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SECTION 2: SUMMARY AND CERTIFICATION

510(K) SUMMARY

SAFETY AND EFFECTIVENESS SUMMARY

Safety and effectiveness information concerning the Modification to the Bio-logic Sleepscan product with Built-In Oximeter 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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DATE ON WHICH THE SUMMARY WAS PREPARED:	May 24, 1996
NAME OF DEVICE:	Modification to the Bio-logic Sleepscan product with Built-In Oximeter.
COMMON NAME:	Sleep and EEG Recorder
CLASSIFICATION NAME:	Electroencephalograph (per CFR 882.1400). — Class II
PREDICATE DEVICES:	Bio-logic Sleepscan with Internal Oximeter (K930790) Bio-logic CEEGRAPH TRAVELER Ambulatory EEG Recorder (K954954)

DESCRIPTION OF THE DEVICE:

This Modification to the Bio-logic Sleepscan product with Internal Oximeter (Sleepscan Recorder) consists of a newly-designed hardware device for data recording. It is intended to complement the predicate device hardware in the Bio-logic Sleepscan product line, offering new features which enhance ease-of-use and transportability. The design of this new device is nearly identical to that of the Bio-logic CEEGRAPH TRAVELER (tm) Ambulatory EEG Recorder (K954954), in that it provides for the data collection and storage of up to 24 channels of patient data in a digital form. The only significant difference in the design of these two devices is that the Sleepscan device includes the addition of an internal oximeter made by NONIN, Inc. The oximeter provides heartrate and blood oxygen level data to the Bio-logic data recording electronics, and this data is recorded along with the other patient data (EEG, body position, etc.). After the recording is completed, it can be analyzed using the existing Sleepscan (tm) analysis system, since the data file format is compatible with that employed in current Bio-logic Sleepscan equipment. It provides an improvement in data recording capacity through the use of the Bio-logic proprietary lossless data compression technique (SMART-PACK). This allows for the storage of up to 12 hours of typical Sleep patient data (EEG, oximetry, etc.) onto a single high-capacity PCMCIA hard disk. Power for the device is supplied by batteries inside the unit. Patient setup is accomplished by connecting the Sleepscan Recorder through an isolated serial link to a computer system running the patient setup program. After the electrodes are attached to the patient and other setup functions are completed (ie, impedance and calibration), the computer is disconnected, the Recorder is closed up, and it is placed close to the patient bedside for the duration of the Sleep recording. All setup functions, including periodic replacement of hard disk and batteries, must be performed by a qualified health care professional trained in the use of this product.

The Sleepscan Recorder is housed in a 2-part enclosure made of high-strength ULTEM 1000 plastic. This material was selected due to its high impact strength over a wide temperature range, resistance to alcohol, acetone and other chemicals, and non-flammability. The size of the enclosure is approximately 4.9" W x 6.4" L x 2.35" H (115 mm x 150 mm x 55 mm). The total weight with hard disk and batteries installed is approximately 2.1 lb (955 g). When closed, the Recorder is water-resistant, conforming to the IEC 529 IPX4 Splash-Proof specification.

The initial patient setup of the Sleepscan Recorder is accomplished through the connection of a computer system running the Sleepscan patient setup program. This connection is made between the serial port on the Recorder and a serial port on the computer system. When the computer used is a battery operated laptop, the connection is made via a standard "null modem" cable. If an AC-powered desktop computer is used, the connection to the Recorder must be made through the serial cable isolation device which provides for proper patient isolation.

There is a 62-pin cable connector on the Recorder which is used to connect to the patient electrodes and sensors. A variety of these cable-electrode assemblies are available, depending on the specific collection montage being used. The Recorder automatically senses which montage cable is in use, and records this in the data file

being recorded. Recording of patient data starts at a pre-specified time defined at setup. The ending time is also specified, or the recording will stop when the montage (electrode) cable is unpluged from the unit.

After the Sleep Recording period has been completed (typically 8 hours), the PCMCIA hard disk containing the patient data is analyzed using the standard Bio-logic Sleepscan Analysis programs. The data is first decompressed and transferred to a file format identical to that used by the predicate Sleepscan with Oximeter device. All analysis functions currently used in existing Bio-logic Sleepscan systems are available to use in the analysis of the data from the Sleepscan Recorder.

