K082540

NOV 28 2008

Premarket Notification 510(k) Summary
As required by section 807.92
GE Entropy Sensor (REF M1038681)

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

GE Healthcare
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

July 30, 2008

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

GE Entropy Sensor (REF M1038681)

COMMON NAME:

Entropy sensor

CLASSIFICATION NAME:

The following Class II classifications appear applicable:

FDA Product Code	Classification Name	21 CFR Section
GWQ	Electroencephalograph	882.1400
GXY	Electrode, cutaneous	882.1320

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The disposable GE Entropy Sensor (REF M1038681) is substantially equivalent in safety and effectiveness to the predicate GE Entropy Sensor (REF M1123614) cleared Dec. 21, 2007 (K062580).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The GE Entropy Sensor (M1038681) is a sensor assembly with three (3) pre-gelled EEG electrodes. The GE Entropy Sensor is applied to the skin of the patient to record electrophysiological (such as EEG and FEMG) signals. It is a low impedance, single patient use, non-sterile disposable electrode sensor that is designed for application to the frontal/temporal area. The GE Entropy Sensor is designed to provide ease of use and electrode placement accuracy. It is used in conjunction with the M-ENTROPY and E-ENTROPY module. The Entropy sensor collects EEG and facial EMG signals from these areas, and the differential signal from the temple to the center of the forehead is used to calculate the Entropy variables. To obtain the lowest possible skin impedance, a preparation pad is used to lightly abrade the skin to remove the insulating outer layer. One preparation pad is included with each sensor. The GE Entropy Sensor is individually packaged inside a moisture tight foil pouch. One preparation pad is included inside the same foil pouch. A selling box for the GE Entropy Sensor contains 25 sensor pouches and an instruction insert. The GE Entropy Sensor is connected directly to the sensor-end of the GE Entropy Cable and the device-end of the cable is connected directly to the M-ENTROPY or E-ENTROPY module.

INTENDED USE as required by 807.92(a)(5)

Indication for use for GE Entropy Sensor (REF M1038681)

This GE Entropy Sensor is intended to be used for adults and pediatric patients older than 2 years with GE Entropy measurement devices to enable recording of physiological signals (such as EEG). To connect this sensor to the measurement device, use the GE Entropy Cable.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The disposable GE Entropy Sensor (REF M1038681) is substantially equivalent in safety and effectiveness to the predicate GE Entropy Sensor (REF M1123614) cleared Dec. 21, 2007 (K062580). The GE Entropy Sensor (REF M1038681) is physically equivalent to the predicate GE Entropy Sensor (REF M1123614).

There are only two changes between the proposed GE Entropy Sensor (M1038681) and the predicate GE Entropy Sensor (REF M1123614).
The proposed disposable GE Entropy Sensor (REF M1038681) has changed labeling to incorporate pediatric use in patients older than 2 years. Only the labeling, artwork and different wording of the instruction for use insert have changed.
The proposed disposable GE Entropy Sensor (REF M1038681) wires has been rerouted inside the connector and shrink wrap/flag sticker has been removed to enable a change in the electrode order from 2-1-3 to 1-2-3. This improves the usability of the product. This change does not affect to form, fit or function nor safety and effectiveness of the product.

The basis for the new claim is the fact that the GE Entropy measurement device with which this sensor can be used has now been cleared by FDA for use in pediatric patients older than 2 years (K061907) cleared March 27, 2008.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The GE Entropy Sensor (REF M1038681) have been assessed against the standards below. The devices have been thoroughly tested through validation and verification of specifications. There are no differences in standards compared to the predicate device (REF M1123614).

- FDA 21 CFR Part 898, § 898.12 (Performance standard for electrode lead wires and cables)
- EN 60601-1:2005 (Part 1: General requirements for safety)
- IEC 601-2-26:1994 Particular requirements for electroencephalographs
- ANSI/AAMI EC12-2000
- ANSI/AAMI ES1:1993
- UL 2601-1
- CAN/CSA C22.2NO601.1
- IEC 664-1 Insulation coordination for equipment within low-voltage systems
- ANSI/AAMI EC53-1995 ECG cables and leadwires
- FDA /ODE Guidance for Content of Premarket Submission for Software Contained in Medical Devices, May 11, 2005
- ISO 15223:2000 Medical Devices - Symbols to be used with medical device labeling and information to be supplied
- EN 980+A1+A2 Graphical symbols for use in the labeling of medical devices
- ISO 10993-1, -5, -10Biological evaluation of medical devices
- ISO 14971:2000 Medical devices – Application of risk management to medical devices

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the disposable GE Entropy Sensor (REF M1038681) and it is substantially equivalent in safety and effectiveness to the predicate GE Entropy Sensor (REF M1123614) cleared Dec. 21, 2007 (K062580).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2008

GE Healthcare
c/oMr. Joel C. Kent
Manager, Quality and Regulatory Affairs
86 Pilgrim Road
Needham, MA 02492

Re: K082540
Trade/Device Name: Entropy Sensor (REF M1038681)
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph.
Regulatory Class: Class II
Product Code: GWQ, GXY
Dated: August 12, 2008
Received: September 02, 2008

Dear Mr. Kent:

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.

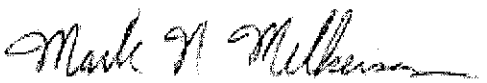
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: GE Entropy Sensor (REF M1038681)

Indications for Use:

Indication for use for GE Entropy Sensor (REF M1038681)

This GE Entropy Sensor is intended to be used for adults and pediatric patients older than 2 years with GE Entropy measurement devices to enable recording of physiological signals (such as EEG). To connect this sensor to the measurement device, use the GE Entropy Cable.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number k082540