August 5, 2021

NeuroWave Systems Inc.
Tatjana Zikov
President
2490 Lee Blvd, Ste 300
Cleveland Heights, Ohio 44118

Re: K202621
Trade/Device Name: NeuroSENSE Monitoring System, Model NS-901
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLW, OMC, ORT, OLT, GXY
Dated: July 8, 2021
Received: July 9, 2021

Dear Tatjana Zikov:

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,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered
Breathing, Respiratory and
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OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K202621

Device Name
NeuroSENSE Monitoring System, Model NS-901

Indications for Use *(Describe)*
The NeuroSENSE Monitoring System, Model NS-901, is intended for monitoring the brain state of adult and pediatric patients (18 years of age and older) in the operating room and other clinical settings by acquiring electroencephalographic (EEG) signals.

The WAVcns Index, a quantifier of EEG activity calculated and displayed by the NeuroSENSE NS-901 Monitor, may be used as an aid in monitoring the hypnotic effect of anesthetics. The anesthetics include inhaled anesthetics and propofol in combination with opioids.

The NeuroSENSE Monitor is intended to be used under the direction and interpretation of a qualified medical professional.

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.**

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NeuroWave
HARNESSING THE POWER OF EEG

# 5. 510(K) SUMMARY

**Company Name:** NeuroWave Systems Inc.
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**Contact:** Tatjana Zikov,
President

**Phone:** (216) 472-6337
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**Date:** August 4, 2021

## 5.1 Device Name

| | |
|---|---|
| Trade Name: | NeuroSENSE Monitoring System, Model NS-901 |
| Common/Usual Name: | EEG Monitor |
| Classification Name: | Electroencephalograph |
| Regulation Number: | 21 CFR 882.1400 |
| Product Code: | OLW |
| Subsequent Product Codes: | OMC, OLT, ORT, GXY |
| Device Class: | Class II |

## 5.2 Predicate Device

| | |
|---|---|
| 510(k) Number: | K072286 |
| Manufacturer: | Aspect Medical Systems Inc. |
| Trade Name: | BIS EEG VISTA MONITOR SYSTEM |

## 5.3 Description of Device

The NeuroSENSE Monitoring System, Model NS-901, is a 2-channel bilateral processed Electroencephalograph (EEG) monitor for brain function monitoring in the operating room and other clinical settings. The acquired EEG waveforms and processed EEG variables are continuously displayed by the system for interpretation by a qualified medical professional and for use as a supplement to the anesthesia standard of care. The user interacts with the system via a touch screen interface.

The NS-901 System consists of the following main components:

- Display Module (DM-901) – processes acquired EEG signals, displays EEG waveforms and processed EEG variables, and archives them for later review
- EEG Module (EM-901) –

1) acquires analog EEG signals through the integrated Patient Cable connected to electrodes on a patient's forehead,
2) converts acquired analog EEG signals into digital EEG signals, and
3) sends the digital EEG signals to the Display Module through the integrated Data Cable

- EasyPrep Sensor Kit (EK-901) – Noninvasive, disposable, single-use patient electrodes for acquiring the EEG signal

The NeuroSENSE Monitoring System displays EEG waveforms and the following EEG processed variables and plots for each EEG channel:

- Wavelet-based Anesthetic Value for Central Nervous System ($WAV_{CNS}$)
- Electromyogram (EMG)
- Suppression Ratio (SR)
- Spectral parameters: Density Spectral Array (DSA), Median Edge Frequency (MEF), Spectral Edge Frequency (SEF), and spectral powers in different EEG frequency bands

For improved reliability, the NeuroSENSE employs circuitry and algorithms for automatic detection, removal and/or filtering of physiological and environmental artifacts that commonly contaminate EEG signals. The NS-901 System also performs self-tests, automatic calibration of the amplifiers and continuous check of the electrode-skin contacts to ensure proper operation and optimal signal quality. Signal quality indicators (electrode status, 50/60 Hz noise level, artifact status) as well as system alarms, notifications and other related messages are displayed by the system. The system also provides protection for the operator and patient during cardiac defibrillation.

