DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 20, 2015

Consolidated Research Of Richmond, Inc
% Richard Kaplan
President
26250 Euclid Ave
Suite 709
Euclid, Ohio 44132

Re: K142825
Trade/Device Name: Zmachine DT-200
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLZ, OLV, OMC
Dated: December 15, 2014
Received: December 19, 2014

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 contact the Division of Industry and Consumer Education 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 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,

Felipe Aguel -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142825

Device Name
Zmachine DT-200

Indications for Use *(Describe)*
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.

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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Leaders in Advanced EEG Technologies

510(k) Summary

Zmachine® 510(k) Notification
Consolidated Research of Richmond, Inc.

510(k) Owner	Consolidated Research of Richmond, Inc.
Address	26250 Euclid Avenue, Suite 709 Euclid, Ohio 44132 Phone: (216) 289-2331 Fax: (216) 393-0079
Contact Person	Richard F. Kaplan, Ph.D., President Phone: (216) 289-2331 Extension 1001 E-mail: kaplan@cri-systems.com
Date Prepared	December 16, 2014
Trade Name	Zmachine® DT-200
Common Name	Sleep monitoring system
Classification Name	Electroencephalograph 21 CFR 882.1400
Product Codes	OLZ, OLV and OMC
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 (wake, light sleep, deep sleep and REM) of the patient every 30 seconds.

Substantial Equivalence

The Zmachine DT-200 is substantially equivalent to the Zmachine DT-100 (K101830) by Consolidated Research of Richmond, Inc., sharing the same indications for use, the same primary wake/sleep detection algorithm, and the same hardware platform. The firmware of Zmachine DT-200 has been upgraded to further subdivide epochs detected as sleep by the primary wake/sleep detection algorithm into light sleep (stages N1 and N2), deep sleep (N3) and REM. The further subdivision of sleep stages are substantially equivalent to the Sleep Profiler algorithm (K120450) by Advanced Brain Monitoring, Inc.

The table below summarizes the technological characteristics of the Zmachine DT-200 in comparison to the predicate devices.

	Zmachine DT-200 (New)	**Zmachine DT-100 (K101830)**	**Sleep Profiler (K120450)**
Manufacturer Name	Consolidated Research of Richmond, Inc.	Consolidated Research of Richmond, Inc.	Advanced Brain Monitoring, Inc.
510(k) Number	This 510(k)	K101830	K120450
Classification Regulation	882.1400	882.1400	882.1400
Product Code	OLZ, OLV and OMC	OLV and OMC	OLZ

	Zmachine DT-200 (New)	Zmachine DT-100 (K101830)	Sleep Profiler (K120450)
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 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.	Sleep Profiler is intended for the diagnostic evaluation by a physician to assess sleep quality in adults only. The Sleep Profiler is a software-only device to be used under the supervision of a clinician to analyze physiological signals and automatically score sleep study results, including the staging of sleep, detection of arousals and snoring.
Patient Population	Adults	Adults	Adults
Type of Device	EEG-based sleep monitor	EEG-based sleep monitor	EEG-based sleep staging software
No. of EEG Channels	1	1	1
Electrode Placement	Mastoid	Mastoid	Frontal
Analyzes EEG Data in Real Time	Yes	Yes	Yes
Sleep Classification	Wake and N1+N2 (light sleep), N3 (deep sleep), and REM	Wake and Sleep	Wake and N1, N2, N3, and REM
EEG Analysis Methodology	Proprietary algorithm using time and frequency domain features	Proprietary algorithm using time and frequency domain features	Proprietary algorithm using time and frequency domain features

	Zmachine DT-200 (New)	Zmachine DT-100 (K101830)	Sleep Profiler (K120450)
Provides Information to Assist the Healthcare Provider in Evaluation of Treatment Efficacy?	Yes	Yes	Yes
Calculates Summary Sleep Statistics?	Yes	Yes	Yes
Battery Powered?	Yes	Yes	Yes

Performance Testing - Clinical

A clinical study was conducted in which overnight laboratory polysomnographic (PSG) data, and data from the differential-mastoids (A_1-A_2), were acquired from 99 subjects (52F/47M, 18-60 years, median age 32.7 years), including those reporting normal sleep and those reporting complaints consistent with various sleep disorders.

The standard PSG channels were scored independently by two to four certified polysomnographic technologists, using the Rechtschaffen and Kales (R&K) visual sleep staging guidelines. The individual score files were then combined, on a 30-second epoch basis, using a majority voting rule, to generate a single score file per subject ("Human Scores"). EEG data acquired from A_1-A_2 was processed by the Zmachine Algorithm which determines wake, light sleep (N1&N2), deep sleep (N3) and REM on a 30-second epoch basis.

The performance of the Zmachine Algorithm was evaluated by comparing against the Human Scores for stages wake, light sleep (N1&N2), deep sleep (N3) and REM. Overall, kappa agreement between Zmachine Algorithm and Human Scores for 85,206 epochs is 0.716, with P1 (the probability that Zmachine will correctly assign an epoch when the PSG Consensus assigns the epoch to a particular stage) and P2 (when the Zmachine assigns an epoch to a particular stage, the probability of such assignment is correct) for each stage summarized in the table below.

Zmachine DT-200				
	Wake	Light Sleep	Deep Sleep	REM
P1	0.908	0.835	0.738	0.721
P2	0.843	0.848	0.782	0.732

Using the performance data published in K120450 (44 subject study) of the predicate Sleep Profiler algorithm, stages N1 and N2 were combined into Light Sleep for both the

algorithm and scorers (to permit a direct comparison with the Zmachine Algorithm) with a resulting P1 and P2 for each stage summarized in the table below.

Sleep Profiler				
	Wake	Light Sleep	Deep Sleep	REM
P1	0.789	0.855	0.757	0.719
P2	0.831	0.812	0.787	0.782

The P1 and P2 values obtained during clinical validation of the Zmachine Algorithm are similar to those obtained by the predicate Sleep Profiler algorithm, which was validated using its own data set.

Conclusion

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