)	• By means of EEG, ECG, EOG, PSG electrodes and sensors (respiratory sensors, snoring sensor, body position sensor-cup electrodes)	Same
Acquired and displayed events:			
- EEG	• Yes	• Yes	Same
- ECG	• Yes	• Yes	Same
- EOG	• Yes	• Yes	Same
- EP	• No	• Yes	Different
- Body Position	• Yes	• Yes	Same
- Chest Movements	• Yes	• Yes	Same
- CPAP	• Yes	• Yes	Same
- Air Flow	• Yes	• Yes	Same
- Nasal Flow Pressure	• Yes	• Yes	Same
- Abdominal Movements	• Yes	• Yes	Same
- Snoring	• Yes	• Yes	Same
Safety Standard Compliance	• IEC 60601-1 • IEC 60601-1-1 • IEC 60601-1-2 • IEC 60601-1-6 • IEC 60601-2-26 • IEC 60601-2-40 • IEC 62304 • IEC 60601-1-11	• IEC 60601-1 • IEC 60601-1-1 • IEC 60601-1-2 • IEC 60601-1-6 • IEC 60601-2-26 • IEC 62304	Same

Characteristic	Subject Device	Predicate Device	Same / Different
Trigger input (synchronization to external events)	• Yes	• Yes	Same
Trigger output (synchronization for external devices)	• Yes	• Yes	Same
Electronic Unit communications to - Computer Interface	• Wireless communication using a 2.4GHz Wi-Fi Radio	• Wired communication using a USB Cable	Different
Size (H/W/D) mm	• Electronic Unit: 141H x 96W x 36D • External Rechargeable Battery Bank: 165H x 106W x 25D	• Electronic Unit: 140x200x45 mm	Similar
Weight (g)	• Electronic Unit: 270g • Electronic Unit plus the Battery Adaptor plus the External Rechargeable Battery Bank: 880 g	• Electronic Unit: Not more than 900g (Floor Stand not included)	Similar
CMRR	• Not less than 100 dB	• Not less than 100 dB	Same
Noise	• <=1 μVrms	• <=1 μVrms	Same
Notch Filter	• 50/60 Hz Selectable	• 50/60 Hz Selectable	Same
A/D Conversion	• 16 Bit ADC	• 16 Bit ADC	Same
Sampling Rate	• 100 - 5000 Hz	• 100 - 5000 Hz	Same
Analysis Time	• 1s - 30s	• 1s - 30s	Same
Signal Delay (pre/post)	• 0 - 10	• 0 - 10	Same
Video Recording	• Yes	• Yes	Same
Bandwidth	• in range from 0.5 up to 60 Hz from -10 up to +5%	• in range from 0.5 up to 60 Hz from -10 up to +5%	Same
Input signal Range	1-12000 μV	1-12000 μV	Same
Max sampling rate	• 5000 Hz	• 5000 Hz	Same
Max storage rate	• 5000 Hz	• 5000 Hz	Same

Characteristic	Subject Device	Predicate Device	Same / Different
Notch Filter	• Not less than 40 dB	• Not less than 40 dB	Same
DC Inputs	• Yes	• Yes	Same
EOG	• Yes	• Yes	Same
EOG Channels	• Yes	• Yes	Same
Pressure transducer	• Yes	• Yes	Same
Effort (chest/abdominal)	• Yes	• Yes	Same
Snore	• Yes	• Yes	Same
Flow (Thermal)	• Yes	• Yes	Same
Pulse Oximetry	• Yes	• Yes	Same
Electronic Unit User Interface	• Yes • Front panel LCD, • Navigation Keys	• No • Requires connection to a computer	Different
Data Storage	• Removable SD memory card and/or computer HDD	• Computer HDD only	Different

7. Summary of Technological Differences

7.1. Home Use

The Subject device can be used in professional healthcare facilities as well as in a home healthcare environment. However, the setup and startup of the device in home healthcare environment will be performed and monitored by trained personnel.

7.2. Electronic Unit Power Source

The Subject is a battery-powered device. The device is powered using the included External Rechargeable Battery Bank which is charged using an external power supply independent of the instrument and outside of the patient environment. External Rechargeable Battery Bank power gives the Subject device ambulatory capabilities. The Predicate device requires to be tethered to a computer USB port for power and data transfer. This difference does not affect the safety and effectiveness of the Subject device when compared to the Predicate device.

7.3. Electronic Unit Communications to Computer Interface

The Subject device uses a radio link utilizing a 2.4GHz Wi-Fi Radio Module for communications between the Electronic Unit and a computer running the NS.NET software, as compared to the Predicate which uses a USB cable link.

7.4. Electronic Unit User Interface

The Subject device Electronic Unit includes a monochrome liquid crystal display and three navigation buttons that allows the instrument to be setup to operate without being connected to a PC. The Predicate device requires a cable connection to a PC for power and setup.

7.5. Data Storage

The Subject device instrument includes industry standard Secure Digital (SD) non-volatile memory technology which allows the device to collect data directly to a removable SD memory card. When used in conjunction with a PC in the Wi-Fi network, the Subject device can simultaneously record and send biopotential data to the removable SD memory card and to the computer connected to the Wi-Fi network.

7.6. EP Recording

The Neuron-Spectrum-AM does not support the recording of EP as this technique is not obligatory to fulfill in accordance with ACNS recommendations on EEG studies.

8. Performance Data Summary

8.1. Summary of Non-Clinical Testing Performed

A program of non-clinical design verification and validation testing, and evaluation was conducted that included:

- Biocompatibility Evaluation
- Safety, Performance and Bench Testing including EMC
- Software Verification and Validation Testing

8.2. Clinical Testing

The substantial equivalence for the Subject device will not be demonstrated by results of clinical testing. Therefore, no clinical testing was performed.

8.3. Conclusions from Biocompatibility Evaluation

A biocompatibility conclusions summary for the all patient-contacting materials of the Subject Device is presented in Table 3.

Table 3: Subject Device Materials Biocompatibility Evaluation

Item	Material (Type)	Where Used	Biocompatibility
Housing (Electronic Unit)	ABS/PVC	• Resides inside Carrying Pouch • No direct or indirect tissue contact	Biocompatible
Housing (Ext. Rechargeable Battery Bank)	PVC	• Resides inside Carrying Pouch • No direct or indirect tissue contact	Biocompatible
Carrying Pouch	Synthetic Leather Fabric	• Worn Over patient clothing • No direct or indirect tissue contact • Occasional Transient contact with hands and arms	Biocompatible

8.4. Conclusions from Safety, Performance and Bench Testing

The safety and performance testing results for Electrical Safety, EMC, Wireless Coexistence, RFID Immunity and bench testing concluded that the Subject device meets and complies with the safety and performance of the applicable standards and bench testing requirements.

8.5. Conclusions from Software Verification and Validation

The software verification and validation results concluded that the Subject device meets and complies with the applicable software requirements specifications.

9. Overall Conclusion

The documentation and test results provided in this submission and comparison of intended use, principle of operation, performance data, design and the overall technological characteristics, demonstrate that the Neuron-Spectrum-AM with Neuron-Spectrum.NET Software device is as safe, as effective, and performs as well as or better than the Neuron-Spectrum-4/P with Neuron-Spectrum.NET Predicate device.