

JAN 24 2000

**510(k) Summary**

**Alpha Omega Ltd.**

**NeuroTrek**

*Physiological Navigation System for Neurosurgery*

510(k) Number K 993622

**Submitter's Name:**

Alpha Omega Ltd.  
Ha'avoda Street, P.O.Box 810  
Nazareth Illit 17105, Israel  
Tel: 972-6-6563327  
Fax: 972-6-6574075

**Contact Person:**

Shoshana Friedman  
117 Ahuzah St.  
Ra'ananna 43373, Israel  
Tel: 972-9-771-8130  
Fax: 972-9-771-8130

**Trade Name:**

**NeuroTrek**

**Classification Name:**

Depth Electrode

**Classification:**

The FDA has classified these devices as class II device (product code 84 GZL) and are reviewed by the Neurology panel.

**Predicate Devices:**

The **NeuroTrek** system is substantially equivalent to:

- Guideline System 3000 (Axon Instruments, Inc), cleared under K970943.
- NeuroMap (RADIONICS), cleared under K981820.

**Performance Standards:**

No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug, and Cosmetic Act. However, the **NeuroTrek *Physiological Navigation System for Neurosurgery*** complies with the following voluntary standards: IEC 601-1, IEC 601-1-2, IEC 601-1-4.

**Indication for Use:**

Alpha Omega **NeuroTrek** system is intended to be used to assist neurosurgeons in the operating room during functional neurosurgery and to record from and stimulate brain motor and sensory neurons to aid in the placement of depth electrode.

**Device Description:**

The **NeuroTrek** is a physiological navigation system designed for clinical use during Pallidotomy or Thalamotomy and other neurosurgical procedures to assist in optimal target localization.

During surgery, a microelectrode is advanced into the brain with on-line recording and stimulation performed for precise focusing on the target organ and for evaluating the symptoms before and after. The physiological navigation and localization during the procedure is done for achieving better clinical results (short and long term). "On line" assessment of the electrophysiological activity assures the doctors that they are not about to cause irreversible damage to adjacent centers (i.e. Vision, Somatosensory), and allows confirmation of the target structure position.

The **NeuroTrek** system also enables design boundaries of target and localization of part position of the target for lesioning and electrode implantation.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 24 2000

Ms. Shoshana Friedman, RAC.  
General Manager  
Alpha Omega Ltd.  
C/O Push-Med Ltd  
117, Ahuza Street  
Ra'ananna 43373  
Israel

Re: K993622  
Trade Name: NeuroTrek System  
Regulatory Class: II  
Product Code: GZL  
Dated: October 20, 1999  
Received: October 26, 1999

Dear Ms. Friedman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

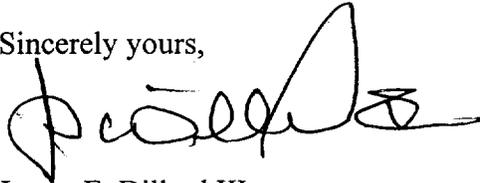
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

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predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III". The signature is fluid and cursive, with a large initial "J" and a long horizontal stroke at the end.

James E. Dillard III  
Acting Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

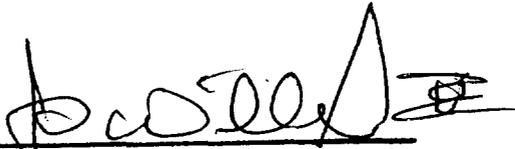
Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K 993622

Device Name: NeuroTrek system

Indications for Use: Alpha Omega NeuroTrek system is intended to be used to assist neurosurgeons in the operating room during functional neurosurgery and to record from and stimulate brain motor and sensory neurons to aid in the placement of depth electrode.



(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K993622

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

510(k) Number K993622

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over the Counter Use \_\_\_\_\_