October 6, 2017

EMS Handels Gesellschaft m.b.H.
% Ms. Yolanda Smith
Consultant
Smith Associates
1468 Harwell Avenue
Crofton, Maryland 21114

Re: K171397
Trade/Device Name: Sienna Ultimate Wireless Amplifier
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological Signal Amplifier
Regulatory Class: Class II
Product Code: GWL, GWQ
Dated: September 6, 2017
Received: September 8, 2017

Dear Ms. Yolanda Smith:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

William J. Heetderks -S
2017.10.06 17:00:34 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K171397

Device Name
Sienna Ultimate EEG Amplifier

Indications for Use *(Describe)*
The Sienna Ultimate EEG amplifier is intended to be used as a front end amplifier to acquire, store and transmit electrophysiological signals in a wired or wireless mode for the EMS Neurodiagnostic system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary

**SPONSOR**


Company Name: EMS Handels Gesellschaft m.b.H.

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Korneuburg
Austria A-2100

Telephone: +43 2262 61655-0
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Contact Person: Ruzena Ortnerova


Summary Preparation Date: April 10, 2017

**DEVICE NAME**

Trade Name: Sienna Ultimate
Common/Usual Name: EEG Amplifier
Classification Name: Amplifier, Physiological Signal
Regulation Number**:** 21 CFR 882.1400
Product Code: GWL, GWQ
Device Class: Class II

**PREDICATE DEVICE**

Legally Marketed Equivalent Device

| ***Company*** | ***Product*** | ***510(k) #*** |
|---|---|---|
| Carefusion 209, In. | Nicolet Wireless EEG Amplifier | K103140 |

**DEVICE DESCRIPTION**

The Sienna Ultimate is a small portable device which is capable of acquiring a variety of electrophysiological signals at variable sampling frequencies and can be used in a wide variety of EEG applications.

The proposed device consists of two models designated as the 32 channel and the 64 channel amplifier in a wireless or wired mode, passive headboxes, medical grade power supply, WLAN access point (for wireless models) or medical grade isolated LAN cable (for wired models), Sienna EEG software. The following accessories can be connected to the passive headboxes: EEG electrodes, EEG headcaps and pulse oximeter sensors. The accessories are not supplied by EMS. EMS recommends the use of FDA cleared EEG electrodes and EEG headcaps from local US suppliers. For use as a pulse oximeter

sensor, the FDA cleared reusable and disposable sensors (K092101, Nonin USA) from the 8000 and 7000 series are recommended.

In wireless models: WLAN access points collect the wireless data transmissions. The amplifiers are IP addressable and can be connected directly to a network device. In all situations the amplifiers store a copy of the data locally to allow for data backup. The amplifiers provide storage and subsequent transmission of data that is not transferred live when the amplifier is in out of range situations.

In wired models: Amplifiers can be connected via medical grade isolated LAN cable to the network. The amplifiers are IP addressable. The amplifiers store a copy of the data locally to allow for data backup. The amplifiers provide storage and subsequent transmission of data that is not transferred live when the amplifier is disconnected from the LAN interface.

The use of 2 pcs. of 64 channel amplifier models (wireless or wired mode) enables EEG acquisition of up to 128 channels.

**DEVICE INDICATIONS FOR USE**

The Sienna Ultimate EEG amplifier is intended to be used as a front end amplifier to acquire, store and transmit electrophysiological signals in a wired or wireless mode for the EMS Neurodiagnostic system.

**COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)**

| Parameters | Subject Device<br>EMS Biomedical<br>Sienna ULTIMATE | Predicate Device<br>CareFusion 209<br>Nicolet Wireless EEG Amplifier | Similarities and Difference |
|---|---|---|---|
| 510(k) Number | | K103140 | |
| Product Code | GWL, GWQ | GWL, GWQ | Same |
| Regulation No. | 21 CFR 882.1400 | 21 CFR 882.1400 | Same |
| Regulation Name | Amplifier, Physiological | Amplifier, Physiological | Same |
| Indications for Use Statement | The Sienna Ultimate Wireless EEG amplifier is intended to be used as a front end amplifier to acquire, store and transmit electrophysiological signals in a wired or wireless mode for the EMS Neurodiagnostic system. | The Nicolet Wireless EEG Amplifier is intended to be used as a front end amplifier to acquire, store, and transmit electrophysiological signals in a wired or wireless mode for the Nicolet Neurodiagnostic system. | Same |