INTENDED USE:

The Bio-logic Sleepscan Product is intended for use when it is necessary for a trained health care professional (for example, a Respiratory or EEG Technologist) to perform a Sleep diagnostic study on a patient with a possible Sleep disorder. This test consists of monitoring and recording various electrical signals from the patient, such as EEG signals from the brain, EOG, respiratory signals from transducers which measure air flow, effort, etc., arm and leg movement, body position while sleeping, pulse rate, and level of oxygen in the blood. Analysis features of the Sleepscan product allow for manipulation and presentation of this data in ways which enhance the physician's ability to reach informed diagnostic decisions quickly and efficiently. Although the addition of an internal oximeter does not, in itself, add to the features or capabilities of the Sleepscan product, it provides a simplification in hardware design which results in faster patient setup with fewer potential errors in setup. This latest modification to the Sleepscan product with Built-In Oximeter does not introduce any changes to the intended use of the product.

Sleepscan with Built-In Oximeter can be used for patients of all ages, although most Sleep disorders occur in adults. The equipment does not provide alarms and cannot be used as an automated apnea monitor.

PATIENT POPULATION: The Sleepscan Recorder can be used for any patient who is a candidate for sleep diagnostic evaluation. This will typically be an adult population, but it can be used for patients of all ages.

SAFETY AND EFFECTIVENESS:

In the normal operation of the Sleepscan Recorder with Internal Oximeter, the power source is only from the internal batteries, and no voltage inside the unit is greater than 9 Volts DC. DC signals from externally-powered transducers used in routine Sleep patient recordings can be connected to the Recorder through the serial cable isolation device. Therefore, there is no danger to the patient of serious injury due to electrical shock.

During patient setup, the Sleepscan Recorder is connected to the computer running the Sleepscan patient setup software through a standard RS-232 serial data communications link. There are two types of computer which can be used for this purpose.

1. If the computer is a battery-powered laptop with no connection to the AC line source, and no externally-powered transducers are used, there is no voltage present in the system which can inflict serious harm to the patient, so no special patient isolation is required.

2. If the computer is an AC-powered system, such as a desktop unit, the serial cable isolation device is required to be used. This device provides optical isolation of all wires in the cable, up to 2500 Volts RMS.

Because of the low-voltage and isolated nature of the hardware design, there are no failure modes in the Sleepscan Recorder software which can cause the hardware to cause injury to the patient. The overall unit is designed to withstand the electrical environments found in typical clinical, office and home use situations, such as interference from other electrical devices and static electricity.

In the event that a failure occurs in normal software operation, either because of a latent design defect or externally-caused, a "watchdog timer" circuit is included in the hardware design. When the software is properly functioning, it periodically resets the timer before it times out, so that under proper operation it will never time out. If the software fails to perform correctly, this reset will not occur, and the timer will time out, causing a general reset to the microprocessor system which acts the same as a start from power up. This effectively prevents a "runaway software" condition of unknown consequences.

Laboratory testing was performed on the Sleepscan Recorder with Internal Oximeter to verify proper operation with respect to EMI and ESD standards. The following testing was performed, with satisfactory results:

Electromagnetic Compatibility:

Radiated Emissions	CISPR 11 / EN55011
Electrostatic Discharge Immunity:	IEC 801-2
Radiated RF Immunity:	IEC 801-3
Magnetic Fields Emissions:	RE101
Magnetic Field Immunity:	RS101
Quasi-Static Electric Fields:	Tested per Reviewer's Guide

To establish the safety and effectiveness of the software which controls the Sleepscan Recorder with Internal Oximeter, the system was validated in accordance with the IEEE Standards for Software Engineering, as well as Bio-logic internal software development policies and procedures modeled after the IEEE Standards. The program in the Sleepscan Recorder, the patient setup program necessary to accommodate the communication to and setup of the unit, and the data decompression/transfer program, were all developed and tested as specified in these procedures. The system, for which this 510(k) notification is submitted, was verified and validated; it was found to perform in accordance with specifications.

The following comparison is provided as a summary of technological characteristics relative to the predicate device (Bio-logic Sleepscan with Oximeter (K930790). This is to demonstrate that this Sleepscan Recorder with Oximeter Modification 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.
Storage Sample Rate	Predicate device: 256 Hz. Subject device: 256 Hz.
Size and weight	The predicate device is over twice as large and weighs considerably more.
Internal oximeter	The internal oximeter in the predicate device is made by Ohmeda. The oximeter in the subject device is made by Nonin, Inc.
Number of Channels	Predicate device:32 channels. Subject device: 24 channels.
Electrode Connection	Predicate device uses touchproof pin connectors for electrodes. Subject device does not use individual pins for electrode connections.
Power source.	Predicate device receives power through cable connected to the computer interface board. Subject device is battery-operated.
Safety Characteristics	Both devices provide for patient isolation and are designed to meet applicable international safety and EMC standards.