December 30, 2020

Corscience gmbH & Co. KG
Stefan Bolleininger
Director Regulatory Affairs
Hartmannstrasse 65
Erlangen, 91052 De

Re: K193159
Trade/Device Name: EEG NeuroAmp II.5s
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, GWE, GWJ, OLV, HCC
Dated: November 30, 2020
Received: November 30, 2020

Dear Stefan Bolleininger:

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,

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)*
K193159

Device Name
EEG NeuroAmp II.5s

Indications for Use *(Describe)*
The EEG NeuroAmp II.5s is intended to acquire, display, store and archive the electroencephalographic (EEG) signals from a patient's brain obtained by placing two or more electrodes on the head. It must be used in combination with appropriate software and computer. The EEG NeuroAmp II.5s is also intended to be used to provide stimulation and recording of visual and auditory evoked response potentials with appropriate software, computer, and accessories.

The EEG NeuroAmp II.5s can also be used for biofeedback and relaxation purposes. For purposes of this training task, information for feedback may be derived from the electroencephalographic signals and from as many as eight channels of peripheral physiology measures such as are conventionally used in biofeedback.

The EEG NeuroAmp II.5s is intended to be used only by trained professionals who can ensure sound handling practices. The device is intended for use in clinical environments (not surgical or emergency environments) as well as in medical and therapeutic practices. It can be used with patients of all ages but is not designed for fetal use.

The device does not draw any diagnostic conclusion. Recorded data of electroencephalogram (EEG) signals or event related potentials (ERPs) need to be interpreted by a clinical expert. The results of such interpretation must be considered only in conjunction with other clinical findings.

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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510(K) SUMMARY

General Information

1 Applicant

Date: November 13, 2020

Name: Corscience GmbH & Co. KG

Address: Hartmannstrasse 65
D-91052 Erlangen
Germany

Contact person in the U.S.: **BEE SYSTEMS INC**
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E-Mail: bwandernoth@bee-systems.net

Contact person in Germany: **Stefan Bolleininger**
Telephone: +49 9131 977986 – 50
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E-Mail: stefan.bolleininger@corscience.de

Signature:

2 Brand Name

EEG NeuroAmp® II (brand name EEG NeuroAmp® II.5s for differentiation to the EEG-biofeedback device EEG NeuroAmp®)

3 Common Name or Classification Name

EEG/ERP measurement & biofeedback device

4 Establishment Registration Number

3005488716

5 Facility Address

Corscience GmbH & Co. KG
Hartmannstrasse 65
D-91052 Erlangen
Germany

6 Device Classification

6.1. Classification

This is a class II device

6.2. Classification panel

Panel: Neurology
Primary Product Code: GWQ
Secondary Product Codes: GWE, GWJ, OLV, HCC

6.3. Regulation Number

21 CFR 882.1400 -- Electroencephalograph

7 Predicate Devices Descriptions

7.1. Names

For the EEG measurement functionality
Mitsar EEG – primary predicate device
Natus Brain Monitor, Embla Dx series

For the EEG-biofeedback (neurofeedback) or peripheral biofeedback functionality
EEG NeuroAmp II

7.2. Predicate Device Companies

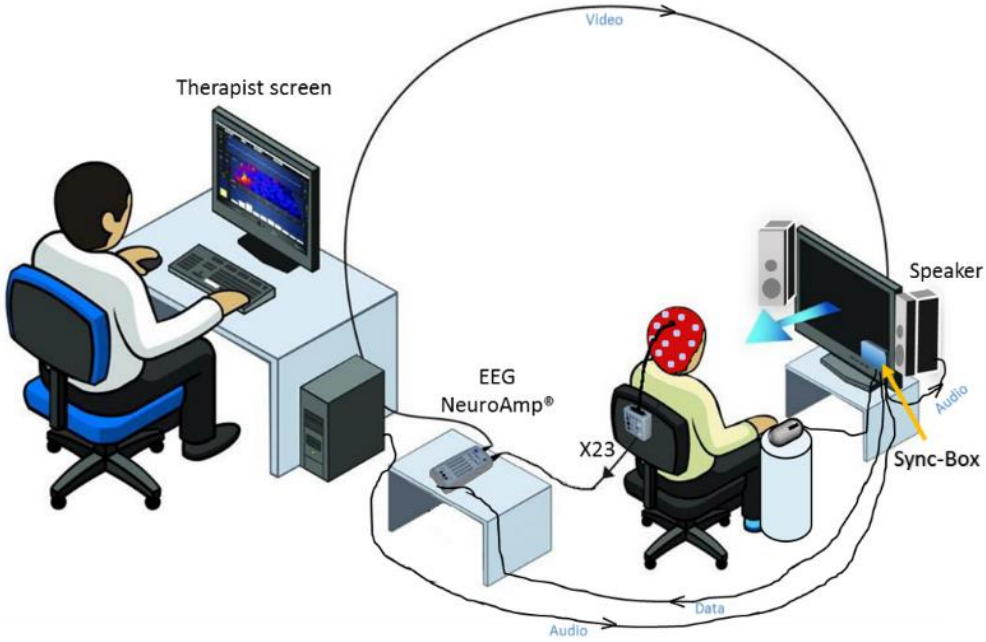
Mitsar Co. Ltd, Novorossiyskaya Str. 21-2, 194021 St. Petersburg, Russian Federation
Natus Medical Incorporated DBA Excel-Tech Ltd., 2568 Bristol Circle, Oakville, ON L6H5S1, Canada
Corscience GmbH & Co. KG, Hartmannstrasse 65, 91052 Erlangen, Germany

