JUN - 9 1998

Section 2: 510(K) Summary & Certification

K974583

2.0 Summary

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

(Requirement: CFR807.92 paragraph (a))

a. **Date:** March 04, 1998

Name & address of the submitter: Telefactor Corporation
1094 New Dehaven Street
West Conshohocken, PA 19428

b. **Establishment registration number:** 2523420

Contact person: James S. Bryan
Chief Engineer
Tel: (610) 825-4555
FAX: (610) 941-0348

c. **Trade Name:** DEEG-LITE-OXY

d. **Common Name:** Portable EEG Recorder

e. **Product Classification** (per CDRH Database):
Product Category: ELECTROENCEPHALOGRAPH
Regulation Number: 882.1400
Medical Specialty: NE
Product Code: GWQ, OLV, DQA
Product class: Class II Device Tier: 2

f. **This device claims equivalence to:** Telefactor Corporation's DEEG-LITE Portable EEG-Recorder for which previously granted 510(k) number is: K972202

g. **Brief functional description of the device:** DEEG-LITE-OXY 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:**

INDICATIONS FOR USE, ***previously*** approved for DEEG-LITE (510(k) #K972202:

DEEG-LITE 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.

INDICATION FOR USE for DEEG-LITE-OXY (modified to include pulse-oximeter)

The DEEG-LITE-OXY is intended for use in long-term 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. An integrated pulse oximeter provides supplemental diagnostic data in the form of blood oxygen saturation (SpO_2 percent).

i. **Technological characteristics**: The DEEG-LITE-OXY 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, and (e) an internal pulse oximeter module supplied by Nellcor(model MP205). The DEEG-LITE-OXY system operates on a safe low voltage power supply. With the exception of the pulse oximeter module, all of the foregoing components are identical of those included in the predicate device DEEG-LITE.

(Requirement: CFR807.92 paragraph (b))

j. **Brief statement of substantial equivalence to Telefactor DEEG-LITE**: The DEEG-LITE system is often operated with an external pulse oximeter device powered from the a-c mains and supplying a non-isolated analog output coupled to the non-isolated analog input of the DEEG-LITE. The DEEG-LITE-OXY is completely equivalent to the foregoing configuration except that the pulse oximeter circuitry and processor have been obtained as an OEM module which can be operated from isolated battery power and coupled digitally to the DEEG-LITE-OXY recording system. Providing an internal pulse oximeter eliminates any possibility of error in the D-to-A and A-to-D communication process used in DEEG-LITE and makes the resulting system portable and more easily set-up in both the office and home environment. The performance of the DEEG-LITE EEG recording capability is in no way degraded by the addition of the internal pulse oximeter, and the oximeter with only 300 milliwatts power consumption does not significantly affect battery life.

(1) Nonclinical (Bench Tests): The results of the bench tests described in volume 3, document the equivalent noise performance of the DEEG-LITE OXY system to that of the DEEG-LITE system. Section 5-**f** of this application summarizes bench test data which confirms that the internal Nellcor oximeter (equivalent to that documented in Nellcor's document for their 510(k) #K962424) meets Nellcor's specifications when installed in the DEEG-LITE-OXY electronic environment.

(2) *Clinical tests:* Because of the identical performance confirmed by the Bench Tests, clinical performance tests are deemed unnecessary.

(3) *Summary of Safety and Effectiveness:* Electrical safety for EEG monitoring equipment is well specified by the UL2601-1 and IEC601-1 standards. The design of the DEEG-LITE-OXY electronics is identical to that of the DEEG-LITE and has been carried out with careful attention to compliance with these standards.

(4) *Conclusion:* It is our conclusion that the nonclinical (Bench Tests) and the substantially equivalent design of the DEEG-LITE-OXY to that of the DEEG-LITE, demonstrate that the device is safe, effective and performs as well as the predicate device DEEG-LITE.

2.1 Certification

I certify, that to the best of my knowledge, the information provided in this summary for the Premarket Notification 510(k) for the DEEG-LITE-OXY, is true and accurate.

Signed

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Date: March 06, 1998

John B. Chatten
President
Telefactor Corporation
1094 New Dehaven Street
West Conshohocken, PA 19428

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. James S. Bryan
Telefactor Corporation
1094 New Dehaven Avenue
West Conshohocken, Pennsylvania 19428

Re: K974583
Trade/Device Name: DEEG-LITE-OXY
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLV, GWQ, DQA
Dated (Date on orig SE ltr): March 6, 1998
Received (Date on orig SE ltr): March 11, 1998

APR - 9 2012

Dear Mr. Bryan:

This letter corrects our substantially equivalent letter of June 9, 1998.

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,

Kesia Alexander

for

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): K974583

Device Name: DEEG-LITE-OXY

Indications For Use:

Indication for use for DEEG-LITE-OXY (modified to include pulse-oximeter)

The DEEG-LITE-OXY is intended for use in long-term 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. An integrated pulse oximeter provides supplemental diagnostic data in the form of blood oxygen saturation (SpO2 percent).

(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 General Restorative Devices
510(k) Number K974583

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)