

K972202

JUL 23 1998

## Section 2: 510(K) Summary & Certification

### 2.0 Summary

This summary is submitted in accordance with the requirements of 807.92 by Telefactor Corporation, and is a part of the Premarket Notification 510(k) Application.

- a. Trade Name: DEEG-LITE
- b. Common Name: Portable EEG Recorder
- c. Establishment registration number: 2523420
- d. Address of the manufacturing facility: 1094 New Dehaven Street  
West Conshohocken, PA 19428  
  
Contact person: James S. Bryan  
Chief Engineer  
Tel: (610) 825-4555  
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- e. Product Classification (per CDRH Database):  
Product Category: ELECTROENCEPHALOGRAPH  
Regulation Number: 882.1400  
Medical Specialty: NE  
Product Code: GWQ, OLV  
Product class: Class II Device Tier: 2
- f. This device claims equivalence to: Telefactor Corporation's BEEHIVE- EEG-Recorder for which previously granted 510(k) number is: K884937.
- g. Brief functional description of the device: DEEG-LITE receives signals from an EEG Amplifier, formats & records them on the digital media for subsequent evaluation by a qualified clinician.
- h. Intended use for the device: The DEEG-LITE is intended primarily to be used for the long term monitoring of EEG of patients with suspected seizure disorders, and sleep disorders.

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i. **Technological characteristics:** The DEEG-LITE system consists of (a) a laptop computer with liquid crystal display, (b) a MicroCoder which consists of state of the art components such as: a high resolution Analog to Digital converter, a DSP (Digital Signal Processor) and XILINX programmable logic devices, (c) a power supply and (d) a wearable, 32 channel EEG amplifier/recorder identical to that used with the current Telefactor BEEHIVE system (510(k) #884937). The DEEG-LITE system operates on a safe low voltage power supply, as compared to the AC mains required for the BEEHIVE system which is based on a standard desk-top personal computer.

j. **Brief statement of substantial equivalence to Telefactor BEEHIVE:** The DEEG-LITE system has recording performance identical to the Telefactor BEEHIVE System. As with BEEHIVE, DEEG-LITE may also be supplied with the supplemental SzAC software package (called "MicroSzAC" in this embodiment), which has the recognition performance exactly equivalent to that of Telefactor SzAC system (510(k) #K870450) since same recognition algorithm is used in the software for both systems. As with Beehive, the DEEG-LITE may be set up with a specific recording montage (referred to as "Nite Lite" in this embodiment), utilizing the additional electrodes, sensors and devices that are normally applied when monitoring sleep. There is no essential difference between BEEHIVE and DEEG-LITE in so far as patient safety is concerned.

5/1/93

## **2.1 Summary of Safety**

Electrical safety for EEG monitoring equipment is well specified by the UL2601-1 and IEC601-1 standards. The design of the DEEG-LITE electronics has been carried out with careful attention to compliance with these standards.

The kinds of hazards that exist for such equipment can be subdivided as follows:

- (1) Failure of isolation from mains voltages resulting in a harmful electrical shock or burn.
- (2) Failure of insulation from low voltage circuits that can cause small currents that may not be noticeable to the patient at first but over a period of several hours or days may result in an electrolytic lesion forming on the skin. Such lesions unless infected are no threat to health, but can result in a painful experience for the patient and may leave visible scarring on the skin.
- (3) Failures as in (2) above but when used with electrodes implanted on the surface of the brain or deep within the brain for diagnostic purposes may produce serious lesions resulting in disability or an epileptogenic focus.
- (4) Abrasions of the scalp from application of electrodes and subsequent abuse or accidents involving pressure on the head where electrodes contact the skin.

Mains hazards as described in (1) above are avoided by following the appropriate standards for electrical safety IEC601-1 and UL2601-1. Figure 1 on page 7 shows a simplified schematic for system. Electrical energy for the patient connected device is provided from a medical grade power supply that provides low voltage DC for the patient connected amplifier. The equipment will pass a 4000 volt rms. voltage breakdown test from mains to patient electrodes. Further, the patient ground is floating with an isolation of 4000 volts from third wire ground, so that inadvertent patient contact with other equipment at mains voltages will not produce current in excess of 50 micro amperes through the patient ground leads.

To protect failure mode (2) above, the Telefactor CTE amplifier used in the system has patient input circuits, shown in Figure 2 on page 8, which connect to the patient only through capacitors that block all direct current. The system is single fault tolerant; that is to say that failure of only one capacitor will not produce harmful currents. Failure of two capacitors simultaneously is required to produce currents that might result in electrolytic lesions.

For all the reasons cited in the foregoing paragraph the CTE amplifiers are safe from mode (3) failures when used in a hospital environment.

Injury from application of scalp electrodes themselves, as mentioned in item (4) above, is beyond the scope of this discussion since it does not involve Telefactor equipment but is dependent on electrodes supplied by other vendors and on the skill of the technologist applying the electrodes.



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APR - 9 2012

Re: K972202

Trade/Device Name: DEEG-LITE  
Regulation Number: 21 CFR 882.1400  
Regulation Name: Electroencephalograph  
Regulatory Class: II  
Product Code: OLV, GWQ  
Dated (Date on orig SE ltr): June 5, 1997  
Received (Date on orig SE ltr): June 11, 1997

Dear Mr. Bryan:

This letter corrects our substantially equivalent letter of July 23, 1997.

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" (21 CFR 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,



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

510(k) Number (if known): K 972202

Device Name: .DEEG-LITE

Indications For Use:

This device is intended for use in long-term digital recording of voltages produced by the brain and measured on the scalp (EEG) for subsequent diagnostic review with a digital workstation supplied by the manufacturer (Telefactor Beekeeper) or similar compatible device.

(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 Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K 972202

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use     

(Optional Format 1-2-96)