AUG 26 2005

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K052066

SECTION 2: SUMMARY AND CERTIFICATION

510(K) SUMMARY

SAFETY AND EFFECTIVENESS SUMMARY

Safety and effectiveness information concerning the Ceegraph/Sleepscan Netlink Traveler device is summarized below.

PREPARED BY: Bio-logic Systems Corp
One Bio-logic Plaza
Mundelein, IL 60060

TELEPHONE: (847)-949-5200

CONTACT PERSON: Norman E. Brunner

DATE ON WHICH THE SUMMARY WAS PREPARED: July 28, 2005

NAME OF DEVICE: Netlink Traveler.

COMMON NAME: Digital EEG/Sleep Recorder.

CLASSIFICATION NAME: Electroencephalograph (per CFR 882.1400).

PREDICATE DEVICE: Bio-logic Ceegraph Netlink (K002570), Sleepscan Netlink (K003681), Ceegraph Traveler (K954954) and Sleepscan Traveler (K962103).

DESCRIPTION OF THE DEVICE:

The Netlink Traveler patient connection module (headbox) consists of a molded plastic enclosure approximately 5.75" x 3.9" x 1.75" in size and weighing approximately 14 oz. It can be configured to perform up to 40 channel data recordings, having 32 AC channels, 4 DC channels, and additional special channels (oximetry, body position, etc.). Power to the box is supplied by an internal battery, and an external medical-grade power supply/charger may also be connected. There are two primary modes of operation: "Ambulatory Mode" (no power or Ethernet connections, data stored to internal flash memory) and "Headbox Mode" (data communicated to host computer via Ethernet). External power is not required in Ambulatory Mode because the Netlink Traveler always derives its power from the battery. However, connecting the external power supply/charger is recommended when feasible, in order to extend battery capacity. There are no electrode connections directly on the Netlink Traveler box; the AC channel electrodes are connected to safety touch-proof jacks on either of the 2 optional electrode connection accessories, the quick-disconnect box and the Netlink Traveler Electrode Block. These connect to the Netlink Traveler box via a 68-pin cable and connector. The DC channels connect to a separate DC channel box, which is then connected to the Netlink Traveler through a separate cable and connector. Other connectors (Ethernet, photic strobe out, oximeter, body position, etc.) are located on the side of the Netlink Traveler box.

The Netlink Traveler consists of a digital board, an analog board and an LCD display board. The analog board is very similar in function to the analog board used in the Netlink Predicate Device. This board provides signal amplification and conversion of the data from analog to digital. The 68-pin electrode array connector allows the use of existing patient connection hardware, such as the 32-channel electrode connection panel called the "quick disconnect box", and the new Netlink Traveler Electrode Block. The Electrode Block may be configured for several different montages and is especially designed to be worn comfortably by the patient. The digital board contains a microprocessor along with program and data memory, and provides control functions for reading the analog data, converting it to digital, and communicating it to the host computer and/or storing it to the flash memory card. Additional features of the Netlink Traveler include the color LCD display to facilitate functions such as electrode impedance measurements, and programmable pushbuttons to activate various collection, setup and impedance features.

INTENDED USE:

The Bio-logic Ceegraph/Sleepscan Netlink Traveler is indicated for use in the recording and analysis of EEG tests. Typical routine EEG tests are 20-30 minutes in duration, but the Ceegraph/Sleepscan Netlink Traveler can also be used for longer tests, including continuous long-term EEG monitoring with patient video. Similarly, the Bio-logic Ceegraph/Sleepscan Netlink Traveler is indicated for use in the recording and analysis of human physiological data necessary for the diagnosis of Sleep-related disorders. It is intended to record and present this data in a form that can improve the speed of diagnosis and assist in potential treatment decisions. In general, EEG and Sleep testing is indicated for use whenever it is necessary to measure and record a patient's electrophysiological activity, including the electrical activity of the brain, by attaching multiple electrodes at various locations on the body.

The Netlink Traveler can be used for patients of all ages, from children to adults, including geriatric patients.

The use of the Ceegraph/Sleepscan Netlink Traveler is to be performed under the prescription and supervision of a physician or other trained health care professional.

PATIENT POPULATION: Adults, children and infants.

SAFETY AND EFFECTIVENESS SUMMARY

To meet required safety and effectiveness issues, the Netlink Traveler was designed and incorporated into the product line in accordance with the Bio-logic internal Product Development procedures which are intended to meet ISO-13485 and FDA QSR Design Control specifications. A detailed Hazard/Risk analysis for the Netlink Traveler was performed using the Failure Mode Effects Criticality Analysis (FMECA) approach, and a detailed Risk Management Report was written in accordance with EN-14971, the International Standard for Risk Management.

