K970942

SUMMARY OF SAFETY AND EFFECTIVENESS

JUN - 2 1997

Date: March 3, 1997

Company: Physiometrix, Inc.
Five Billerica Park
101 Billerica Avenue
N. Billerica, MA 01862

Contact: Dawn E. Frazer
Director, Regulatory Affairs & Quality Assurance
(508) 670-2422
(800) 474-9746

Subject Device: NeuroLink II, Model 1320

Predicate Device: K962157, NeuroLink NeuroMonitoring System, Model 1310

Classification: Class II, 21 CFR Part 882.1835, Physiological Signal Amplifier

Description: The NeuroLink NeuroMonitoring System (predicate device) consists of a set of components that work together to acquire and present EEG signal to any existing EEG recording and analysis equipment. The components include Biosensor electrodes, e-Net headpiece, Patient Module, battery module, fiber optic cable, and DSP Interface Card. Changes in the Patient Module and power supply are described in this submission. An electrode headbox has been added to the Patient Module and an AC power supply is available as an alternate to the battery module.

The Patient Module is a small battery powered or AC powered amplifier. The EEG signals are transmitted from the head via conventional electrodes that are input into the attached headbox or e-Net that has a mating connector on the patient module.

Power is enabled when the Patient Module is plugged into the DSP Card via the fiber optic cable, the host digital EEG computer is in the powered state and the Patient Module is enabled by pressing the control button located on the Patient Module. A five meter fiber optic cable is standard. The fiber optic cable provides patient isolation and flexible patient EEG Record Station placement options.

Self test, calibration and impedance tests are remotely activated from the Host Digital EEG Machine through the DSP Interface Card or locally by depressing the appropriate test button on the Patient Module. A visual indication of control button function, system status and out of range impedance can be provided on the LCD display as controlled from the Host Digital EEG Machine.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Dawn E. Frazer
Director, Regulatory Affairs & Quality Assurance
Physiometrix, Inc.
Five Billerica Park
101 Billerica Avenue
North Billerica, Massachusetts 01862

Re: K970942
Trade Name: Model 1320: NeuroLink II NeuroMonitoring System
Regulatory Class: II
Product Code: 84GWQ
Dated: March 3, 1997
Received: March 14, 1997

JUN - 2 1997

Dear Ms. Frazer:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4648. 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

510(K) Number (if known): Unknown

Device Name: NeuroLink II NeuroMonitoring System

Indications for Use: System for recording electroencephalogram of brain electrical activity to Host Digital EEG Machine.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K970942

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