JUL 13 1998

PRO-TECH
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ISO 9001 CERTIFIED
REGISTERED FIRM
FM 39012

K982293

SUMMARY AND CERTIFICATION

510(K) SUMMARY

SAFETY AND EFFECTIVENESS SUMMARY

Safety and Effectiveness information concerning this Airflow Sensor is summarized below.

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

PREPARED BY: Pro-Tech Services, Inc.
12826 NE 178th Street
Suite A
Woodinville, WA 98072

TELEPHONE: (425) 481-5452

CONTACT PERSON: Anthony Zaragoza

DATE ON WHICH THE SUMMARY WAS PREPARED: July 9, 1998

NAME OF DEVICE: Pressure Transducer Airflow Sensor

COMMON NAME: Airflow Sensor

CLASSIFICATION NAME: Breathing Frequency Monitor (per CFR 868.1860)

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

DESCRIPTION OF THE DEVICE:

The Pressure Transducer Airflow Sensor 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: the active or positive output and the reference or negative output.

This device uses a disposable nasal cannula that attaches to the patient and connects to the pressure input labeled ""INPUT". The electrical outputs connect to the corresponding AC-coupled inputs of the system's patient connection module typically the bipolar input channels of an electrode jack box. The output jack on the interface device is a modular 4-pin jack. Electrical connections are made with 1.5mm "safety" connectors.

The device consists of a two-part plastic enclosure measuring approximately 7cm(W) x 12.5cm(L) x 2.5cm(H). The material is Cycolac ABS GSM, color light gray. It is battery-powered with one standard 9V alkaline cell. The estimated battery life is 320 hours (40 – eight hour uses), with an on-off switch provided to conserve battery life when not in use. The switch will also indicate a "battery test" that lights an LED indicating at least 8 hours of battery life remaining. Batteries can be replaced by removing the battery cover, removing the battery and inserting a new one in the orientation shown in the battery compartment of the unit.

INTENDED USE:

The Pressure Transducer Airflow Sensor 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 patient use, disposable nasal cannula with a .2 micron hydrophobic filter that attaches to the patient and connects into the input of the Pressure Transducer Airflow Sensor. 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 (EEG, etc.).

PATIENT POPULATION:

The Pressure Transducer Airflow Sensor can be used to monitor the respiration for patients who are candidates for a Sleep Diagnostic evaluation. It can be used for pediatric patients - 2 years and above, and adult patients, to and including geriatric patients. The device is not intended for pediatric and infants below 2 years of age for the purpose of respiration or SIDS monitoring.

SAFETY AND EFFECTIVENESS:

The maximum voltage within the Pressure Transducer Airflow Sensor is 9 Volts DC, based on the use of one 9-Volt battery. 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 in two ranges: ±2.5mV and ±2.5V depending on the users' need. Due to these low-voltages, there is no danger to the patient or provider 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 Pressure Transducer Airflow Sensor provide equivalent informational content to the signals recorded using the predicate device. In some instances, the specifications for the Pressure Transducer Airflow Sensor 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 Pressure Transducer Airflow Sensor has no significant differences from the predicate device that would adversely affect product safety and effectiveness.

COMPARISON PARAMETER	SIMILARITY OR DIFFERENCE
INTENDED USE	NO DIFFERENCE
POPULATION	NO SIGNIFICANT DIFFERENCE
POWER SOURCE	THE DEVICE USES A 9-VOLT BATTERY. THE PREDICATE DEVICE IS SELF-GENERATING
NUMBER OF CHANNELS	THE DEVICE PROVIDES ONE INPUT CHANNEL, THE PREDICATE DEVICE PROVIDES UP TO THREE.
METHOD OF CONNECTION TO PATIENT	THE 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 A PHYSIOLOGICAL RECORDER.
RE-USE RESTRICTIONS	CLEANING AND DISINFECTING PROCEDURES ARE REQUIRED FOR RE-USE OF THE THERMOCOUPLE PREDICATE DEVICE. THE SUBJECT DEVICE IS FOR SINGLE PATIENT USE ONLY.
SENSOR TECHNOLOGY	THE SUBJECT DEVICE USES A SOLID-STATE PRESSURE TRANSDUCER THAT CONVERTS SMALL CHANGES IN AIR PRESSURE INTO SMALL VOLTAGE CHANGES. THE PREDICATE DEVICE USES AN ELECTRICAL THERMOCOUPLE THAT 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

JUL 13 1998

Mr. Anthony Zaragoza
Pro-Tech Services, Inc.
P.O. Box 2165
12826 NE 178th Street, Suite A
Woodinville, WA 98072

Re: K982293
Pressure Transducer Airflow Sensor
Regulatory Class: II (two)
Product Code: 73 MNR
Dated: June 26, 1998
Received: July 1, 1998

Dear Mr. Zaragoza:

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 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). 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/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (If known) **K982293**

Device Name: **PRESSURE TRANSDUCER AIRFLOW SENSOR**

Indications for Use:

The Pressure Transducer Airflow Sensor is indicated for use during sleep disorder studies to detect respiratory airflow onto a physiological recorder. It is a battery –powered device, with a disposable nasal cannula that attaches to the patient and connects into the input of the Pressure Transducer Airflow Sensor device. The outputs of the device provide low-level voltage signals that are intended to be input to a physiological recorder.

It can be used for pediatric patients - 2 years and above, and adult patients, to and including geriatric patients. The device is not intended for pediatric and infants below 2 years of age for the purpose of respiration or SIDS monitoring.

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

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number

Mark Kramer

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

(Optional Format 1-2-96)