K092685

NOV 2 4 2009

SALTER LABS

Special 510K, Summary

Salter Labs
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Contact Person: Terry Newton

August 21, 2009

Name of device: Thermocouple
Trade name: PneumoTherm
Common name: Thermal Airflow Sensor
Classification name: Monitor, Breathing Frequency (21 CFR 868.2375)
Product Code: BZQ

Equivalent Device: K080922 Salter Labs Thermal Airflow Sensor

- Description of device as found in the labeling
  The modified device has a minor construction change from that of the predicate device where a series of connected thermocouples replace a series / parallel connection of thermistors. Both elements are placed at the bridge of the nose to measure the same temperature changes during breathing from each nare and from the mouth. The lower cost thermocouples provide a low-cost single-use replacement for the more expensive thermistor device already cleared.

- Device function
  The thermocouple device functions in the same manner as does the predicate device and that is it detects changes in temperature, corresponding to an exhalation and inhalation of the patient. The goal here is to determine rate of respiration for sleep lab studies.

- Scientific concept
  The scientific concept governing the Thermocouple is called the "Seebeck Effect".

- Physical & Performance characteristics (device design, material used, properties)
  Physically, both devices are small enough to be placed directly in the path of the air stream of the nares and mouth.

From a performance standpoint, where the Thermistor required an interface box to energize the changed resistance to provide a signal, the Thermocouple self-generates a microvolt signal by having dissimilar materials.

- Intended Use:

  The Salter Labs Oral/Nasal Thermal Airflow Sensor is used as a cannula accessory with existing recording devices and data acquisition systems in a sleep laboratory setting to support the diagnostic recording of nasal and/or oral airflow. The subject device itself performs no diagnostic functions, and only supports the diagnostic recording of airflow for use as an accessory component to a polysomnography recorder. The target population is adult and pediatric patients during a sleep study in a sleep laboratory.

- Technological Characteristics compared to predicate device
  The predicate device is a "thermal resistive element" and the Thermocouple is a "Thermal Electric device". Both devices can be said to be a "Thermal responsive device", wherein "RTD" would fall into this category.

Comparison Chart

| Feature | Modified Device | Predicate Device |
|---|---|---|
| Thermal Responsive | Thermocouple | Thermistor |
| Target Holder used on | Same | Salter Cannula Adult and Pediatric Series |
| Patients used on | Adult and Pediatric Currently | Adult, Pediatric and Neonatal |
| Length of use | Disposable | Reusable |
| Need for an interface box | Not Needed | Needed |
| Skin Contact | Intented use is to fit in design Cannula | Intented use is to fit in design Cannula |
| | | |

- Brief description of clinical test and how results support SE
  Clinical Testing was simply down to show that the Thermocouple device was not only sensitive enough to provide an adequate signal on the Test Fixture (which includes a Polysomnograph system) but that it was sensitive and timely enough to record a substantial signal compared to that of other physiological respiratory events.
  Clinically, the device adds no additional adverse effects or complications as did the predicate device, primarily because their structure is similar and both fit in properly designed cannulas.

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- Summary for conclusions drawn from tests that demonstrate the device is safe, effective and performs as well or better as the predicate.
The tests show that the Thermocouple device provides a safe and effective signal.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV 24 2009

Ms. Terry Newton
Manager of Regulatory Affairs/Quality Assurance
Salter Labs
100 West Sycamore Road
Arvin, California 93203-2300

Re: K092685
Trade/Device Name: Thermal Airflow System (PneumoTherm, 5800 Series)
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: BZQ
Dated: October 20, 2009
Received: October 30, 2009

Dear Ms. Newton:

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.

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,

for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K092685

Device Name: Thermal Airflow System (PneumoTherm 5800 Series)

Indications for Use:

The Salter Labs Oral/Nasal Thermal Airflow Sensor is used as a cannula accessory with existing recording devices and data acquisition systems in a sleep laboratory setting to support the diagnostic recording of nasal and/or oral airflow. The subject device itself performs no diagnostic functions, and only supports the diagnostic recording of airflow for use as an accessory component to a polysomnography recorder. The target population is adult and pediatric patients during a sleep study in a sleep laboratory.

Prescription Use Yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

L. Schultheiss

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices



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