## 5.4 Performance Characteristics of the Device

The device specifications are shown in the table below:

| Characteristic | Specification |
|---|---|
| ***NeuroSENSE System (NS-901)*** | |
| Safety/EMC | IEC 60601-1 & IEC 60601-2-26 / IEC 60601-1-2 |
| Operating Conditions<br>Temperature<br>Humidity<br>Pressure | <br>10°C to 40°C;<br>30 to 75% RH;<br>70 to 106 kPa |
| Storage Conditions<br>Temperature<br>Without batteries installed<br>With batteries installed<br>Humidity<br>Pressure | <br><br>-10°C to 60°C;<br>0°C to 40°C;<br>15 to 95% RH (non-condensing);<br>50 to 106 kPa |
| Display of EEG Waveforms | Continuous display of 2 frontal, bilateral EEG channels;<br>Time Scale: 1, 2, 4 or 8 s per division;<br>Vertical Scale; 5, 25, 50, 100, or 250 µV per division;<br>Notch Filter @ 50/60 Hz: On/Off |

| | |
|---|---|
| Display Range [Resolution] for Processed EEG and Other Parameters | |
| $WAV_{CNS}$ | 0 to 100 [1]; |
| EMG | 20 to 80 dB [<1 dB]; |
| SR | 0 to 100% [1%]; |
| Artifact Presence | 0 to 100% [1%]; |
| Electrode Impedance | 0 to 30 KΩ [0.1 KΩ]; |
| SEF/MEF | 0 to 30 Hz [1 Hz]; |
| DSA | Blue to red (20 to 60 dB), with respect to 0.0001 $\mu V^2$ [<1 dB]; |
| Spectral Powers | |
| Delta band (1-3 Hz) | 20 to 60 dB, with respect to 0.0001 $\mu V^2$ [0.1 dB]; |
| Theta band (4-7 Hz) | 20 to 60 dB, with respect to 0.0001 $\mu V^2$ [0.1 dB]; |
| Alpha band (8-12 Hz) | 20 to 60 dB, with respect to 0.0001 $\mu V^2$ [0.1 dB]; |
| First Beta band (13-19 Hz) | 20 to 60 dB, with respect to 0.0001 $\mu V^2$ [0.1 dB]; |
| Second Beta band (20-29 Hz) | 20 to 60 dB, with respect to 0.0001 $\mu V^2$ [0.1 dB]; |
| Gamma band (30-48 Hz) | 20 to 60 dB, with respect to 0.0001 $\mu V^2$ [0.1 dB] |
| ***Display Module (DM-901)*** | |
| Type | 10.4" True Color High Contrast LCD with Touch Screen |
| Luminance | 500 Max cd/m2 |
| Viewing Angle | 176°(H) / 176°(V) |
| IP Rating | IPX3;<br>IPX4 - All surfaces except for the bottom surface |
| Weight | 7.5 lb (3.4 kg) - Without batteries installed;<br>8.0 lb (3.6 kg) - With 1 Smart Pack battery (SP-901) installed<br>8.4 lb (3.8 kg) - With 2 Smart Pack batteries (SP-901) installed |
| Dimensions | 11.5" x 9.75" x 3.0" |
| Mounting | VESA 75 |
| Attachments | C clamp (provided) for attachment to I.V. poles or similar |
| Noise | 40 dB (A) |
| Input Power Rating | 100-240 V/50-60 Hz, 2A/1A |
| Power Consumption | 26 VA |
| Earth Leakage Current | <5 mA |
| Power Supply MTBF | > 3,000,000 hrs operation at 40°C ambient |
| Touch Screen Lifetime | 10 million activations |
| LCD Back Light MTBF | 50,000 hrs |
| Audio Alarms | IEC 60601-1-8 compliant |
| Storage Capacity | 256 GB |
| Mechanical Strength | Compliant with IEC 60601-1 requirements for portable equipment |
| Protection against electric shock | Type: Class I equipment;<br>Degree: Not classified |
| Mode of Operation | Continuous |
| ***EEG Module (EM-901)*** | |
| Inputs (Sensor Type) | External; pre-gelled snap electrodes |
| Input Channels | 2 analog referential (4 leads) |
| Input Range | ± 375 mV |
| High Pass Filter | 0.125 Hz |
| Low Pass Filter | 200 Hz |
| Noise | <2 $\mu$Vpp (0.125 - 100 Hz) |

