mennen medical

Date: Dec 25,2013

Topic: **K131789- CerebraLogik - Traditional 510K for addition of aEEG to the Monitors family**

Establishment Name, Registration Number and Address:

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The following information is being submitted in conformance with 21 CFR 807.87:

1. Classification Name	Electroencephalograph
2. Classification Number:	21 CFR 882.1400
3. Common/Usual Name	Electroencephalograph
4. Trade/Proprietary Name	CerebraLogik
5. Part Number of CerebraLogik	681-138-010
6. Establishment Registration Number	9611022
7. FDA Classification	Class II
8. **Classification Product Code**	OMA, OMC
9. The Monitor Product Codes (VitaLogik)	DSI23
10. Reviewing Panel	Neurological
11. Performance Standards	see page 8

Terminology

CerebraLogik aEEG – the monitor records EEG signals from two pairs of electrodes placed on the patient's head. The signal is filtered, rectified and compressed.

The CerebraLogik aEEG module will be interfaced to the VitaLogik monitor family, as below.

510(k) Marketing clearance for VitaLogik monitors:

VitaLogik 5000/5500 Patient Monitor = subject of this traditional 510(k). was approved for marketing by the FDA (**K052288** – 20 Dec 2005)

VitaLogik 4000/4500 Patient Monitor = subject of this traditional 510(k). was approved for marketing by the FDA (**K073140** – 21 Nov 2007)

VitaLogik 6000/6500 Patient Monitor = subject of this traditional 510(k). was approved for marketing by the FDA (**K093766** – 7 May, 2010)

All monitors detailed above, belong to the same family, use the same menus and differ only in display size and packaging

All monitors detailed above, will be upgraded with the CerebraLogik module. The user will be able, in addition to existing capabilities, to also measure EEG signals and displays aEEG history.

Predicate Device

Olympic CFM 6000 –K031149, cleared May, 14, 2003

1. Device Description: CerebraLogik

The CerebraLogik consists of a dual channel EEG amplifier that is put near the monitored patient. The amplifier is connected, using an interface cable, to a Mennen Medical patient monitor via the UIM input of the monitor

The monitor has display options for both real time EEG and history of Amplitude Integrated EEG – aEEG.

The monitor stores both EEG and aEEG signals for the duration of the EEG monitoring

Functional Description of the Monitors family

The patient monitors measure vital signs such as ECG/Heart rate, NIBP, SpO2, Temperature, Invasive pressures, Cardiac output and EtCO2 as an option.

The only change to the monitors is the modification of the software to allow the monitors to interface to the CerebraLogik aEEG modules to measure and display aEEG.

2. Substantial Equivalence: Comparison: CerebraLogik- aEEG with OLYMPIC CFM 6000

Comparison between the intended use and indication for use:

Intended/indication for use	**OLYMPIC CFM 6000** **K031149**	**CerebraLogik- aEEG** **K131789**
Intended for use	The Olympic CFM 6000 **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.	CerebraLogik - aEEG The intended use of the CerebraLogik **is to monitor the state of the brain by acquisition of EEG signals** and display the stored EEG in a compressed form of Amplitude Integrated EEG – aEEG and in **conjunction with other clinical data**
Indication for use	The Olympic CFM 6000is intended to be used by a variety of clinicians to acquire and utilize SSG signals, **when used in conjunction with other clinical data**, in intensive car 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	The Intended Use is same as the Indications For Us

	CFM - To assist in the predication of neurological outcome - To monitor and record frequency and intensity of seizures 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.	

Note: The term aEEG used by Mennen Medical is equivalent to the term CFM used by the Olympic CFM 6000

We have preferred to use the term aEEG to describe the Amplitude Integrated EEG since this is the generic term.

Conclusion of comparison of intended/indication for use:

The indication for use of both the CerebraLogik and the Olympic CFM 6000 (the predicate device) are not identical but have a similar content. Both devices intend to monitor the state of the brain by acquisition of EEG signals by acquisition of EEG signals and display the stored EEG in a compressed form of Amplitude Integrated EEG – aEEG and in conjunction with other clinical data.

