Section 2: 510(K) Summary & Certification

K974587 MAR - 9 1998

2.0 Summary

This summary is submitted in accordance with the content and format requirements as stated in section 807.92 of CFR, by Telefactor Corporation, and is a part of the Premarket Notification 510(k) Application for their new device H2O.

Requirement: CFR807.92 paragraph (a)

a. **Date:** March 03, 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:** H2O

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" EEG-Recorder for which previously granted 510(k) number is: #K972202

g **Brief functional description of the device:** H2O 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 H2O is intended primarily to be used for the long term monitoring of EEG of patients with suspected seizure disorders, and sleep disorders.
H2O Indications For Use:
This device 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).

i. **Technological characteristics**: The H2O system is battery powered, wearable, 32 channel EEG amplifier/recorder. The H2O system operates on a pack of eight Alkaline batteries for twelve hours or a pack of two lithium batteries for 24 hours. Unlike DEEG-LITE, the H2O recorder never operates from mains power, but only from batteries. Like DEEG-LITE, a binary, optically isolated output data stream is utilized by a notebook or desktop computer for initial setup. Unlike DEEG-LITE, all data recording in H2O is performed internally in the wearable device in a Flash-RAM for short recordings, or on an internal rotating disk for long recordings. The DEEG-LITE utilizes DSPs (Digital Signal Processors) for data manipulation and preparation. It uses a Intel-486 or Pentium processor in a notebook computer for data recording and display. H2O uses a single internal INTEL 186 processor for data manipulation and recording and an external notebook or desktop computer only for initial set-up and electrode application to verify good EEG waveform at the beginning of the data recording session. To provide an added sensor modality useful in sleep recordings, the H2O incorporates a NONIN pulse oximeter board (NONIN OEM2 Pulse Oximeter Module), with a DB9 Female connector for one of the compatible NONIN finger probes.

(Requirement: CFR807.92 paragraph (b))

j. **Brief statement of substantial equivalence to Telefactor DEEG-LITE**: The H2O System has recording performance identical to the Telefactor DEEG-LITE System. The wearable amplifiers although of a different design, have equal or better signal to noise ratio, equal digital resolution, and identical sample rates. The inclusion of an internal pulse oximeter parallels the frequent use of an external pulse oximeter with the DEEG-LITE instrument.

(1) *Nonclinical (Bench Tests):* The results of the Bench Tests described in Volume 3 of the original premarket 510(k) application # K974587, document the equivalent noise performance of the DEEG-LITE system.

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

(3) *Summary of Safety & Effectiveness:* Electrical safety for EEG monitoring equipment is well specified by the UL2601-1 and IEC601-1 General Safety Standards for Medical Devices. The design of the electronics for both the predicate device DEEG-LITE, and the new device H2O have been carried out with careful attention to compliance with these standards.

(4) *Conclusion:* It is our conclusion that the nonclinical (Bench Tests) demonstrate that the device is safe, effective and performs as well as the predicate device.

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 H2O, is true and accurate.

Signed

Date: March 03, 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
Chief Engineer
Telefactor Corporation
1094 New DeHaven Street
West Conshohocken, Pennsylvania 19428

APR - 9 2012

Re: K974587
Trade/Device Name: H20
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLV, GWQ, DQA
Dated (Date on orig SE ltr): December 4, 1997
Received (Date on orig SE ltr): December 9, 1997

Dear Mr. Bryan:

This letter corrects our substantially equivalent letter of March 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): K974587

DEVICE NAME: H2O

INDICATIONS FOR USE:

THIS DEVICE 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 WORK-STATION 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).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974587