| | |
|---|---|
| A/D Resolution | 24 bits |
| Sampling Rates | 896 samples/sec and per channel |
| DC Offset Rejection | 300 mV (max) |
| In-band Input Impedance | >100 MΩ @ 10 Hz |
| Common Mode Rejection | > 110 (90) dB @ 60 Hz in isolation (direct) mode |
| Cross Talk | <-60 dB @ 10 Hz |
| Patient Isolation | 5000 VDC |
| Patient Auxiliary Current | <10 $\mu$A DC / <100 $\mu$A AC |
| Patient Leakage Current | <10 $\mu$A |
| Impedance Check | On-demand & Continuous @ 165 Hz |
| Protection Circuitry | For the operator and patient during cardiac defibrillation;<br>Circuitry for detection and minimization of electro-surgical unit interference |
| Weight | 10 oz (300 g) including cables |
| Size | 4.75" x 2.9" x 0.75" |
| IP rating | IPX4 |
| Attachments | Garment clip |
| Mechanical Strength | Compliant with IEC 60601-1 requirements for portable equipment |
| Protection against electric shock | Type: Class II equipment;<br>Degree: Type BF |
| Mode of Operation | Continuous |
| ***Smart Pack Rechargeable Battery (SP-901)*** | |
| Safety | IEC 62133 and UN 38.3 |
| | Up to 2 (4) hr with 1 (2) Smart Packs SP-901 installed |
| Capacity (Standard Charge/Discharge) | 6.0 Ah (44.4 Wh) |
| Nominal Voltage (Average for Standard Charge) | 7.4 V |
| Standard Charge<br>Constant Current<br>Constant Voltage<br>End Condition (Cut Off) | <br>3000 mA;<br>8.4 V;<br>100 mA |
| Fast Charge | 3800 ± 200 mA |
| Maximum Charge Voltage | 8.4 ± 0.5 V |
| Maximum Charge Current | 3800 ± 200 mA |
| Standard Discharge<br>Constant Current<br>End Voltage (Cut Off) | <br>4500 mA;<br>5.2 V |
| Fast Discharge | 5000 ± 250 mA |
| Maximum Discharge Current | 5000 ± 250 mA |
| Weight | 7.4 oz (210 g) |
| Operating Temperature<br>Charge<br>Discharge | <br>10°C to 45°C;<br>0°C to 65°C |
| Storage Temperature | 0°C to 40°C |

## 5.5 Intended Use / Indications for Use

The proposed intended use / indications for use of NeuroSENSE NS-901 Monitor are as follows:

> "The NeuroSENSE Monitoring System, Model NS-901, is intended for monitoring the brain state of adult and pediatric patients (18 years of age and older) in the operating room and other clinical settings by acquiring electroencephalographic (EEG) signals.
>
> The $WAV_{CNS}$ index, a quantifier of EEG activity calculated and displayed by the NeuroSENSE NS-901 Monitor, may be used as an aid in monitoring the hypnotic effect of anesthetics. The anesthetics include inhaled anesthetics and propofol in combination with opioids. The NeuroSENSE Monitor is intended to be used under the direction and interpretation of a qualified medical professional."

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

## 5.6 Technological Characteristics

### *5.6.1 Theory of Operation*

The NeuroSENSE Monitoring System, Model NS-901, is a reduced-montage electroencephalographic (EEG) device. Electroencephalographs are used by medical professionals to view and record the electrical activity of the brain to obtain insight into the patient's brain state or function.

The brain is the end-target organ of anesthetic drugs. Most general anesthetics produce dose-dependent suppression of neuronal activity within the Central Nervous System (CNS), and consequently alter EEG activity in a dose-dependent manner. The NeuroSENSE System continuously calculates a proprietary processed EEG variable, referred to as $WAV_{CNS}$ (Wavelet-based Anesthetic Value for CNS), which relates to the hypnotic effect of anesthetic drugs on the patient's brain. The $WAV_{CNS}$ quantifies the level of patient's brain activity using wavelet analysis of the gamma frequency band of the normalized EEG signal and has been shown to correlate with changes in anesthetic drug dosing in adult patients.

The NeuroSENSE System continuously displays for each brain hemisphere the acquired EEG waveforms and related processed EEG variables including the $WAV_{CNS}$, for interpretation by a clinician and for use as a supplement to the anesthesia standard of care.