The following table compares the major elements in the **CerebraLogik- aEEG** vs. the **OLYMPIC CFM 6000** (predicate device):

Component	**OLYMPIC CFM 6000**	**CerebraLogik- aEEG**
Principle of Operation	Recording of EEG and storage and display of Amplitude integrated EEG	Same: Recording of EEG and storage and display of Amplitude integrated EEG
Number of channels	Single channel EEG & aEEG	Dual channel EEG & aEEG
Number of electrode inputs	3	5
Display size	10"	12" on VitaLogik 4000/4500 15" on VitaLogik 6000/6500 17" on VitaLogik 5000/5500

aEEG Display area	180 x 50 mm	On VitaLogik 4000/4500 Single channel 180 x 50 mm Dual Channel 180 x 35 mm
GUI	EEG + CFM (aEEG)	EEG + aEEG + VitaLogik Vital Signs
LAN	No	Yes
Touch screen	Yes (only)	Yes (optional)
Electrode quality	Resistance	Quality
Data storage	20,000 hours of data	3 patient , 7 days per patient
Output Storage Device	CD-RW drive	USB (Data Storage Device)
Recorder	Built-in	Built-in (option)
	RS-232 I/O port	
Ethernet port	RJ-45 (10/100) Ethernet port	RJ-45 (10/100) Ethernet port
Serial port	PS2 standard keyboard serial port (service only)	PS2 standard keyboard serial port
Serial port	PS2 standard mouse serial port (service only)	PS2 standard mouse serial port
Marker	Yes	Yes
Section selection	No	Yes
Amplifier**		
EEG Noise floor	1.5 micro Volt peak to peak	1.5 micro Volt peak to peak
aEEG Noise floor	1.0-1.5 micro Volt peak to peak	0.5-1 micro Volt peak to peak
Input Impedance active electrodes	25 K Ohm	600 K Ohm
Input Impedance active electrodes to reference	200 K Ohm	250 K Ohm
CMRR	120DB	110DB
Frequency response	2-15 Hz	Same, within + / – 2 dB

**Note: These values are measured values from bench testing of the subject and predicate devices

Summary of comparison tests

Bench test

Two types of bench testing of the subject and predicate device was performed. The first type compared amplifier characteristics of the devices. These tests included measurement and comparison of noise floors, input impedances, CMRR, and frequency responses. The second type of bench testing compared the output of the devices in a simulated use. In this test, EEG signal from Grass EEG Simulator model EEG SIM was inserted in parallel to both Olympic CFM 6000 and the CrebraLogik for periods of 3 hours. Both devices showed same aEEG graphs.

Animal Study

EEG signals of anesthetized piglets were recorded in parallel on Olympic CFM 6000 and the CerebraLogik for periods of 3 and 7 hours. EEG and aEEG recording changes caused by variation in ventilation and anesthesia during the test were compared and showed same aEEG pattern

The results confirm that the device under test, the CerebraLogik, is accurate and gave same results as the predicate device.

We consider the **CerebraLogik- aEEG** to be substantially equivalent to the **OLYMPIC CFM 6000** and we submit that any differences between the two systems

• do not raise any new issues of safety and effectiveness

Reasons for change of Monitors family

Mennen Medical made the changes to the monitors' family for the following reasons:

- As part of continuous improvement and innovation and in order to comply with market's requirements, Mennen Medical added the aEEG parameter to its patient monitors family.
- The benefit of the incorporation of EEG and aEEG to the patient monitors is in the synchronous monitoring, and storage, of the standard vital signs with the EEG waveform.

3. Detailed description of the changes made to the VitaLogik monitors to incorporate CerebraLogik

GUI

No changes were made to the GUI in the display or monitoring of standard vital signs.

For the display of EEG and aEEG an EEG menu was added, and display panels for single or dual channel EEG and aEEG real time and history were added.

Software

Software versions are the same for all VitaLogik monitors to ensure compatibility of all system components along the history of the system.

The change is limited to the addition of the CerebraLogik dual channel EEG amplifier, and use of algorithm for display of Amplitude Integrated EEG - aEEG

4. Verification, Validation and Testing

The CerebraLogik was tested in bench test and in animals by connecting in parallel the inputs of the Olympic CFM 6000 and the CerebraLogik.

Similar waveforms of both EEG and aEEG were received in these tests.

Internal tests called STD (Software Test Descriptions) were also performed on the CerebraLogik's software to ensure its verification and validation. The tests ensure the CerebraLogik aEEG monitor interfaces properly with the monitors and perform according its specifications.

5. Proposed Labeling

The system will be called CerebraLogik and will be added to the VitaLogik monitors.

