JUL 19 2011

K103129

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	Oct 19th, 2010
Submitter:	GE Healthcare Finland Oy Kuortaneenkatu 2 Helsinki FIN-00510 FINLAND
Primary Contact Person:	Tommi Jokiniemi RA Leader GE Healthcare Finland Oy Tel +358-10-394 6561 Fax +358-9-272 6532
Secondary Contact Person:	Mari Salmenkaita RA Leader GE Healthcare Finland Oy Tel +358-10-394 2122 Fax +358-9-272 6532
Device: Trade Name:	Entropy EasyFit Sensor
Common/Usual Name:	Entropy Sensor, Electrode, Cutaneous
Classification Names:	882.1400, 882.1320
Product Code:	GWQ, GXY
Predicate Device(s):	K082540 GE Entropy Sensor K061907 Entropy Sensor
Device Description:	Cutaneous sheet electrode to be used with GE Entropy measurement devices.
Intended Use:	Entropy EasyFit Sensor is intended to be used for adults and pediatric patients older that 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.

Technology: The Entropy EasyFit Sensor employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The Entropy EasyFit Sensor and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

To support EMC, safety and bench testing in demonstrating the proposed devices are equivalent to the cleared predicate devices regarding safety and effectiveness a clinical validation test was performed on the proposed devices in hospital environment.

The results of the validation conclude that both the usability and signal quality of the Entropy EasyFit Sensor are substantially equivalent to the compared predicate device(s).

Conclusion: GE Healthcare considers the Entropy EasyFit Sensor to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

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

Mr. Joel Kent
Regulatory Affairs Manager
GE Healthcare
86 Pilgrim Road
Needham, Massachusetts 02492

JUL 19 2011

Re: K103129
Trade/Device Name: Entropy EasyFit Sensor
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ, GXY
Dated: July 5, 2011
Received: July 6, 2011

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. 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,

Anthony D. Watson, B.S., M.S., M.B.A.

Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K103129

Device Name: Entropy EasyFit Sensor

Indications for Use:

Entropy EasyFit 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___ AND/OR Over-The-Counter Use_ _
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103129