K093728

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21 CFR 807.92.

807.92(a)(1)

Submitter Information

EBNeuro, S.p.A.
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APR 29 2010

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Date: December 2, 2009

807.92(a)(2)

Trade Name: BE micro/Trea

Regulation Number: 21 CFR 882.1400

Regulation Name(s): Electroencephalograph

Regulatory Class: Class II

Product Code: OLV

Additional Product Codes: GWQ, GWL, MNR, and DQA

807.92(a)(3)

Predicate Device(s)

K#	Name	Manufacturer
K010460	Track-it	Lifelines Ltd
K052066	Netlink Traveler	Bio-logic System Corp.
K061996	Sandman Pocket	EBNeuro S.p.A.

Additional substantial equivalence information is provided below.

807.92 (a)(4)

Device Description

The ***BE micro*** is manufactured by EBNeuro and intended for use in collecting and recording physiological data to be used in diagnosis in EEG (electroencephalography) and PSG (sleep disorder studies) clinical investigation.

The ***BE micro*** is a portable multi-channel recording system that capture and digitally amplifies neurological (EEG) and/or Polysomnography (PSG) physiological activity and records the acquired data onto an internal *NAND flash memory* chip and/or sends those data directly to a PC via the *USB* port. The *BE micro* system is a small, lightweight recording system that is comfortable for the patient and simple for the clinician to set up.

The Amplifier can be worn by the patient allowing in such way the patient to freely move or sleep while recordings are being made, allowing a more comfortable and efficient test.

807.92(a)(5)

Intended Use(s)

BE micro/Trea intended use is collecting and recording physiological data to be used in neurology (EEG), polysomnography (PSG) and sleep disorder studies. The BE micro is intended for pediatric to adult population , and can be used either home or hospital environments

The BE micro/Trea is only to be used under the direction or supervision of a physician, or other trained health care professional.

807.92(a)(6)

Technological Characteristics

The BE micro/Trea system utilizes the same technological characteristics as the predicate devices. A comparison of these characteristics can be summarized as follows:

- Design
  - BE micro/Trea and predicate(s) are designed for the **same** target populations and environments of use.
  - BE micro/Trea and predicate(s) utilize **same** type of operator interface.
  - BE mirco/Trea and predicate(s) have **same** type of configuration.
  - BE micro/Trea and predicate(s) have **same/similar** sampling rates, data storing, data compression, A/D resolution, and maximum number of channels.
- Material
  - BE mirco/Trea and predicate use **same** microprocessor.
- Energy source
  - BE micro/Trea and predicate(s) utilize **same** type of energy source(s).

Summary of Substantial Equivalence

EBNeuro believes that the BE micro/Trea system is substantially equivalent to the Track-it (K010460), Netlink Traveler (K052066) and Sandman Pocket (K061996). Please see table below for detailed comparison of the specifications, characteristics, and performance/safety testing of the BE micro/Trea to the respective predicate devices.

807.92(b)(1)

Summary of Non-Clinical Performance Data

The following non-clinical performance data were gathered:

- Data to verify and validate the measurement algorithm and software functionality.
    - RESULT: PASS
- Data to evaluate electrical safety and electromagnetic compatibility (per IEC 60601-1, IEC 60601-1-2, and other standards).
    - RESULT: PASS

Non-Clinical Performance Data Conclusions

Software V&V testing demonstrated that the software functions as intended. Electrical safety and electromagnetic compatibility testing demonstrated that, like the referenced predicate device(s), the BE micro/Trea complies with IEC 60601-1, IEC 60601-1-2, and other safety/EMC standards (per table below).

Product Characteristic	***BEmicro (Trea)*** ***Submission device***	***Track-it*** ***(Predicate Device)***	***Netlink Traveler*** ***(Predicate Device)***	***Sandman Pocket*** ***(Predicate device)***
Manufacturer	EBNeuro S.p.A.	Lifelines Ltd	Bio-logic System Corp.	EBNeuro S.p.A.
510(k) number	TBA	K010460	K052066	K061996
Device class	Class II	Class II	Class II	Class II
Intended use	BE micro intended use is collecting and recording physiological data to be used in neurology (EEG), polysomnography (PSG) and sleep disorder studies. The BE micro is intended for pediatric to adult population, and can be used either home or hospital environments	The lifelines Track it Recorder is a 36 channel ambulatory electroencephalograph that is designed for use in a variety of monitoring application to record physiological data for EGG and Sleep studies	The Bio-logic 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 Netlink Traveler can also be used for longer tests, including continuous long-term EEG monitoring with patient video. Similarly, the 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.	Intended for use in collecting and recording physiological data to be used in polysomnography and sleep disorder studies. For use in either home or hospital environments with a pediatric through adult patient population.
Target population	Pediatric through adult	Patients of all ages, from children to adults.	Patients of all ages, from children to adults, including geriatric patients.	Pediatric through adult (including all pediatric subpopulations)
Environment of use	Hospital and home	Hospital and home	Hospital and home	Hospital and home