7.3. Predicate Device 510(k)#

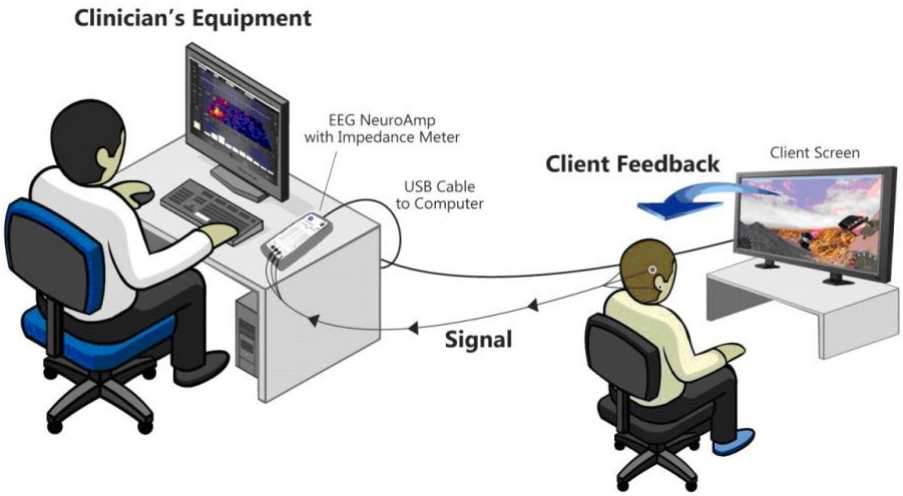
Mitsar EEG: K143233
Natus Brain Monitor, Embla Dx series: K180290
EEG NeuroAmp: K073557

8 Device Description

The EEG NeuroAmp II.5s is a user-friendly high-performance interface between client and clinician computer. It can be used in two different functionalities: In an **EEG/ERP measurement** and in an **EEG biofeedback (neurofeedback)** and/or peripheral biofeedback setting. The following two figures show the two different settings.



Use of the EEG NeuroAmp II.5s and x23 in an EEG/ERP measurement setting



Use of the EEG NeuroAmp II.5s in an EEG biofeedback setting

The EEG NeuroAmp II.5s device itself contains three function blocks:

1. EEG amplifier, two channels, interface for 23- or 39-channel EEG recording front-end
2. Impedance meter function
3. peripheral channels for additional sensors, ERP synchronization and biofeedback