We have assigned a new Part Number to the CerebraLogik P/N 681-138-010

User Manuals of each of the monitors will have a chapter describing the use of the CrebraLogik.

Page 1-1 of the introduction to the VitaLogik (6000&4X00) User Manuals contains the following **Prescription Notice**: "*Caution: Federal law restricts this device to sale by or on the order of qualified medical personnel only.*"

The following symbols appear on page 2-5 of the User Manuals and/or on the side panel of the VitaLogik/CerebraLogik accordingly.

"Attention – see Accompanying Instructions for Use"

Type BF Applied part (next to NIBP, SpO2, Temperature and EtCO2 connectors)

TYPE BF APPLIED PART

Type CF Applied Part – Defibrillation Proof
(next to ECG, IBP and CO connector)

Symbols and labeling

6. Voluntary Standards

Appropriate voluntary standards for this device, to which conformance have been demonstrated:

- **IEC 60601-1:** (2005) Medical Electrical Equipment Part:1 General Requirements for Safety
- **IEC 60601-1-1** (2000) Medical Electrical Equipment Part 1-1: General Requirements for Safety Collateral Standard: Safety Requirements for Medical Electrical Systems
- **IEC 60601-1-2** (2007): Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.
- **IEC 60601-2-27** (2005):
  Medical electrical equipment, Part 2,
  Requirements for safety of electrocardiograph monitoring equipment.
- **IEC 60601-2-30** (1999):
  Medical electrical equipment, Part 2 - requirements for safety of automatic cycling indirect blood pressure monitoring equipment
- **IEC 60601-2-34** (2005):
  Medical electrical equipment, Part 2 - Particular requirements for the safety of direct blood pressure monitoring equipment
- **IEC 60601-2-49** (2001):
  Particular Requirements for the safety of multifunction patient monitoring equipment
- **IEC 60601-2-26 ed3.0** (2012):
  Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

7. Indication for use

Monitor's Indications for Use (unchanged since latest approval: VitaLogik 6000 K093766, 7 May, 2010):

The VitaLogik is intended for use as a multiparameter physiological patient monitoring system. The VitaLogik can monitor ECG/heart rate, invasive blood pressure channels, temperature channels, pulse oximetry, respiration, non-invasive blood pressure and EtCO2.
This effectively allows the VitaLogik to monitor a wide-range of adult, pediatric and neonatal patient conditions, in many different areas of the hospital.
Functions include display of multiparameter waveforms, vital signs, alarm & status messages.
The Mennen Medical VitaLogik is intended for sale as a system for monitoring and recording patient information or any in-hospital application requiring patient monitoring.
The following are examples of intended clinical applications:

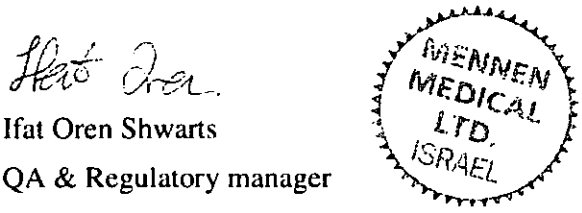
* Critical Care Patients
* Cardiac Step-down/Telemetry Units
* Emergency Departments
* Intra.-operative (Anesthesia) Monitoring
* Post Anesthesia Care

CerebraLogik - aEEG

The intended use of the CerebraLogik is to monitor the state of the brain by acquisition of EEG signals and display the stored EEG in a compressed form of Amplitude Integrated EEG – aEEG and in conjunction with other clinical data.

*The Intended Use of the CerebraLogik as indicated above is same as the Indications for Use.

Signature:



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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December 27, 2013

Mennen Medical, Ltd.
Ms. Ifat Shwarts
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Rehovot, Israel, 76100

Re: K131789
Trade/Device Name: CerebraLogik aEEG
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroenchphalograph
Regulatory Class: Class II
Product Code: OMA, OMC
Dated: November 21, 2013
Received: November 27, 2013

Dear Ms. Shwarts:

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 contact 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. 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,

Carlos L. Pena -S

Carlos L. Peña, Ph.D., M.S.
Director Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131789

Device Name: CerebraLogik aEEG

Indications For Use:

The intended use of the CerebraLogik is to monitor the state of the brain by acquisition of EEG signals and display the stored EEG in a compressed form of Amplitude Integrated EEG – aEEG and in conjunction with other clinical data.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Carlos L. Pena -S