The Netlink Traveler patient-connection hardware utilizes many of the same design principles and circuit designs as are used in the Bio-logic Ceegraph and Sleepscan Predicate Devices. There are no newly-introduced hardware-related methods by which the patient can be harmed or injured through the use of this device. The Netlink Traveler utilizes a medical-grade battery charger / power supply, but power is supplied directly to the unit from the internal battery. Direct hardware control of all Netlink Traveler functions is provided from the embedded microprocessor and its program code located inside the Netlink Traveler box, instead of directly from the host computer program. By distributing the hardware-specific functions to the Netlink Traveler headbox, the Windows-based host computer program has fewer real-time demands, and performance and reliability are improved.

The Netlink Traveler software does not make any final decisions that result in any automatic forms of diagnosis or treatment. All Ceegraph and Sleepscan program "recommendations" are subject to review by a qualified health care professional, such as an EEG/PSG Technologist or Physician, and may be modified, overridden or deleted as determined by a trained user. The program provides additional functionality to allow the qualified user to review all raw data collected and perform other data analysis to suit his or her requirements.

The chart on the next page provides a summary comparison of the technological characteristics of the new modified device relative to the predicate devices. This is to demonstrate that this new Netlink Traveler device has no significant differences which would adversely affect product safety and effectiveness.

Parameter for comparison	Similarity or Difference – Netlink Predicate Device	Similarity or Difference – Traveler Predicate Device
Intended Use	No differences.	No differences.
Population	No differences.	No differences.
Recording capacity	The Netlink predicate device has up to 40-channel capacity with 8 DC channels. The Netlink Traveler has up to 32 channels of AC, 4 channels of DC and 4 special channels (oximetry, etc.).	This Predicate Device has up to 24 channels for AC "head" channels, but no DC channels.
Host Computer to Headbox Connection.	No differences.	This predicate device does not connect to a host computer except for setup. The connection is through a serial port.
Computer Control Software	Netlink uses the same Ceegraph and Sleepscan (Vision) software as this Predicate Device, with minor additions for control of the new hardware.	The Traveler predicate device uses a special setup application, separate from the Ceegraph and Sleepscan applications.
Patient information and tracking	No differences. The P&TI ACCESS database is used for both devices.	The Traveler predicate device uses a simple DB4 database for patient and test information. This database is compatible with the newer ACCESS-compatible database through the import feature.
Safety Characteristics	No differences. The basic patient connection and isolation circuits are the same for both products.	No differences. The basic patient connection and isolation circuits are the same for both products.
Power Source	The Netlink predicate device uses a medical grade power supply whereas the Netlink Traveler is battery powered.	No differences. Both devices are battery powered.
Data Quality	No differences.	Predicate device has 12 bit resolution, whereas Netlink Traveler has 18 bit.
Patient Connections	This predicate device has electrode connections directly on the headbox, whereas the electrode connections for Netlink Traveler are located on the Electrode Block or optional Quick-Disconnect box.	This Predicate Device requires the use of one of several patient montage cables. There are no electrode jacks located directly on the box.
Impedance display on headbox.	The Netlink predicate devices uses an array of LED's for impedance display. Netlink Traveler uses an LCD display.	Not provided for on this Predicate Device
Physical Characteristics	The Netlink predicate device is larger than Netlink Traveler.	This predicate device is larger than Netlink Traveler.
Product Labeling	Similar safety, information and warning labels. Different size and shape of box requires some different labels.	Similar safety, information and warning labels. Different size and shape of box requires some different labels.
Anatomical sites	No differences.	No differences.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 2005

Mr. Norman E. Brunner
Vice-President of Research and Development
Bio-Logic Systems Corp.
One Bio-logic Plaza
Mundelein, Illinois 60060-3700

Re: K052066
Trade/Device Name: Ceegraph/Sleepscan Netlink Traveler
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: August 16, 2005
Received: August 17, 2005

Dear Mr. Brunner:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Richards for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K052066

Device Name: Ceegraph/Sleepscan Netlink Traveler.

Indications For Use:

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The use of the Ceegraph/Sleepscan Netlink Traveler is to be performed under the prescription and supervision of a physician or other trained health care professional.

Prescription Use XXX AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Barbara Brenner for MXM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052066