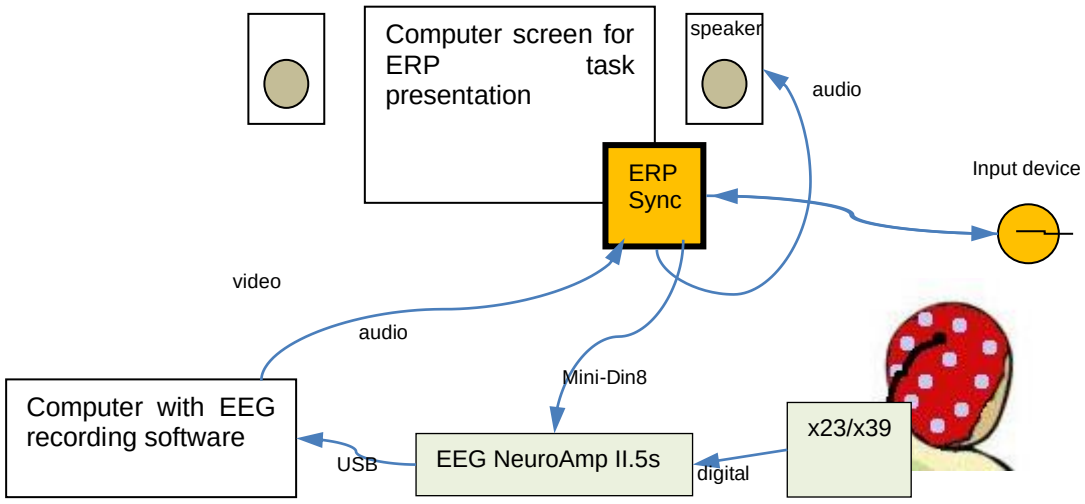
Apart from the EEG-biofeedback functionality, together with the x23/x39 accessories, it is possible to utilize the equipment as an EEG/ERP measurement device. A 23- or 39-channel EEG can be measured with conventional EEG caps, which are not part of the device, according to the standard 10-20 system. The device does not draw any diagnostic conclusions and does not invite the clinician to do so. Recorded data of electroencephalogram (EEG) signals need to be interpreted by a clinical expert. The results of such interpretation must be considered in conjunction with other clinical findings to provide context. There is no therapeutic effect of the EEG NeuroAmp II.5s used in this setting.

The NeuroAmp x23/x39 devices are a full 23-/39-channel digital EEG recording front-end with integrated impedance meter. They are an accessory to the EEG NeuroAmp II.5s and work only in conjunction with it.

The cable that connects the x23/x39 devices to the EEG NeuroAmp II.5s may be up to 3m long allowing for flexibility for the arrangement of the recording environment.

The front-connector interfaces directly with all typically available EEG cap systems. Ground, ear electrodes and two additional channels are available at the top panel of the device for convenient connection of standard electrodes.

In case of an event related potential (ERP) recording, the ERP task is presented to the client on a second monitor. The Sync-Box is connected to the second screen to record a visual signal for task presentation synchronization and to the audio output. An event button is connected to the Sync-Box to align the clients' reaction to the presented tasks. The following figure shows a schematic of the whole system with all connections. **Please note: EEG cap, computer and speakers are not part of the device and must be purchased from external sources.**



Schematic of the event related potential (ERP) recording set-up

EEG NeuroAmp II.5s provides the following characteristics:

- Easy to use
- Power supply via serial PC-port
- Impedance Meter:
  - Wide impedance range
  - Cancellation of electrode galvanic voltages
  - Cancellation of power line pick-up (notch filters)
  - Bright easy-to-read LED bar display
  - Balance display for optimum EEG signal noise reduction
- EEG Amplifier
  - Low-noise, DC coupled
  - Fast settling time
  - High-performance filters for optimum anti-aliasing
- Peripheral Sensor Interface
  - Supply of power for active sensors
  - High performance filters for optimum noise suppression
- Stimulation interface for EEG/ERP measurements
- Optional peripheral physiological signal sensors as accessories
- Interface to an optional full 23-/39-channel digital EEG recording front-end
- Event button for the measurement of event related potentials as optional accessory (ERP Sync)
- Peripheral channels for biofeedback (Audio/Visual/Tactile feedback)

8.1. All accessories to be marketed for use with the subject device

Device name	**Description**	**510(k) number**
NeuroAmp x23	23-channel EEG recording front-end, works only with EEG NeuroAmp II.5s	No prior clearance
NeuroAmp x39	39-channel EEG recording front-end, works only with EEG NeuroAmp II.5s	No prior clearance
ERP Sync	Device to record the audio-visual stimuli and patient inputs synchronously with the EEG, used for Event Related Potential measurements, works only with EEG NeuroAmp II.5s	No prior clearance
Combination sensor	For measurement of heart rate, galvanic skin response (GSR) and skin temperature**,** works with EEG NeuroAmp and EEG NeuroAmp II.5s	No prior clearance
Brummi	Tactile feedback device, works with EEG NeuroAmp and EEG NeuroAmp II.5s	No prior clearance
pIRx3	Temperature sensor, works with EEG NeuroAmp and EEG NeuroAmp II.5s	K073557
Software accessories	**Description**	**510(k) number**
Cygnet	EEG biofeedback software, works with EEG NeuroAmp and EEG NeuroAmp II.5s	K073557
ERPrec	EEG measurement/recording functionality, works only with EEG NeuroAmp II.5s	No prior clearance
BEE Lab	EEG-biofeedback functionality, works with EEG NeuroAmp and EEG NeuroAmp II.5s	No prior clearance

9 Indications for Use Statement

The EEG NeuroAmp® II.5s is intended to acquire, display, store and archive the electroencephalographic (EEG) signals from a patient's brain obtained by placing two or more electrodes on the head. It must be used in combination with appropriate software and computer. The EEG NeuroAmp® II.5s is also intended to be used to provide stimulation and recording of visual and auditory evoked response potentials with appropriate software, computer, and accessories.

