NOV 25 1998

K983913

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SECTION 2: SUMMARY AND CERTIFICATION

510(K) SUMMARY

Safety and effectiveness information concerning the Bio-logic Sleepscan product and this Software modification is summarized below.

Because this is not a CLASS III device, the special certification defined for this section is not required.

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CONTACT PERSON: Norman E. Brunner

DATE ON WHICH THE SUMMARY WAS PREPARED: October 30, 1998

NAME OF DEVICE: Bio-logic Sleepscan.

COMMON NAME: Polysomnography System.

CLASSIFICATION NAME: Conditioner, Signal, Physiological (per CFR 882.1845).

PREDICATE DEVICE: Bio-logic Sleepscan, reference 510(k) #K894155.

DESCRIPTION OF THE DEVICE:

The Bio-logic Sleepscan family of products is intended to be used for the recording and analysis of human physiological data for the purpose of diagnosis and treatment of Sleep-related disorders. The predicate device referenced above was the first such system marketed by Bio-logic. Other related devices comprising the Sleepscan family include:

1. 510(k) #K930790 - Addition of Oximeter to Sleepscan Product.
2. 510(k) #K964132 - Modification to Bio-logic Sleepscan product with Built-in Oximeter.
3. 510(k) #K971501 - Sleepscan Airflow Pressure Transducer.

The predicate device performs both Sleep recording and analysis functions, providing up to 40 channels of simultaneous data recording from a variety of sensors and transducers, and a number of specialized analysis functions including event highlighting and Sleep stage identification. Related Device #1 above is a recording hardware modification to Bio-logic's standard 32-channel EEG recording system, incorporating a built-in Oximeter module and DC channels specifically designed for Sleep recordings. Related Device #2 above is another recording hardware modification, this one based on the Bio-logic "Ceegraph Traveler" (510(k) #K954954) device. Also incorporating a built-in oximeter, this is a smaller battery-operated device offering fewer recording channels at a lower price. Related Device #3 above is a very sensitive transducer for the recording of airflow associated with breathing, based on the measurement of air pressure variations instead of the more indirect method using temperature measurements.

Throughout the history of the Sleepscan product, from the introduction of the predicate device to the present, all Sleepscan software has been developed and based on the Microsoft MS-DOS Operating System. This new Special 510(k) is for the Device Modification of Sleepscan software, the primary new feature being the use of the Microsoft Windows Operating System. As such, although most of the standard Sleepscan functions are very similar to those used in the DOS version, much of the User Interface and presentation of graphical data is now performed using Windows-standard Graphical User Interface (GUI) methods. This 510(k) does not cover the recording functions of the Sleepscan family, which are defined in the predicate device and Related Devices #1 and #2 above. Data recording may be performed using any of the Bio-logic approved-for-market Sleepscan and Ceegraph recording devices with the associated recording software. Any recordings made for the diagnosis and treatment of Sleep disorders can be analyzed with either the existing DOS-based software or the new Windows-based software. This latter software package is the subject of this 510(k).

Most of the functional features of the Bio-logic Sleepscan for Windows software package are similar to those of the predicate device. These include:

- Graphical presentation of the "raw data" as recorded by one of the recording devices.
- Epoch-based data scaling to simulate paper recordings.
- Variable time scaling of data (simulating a variety of "paper speeds") and variable epoch sizes for detailed or summary viewing.
- Rapid report generation based on operator review and interaction with the data presented by the Analysis software.
- Several summary graphs allow for the display of the complete night's Sleep recording on one screen, allowing the user to quickly identify periods of the study requiring closer scrutiny.
- Graphical Overlay with Zoom-In allows the user to quickly look at "interesting" periods of a night's Sleep recording at the raw data level.
- User-defined montages and comments.
- Screen presentations can be customized to display several different kinds of data in separate windows at the same time.
- Data analysis is performed on specific channels of raw data for the identification of possible respiratory or neurological events.
- Color-coded events highlight areas of the data for further review by the technologist or physician.
- Computer–assisted highlighting of data events can be easily modified or deleted by the user, and new events not highlighted by the program can be added at the user's discretion.

