OCT 1 4 1997

Bio-logic SYSTEMS CORP One Bio-logic Plaza Mundelein, Illinois 60060-3700 1-800-323-8326 Fax: 847-949-8615

SECTION 2: SUMMARY AND CERTIFICATION

510(K) SUMMARY

SAFETY AND EFFECTIVENESS SUMMARY

Safety and effectiveness information concerning this Airflow Sensor device is summarized below.

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

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: April 23, 1997

NAME OF DEVICE: Bio-logic SLEEPSCAN Airflow Pressure Transducer.

COMMON NAME: Respiration Monitor.

CLASSIFICATION NAME: Breathing Frequency Monitor (per CFR 868.1860)

PREDICATE DEVICE: Cannula-Style Thermocouple Airflow Sensor, Pro-Tech, Inc.. 510(k) #K913396.

DESCRIPTION OF THE DEVICE:

The Bio-logic Airflow Pressure Transducer is a small interface device which converts low levels of air pressure to corresponding low levels of voltage which can be recorded on any physiological recorder intended to record low-level electrical signals. There is one pneumatic input for air pressure, and one set of electrical outputs representing the electrical equivalent of the pressure. These electrical outputs are: ACT (the active or positive output), REF (the reference or negative output), and COM (the electrical common). Within the device itself, the REF and COM are connected together. However, three leads are brought out for connection to a physiological recorder (such as the Bio-logic Sleepscan product), so the ACT and REF can be inputs to a differential amplifier, and COM can be connected to the system common.

For the airflow pressure input, this device uses a disposable nasal cannula which attaches to the patient and connects to the pressure input labeled "NASAL CANNULA". The electrical outputs connect to the corresponding AC-coupled inputs of the system's patient connection module. For the Bio-logic Sleepscan system, the connection is made to one of the bipolar input channels on the electrode jack box labeled IN1(A) & IN2(R), for ACT and REF respectively. The COM is connected to the common jack on the headbox. The jacks on both the interface device and the electrode jack box are 1.5mm "safety" jacks, and the electrical connections are made with a reusable wire set with "safety" plugs on both ends.

This device consists of a two-part plastic enclosure measuring approximately 105 x 58 x 18.5 cm. The material is a composite of ABS and PMMA, color off-white. It is battery powered with two standard 1.5v AAA cells. The estimated battery life is 100 hours, and an on-off switch is provided for conserving battery life when the unit is not in use. Batteries can be replaced by removing two screws on the battery compartment of the unit.

INTENDED USE:

The Bio-logic Airflow Pressure Transducer is intended for use in sleep disorder studies to detect respiratory airflow for recording onto a physiological recorder. It is battery-powered, using a single-use, disposable nasal cannula which attaches to the patient and plugs into the input of the Airflow Pressure Transducer device. The cannula cannot be adequately cleaned for re-use. The outputs of the device provide low-level electrical signals for input to a physiological recorder (such as the Bio-logic Sleepscan product).

PATIENT POPULATION:

The Bio-logic Airflow Pressure Transducer can be used to monitor respiration 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:

The maximum voltage within the Bio-logic Airflow Pressure Transducer is 3 volts DC, based on the use of two 1.5 volt AAA batteries connected in series. There is no direct electrical connection to the patient, since the airflow pressure input uses an approved nasal cannula made of non-conducting plastic. The maximum output voltage is +/- 150 mV, with an output signal range corresponding to normal breathing of +/- 1 mV. Therefore, there is no danger to the patient of serious injury due to electrical shock.

Laboratory testing has been performed using this device in place of the predicate device for respiratory airflow monitoring. These tests conclude that the electrical signals recorded using the Bio-logic Airflow Pressure Transducer provide equivalent informational content to the signals recorded using the predicate device. In some instances, the specifications for the Airflow Pressure Transducer exceed those of the predicate device. These areas are clarified in more detail in the following section.

The following comparison is provided as a summary of technological characteristics relative to the predicate device. This is to demonstrate that the Bio-logic Airflow Pressure Transducer has no significant differences from the predicate device which would adversely affect product safety and effectiveness.

Parameter for Comparison	Similarity or Difference
Intended Use	No differences.
Population	No differences.
Power Source	This device uses 2 AAA batteries. The predicate device does not require batteries.
Number of Channels	This device provides one input channel; the predicate device provides two.
Method of Connection to Patient	This device uses a plastic tubing and cannula set for patient connection. There are no wires or other metal parts connected to the patient. The predicate device sensor assembly also attaches to the patient in a manner similar to a cannula.
Safety Characteristics	Both devices provide for patient isolation because there is no direct connection of wires to the patient in either case. The predicate device uses an insulated thermocouple assembly; the subject device uses plastic tubing. Both devices connect to the Sleepscan patient connection module using approved safety jacks.
Re-use Restrictions	Cleaning and disinfecting procedures are required for reuse of the thermocouple predicate device. The subject device is for single-use only.
Sensor Technology	The subject device uses a solid-state pressure transducer which converts small changes in air pressure into small voltage changes. The predicate device uses an electrical thermocouple which converts temperature changes caused by the airflow into small voltage changes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 1997

Mr. Norman E. Brunner
Bio-Logic Systems Corporation
One Bio-logic Plaza
Mundelein, Illinois 60060-3700

Re: K971501
Bio-logic Airflow Pressure Transducer
Regulatory Class: II (two)
Product Code: 73 MNR
Dated: July 17, 1997
Received: July 18, 1997

Dear Mr. Brunner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Not Assigned

Device Name: BIO-LOGIC AIRFLOW PRESSURE TRANSDUCER FOR SLEEPSCAN PRODUCT

Indications For Use:

The Bio-logic Airflow Pressure Transducer is indicated for use during sleep disorder studies to detect respiratory airflow for recording onto a physiological recorder. It is a battery-powered device, with a disposable nasal cannula which attaches to the patient and plugs into the input of the Airflow Pressure Transducer device. The outputs of the device provide low-level voltage signals which are intended to be input to a physiological recorder (such as the Bio-logic Sleepscan product).

It can be used for patients of all ages, from newborn infants through adults, to and including geriatric patients.

(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 Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K971501

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

(Optional Format 1-2-96)