

K062580

**Premarket Notification 510(k) Summary
As required by section 807.92
GE Entropy Sensor (REF M1123614) and
GE Entropy Cable (REF M1050784)**

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:

December 19, 2007

DEC 21 2007

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

TRADE NAME:

GE Entropy Sensor (REF M1123614)
GE Entropy Cable (REF M1050784)

COMMON NAME:

Entropy sensor
Entropy cable

CLASSIFICATION NAME:

The following Class II classifications appear applicable:

<u>FDA Product Code</u>	<u>Classification Name</u>	<u>21 CFR Section</u>
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 M1123614) is substantially equivalent in safety and effectiveness to the predicate Datex-Ohmeda Entropy Sensor cleared with the M-Entropy/E-Entropy modules and accessories submissions (K023459 and K050835). The reusable GE Entropy Cable (REF M1050784) is substantially equivalent in safety and effectiveness to the predicate Datex-Ohmeda ENT-3 Entropy Sensor Cable cleared with the M-Entropy/E-Entropy modules and accessories submissions (K023459 and K050835).

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

The GE Entropy Sensor 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 Cable is a reusable cable that connects the GE Entropy Sensor (REF M1123614) or Entropy Sensor (REF 8002858) to the M-ENTROPY or E-ENTROPY module both mechanically and electrically. 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. The GE Entropy Cable is individually packaged in a plastic bag together with an instruction insert.

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

Indication for use for GE Entropy Sensor (REF M1123614)

This GE Entropy Sensor is intended to be used for adults 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

Indication for use for GE Entropy Cable (REF M1050784):

Use the sensor cable only with GE Entropy measurement devices together with GE Entropy Sensor or Entropy Sensor

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

The disposable GE Entropy Sensor (REF M1123614) is substantially equivalent in safety and effectiveness to the predicate Datex-Ohmeda Entropy Sensor cleared with the M-Entropy/E-Entropy modules and accessories submissions (K023459 and K050835). The GE Entropy Sensor has the following similarities to the predicate device:

- 3 wet gel electrodes, conductivity, adhesion on the patient's forehead, plug interface, and air clearances that ensures safe use during electrosurgery and defibrillation.

The proposed disposable GE Entropy Sensor has the following differences compared to the predicate device:

- Pre-attached leadwires, materials, dimensions, labeling, artwork and different wording of the instruction for use insert

The reusable GE Entropy Cable (REF M1050784) is substantially equivalent in safety and effectiveness to the predicate Datex-Ohmeda ENT-3 Entropy Sensor Cable cleared with the M-Entropy/E-Entropy modules and accessories submissions (K023459 and K050835).

The GE Entropy Cable has the following similarities to the predicate device:

- Materials, cable and cable surface, connector interfaces, dimensions

The proposed reusable GE Entropy Cable has the following differences compared to the predicate device:

- Labeling, artwork and different wording of the instruction for use insert

In summary, GE Entropy Sensor and GE Entropy Cable, described in this submission are substantially equivalent in safety and effectiveness to the predicate Datex-Ohmeda Entropy Sensor and ENT-3 Entropy Sensor Cable (K023459 and K050835).

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

The GE Entropy Sensor (REF M1123614) and GE Entropy Cable (REF M1050784) have been assessed against the standards below. The devices have been thoroughly tested through validation and verification of specifications.

- 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, -10 Biological 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 GE Entropy Sensor (REF M1123614) and GE Entropy Cable (REF M1050784) as compared to the predicate device.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

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

APR - 9 2012

Re: K062580
Trade/Device Name: GE Entropy Sensor (REF M1123614)
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: II
Product Code: GXY
Dated (Date on orig SE ltr): November 16, 2007
Received (Date on orig SE ltr): November 20, 2007

Dear Mr. Kent:

This letter corrects our substantially equivalent letter of December 21, 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.

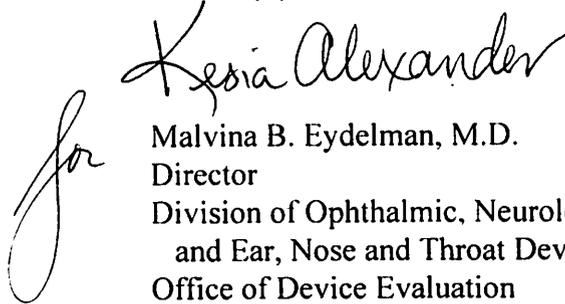
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

A handwritten signature in cursive script, appearing to read "Malvina B. Eydelman". To the left of the signature is a large, stylized initial "M" or "J" that overlaps the start of the signature.

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

Indications for Use

510(k) Number (if known): K062580

Device Name: **GE Entropy Sensor (REF M1123614) and GE Entropy Cable (REF M1050784)**

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



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

510(k) Number 12062586