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|---|---|---|---|
| Description of Device | The Sienna Ultimate EEG Wireless Amplifier is a small portable device which is capable of acquiring a variety of electrophysiological signals at variable sampling frequencies and can be used in a wide variety of EEG applications. The amplifier has wireless capability and an optional feature of pulse oximetry is available. | The Nicolet EEG Wireless Amplifier is a small portable device which is capable of acquiring a variety of electrophysiological signals at variable sampling frequencies and can be used in a wide variety of EEG applications. The amplifier has wireless capability and an optional feature of pulse oximetry is available. | Same |
| Clinical Application Environment | For use in research institutions, clinics, hospital, operating room and epilepsy evaluation environments. | For use in research institutions, clinic, hospital, operating room and epilepsy evaluation environments. | Same. |

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| Intended User | A healthcare professional who has the training and knowledge to undertake EEG examinations and is familiar with EEG equipment and practice. | A healthcare professional who has the training and knowledge to undertake EEG examinations and is familiar with EEG equipment and practice. | Same |
| Channels | 32 EEG (all configurable as bipolar) + SpO2 + patient event button. | 32 EEG (8 configurable as bipolar) + SpO2 + patient event button. | Same |
| ADC Resolution | 16 bits (16 bits software) | 24 bits (16 bits software) | Different<br>Sienna Ultimate uses a 16 bits analog digital convertor in SAR technology<br><br>Nicolet Wireless EEG amplifier (K103140) uses 24 bit analog digital convertor, SD technology.<br><br>Using the SAR technology, EMS EEG amplifier delivers more precise results.<br>The difference does not affect adversely safety and effectiveness. |
| Full Scale Input | ±5 mV | ± 5 mV | Same |
| Sampling Rate | 256-4000 Hz | 125 - 12000 Hz | Different<br>Sienna Ultimate uses ADC's in SAR technology and the predicate device uses ADC's in SD technology<br><br>The result is the same and the difference in sampling rate range does not adversely affect safety and effectiveness. |
| Input Impedance | >100 MΩ | > 40 MΩ | Different<br>The quality of the signal is depending on the input impedance. The higher the input impedance, the more accurate is the signal quality.<br>The better signal quality positively affects the device effectiveness and does not adversely affect safety. |

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| CMRR | > 110dB at 50-60Hz | > 110dB at 50-60Hz | Same |
| Input Noise | < 2.0 µV pk-pk | < 2.0 µV pk-pk | Same |
| Bandwidth (-3dB) | 0,1-1500 Hz max. | 0.048 to 5856 Hz max. | Different<br>Range is sufficient for EEG examinations, does not adversely affect safety and effectiveness. |
| Input Bias Current | < 200 pA | < 200 pA | Same |
| Calibration | 100 µV at 1 sec period | 10, 50, 100, 1000 µV at 1, 5, 10, 20 sec period | Different<br>EMS uses 100 µV square wave 1Hz calibration signal, because this signal is commonly used in EEG acquisition.<br>Using this commonly used 100 µV at 1 sec signal, the experienced user quickly can identify the filter characteristics. |
| Impedance Pass/Fail Levels | 1-50 kΩ<br>Linear measurement on all channels, user definable steps from the above range. | 2, 5, 10, 20, 50 kΩ | Substantially equivalent to Nicolet Wireless EEG amplifier (K103140), more flexible – user definable steps from the range |
| Host PC Communication | Wired (Ethernet) or Wireless (802.11b/g) | Wired (Ethernet) or Wireless (802.11b/g) | Same |
| Power | Battery or medical grade power supply | Battery or medical grade power supply | Same |
| Internal Storage | 32 GB flash card | 32 GB flash card | Same |
| Internal Battery | Li-ion rechargeable | Li-ion rechargeable | Same |
| Patient Event Button Input | Yes | Yes | Same |
| Patient Contact | Device does not directly contact the patient | Device does not directly contact the patient | Same |
| Size | 13 x 7,2 x 4 cm | 13 x 16 x 7 cm | Smaller size, more comfortable for patient, does not adversely affect safety and effectiveness. |
| Weight | 230 gm | 725 gm | Smaller weight, more comfortable for patient, does not adversely affect safety and effectiveness. |
| Compliance/ regulatory | EN60601-1<br>EN60601-2-26<br>EN60601-1-2<br>CE Mark | IEC 60601-1 + ANSI + CAN<br>IEC 60601-2-26<br>IEC 60601-1-2<br>CE Mark | Substantially equivalent to the Nicolet Wireless EEG amplifier (K103140). |