Product Characteristic	***BEmicro (Trea)*** ***Submission device***	***Track-it*** ***(Predicate Device)***	***Netlink Traveler*** ***(Predicate Device)***	***Sandman Pocket*** ***(Predicate device)***
Recording modality	Attended and Unattended	Attended and Unattended	Attended and Unattended	Attended and Unattended
Prescription status	Available only on the order of a physician.	Available only on the order of a physician.	Available only on the order of a physician.	Available only on the order of a physician.
Power	Battery powered or USB powered	Battery powered	Battery Powered	Battery powered or USB powered
Communication Interfaces	Physiological signals are sent from the patient sensors to the device through the sensor cables. In the recorder the data are stored in flash memory in both attended and unattended studies. During attended studies, the data is also transmitted to a computer in real-time via a USB bridge. After unattended studies, data can be downloaded from the recorder using the USB bridge.	Physiological signals are sent from the patient sensors to the device through the sensor cables. In the recorder the data are stored in flash memory in both attended and unattended studies. During attended studies, the data is also transmitted to a computer wireless (Bluetooth) interface. After unattended studies, data can be downloaded from the recorder using the Bluetooth connection	Physiological signals are sent from the patient sensors to the yoke through the sensor cables. The yoke sends the data to the recorder where the data is stored in flash memory in both attended and unattended studies. During attended studies, the data is also transmitted to a computer in real-time via a Ethernet LAN connection. After unattended studies, data can be downloaded from the recorder using the LAN connection	Physiological signals are sent from the patient sensors to the yoke through the sensor cables. The yoke sends the data to the recorder where the data is stored in flash memory in both attended and unattended studies. During attended studies, the data is also transmitted to a computer in real-time via a USB cable. After unattended studies, data can be downloaded from the recorder using a USB cable.
Operator Interface	LCD Display	LCD Display	LCD Display	LCD Display
Microprocessor	TMS320UC5409	Unknown	Unknown	TMS320UC5402

Product Characteristic	***BEmicro (Trea)*** ***Submission device***	***Track-it*** ***(Predicate Device)***	***Netlink Traveler*** ***(Predicate Device)***	***Sandman Pocket*** ***(Predicate device)***
A/D Resolution	16 bit	16 bits	18 bit	16 bit
Data Storing	On internal NAND flash chip	PCMCIA type II Compact flash card	Compact flash memory	On internal NAND flash chip
Data compression	No	No	Yes	No
Configuration	Wearable	Wearable	Wearable	Wearable
Sensors	Commercially available sensors only	Commercially available sensors only	Commercially available sensors only	Commercially available sensors only
Maximum number of channels	21	36	36	22
Derived channel	Pulse Transit Time (PTT) – A calculation of the time between the occurrence of the R-wave on the EKG and 50% ascending slope on the plethysmogram. Heart rate – Derived from the ECG channel	Heart rate – Derived from the ECG channel	Heart rate – Derived from the ECG channel	Pulse Transit Time (PTT) – A calculation of the time between the occurrence of the R-wave on the EKG and 50% ascending slope on the plethysmogram. Heart rate – Derived from the ECG channel
Oximetry (option)	Yes	Yes	Yes	Yes
Sampling rate	Up to 2048 samples/s	1-256 sample/s selectable	256, 512 samples/s	up to 2048 samples/s

Product Characteristic	***BEmicro (Trea)*** ***Submission device***	***Track-it*** ***(Predicate Device)***	***Netlink Traveler*** ***(Predicate Device)***	***Sandman Pocket*** ***(Predicate device)***
Passbands	0.5 – 128 Hz	0.16 – 70 Hz	0.1 – 100 Hz	0.1 – 256Hz 0.1 – 64 Hz DC – 10 Hz (depending on channel type)
CMRR	>100 dB	>100 dB	>100 dB	>100 dB
Impedance check	Yes	Yes	Yes	Yes
Safety	Device complies with the International Standard IEC 60601-1 IEC 60601-1-4 IEC 60601-1-26 CSA C22.2 No 601.1-M90 UL STD No 60601-1	Unknown	Device complies with the International Standard IEC 601-1 UL 2601 UL 60601 CSA C22.2 No 601-1	Device complies with the International Standard IEC 60601-1 IEC 60601-1-4 IEC 60601-1-26 CSA C22.2 No 601-1-M90 UL 2601

Product Characteristic	***BEmicro (Trea)*** ***Submission device***	***Track-it*** ***(Predicate Device)***	***Netlink Traveler*** ***(Predicate Device)***	***Sandman Pocket*** ***(Predicate device)***
Electromagnetic Compatibility (EMC)	Device complies with the International Standard IEC 60601-1- 2, including the following standards: IEC 61000-3-2 IEC 61000-3-3 IEC 61000-4-2 IEC 61000-4-3, IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-8 IEC 61000-4-11 EN55011 class B EN55014-1	Unknown	Unknown	Device complies with the International Standard IEC 60601-1- 2, including the following standards: IEC 61000-3-2 IEC 61000-3-3 IEC 61000-4-2 IEC 61000-4-3, IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-8 IEC 61000-4-11 EN55011 class B EN55014-1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

EB Neuro S.P.A.
c/o Ms. Jamie L. Austin, RAC
The Anson Group, LLC
11460 North Meridian Street, Suite 150
Carmel, IN 46032

APR 29 2010

Re: K093728
Trade/Device Name: BE Micro Trea
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLV, GWQ, GWL, MNR, and DQA
Dated: March 22, 2010
Received: March 24, 2010

Dear Ms. Austin:

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,

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

Indications for Use

510(k) Number (if known): K093728

Device Name: BE micro (Trea – OEM version)

Indications For Use:

BE micro/Trea intended use is collecting and recording physiological data to be used in neurology (EEG), polysomnography (PSG) and sleep disorder studies. The BE micro is intended for pediatric to adult population, and can be used either home or hospital environments

The BE micro/Trea is only to be used under the direction or supervision of a physician, or other trained health care professional.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

KRISTEN BOWSHER

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K093728