DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 9 1999

Robert L. Rogers, Ph.D.
Chief Scientist
Microrecording Systems Consultants
2842 East Foothill Boulevard
Pasadena, California 91107

Re: K991077
Trade Name: μEEG™ Pro System 5000
Regulatory Class: II
Product Code: GZL, GWQ, GWL, or MNR
Dated: March 26, 1999
Received: March 31, 1999

Dear Dr. Rogers:

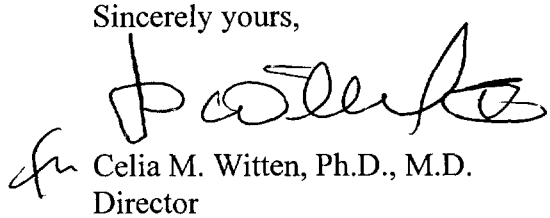
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): 991077

DEVICE NAME: µEEG Pro System 5000

INDICATIONS FOR USE:

Intended Use

The intended use of our µEEG™ Pro System 5000 is for temporary recording of intracranial neural activity, temporary intracranial stimulation of neurons, and mapping of neural activity and evoked potentials.

Duration of Use

Our µEEG™ Pro System 5000 is intended to be used during neurosurgical procedures for an amount of time that is sufficient to obtain the necessary information. During recording procedures, the required time duration is between 30 minutes to several hours. During this time, an electrode will be in continuous contact with tissue for no longer than about 30 minutes.

Environment of Use

The µEEG™ Pro System 5000 is designed for use in operating rooms appropriate for functional neurosurgery. (Warning Labels are attached to machine indicating that it is not to be used in the presence of flammable anesthetics).

dications for Use

µEEG™ Pro System 5000 is indicated for use during intraoperative intracranial neurophysiological recording and stimulation during deep brain stimulation, epilepsy surgery, and other procedures where it is appropriate to perform intracranial depth or subdural electrode recordings.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use ___
(Per 21 CFR 801.109) (Optional Format 1-2-

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991077