K071449

BRAINZ

7 September 2007

SEP 14 2007

510(k) SUMMARY

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 Number / Name: **BRM3 Brain Monitor**

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

(a)(3) Identification of Legally Marketed Devices

K030489	BRM2 Brain Monitor	Brainz Instruments Ltd
K033010	BRM2 Brain Monitor	Brainz Instruments Ltd
K983229	Lectromed Cerebral Function Monitor	Olympic Medical Corp

(a)(4) Description of the Device

The BRM3 Brain Monitor is a three-channel electroencephalograph (EEG) system, as per 21 CFR §882.1400: a device used to measure and record the electrical activity of the patient's brain by placing two or more electrodes on the head.
The BRM3 Brain Monitor system consists of a Neonatal Sensor Set (EEG skin electrodes) or Sensor Adaptor Set (electrode adaptor), Data Acquisition Unit (EEG head stage), Data Cable, Monitor, Power Supply Unit, and Roll-Pole. These components have equivalent configuration and functions to those described in 510(k) K030489 and K033010 for the BRM2 Brain Monitor.

Changes to the BRM3 Brain Monitor consist of a new touch-screen panel PC (Monitor), new EEG head stage (Data Acquisition Unit) and new mobile mounting hardware (Roll-Pole). New software features include display of a further EEG channel, display of an aEEG parameter, and improved signal quality indication and file reviewing capacity. User instructions have been updated accordingly.

(a)(5) Statement of the Intended Use

The Brainz Instruments Ltd **BRM3 Brain Monitor** is an electroencephalograph or EEG system, 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 BRM3 Brain Monitor is intended for use to monitor the state of the brain by acquisition of electroencephalogram (EEG) signals, in clinical environments such as the intensive care unit, and for clinical research.
- The BRM3 Brain Monitor is intended for use only with neonatal patients, defined as from birth to 28 days post-delivery, and corresponding to a post-conceptual age of 24 to 46 weeks.
- The BRM3 Brain Monitor does not provide any diagnostic conclusion about the patient's condition.

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see inside

(a)(6) Technological Characteristics Summary

The technological characteristics of the BRM3 Brain Monitor are equivalent to the predicate devices listed above. The system uses similar components for the touch-screen panel PC display unit, EEG head stage electronics module, and mobile mounting hardware. Technical equivalence has been established to ensure accuracy of the aEEG parameter implementation. Software is updated for compatibility with those changes, and the same skin electrodes are used as previously notified in 510(k) K033010.

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

Non-clinical testing of the BRM3 Brain Monitor has been carried out to cover the changes to the system. These include performance testing of the new EEG head stage electronics module, full software verification procedures for updated device functionality, comparative results of the aEEG parameter implementation, and third-party testing of the entire system for compliance to IEC 60601 standards for electromagnetic compatibility, electrical safety, particular requirements for electroencephalographs, and US national requirements. This established correct functionality of the BRM3 Brain Monitor system according to requirements, and is equivalent to the predicate devices.

(b)(2) Discussion of the Clinical Tests

Clinical testing was not required to demonstrate the safety and effectiveness of the modifications involved in the BRM3 Brain Monitor. The changes to hardware, electronics, and software have been adequately assessed by establishing technical equivalence and bench testing as above.

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

The testing carried out for the BRM3 Brain Monitor indicates that it meets design and performance functional requirements. The software verification demonstrates that the modified device features are effective, and the hardware / electronics configuration functions equivalently to the predicate devices.

This information indicates that the BRM3 Brain Monitor is equivalent to the predicate devices in terms of device safety, effectiveness and performance.

signed: _____ date: 7 Sept 2007

Chris Mander
Operations Manager
Brainz Instruments Ltd

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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APR - 9 2012

Re: K071449
Trade/Device Name: BRM3 Brain Monitor
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OMA, OMC, OLT
Dated (Date on orig SE ltr): August 13, 2007
Received (Date on orig SE ltr): August 14, 2007

Dear Mr. Christensen:

This letter corrects our substantially equivalent letter of September 14, 2007.

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 (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.

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

11 June 2007

INDICATIONS FOR USE

510(k) Number: K071449

Device Name: BRM3 Brain Monitor

Indications for Use:

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K071449