The Sienna Ultimate EEG amplifier has the same indication for use, clinical application environment, same intended users and substantially same features as the predicate device Nicolet Wireless EEG amplifier (K103140). The differences between the subject device and the predicate device are:

- ADC resolution. Sienna Ultimate uses a 16 bits analog digital convertor in SAR technology, which causes no delay between input and output. Sienna Ultimate uses the full 16 bit of the ADC by software. Nicolet Wireless EEG amplifier (K103140) uses 24 bit analog digital convertor, SD technology, which causes delay between input and output. When using this technology, high oversampling is needed to minimize the delay. Nicolet Wireless EEG amplifier uses only the first 16 bit from the analog digital convertor by the software – same resolution to Sienna Ultimate. Using the SAR technology, EMS EEG amplifier delivers more precise results. The subject and predicate devices both finally transfer and store the data in software with 16 bits. The safety is not adversely affected by this feature. The efficacy is positively influenced in the new device.

- Sampling rate - The difference in sampling rate between the subject device and the predicate device is caused by the different ADC technologies which are used. The predicate device uses the ADC (analog digital convertor) SD (sigma delta) technology which requires a very high oversampling to minimize the delay of final output sampling rate. The subject device, Sienna Ultimate uses the ADC´s in SAR technology which does not require oversampling up to 12000 Hz. Therefore, the sampling rate from 256-4000Hz is fully sufficient.

- Input impedance - The quality of the signal is depending on the input impedance. The higher the input impedance, the more accurate is the signal quality. The Sienna Ultimate uses higher input impedance. The safety is not adversely affected by higher impedance values.

- Bandwidth - The range from 0,1 up to 1500 Hz is sufficient for EEG examinations. Typical EEG spectrum ranges from 0.1 Hz up to 100 Hz. Therefore, the difference in bandwidth up to 1500 Hz and up to 5856 Hz does not influence the product effectiveness and the safety.

**PERFORMANCE DATA**

Safety Testing

| Test | Test description | Purpose | Results |
|---|---|---|---|
| Basic safety test<br><br>IEC 60601-1:2012 ed. 3.1 | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.<br>Following tests were performed:<br>4.11 power input<br>5.7 humidity preconditioning<br>5.9.2 determination of accessible parts<br>7.1.2 legibility of marking<br>7.1.3 durability of marking<br>8.7 leakage currents<br>8.8.3 dielectric strength test<br>9.3 surfaces, corners and edges | This standard applies to Medical electrical equipment and to general requirements for basic safety and essential performance of Medical electrical equipment.<br>Test was performed on the subject device to demonstrate the compliance with the requirements for basic safety and essential performance. | There were no deviations from the standard and the proposed device passed the applicable tests and standards. |