The EEG NeuroAmp® II.5s can also be used for biofeedback and relaxation purposes. For purposes of this training task, information for feedback may be derived from the electroencephalographic signals and from as many as eight channels of peripheral physiology measures such as are conventionally used in biofeedback.

The EEG NeuroAmp® II.5s is intended to be used only by trained professionals who can ensure sound handling practices. The device is intended for use in clinical environments (not surgical or emergency environments) as well as in medical and therapeutic practices. It can be used with patients of all ages but is not designed for fetal use.

The device does not draw any diagnostic conclusion. Recorded data of electroencephalogram (EEG) signals or event related potentials (ERPs) need to be interpreted by a clinical expert. The results of such interpretation must be considered only in conjunction with other clinical findings.

10 Required Components

For EEG measurement functionality:

- EEG NeuroAmp II (brand name EEG NeuroAmp II.5s)
- Either NeuroAmp x23 or NeuroAmp x39, 23- or 39-channel EEG recording front-end
- Software ERPrec
- User manuals

Computer, monitor and electrode caps are purchased from other sources

Optional accessories – to be obtained from EEG NeuroAmp II.5s manufacturer

- ERP Sync – device to record the audio-visual stimuli and patient inputs synchronously with the EEG, used for Event Related Potential measurements
- Combination sensor for measurement of heart rate, galvanic skin response (GSR) and skin temperature

For EEG-biofeedback functionality:

- EEG NeuroAmp II.5s
- Software Cygnet (optional)
- Software BEE Lab (optional)
- User manuals

Computer, monitor and electrodes are purchased from other sources

Optional accessories – to be obtained from EEG NeuroAmp II.5s manufacturer

- Combination sensor for measurement of heart rate, galvanic skin response (GSR) and skin temperature
- Tactile feedback device Brummi

11 Summary Table of Comparisons

11.1. EEG/ERP measurement functionality

Specification	**Subject Device** **EEG NeuroAmp II.5s**	**Primary Predicate Device** **Mitsar EEG** K143233	**Predicate Device** **Natus Brain Monitor** K180290	**Discussion on safety and effectiveness**
Indications for Use (short version)	Acquire, display, store and archive the electro-encephalographic (EEG) signals from a patient's brain obtained by placing two or more electrodes on the head incl. stimulation and recording of visual and auditory evoked response potentials.	Acquire, display and store the electrical activity of a patient's brain obtained by placing two or more electrodes on the head to aid in diagnosis.	Acquire, display, store and archive electrophysiological signals. Scalp and Intracranial EEG as well as polysomnographic signals.	Both predicates also offer the capability of stimulation and recording of visual and auditory evoked response potentials.
Common name, Product code, Regulation number	EEG/ERP measurement & biofeedback device, GWQ, GWE, GWJ, OLV & HCC 21 CFR 882.1400, 21 CFR 882.5050, 21 CFR 882.1890 & 21 CFR 882.1900	Electroencephalograph GWQ 21 CFR 882.1400	Electroencephalograph GWQ & OLV 21 CFR 882.1400	Codes GWE, GWJ not listed in product 510k of predicate Mitsar EEG but the product fulfills the equal functionality. Thererore, the additional codes are applicable.
Power supply	Power supply via USB port (galvanic isolation according to IEC 60601-1)	Power supply via USB port	USB port	USB port is the only power source, i.e. as for predicate device no other safety-relevant power sources are to be considered. The galvanic insulation of USB data and power conforms to IEC 60601-1. ➔ Same or better safety
Software	ERPrec	EEG Studio	Natus NeuroWorks™/ SleepWorks. Data stored in 16-bit resolution only	The ERPrec software stores the data in full resolution without loss. It is better than the predicate devices ➔ Same or better effectiveness
Windows 10 and 7 compatible	Yes	Windows 7, perhaps also Windows 10	Yes	Software is fully qualified on actual Windows systems and covers same or more operating systems as predicate device ➔ Same or better effectiveness
EEG channels	up to 41 plus 8 peripheral channels	21 + 4 active/reference pairs, one auxiliary channel	40	More channels ➔ Same or better effectiveness

