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K992291

# Section 1: 510(K) Summary & Certification
# Special 510K: Device Modification

## *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:** H2O – Tethered Option
b. **Common Name:** Portable EEG Recorder with cable telemetry

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
FAX: (610) 941-0348

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 "H2O" EEG-Recorder for which previously granted 510(k) number is: #K974587

g. **Brief functional description of the device:** H2O receives signals from an EEG Amplifier, formats, and transmits them via a cable to a data collection and review workstation. The device can function either as a self-contained, battery-powered recorder or as an externally powered cable telemetry device.

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.

i. **Technological characteristics:** The original H2O system is battery powered, wearable, 32 channel EEG amplifier/recorder. The H2O system operates on a pack of eight Alkaline batteries for 24 hours or a pack of two lithium batteries for 30hours. The "tethered option" which is the subject of this application is identical to the original H2O in every respect except that the battery pack is replaced with an isolating dc to dc converter power supply and a 115 kbaud optical isolator link for data communication. The function of this communication link is to replace the rotating wearable disk. Both the dc to dc converter and the optical isolator maintain a 4000 volt insulation barrier between the patient all external wire and cables. Power is supplied in the form of 5volts dc at one half ampere maximum current. This power is most commonly supplied through the keyboard adapter of a host computer, but when long communication distances are required may be supplied by a small local medical-grade 5 volt supply. The dc to dc converter operates at about 25 kHz and is of the resonant variety so that no measurable interference is produced by its switching action. 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. This option is retained in the tethered mode.

***500 volt Spark Gap:***

Although 4000 volt insulation requirements are met in all components relating to the isolation barrier, a calibrated spark gap has been added to the circuit which is intended to break down at 500 volts dc. The 500 volt breakdown path is provided to limit static charge buildup which can cause severe motion artifact in the EEG traces. IEC 601 standards permit this feature. The 4000 volt design barrier can be thought of as a safety factor in the design, when the actual barrier is limited precisely by a calibrated spark-gap component.

j. **Brief statement of substantial equivalence to Telefactor H2O:**

Figure 1a shows the H2O configuration for set-up with battery power and an on-line computer monitor, while Figure 1b shows the configuration in the tethered mode, when recording is made directly to the monitor computer's disk. With the *tethered option,* the H2O System has recording performance identical to the original H2O which uses battery power and local disk recording. The indications for use are identical for the two H2O configurations.

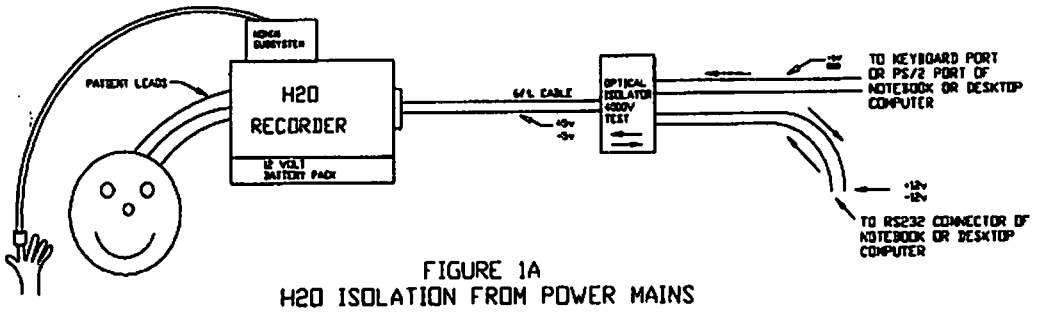


FIGURE 1A
H2O ISOLATION FROM POWER MAINS
DURING INITIAL SETUP

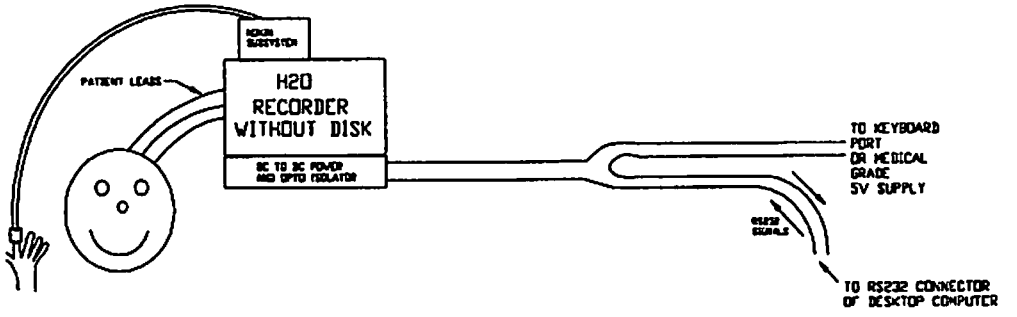


FIGURE 1B
H2O OPERATING WITH TETHERED OPTION.
NOTE THAT THE BATTERY PACK HAS BEEN
REPLACED BY A DC TO DC CONVERTER AND
OPTICAL ISOLATOR. BOTH MAINTAIN
ISOLATION WITH 4000V INSULATION
BARRIERS.

## *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 H2O electronics has been carried out with careful attention to compliance with these standards. The addition of the tethered supply with its low voltage dc-dc converter does not change patient safety considerations in any material way.

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.

Appendix C contains a comprehensive hazard analysis for the H2O system.

## *2.2 Summary of Effectiveness (this section identical to previous H2O application)*

Long term EEG monitoring for differential diagnosis of epilepsy has a long history. Telefactor, as a company, has grown by providing products that serve this market. With the advent of miniaturized amplifiers and miniaturized computing equipment, the cost and size of EEG recording systems has been reduced to the extent that wearable recording systems for use in patient rooms, doctor's offices, or the patient's home are now possible. To this end, Telefactor has undertaken to miniaturize its EEG recording equipment in two steps. The first of these steps was the development of a completely portable EEG recorder which it now markets as "DEEG-LITE" (510 k #K972202). The H2O (Home to Office) device (510k #K974587) represents the second step in this process which provides a completely wearable recording system with full 12 bit A to D resolution, 200 Hz sample rate and full referential recording which can be reconfigured to any montage in a compatible digital review station. The tethered option to the H2O provides a measure of cost reduction to the recording process and convenience without effecting the quality of the recording.

(A) The minimum residual amplifier noise level of 2 micro volts peak to peak is normally specified to permit legal brain-death determinations from the EEG record. Miniaturization requirements and power supply requirements in wearable EEG equipment result in a measured noise level of 5 micro-volts peak to peak, which is totally adequate for diagnostic determinations for epilepsy and sleep.

(B) H2O system has no display for EEG review. The H2O can be connected to a lap-top computer for entering patient information and for setting up recording parameters. The LCD display panel of the lap-top computer is intended only to confirm the quality of recorded EEG, e.g., freedom from artifacts, etc.. The completed digital record will always be evaluated on a companion EEG workstation display intended for diagnostic review, which will have 1024 x 768 pixels or more resolution.

## *2.3 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 - Tethered Option, is true and accurate.

Signed

.....

John B. Chatten
President
Telefactor Corporation

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 Avenue
West Conshohocken, Pennsylvania 19428

APR - 9 2012

Re: K992291
Trade/Device Name: H20-Tethered Option
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLV, GWQ
Dated (Date on orig SE ltr): July 6, 1999
Received (Date on orig SE ltr): July 7, 1999

Dear Mr. Bryan:

This letter corrects our substantially equivalent letter of August 6, 1999.

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,

for Kesia Alexander

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): K992291

DEVICE NAME: H2O – TETHERED OPTION

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 (SPO2 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
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992291