



April 5, 2013

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

Alpha Omega Engineering Ltd.  
c/o Ilan Sharon  
P.O. Box 4414 (A109)  
Caesarea, 30889  
Israel

Re: K123796

Trade/Device Name: Neuro Omega System  
Regulation Number: 21 CFR 882.1330  
Regulation Name: Depth electrode  
Regulatory Class: Class II  
Product Code: GZL, GWF, IKN, GWQ  
Dated: March 10, 2013  
Received: March 15, 2013

Dear Mr. Sharon:

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 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>.

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): K123796

Device Name: Neuro Omega System

### Indications For Use:

The Neuro Omega System, including the NeuroDrive unit, is intended to assist neurosurgeons in the operating room during functional neurosurgery and to record from and stimulate brain motor and sensory neurons and to aid in the placement of depth electrodes.

The Neuro Omega System is also intended to monitor, record and display the bioelectric signals produced by muscles, to stimulate peripheral nerves, and to monitor, record and display the electrical activity produced by nerves to aid the clinician in the diagnosis and prognosis of neuromuscular disease (EMG). The device may also be used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head (EEG).

The device is intended for use by medical personnel within a hospital, laboratory, clinic or nursing home setting or outside of a medical facility under direct supervision of a medical professional. The device may also be placed in the intensive care unit or operating room for continuous recording.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

<p><b>Joyce M. Whang</b></p> <p>(Division Sign Off) Division of Neurological and Physical Medicine Devices (DNPMD)</p> <p>510(k) Number <u> K123796 </u></p>
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