K073557

5 510(K) SUMMARY

General Information

FEB 28 2008

5.1 Applicant

Date: February 06, 2008

Name: Corscience GmbH & Co. KG

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D-91052 Erlangen
Germany

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Signature: C. Baumann

5.2 Trade Name

EEG NeuroAmp

5.3 Common Name or Classification Name

Biofeedback device

5.4 Establishment Registration Number

3005488716

5.5 Facility Address

Corscience GmbH & Co. KG
Henkestr. 91
D-91052 Erlangen
Germany

5.6 Device Classification

5.6.1 Classification

This is a class II device

5.6.2 Classification panel

Panel: neurology
Product Code HCC

5.6.3 Regulation Number

882.5050

5.7 Reason for Premarket Notification

Approval of biofeedback device and computer software. Included in this premarket notification is the peripheral temperature sensor pIRx3 as optional accessory. This sensor measures forehead temperature and thus supports conventional thermal biofeedback.

The device has been exempt, but is not any longer because power supply is changed from battery-supply to supply via serial (USB-) port of the therapist computer.

5.8 Predicate Devices Descriptions

5.8.1 Names

ProComp
BrainMaster

5.8.2 Predicate Device Companies

Thought Technology Ltd., Montreal, Canada
BrainMaster Technologies, Inc., Oakwood Village, OH 44146, formerly: Cleveland, OH 44124

5.8.3 Predicate Device 510(k)#

ProComp: K903497
BrainMaster: K990538

5.9 Device Description

The purpose of the EEG NeuroAmp is to act as user-friendly high-performance interface between client and clinician computer for EEG biofeedback (neurofeedback) and/or peripheral biofeedback therapy. The EEG NeuroAmp contains four function blocks:

1. EEG amplifier, two channels, aligned and high-resolution
2. Built-in impedance meter for five electrodes helps achieve good electrode contact and warns if electrodes are worn out
3. Peripheral sensor amplifiers, three channels, allow measurement of peripheral biofeedback signals such as GSR (Galvanic Skin Response) and temperature. The latter may be by means of a contact probe (thermistor) or non-contact infrared thermal sensor (infrared thermometer).
4. An output for audio/visual/tactile feedback

EEG NeuroAmp 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, quasi 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
- Optional peripheral temperature sensor pIRx3 as accessory
- Audio/Visual/Tactile Output
  - DC -2.5 to +2.5V
  - AC 1 ... 250Hz, max 5Vss

User manuals with detailed descriptions of NeuroAmp, computer software Cygnet, and optional accessory pIRx3 are submitted in section 13 "Proposed Labeling".

5.10 Intended Use Statement

The EEG NeuroAmp is intended for biofeedback and relaxation purposes. To perform its intended function it must be used in combination with a computer and appropriate software.

For purposes of this training task, information for feedback may be derived from one or two channels of EEG and from as many as three channels of peripheral physiology measures such as are conventionally used in biofeedback.

The EEG NeuroAmp is intended to be used in the office by trained professionals who can ensure sound handling practices.

The EEG NeuroAmp is not intended for diagnostic purposes.

5.11 Required Components

- EEG NeuroAmp
- Software Cygnet
- User manuals

Optional accessory

- Passive infrared temperature sensor pIRx3
- User manual for pIRx3

5.12 Summary Table of Comparisons

Parameter	EEG NeuroAmp	Predicate Device ProComp	Predicate Device BrainMaster 2E
Intended Use	The EEG NeuroAmp is intended for biofeedback and relaxation purposes. To perform its intended function it must be used in combination with a computer and appropriate software (Cygnet). For purposes of this training task, information for feedback may be derived from one or two channels of EEG and from as many as three channels of peripheral physiology measures such as are conventionally used in biofeedback. The EEG NeuroAmp is intended to be used in the office by trained professionals who can ensure sound handling practices. The EEG NeuroAmp is not intended for diagnostic purposes.	Biofeedback, relaxation and muscle re-education purposes.	The Brainmaster 2E is indicated for relaxation training using alpha EEG Biofeedback. In the protocol for relaxation, Brainmaster provides a visual and/or auditory signal that corresponds to the patient's increase in alpha activity as an indicator of achieving a state of relaxation.
Power supply	Power supply via USB port (galvanic isolation according to IEC 60601-1)	4 AA batteries, single-use or rechargeable	Rechargeable batteries
Software	Cygnet	Biograph	BMT
No. of input channels	5	8	2
No. of output channels	1	0	0
ADC resolution	13 bit	14 bit	8 bit
Anti-aliasing filter	5th order Butterworth	5th order Butterworth	none
DC gain accuracy	±1%	±0.5%	±5%
DC offset	±1 LSB	±3 LSB	±4 LSB

