K101830

MAR 3 1 2011

Zmachine® 510(k) Summary

Submitter	Consolidated Research of Richmond, Inc.
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Date Prepared	March 28, 2011
Trade Name	Zmachine®
Common Name	Sleep monitoring system
Classification Name	Electroencephalograph
Classification	21 CFR (882.1400)
Product Codes	OLV and OMC
510(k) Number	K101830
Indications for Use	The CRI Zmachine is a single-channel, EEG acquisition and analysis system, designed for use in the home or clinical environments. This device is intended to be used by qualified healthcare practitioners to monitor the wake and sleep states of adult patients and as an adjunct to their diagnosis of sleep disorders.

Device Description

The CRI Zmachine is a battery-operated, single-channel, EEG acquisition and analysis system. The Zmachine system includes the Zmachine device, disposable EEG sensors, sensor cable, and a wall charger. The device operates on data from the differential-mastoid EEG channel to determine the wake and sleep states of the patient every 30 seconds.

Substantial Equivalence

The Zmachine is substantially equivalent to the Oxford BioSignals Biosomnia device, manufactured by Oxford Biosignals Limited (K021485). The table below summarizes the technological characteristics of the Zmachine in comparison to the predicate device.

Device	Zmachine	BioSomnia
Classification	21 CFR (882.1400)	21 CFR (882.1400)
Product Code(s)	OLV and OMC	GWQ
Indications for Use	The CRI Zmachine is a single-channel, EEG acquisition and analysis system, designed for use in the home or clinical environments. This device is intended to be used by qualified healthcare practitioners to monitor the wake and sleep states of adult patients and as an adjunct to their diagnosis of sleep disorders.	The Oxford BioSignals BioSomnia is a single channel ambulatory EEG with a software package designed for use as an adjunct for the physician in their diagnosis of sleep disorders and to quantify sleep and wakefulness on a second by second basis. The device is designed to be used overnight in the patient's home environment to assist the physician in diagnosing sleep disorders.
Patient Population	Adults	Adults
Type of Device	EEG-based sleep monitor	EEG-based sleep monitor
No. of EEG Channels	1	1
Electrode Placement	Mastoid	Mastoid Frontal EOG Upper Central
Analyzes EEG Data in Real Time	Yes	Yes
Sleep Classification	Wake and Sleep	Wake and Sleep (light sleep, deep sleep, and REM sleep)
EEG Analysis Methodology	Proprietary adaptive algorithm using time and frequency domain features	Proprietary artificial neural network-based algorithm
Can Provide Information to Assist the Physician in Diagnosis of Sleep Disorders?	Yes	Yes
Can Provide Information to Assist the Physician in the Application of Treatment?	Yes	Yes

Device	Zmachine	BioSomnia
Provides Information to Assist Physician in the Evaluation of Treatment Efficacy?	Yes	Yes
Calculates Summary Sleep Statistics?	Yes	Yes
Battery Powered?	Yes	Yes

Performance Testing - Nonclinical
The Zmachine system has been assessed against the following standards:

Electrical safety in accordance with *IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems;*

Electromagnetic compatibility in accordance with *IEC 60601-1-2, Medical Electrical Equipment - Part 1- 2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests. (General).*

In addition, software testing was performed in accordance with *FDA guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices- Document issued on: May 11, 2005" regarding a moderate level of concern device;*

Performance Testing - Clinical
A ninety-nine subject (99) clinical study was conducted in which polysomnographic (PSG) data was acquired and analyzed by human scorers, and simultaneously data from the mastoid was acquired and processed by the Zmachine wake/sleep algorithm. Each PSG record was scored independently by at least two (2) certified polysomnographic technologists (3 records scored by 2 technologists, 16 records scored by 3 technologists, and 80 records scored by 4 technologists) using the Rechtschaffen & Kales (R&K, 1968) visual sleep scoring rules. The performance of the Zmachine was evaluated by comparing wake/sleep as determined by the Zmachine algorithm to the consensus of human scorers. The analysis demonstrates substantial agreement for wake/sleep determination, on an epoch-by-epoch basis, between the Zmachine algorithm and the consensus of human scorers. Of the 16,908 epochs indicated by the consensus of human scorers as wake, the Zmachine algorithm correctly identified 91.6% as wake (Zmachine specificity). Similarly, of the 65,873 epochs indicated by the consensus of human scorers as sleep, the Zmachine algorithm correctly identified 95.8% as sleep (Zmachine sensitivity). The overall Kappa agreement between the consensus of human scorers and the Zmachine algorithm is 0.8275, exceeding the 0.75 threshold for "high association". In conclusion, the Zmachine algorithm demonstrates accurate performance in detecting wake and sleep from a single channel (mastoid) of EEG data.

Conclusion

This submission demonstrates that the Zmachine is substantially equivalent to the predicate device based on descriptive information, non-clinical and clinical performance testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room W-O66-0609
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MAR 3 1 2011

Re: K101830
Trade/Device Name: ZMachine, Model DT-100
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLV and OMC
Dated: February 1, 2011
Received: February 4, 2011

Dear Dr. Kaplan:

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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K101830

Device Name: Zmachine

Indications for Use: The CRI Zmachine is a single-channel, EEG acquisition and analysis system, designed for use in the home or clinical environments. This device is intended to be used by qualified healthcare practitioners to monitor the wake and sleep states of adult patients and as an adjunct to their diagnosis of sleep disorders.

Prescription Use ___X___ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

KRISTEN BOWSHER

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K101830