DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Kay Spiekerman Eason
Omega Results, Inc.
3322 Shorecrest, Suite 235
Dallas, Texas 75235

APR - 9 2012

Re: K963631
Trade/Device Name: Sleep Study Analysis (SSA) Version 96.10
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLZ
Dated (Date on orig SE ltr): December 31, 1996
Received (Date on orig SE ltr): January 3, 1997

Dear Ms. Eason:

This letter corrects our substantially equivalent letter of April 2, 1997.

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,

Kesia Alexander

for

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

:0(k) Number (if known): K963631

evice Name: Sleep Study Analyzer

:dications For Use:

This product is indicated for use under the supervision of a Physician.

This product is indicated for use in the computer aided scoring of sleep study recordings.

PATIENT POPULATION
SSA is intended for use in the adult population with suspected disorders of sleep.

PHYSIOLOGICAL PARAMETERS
SSA is intended for use in providing computer assisted human review of the following physiological parameters for the purpose of staging and identifying events in sleep:

Electroencephalogram
Electromyogram
Electrocardiogram
Respiratory Effort
Respiratory Air Flow
Pulse Oximetery

CLINICAL UTILITY OF SUMMARY REPORT OUTPUT
The clinical utility of SSA summary report output is to assist a trained clinician in the review of polysomnographic recordings so that the clinician may more easily identify sleep stage events. SSA is indicated for use only when operated by a trained clinician who reviews and determines the presence of sleep stage events . SSA is in no way intended to replace a human clinician in discriminating the existence and type of any sleep event which may have occurred.

ENVIRONMENT OF USE
SSA is indicated for use in a hospital sleep laboratory or a free standing sleep laboratory.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Linda Wadoo 3-31-97

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number

Prescription Use ✓ OR Over-The-Counter Use
Per 21 CFR 801.109)

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