Parameter	**EEG NeuroAmp**	**Predicate Device ProComp**	**Predicate Device BrainMaster 2E**
Bandwidth (3dB) and sample rate	EEG amplifier (2 channels): 0.08 Hz (1st order roll-off) ...70 (5th order roll-off) Sample rate for 50Hz line: 1000 sps Sample rate for 60Hz line: 960 sps Subsample rate = sample rate / 4 (250/240) Peripheral Amplifier (3 channels): DC ... 10Hz Same sampling rate scheme	DC – 512Hz @ 2048 samples/second DC – 64Hz @ 256 samples/second DC – 64Hz @ 200 samples/second DC – 8Hz @ 32 samples/second DC – 8Hz @ 20 samples/second (depending on channel)	0.8 – 40 Hz 120 sps
Full-scale input range, DC	±250 mV	2.8V ± 1.696V	±0.8 V
Overvoltage warning	yes	no	no
Impedance measurement EEG electrodes (electrode contact quality)	Both channels simultaneously; displayed by colored LED bars on device	One channel after the other; displayed only on the software	No impedance measurement
Common-Mode Rejection Ratio (CMRR) – EEG sensor only	>130 dB	> 130 dB	> 100 dB
Temperature sensor (Accessory)			
Temperature range	29°C – 43°C or 84°F - 109°F	10°C - 45°C (50°F - 115°F)	n.a.
Accuracy	< 1°K	±1.0°C (±1.8°F) at 20°C - 40°C (68°F - 104°F)	n.a.

All three devices are intended for EEG biofeedback (neurofeedback). EEG biofeedback is a process that is intended to help the client to learn to control his own state through shaping electrical brain activity in a manner that promotes a state of relaxed alertness. The NeuroAmp and the predicate device Procomp can also be used with other conventional biofeedback sensors. ProComp can be operated with a wider range of sensors than the NeuroAmp, e.g. with sensors intended for performing muscle reeducation. Therefore, the intended use of the NeuroAmp does not include biofeedback for the purpose of muscle reeducation, as that term is conventionally understood (application to spinal cord injury, etc). On the other hand, simply training the person toward a relaxed and alert state also has implications for regulation of the motor system. A trainee is likely to also feel motorically calmed.

The differences in technological characteristics between EEG NeuroAmp and the predicate devices ProComp and Brainmaster can be summarized as follows:

- Power supply via USB-port (5V) instead of battery supply (in the case of the Procomp)

- Results of electrode contact measurement (impedance check) are displayed directly on the device
- The impedance measurement needs to be engaged explicitly, and is disabled during EEG neurofeedback. This feature differentiates the EEG NeuroAmp from the current Brainmaster, where the impedance measurement is continuous throughout.
- The device monitors galvanic voltages throughout the training process.
- The bandwidth extends to lower EEG frequencies.
- The temperature range of the pIRx3 is narrower than that of the Procomp temperature sensor, but is totally sufficient for measuring forehead temperature.

The fact that the EEG NeuroAmp is powered via the serial port of the therapist computer does not affect safety or effectiveness because the device is galvanically isolated from the computer by means of a medical grade isolating transformer and has shown full compliance to IEC 60601-1.

Since good electrode contact quality is essential for effective EEG-biofeedback therapy, the easy-to-use impedance measurement function of the NeuroAmp contributes to clinical success.

The software provides for continuous monitoring of any 60-Hz or 50-Hz contamination of the EEG, as an index to contact quality throughout the biofeedback process. The clinician is alerted on screen whenever criteria are violated.

The NeuroAmp extends the bandwidth to lower frequencies than typical EEG amplifiers because these have turned out to be of biological interest as well.

5.13 Summary of Device Testing

The EEG NeuroAmp and its optional accessory pIRx3 have been tested according to IEC 60601-1 and IEC 60601-1-2 by accredited laboratories and have shown full compliance to these standards and the other standards listed in chapter 9 of this 510(k).

The software was tested as described in section 16 "Software".

The optional accessory "passive infrared temperature sensor pIRx3" has been tested according to ISO 10993-1 by an FDA recognized testing laboratory according to GLP standards. The housing material and the elastic belt that fastens the device to the head have both been tested.

The elastic belt conforms to the German "Öko-Tex-Standard" which is a quality mark for clothing regarding certain residues. The belt is made of cotton and therefore did not pass the test for cytotoxicity. Due to this effect the belt is suitable for use on intact skin only. It did pass the tests for dermal irritation and sensitization. Normally, there is hair between the belt and the client's skin, unless the client is bald.

The housing material has passed all tests. It shows full compliance to the standard 10993-1. See also section 15 "Biocompatibility".

5.14 Conclusions

Based on the above, Corscience GmbH & Co. KG concludes, that EEG NeuroAmp 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 28 2008

Corscience GmbH & Co. KG
% Ms. Christine Baumann
Henkestrasse 91
91052 Erlangen
GERMANY

Re: K073557
Trade/Device Name: EEG NeuroAmp
Regulation Number: 21 CFR 882.5050
Regulation Name: Biofeedback Device
Regulatory Class: Class II
Product Code: HCC
Dated: December 12, 2007
Received: December 19, 2007

Dear Ms. Baumann:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073557

Device Name: EEG NeuroAmp

Indications for Use:

The EEG NeuroAmp is intended for biofeedback and relaxation purposes. To perform its intended function it must be used in combination with a computer and appropriate software.

For purposes of this training task, information for feedback may be derived from one or two channels of EEG and from as many as three channels of peripheral physiology measures such as are conventionally used in biofeedback.

The EEG NeuroAmp is intended to be used in the office by trained professionals who can ensure sound handling practices.

The EEG NeuroAmp is not intended for diagnostic purposes.

"Federal law restricts this device to sale by or on the order of a physician or any other practitioner licensed by the law of the State in which he practices to use or order the use of the device."

Prescription Use Yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N. Milano

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073557 06.02.2008