JUN 1 8 2002

K020335

Section 4 Summary & Certification

4.1 510(k) Summary of Safety and Effectiveness

4.1.1 Classification

Electroencephalograph, 21 CFR 882.1400, Class II, OMC
Neurology

4.1.2 Device Name

Proprietary: Olympic Medical Lectromed Cerebral Function Monitor System

Common Name: EEG Monitor

4.1.3 Company

Olympic Medical
5900 First Ave. S.
Seattle, WA 98108

4.1.4 Contact

Edward B. (Ted) Weiler, Ph.D.
Vice President, Research and Development
Phone (206) 268-5151; Fax (206) 762-4200

4.1.5 Intended Use

The Olympic Medical Lectromed Cerebral Function Monitor System is intended to monitor the state of the brain by acquisition of EEG signals in the intensive care unit, operating room, and for clinical research.

4.1.6 Predicate Device

- Olympic Medical Lectromed Cerebral Function Monitor (K983229).
- Devices Limited Cerebral Function Monitor 4640 in commercial distribution in the U. S. prior to May 28, 1976.
- Applied Medical Research Corporation Cerebral Function Monitor Model 870 (K791580)

4.1.7 Device Description

The Olympic Medical Lectromed Cerebral Function Monitor System consists of three modules. A header amplifier module is used to connect the patient electrode leads to a plug-in module that produces three outputs that may be monitored or recorded on a 2-channel strip-chart recorder. The three outputs are cerebral function (activity), impedance, and raw EEG.

4.1.8 Safety and Standards

The device meets the following safety standards:

- BS EN 60601-1-1
- BS EN 60601-1-2: 1993 Medical Electrical Equipment
  Part 1. General requirements for safety
  Section 1.2 Collateral Standard for EMC

4.2 Class III certification

Not applicable

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

Mr. Edward B. Weiler, Ph.D.
Director of Special Projects
Olympic Medical
5900 First Avenue South
Seattle, WA 98108

APR 9 2012

Re: K020335
Trade/Device Name: Olympic Medical Lectromed Cerebral Function Monitor
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OMC
Dated (Date on orig SE ltr): May 10, 2002
Received (Date on orig SE ltr): May 13, 2002

Dear Mr. Weiler:

This letter corrects our substantially equivalent letter of June 18, 2002.

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,

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

Section 3 Indications for use

510(k) NUMBER (IF KNOWN): K020335

DEVICE NAME: Olympic Medical Lectromed Cerebral Function Monitor System

INDICATIONS FOR USE:

The Olympic Medical Lectromed Cerebral Function Monitor System is intended to be used by a variety of clinicians to acquire and utilize EEG signals, when used in conjunction with other clinical data, in intensive care areas, Operating Room, Emergency Room, and clinical research lab:

- to monitor the state of the brain
- for determination of, and long-term monitoring of, the neurological status of patients that may have suffered an hypoxic-ischemic event.
- for monitoring of neurological status to assist in the clinical management and treatment of the patient by observing how the treatment affects the neurological status as shown by the CFM.
- to assist in the prediction of neurological outcome
- to monitor and record frequency and intensity of seizures to assist in management of anti-convulsive therapy.
- to assist in the prediction of severity of Hypoxic-Ischemic Encephalopathy and long-term outcome in infants who have suffered an hypoxic-ischemic event.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020335