K030489

MAY - 2 2003

BRAINZ
INSTRUMENTS LIMITED

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30 April, 2003

510(k) Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

(a)(1) Refer to information above and concluding this summary.

(a)(2) Name of the Device

Model No. / Name: **BRM2 Brain Monitor**

Classification Name: Electroencephalograph
Neurology Devices, 21 CFR §882.1400, Class II, OLT, OMC

(a)(3) Identification of Legally Marketed Devices

Aspect Medical Systems Inc	A2000 EEG Monitor	K974496
Olympic Medical Corp	Lectromed CFM	K983229
Fisher & Paykel Healthcare Ltd	PW810 Patient Warmer	K982636

(a)(4) Description of the Device

The BRM2 Brain Monitor is a two-channel EEG device, consisting of Skin Electrodes, Sensor Lead, Acquisition Unit, Isolation Unit, Serial and Power Cables, Monitor, and Roll-Pole.

The Acquisition Unit is an EEG head stage, providing filtering, amplification and digitization of EEG signals. The Acquisition and Isolation Units provide electrical isolation of the equipment from the patient and protection of the equipment from defibrillator discharges. The Monitor provides processing, display and storage of EEG signals.

User operation of the BRM2 Brain Monitor is via the Monitor graphical user interface (GUI) and touch-sensitive screen. The main display formats are Spectral Edge, Integrated Amplitude, and EEG Waveform. Various time and amplitude display scale options, time-averaged display traces and numeric values, and event marking features are available.

EEG signal processing includes data checking for environmental, equipment, and electrode contact quality problems, with continuous signal quality monitoring for the user. Data file transfer to removable media, and printing of summary report data features are included.

510(k) Summary continued - BRM2 Brain Monitor K030457

A telescoping-pole mounting system supports the Monitor, providing tilt- and height-adjustment options. The lower pole section is mounted into a stabilizer weight attached to a five-arm base unit, with casters that include foot-operated brake levers.

(a)(5) Statement of the Intended Use

The BRM2 Brain Monitor is an Electroencephalograph as per 21 CFR §882.1400.
It is used to measure and record the electrical activity of a patient's brain, obtained by placing electrodes on the head. Refer to the Indications for Use Statement for further information.

(a)(6) Technological Characteristics Summary

The technological characteristics of the BRM2 Brain Monitor are equivalent to the predicate devices listed above. The systems have equivalent components and hardware, self-test and impedance checking capabilities, electrical safety design, and similar displayed data formats.

(b)(1) Discussion of the Non-Clinical Tests

Non-clinical testing of the BRM2 Brain Monitor has been carried out covering mechanical, electrical and thermal safety, environmental conditions and electromagnetic compatibility, functional verification, and performance.

The BRM2 Brain Monitor meets the requirements of the IEC 60601-1 general safety and IEC 60601-1-2 EMC international standards. It meets relevant USA deviations of the UL 2601-1 standard for general safety, and particular requirements of the IEC 60601-2-26 standard for electroencephalographs.

(b)(2) Discussion of the Clinical Tests

No clinical testing was necessary to demonstrate substantial equivalence for this product.

(b)(3) Conclusions Demonstrating Safety, Effectiveness and Performance

The testing carried out for the BRM2 Brain Monitor indicates that it meets design and performance functional requirements. The subject device meets the requirements of IEC and UL medical electrical equipment standards for safety, and the IEC particular standard for electroencephalographs.

This information indicates that the BRM2 Brain Monitor is equivalent to the predicate devices in terms of safety, effectiveness and performance.

signed: _____ date: 30 April 2003

Chris Mander
Regulatory & Quality Manager
Brainz Instruments Ltd

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

Brainz Instruments Ltd.
c/o Mr. Charles Mack
Underwriters Laboratories, Inc.
Laboratory and Testing
2600 NW Lake Road
Camas, Washington 98607-9526

APR - 9 2012

Re: K030489
Trade/Device Name: BRM2 Brain Monitor
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLT, OMC
Dated (Date on orig SE ltr): April 23, 2003
Received (Date on orig SE ltr): April 24, 2003

Dear Mr. Mack:

This letter corrects our substantially equivalent letter of May 2, 2003.

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,

Kesia Alexander

for

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

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15 April, 2003

[510(k)] Number: K030489

Brainz Instruments Ltd - BRM2 Brain Monitor

PREMARKET NOTIFICATION 510(k)
INDICATIONS FOR USE STATEMENT

The Brainz Instruments Ltd **BRM2 Brain Monitor** is an Electroencephalograph as per 21 CFR §882.1400 (a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head).

The **BRM2 Brain Monitor** is intended to monitor the state of the brain by acquisition of electroencephalogram (EEG) signals, in the intensive care unit, operating room, and for clinical research.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K030489

Prescription Use ____
(Per 21 CFR §801.109)