New features in the Windows-based software include:

- Standard Windows GUI functionality.
- Extensive On-line Help.
- More extensive and user-configurable reporting features.
- Patient database information features.
- Enhanced sleep stage scoring features.

INTENDED USE: The Bio-logic Sleepscan product family is intended 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. Sleepscan Analysis performs calculations and presents recorded data in various ways on the computer screen and in reports. The Analysis features in the Sleepscan product are intended to be performed without patient hookup being necessary, and may even be performed on a different computer system from that which was used for the patient recording.

It can be used for patients of all ages, from children to adults, including geriatric patients. The use of the Sleepscan family of products is to be performed under the prescription and supervision of a physician or other trained health care professional.

The primary feature modification represented in this Special 510(k) is for the use of the Microsoft Windows operating system and its associated user interface functionality.

SAFETY AND EFFECTIVENESS SUMMARY

To establish the safety and effectiveness of the Sleepscan for Windows software, the system was designed in accordance with the Bio-logic internal Product Development procedures which meet ISO-9001 and FDA QSR Design Control specifications. A detailed Hazard/Risk analysis was performed using the Fault Tree analysis (FTA) approach, and a detailed Risk Assessment was written in accordance with EN-1441, the International Standard for Hazard/Risk analysis.

Because this modification to Sleepscan consists of only software and there is no patient connection required, there are no hardware-related methods by which the patient can be harmed or injured through the use of this device. In addition, although extensive signal analysis and computer-assistance is provided to the user in the form of event identification and data highlighting, the program does not make any final decisions that result in any automatic forms of diagnosis or treatment. All program "recommendations" are subject to review by the Sleep Technologist or Physician, and may be modified, overridden or deleted as determined by a qualified user. The program provides extensive functionality to allow the qualified user to review all raw data collected, create and highlight new and/or custom events, and otherwise customize the data analysis to suit his or her requirements.

The following comparison is provided as a summary of technological characteristics relative to the predicate Sleepscan device. This is to demonstrate that this new modification to the Sleepscan program has no significant differences which would adversely affect product safety and effectiveness.

Parameter for comparison	Similarity or Difference
Intended Use	No differences.
Population	No differences.
Hardware Configuration	There is no patient-connected hardware required. The predicate device was designed to work on 386-based computers, whereas this modification is recommended for use with Pentium computers.
Computer Control Software	The predicate device is DOS-based, whereas the new modified device uses the Windows operating system.
Patient database.	The predicate device provides for only the basic patient demographic information. The modified device has extensive database functionality which allows the user to search, sort and create custom reports.
On-line Help system.	The predicate device has no significant Instructions for Use built into the program, instead relying on the use of a comprehensive User's Manual. The Windows program provides a simple User Manual and an extensive On-Line Help Instruction built into the Windows program.
Performance	No differences.
Safety Characteristics	No differences. There is no required direct electrical connection to the patient for Sleepscan Analysis.

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

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APR - 9 2012

Re: K983913
Trade/Device Name: BIO-LOGIC SLEEPSCAN
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLV
Dated (Date on orig SE ltr): October 30, 1998
Received (Date on orig SE ltr): November 4, 1998

Dear Mr. Brunner:

This letter corrects our substantially equivalent letter of November 25, 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): K983913 ~~Not Assigned~~

Device Name: Modification to Bio-logic Sleepscan

Indications For Use:

The Bio-logic Sleepscan product family 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. Sleepscan Analysis performs calculations and presents recorded data in various ways on the computer screen and in reports. The Analysis features in the Sleepscan product are intended to be performed without patient hookup being necessary, and may even be performed on a different computer system from that which was used for the patient recording.

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(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 K983913

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

(Optional Format 1-2-96)