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| | 11.1 excessive temperatures in ME equipment<br>11.6.1 overflow, spillage, leakage, ingress of water<br>13.2 abnormal operation<br>15.3 mechanical strength tests | | |
| EMC compatibility test<br><br>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.<br>Tests of EMC emission and immunity were performed on the subject device including the accessories (see 2.2 of the test report). | This standard applies to Medical electrical equipment and to general requirements for basic safety and essential performance. It specifies the Requirements and tests with regard to Electromagnetic disturbances.<br>Test was performed on the subject device to demonstrate the compliance with the EMC standard and to confirm the substantial equivalence to the predicate device. | There were no deviations from the standard and the sample of the proposed device passed the acceptance criteria of the applicable tests and requirements. |
| Usability<br><br>IEC 60601-1-6, Edition 3.1 | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability | This standard specifies a process for a manufacturer to analyze, specify, design, verify and validate usability, as it relates to basic safety and essential performance of medical electrical equipment. This usability engineering process assesses and mitigates risks caused by usability problems associated with correct use and use errors, e.g., normal use.<br>The test was performed on the subject device to demonstrate the compliance with the usability requirements standard. | There were no deviations from the standard and the proposed device passed the applicable tests and requirements. |
| Electroencephalographs<br><br>IEC 60601-2-26 Edition 3 | Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs | This standard applies to basic safety and essential performance of electroencephalographs used in a clinical environment (e.g., hospital, physician's office, etc.).<br>Test was performed on the subject device to demonstrate the compliance with the basic safety and essential performance of electroencephalographs standard and to determine the substantial equivalence of the proposed device. | There were no deviations from the standard and the proposed device passed the applicable tests and requirements. |

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| Risk Management<br><br>ISO 14971:2012 | Medical devices. Application of risk management to medical devices | This standard specifies the requirements with regard to the application of risk management to medical devices.<br>The risk management was conducted on the subject device to demonstrate the compliance with the standard. | The applied risk management and the evaluation of the risks connected with the use of the proposed device demonstrate, that the device complies with the requirements of risk management to medical devices. |
| Biological evaluation<br><br>ISO10993-1 | Biological evaluation of medical devices – evaluation and testing within the risk management process | This standard specifies the requirements to the biological evaluation of medical devices.<br>Test was not applicable – the subject device is non contact device. | The proposed device is non contact device, same as the predicate device K103140 – Nicolet Wireless EEG Amplifier. |
| FCC Specific Absorption Ratio (SAR)<br><br>FCC Part 15C | FCC Specific Absorption Ratio (SAR) | These are federal rules and regulations regarding unlicensed transmissions.<br>The data was leveraged by review of manufacturer´s labeling information (datasheet and user manual). | The proposed device passes the applicable rules and regulations. The compliance with these regulations is substantially equivalent to the predicate device K103140 – Nicolet Wireless EEG Amplifier. |
| Radio Spectrum tests<br><br>Wideband transmission systems; Data transmission equipment operating in the 2.4 GHz ISM band and using wide band modulation techniques – EN 300 328 | Following tests were performed: RF output power, Power spectral density, Duty Cycle, Medium utilization factor, Occupied channel bandwidth, Transmitter unwanted emissions in the out-of-band domain, transmitter unwanted emissions in the spurious domain, Receiver spurious emission, Receiver blocking | This harmonized standard covers the essential requirements on data transmission equipment operating in the 2.4 GHz ISM band.<br>The tests were performed on the subject device to demonstrate the compliance with the requirements of the harmonized standard. | There were no deviations from the standard and the proposed device passed the applicable tests and requirements. |

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| EMC tests<br><br>Electromagnetic compatibility and Radio Spectrum matters (ERM) – EN 301 489-1 and EN 301 489-17 | Electromagnetic compatibility tests, tests of EMC emission and immunity, conducted emission, radiated emission, limits and requirements | This harmonized standard covers the requirements on electromagnetic compatibility and Radio Spectrum matters | There were no deviations from the standard and the proposed device passed the applicable tests and requirements. |
| Battery safety tests<br><br>UN/DOT 38.3 | Transportation testing for lithium batteries | The data was leveraged by review of manufacturer´s labeling information. | The proposed device passed the UN Transportation tests T1-T8. |

## Summary Discussion of Bench Performance Data

The Sienna Ultimate amplifier passed all specified test requirements.
Testing confirmed that the device design and device performance meet the requirements of the standards listed in the above performance testing summary.

The a.m. standards address safety, particular safety for Electroencephalographs, biocompatibility, EMC compatibility, risks, usability, battery safety and radiated energy.

The safety, performance and effectiveness are substantially equivalent to the predicate device K103140 – Nicolet Wireless EEG Amplifier.

Clinical testing was not performed with this device.

**CONCLUSION**

The Sienna Ultimate EEG amplifier meets the functional claims and intended use as described in the product labeling. The safety and effectiveness are substantially equivalent to the predicate device, Nicolet Wireless EEG Amplifier.