Resolution EEG channels	24 bit, stored loss-free 24bit and full sampling rate	16 bit	24 bit (16 bit stored)	Same or higher digital resolution, better resolution in stored data ➔ Better effectiveness
Sampling frequency	1Msample/second gross sampling rate, down sampled to 250 or 500 sps. synchronous sampling over all EEG- and peripheral channels	500 Hz per channel, multiplexed	256, 512, 1024, 2048, 4096 256, 512Hz (Embla SDx)	Gross sampling rate much higher than predicate device -> improved anti-aliasing performance. Net sampling rate sufficient for given bandwidth ➔ Better effectiveness
Common-Mode Rejection Ratio (CMRR)	>130 dB	at least 100 dB at 10 Hz	›106db@60Hz	The CMRR of the subject device is much better than the predicate device. Better CMRR results in better signal quality and immunity against noise. ➔ Better effectiveness
Notch filter	<-60 dB at 50 or 60 Hz, optional setting in software. Recording always unfiltered raw signal.	-30 dB at 50(60) Hz	No data	Not relevant, display only
Input impedance EEG channels	>1000 MOhm	> 200 MΩ	>1000 MOhm	High impedance important for proper recording. Same or better performance as predicate device. ➔ Same or better effectiveness
Bandwidth (3dB) and sample rate	DC … 100Hz/160Hz	0.16 – 70 Hz	0.1 Hz – 100 Hz	Subject device has full DC coupling, which allows for recording of slow cortical potentials. ➔ Better effectiveness
Impedance measurement EEG electrodes (electrode contact quality)	Yes 0 … 140kΩ	Yes 5kΩ – 40kΩ	Yes 2.5kΩ, 5kΩ, 10kΩ, 25kΩ	Wider range as predicate device. With that, better guidance for technician when mounting the electrodes. ➔ Better effectiveness
Input Noise	< 0.01µV/√Hz < 1.0 µV peak toPeak	< 1.5 µV peak to peak	≤ 2 uV pk-to-pk (0.1Hz to 100 Hz),	Better noise performance. Therefore, better signal-to-noise ratio of recording ➔ Better effectiveness
Overvoltage warning	yes	No data	No data	Overvoltage may saturate input amplifier and distort the signal. Subject device has overvoltage warning to prevent this from happening. ➔ Same or better effectiveness and safety

Input signal range	1100mVp-p	10 - 5000 µV	20mV pk-to-pk, +/- 0.3VDC	As the subject device is DC coupled, the signal range equals the offset range. Operation of fully DC coupled device is simpler than AC coupled device as high noise levels may removed by software further down the signal chain ➔ Better effectiveness
Maximum Operational DC input voltage electrode offset	±550mV	±350 mV (Offset tolerance)	±300mV	Input offset range of subject device is much higher than predicate device. A large offset range is important to cover offset voltages by electrodes. ➔ Better effectiveness
ERP measurement: synchronization mechanism and precision in ms	Active audio and video synchronization with Sync device; Event button, 24 bit trigger.. Accuracy/jitter: ±1ms/<1ms	Event button No active synchronization Accuracy/jitter: ±10ms/<20ms	Integrated 8-bit trigger for synchronizing external events Accuracy/jitter: ±10ms/<20ms	Stimulus synchronization of subject device much more precise. Analysis of event-related potentials relies on precision of stimulus synchronization. Subsequent conclusions may be better and safer for patient ➔ Better effectiveness and safety
Visual and auditory stimuli for ERP measurement	Stimulus presentation software incorporated in software ERPrec Audio and video sensors for continuous calibration and selftest of the system initial to each recording.	Stimulus presentation software incorporated in software EEG Studio. Audio and video sensors for initial calibration.	no data	Same or better effectiveness
Measurement of physiological data	Combination sensor, applied to the finger, for heart rate and galvanic skin response (GSR). Skin temperature of the finger can be measured, not absolute values, only trends. No therapeutic effect of sensor.	Multi-purpose inputs for peripheral biosignal acquisition such as heart rate, skin conductance (GSR), temperature, breathing, SpO2. ECG adapter clips supplied, breathing sensor available	SpO2 Pulse Rate, Plethysmogram, PPG	Subject device and software work only with accessories supplied. Therefore mis-reading or false values less likely to occur ➔ Better effectiveness and safety
Video recording	Possible	Possible	Possible	Same or better effectiveness