### *5.6.2 Summary of Technological Characteristics of Subject Device Compared to Predicate Device*

The subject device, NeuroSENSE Monitoring System, Model NS-901 and the predicate device, BIS VISTA Monitor System (K072286), have the following key similarities:

a) Both systems are reduced-montage EEG monitors.
b) Both systems display real-time EEG waveforms and processed EEG parameters on a touch-screen monitor, which also provides a graphical user interface.

c) Both systems include a separate analog-to-digital converter module that acquires EEG signals and contains patient electrical isolation.

d) Both systems use single-patient use EEG electrodes placed on the patient's forehead to acquire fronto-frontotemporal EEG signals.

e) Both systems calculate and display an EEG-based proprietary index with a scale of 0 to 100 for use as an aid in monitoring the hypnotic effect of anesthetics on the brain of adult patients. An appropriate range for general anesthesia for both indexes is 40-60.

f) Both systems are capable of bilateral brain monitoring: bilateral EEG signals are acquired and displayed for each brain hemisphere, and further used for calculation and display of bilateral proprietary indexes, one per brain hemisphere.

The NeuroSENSE is different from the predicate device in the following ways:

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

b) There are some differences in weight, dimensions, battery backup life and environmental requirements between the two systems with no impact on safety or effectiveness since all the requirements for the subject device are adequate for its intended use.

c) The duration of the processed EEG epoch is 1 second for the NeuroSENSE, while the predicate device uses a 2-second epoch. This difference does not impact safety or effectiveness since the calculations of EEG parameters and their display by the NeuroSENSE are being updated as often as that of the predicate.

d) There is a difference in signal processing technology used by the subject device when compared to the predicate device (wavelets vs. bispectral analysis), which may lead to differences in the proprietary indexes of the two devices. Clinical and other data provided in this submission support substantial equivalence of the subject device's index for its intended use.

## 5.7 Nonclinical Performance Data

The following is a list of the non-clinical testing that was completed.

- Electrical, Mechanical and Environmental Safety Testing per IEC 60601-1
- Electrical Safety and Essential Performance Testing per IEC 80601-2-26
- EMC Testing per IEC 60601-1-2
- Alarm Evaluation per IEC 60601-1-8
- Usability Evaluation per IEC 60601-1-6 and IEC 62366-1:2015
- Software Verification and Validation per FDA Software Guidance
- Risk Assessment per ISO 14971
- Battery Safety Testing per IEC 62133
- In-house bench testing for performance evaluation included: amplifier noise level, common mode rejection, DC offset, input impedance, frequency response, linearity, and crosstalk; electrode impedance measurement accuracy; lead disconnection; electro-surgical unit (ESU) detection; capacitive coupling; patient electrical isolation, and water ingress protection.

The results demonstrate that all requirements and performance specifications were met and that the subject device, like the predicate device, complies with the requirements for electro-encephalographic medical devices and is as safe and effective for brain function monitoring in clinical settings, thus supporting a substantial equivalence determination between the subject device and the predicate.

## 5.8 Clinical Performance Data

Validation of the subject device was performed in a prospective clinical study in 75 adult surgical patients (age: 18-71 years, male/female: 18/57. ASA: I-III). The proprietary $WAV_{CNS}$ index was assessed against clinical observations and was shown to discriminate effectively between clinical endpoints such as loss of consciousness during propofol induction and return of consciousness during emergence from inhalational anesthesia. Both the $WAV_{CNS}$ and SR were shown to correlate with changes in inhalational anesthetic dosing. Also, the $WAV_{CNS}$ range of 40 to 60 was found to be appropriate for general anesthesia. The clinical data was collected in the operating room and no adverse effects or complications were observed. Clinical data used for the analysis included EEG signals, $WAV_{CNS}$ index, SR, drug dosing information and clinical observations. The data from this trial was further re-processed to compare the SR parameter calculated by the subject device with that calculated by the predicate. The results showed an excellent agreement between the two SR measures in this patient population.

Clinical testing demonstrates that the subject device can be used as safely and as effectively as the predicate device to monitor the hypnotic effect of anesthetic drugs. The data thus support a substantial equivalence determination between the subject device and the predicate for use as an aid in monitoring the hypnotic effect of anesthetics.

## 5.9 Conclusion

Although there are some differences between the subject device and the predicate, the nonclinical and clinical performance data provided in this 510(k) submission demonstrate that the subject device is as safe and as effective in monitoring brain function and the hypnotic effect of anesthetics in clinical settings. The subject device is therefore substantially equivalent to its predicate.