EEG Software

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR §807.92.

Submitter:
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Contact Person:
Howard P. Lightstone

Summary preparation date:
30 January 2013

Trade name: EEGer4

Common name: EEG biofeedback device

Classification name: Biofeedback device (HCC, 21 CFR §882-5050)

Predicate devices:

Device	*510(k)*	*Product code*	*Manufacturer*
Brainmaster2E	K990538	HCC	BrainMaster Technologies, Inc ,Bedford, OH
NeuroAmp	K073557	HCC	Corsoience GmbH & Co. KG, Germany
ProComp	K903497	HCC	Thought Technology LTD., Montreal,Quebec

Device Description:
This software-only component of an EEG biofeedback system uses industry-accepted standard Microsoft Windows-based computers to accept EEG data from external FDA-approved amplifier/encoders and provide biofeedback information. The software does not provide any diagnostic conclusions nor provide any index, classification, diagnosis, or clinical interpretation of the data.

The device processes EEG information, separates it into user-specified frequency bands, and

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displays the results as biofeedback indications to a user.

Intended Use Statement

This device is to be used for general relaxation training when used with supported amplifier/encoders.

The Operator Manual contains the following text:

> **Indications for Use**
> This device is to be used for general relaxation training when used with supported amplifier/encoders.
>
> **General Warnings**
> • US Federal Law restricts this device to sale by or on the order of health care practitioners.
> • Operators of this device are expected to be health care practitioners trained in neurofeedback or technicians trained in neurofeedback supervised by health care practitioners.

The top level screen of the EEGer4 software contains the following message in the lower right corner:

> Caution: Federal law restricts this device
> to sale by or on the order of
> a health care practitioner.
> Intended use: General relaxation

Comparison to predicate devices:

Parameter	EEGer4	Brainmaster 2E K990538	NeuroAmp K073557	ProComp K903497
Software	EEGer4	BMT	Cygnet (proprietary version of BioEra)	Biograph
Intended use	General relaxation when used with supported amplifier/encoders.	Relaxation Training	Biofeedback and Relaxation	Biofeedback and Relaxation
Supported devices	Mfr: Brainmaster Brainmaster 2E Atlantis versions Mfr: Thought Technology ProComp versions Infiniti versions Flexcomp Mfr: J&J Engineering C2 versions C2+ versions	Brainmaster only	NeuroAmp only	ProComp or Infiniti devices only

Parameter	EEGer4	Brainmaster 2E K990538	NeuroAmp K073557	ProComp K903497
	Mfr: Telediagnostics A200 versions A400 versions			
Operating System	Microsoft Windows (XP and later)			
Computer	Generic PC computer supported by Microsoft Windows			
Sampling Rate	256 Hz	120-256 Hz	240/250 Hz	64-512 Hz
Number of EEG channels	4	2	2	4
Bandwidth	0 – 50 Hz	0.8 – 40 Hz	0.08-70 Hz	2-1000 Hz
Power Supply	Not Applicable (software only)	Rechargeable batteries	Via USB port	AA batteries, single use or rechargeable
Filtering	Digital Filters			
Device Interface	Depends on amplifier/encoder used (serial, USB, Bluetooth, etc.)	Serial port	USB	USB or serial port

Conclusion:

The EEGer4 software is substantially equivalent to the software component of the predicate devices, indeed using some of the same hardware components. All devices use EEG signals, measure EEG, and process it to produce frequency band energy indications for feedback. Differences between the predicates and EEGer4 are in the area of user interfaces and the ability to use multiple devices (one at a time). EEGer4 does not incorporate any changes in intended use, method of operation, material or design that could affect safety or effectiveness.

This summary includes only information that is also covered in the body of the 510(k). This summary does not contain any trade secret or confidential information. This summary does not contain any patient identification information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 6, 2013

EEG Software LLC
c/o Mr. Howard Lightstone
17625 Mayall Street
Northridge, California 91325

Re: K122879
Trade/Device Name: EEGer4
Regulation Number: 21 CFR 882.5050
Regulation Name: Biofeedback Device
Regulatory Class: Class II
Product Code: HCC
Dated: January 15, 2013
Received: January 23, 2013

Dear Mr. Lightstone:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Joyce M. Whang

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122879

Device Name: EEGer4 Neurofeedback Software

Indications for Use:

This device is to be used for general relaxation training when used with supported amplifier/encoders.

Prescription Use X
(Part 21 CFR 801 Subpart D)

Joyce M. Whang

Division of Neurological and
Physical Medicine Devices
510(k) Number: K122879