11.2. EEG-Biofeedback (Neurofeedback) Functionality

The EEG NeuroAmp II.5s and its predicate device EEG NeuroAmp (K073557) have the same functionality and similar technical data. The technical data of the EEG NeuroAmp II.5s are superior to those of the **EEG NeuroAmp** and it has more peripheral channels. In addition, the EEG NeuroAmp II.5s can be equipped to be a 23- or 39-channel EEG recording device by connecting the NeuroAmp x23/x39 accessories. The differences in technical data between the subject and predicate device are listed in the table below. The neurofeedback functionality of both devices is the same.

Specification	**Subject Device EEG NeuroAmp II.5s**	**Predicate Device Corscience EEG NeuroAmp** K073557	**Comparison of subject device with predicate device based on safety and effectiveness**
Indications for Use	Biofeedback and relaxation purposes	Biofeedback and relaxation purposes	same
Common name, Product code, Regulation number	EEG/ERP measurement & biofeedback device, GWQ, GWE, GWJ, OLV & HCC 21 CFR 882.1400, 21 CFR 882.5050, 21 CFR 882.1890 & 21 CFR 882.1900	Biofeedback device HCC 21 CFR 882.5050	same or better effectiveness
Power supply	Power supply via USB port (galvanic isolation according to IEC 60601-1)	Power supply via USB port (galvanic isolation according to IEC 60601-1)	Same ➔ Same safety
Software	Cygnet, BEE Lab	Cygnet, BEE Lab	Same ➔ same effectiveness
Windows 10 and 7 compatible	Yes	Yes	Same ➔ Same effectiveness
x23/x39 EEG amplifier interface	Yes	No	Subject device allows to connect additional peripherals ➔ Same or better effectiveness
No. peripheral channels inputs	8	3	More peripheral channels allow for more peripherals attached simultaneously. ➔ Better effectiveness
No. peripheral channels outputs	8	1	
EEG resolution	32 bit	13 bit	Much better technical performance. The subject device has full DC coupling, which allows the work with slow cortical
Input noise	< 0.01µV/√Hz; < 1.0 µVp-p	< 1.5 µVp-p	
Overvoltage warning	yes	yes	
EEG bandwidth	DC … 100/160Hz	0.056 … 70Hz	
Peripheral channel resolution	24 bit	13 bit	
Peripheral channel	DC … 100/160Hz	DC … 70Hz	

bandwidth			potentials, higher bandwidth and lower noise. This results in better signal-to-noise ratio and signal quality. Higher resolution and better signal quality allow for better signal processing. ➔ Better effectiveness
Neurofeedback functionality	Yes	Yes	
Biofeedback sensor interface	Yes	Yes	

12 Brief Summary of Performance Testing

Electrical Safety

The EEG NeuroAmp II.5s was tested according to the following standard:

- IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 +A1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

(or IEC 60601-1: 2012 reprint) – CB Scheme

Results indicate that the EEG NeuroAmp II.5 complies with the applicable standard.

Electromagnetic Compatibility

The EEG NeuroAmp II.5s was tested according to the following standards:

- IEC 60601-1-2: Edition 4.0; 2014-02, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.*
- *IEC 60601-2-26: 2012, Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs.*

Results indicate that the EEG NeuroAmp II.5s complies with the applicable standards.

Performance Testing - Bench

The EEG NeuroAmp II.5s was verified for EEG hardware performance in accordance with internal requirements and the applicable clauses of the following standards:

- *IEC 62366-1: 2015, Medical devices – Application of usability engineering to medical devices.*
- *IEC 80601-2-26: 2019, Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs.*
- *IEC 60601-2-40:2016 Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment.*

Results indicate that the EEG NeuroAmp II.5s complies with its predetermined specifications and the applicable standards.

The optional accessories “NeuroAmp x23”, “NeuroAmp x39”, “ERP Sync”, “Combination Sensor” and tactile feedback device “Brummi” have been tested according to ISO 10993-1, IEC 60601-1 and IEC 60601-1-2 and have shown full compliance to these standards. ISO 10993-1 applies only to “Combination Sensor” and “Brummi”.

13 Conclusions

Based on the above, Corscience GmbH & Co. KG concludes, that EEG NeuroAmp II.5s is substantially equivalent to legally marketed predicate devices and is safe and effective for its intended use and performs as well as or better than the predicate devices.