6.0 510(k) Summary

JUL 25 2008

Salter Labs Oral/Nasal Thermal Airflow Sensor

510(k) Summary

K080922

Official Contact	Duane Kazal Director Regulatory Affairs and Quality Assurance Salter Labs 100 W. Sycamore Road Arvin, California 93203

Classification Reference	21 CFR 868.2375 Breathing Frequency Monitor
Product Code	BZQ
Proprietary Name	Oral/Nasal Thermal Airflow Sensor
Common Name or Usual Name	Airflow Sensor
Predicate Device	Braebon Medical Corp. Airflow Sensor (K981445)
Reason for Submission	Initial Introduction into Interstate Commerce

Substantial Equivalence

The Salter Labs Oral/Nasal Thermal Airflow Sensor is substantially equivalent to the Braebon Medical Corp. Airflow Sensor for the following reasons:

- Same intended use.
- Same operating principle.
- Same technology.
- Similar manufacturing processes.
- Equivalent performance in all operating ranges.

Description of the Device

The Salter Labs Thermal Airflow Sensor is composed of a Thermistor as the element which changes resistance as airflow from the patient is delivered across the element of the thermistor. The thermistor elements are located directly underneath the nares and in the airflow of the mouth. In both cases the element is kept from touching the skin of the patient in order to be the most effective change in temperature.

The thermistor will be mounted in the Cannula to position the thermistor properly under the nares and in the airflow path of the mouth. The thermistor will be covered with a heat shrink tubing to protect it from moisture from the patient.

The thermistor will require a battery source in order to derive a current flow through the circuit. This battery source will be located in a small container called a signal-conditioning unit. This unit has circuitry that will remove noise, display a smooth signal and is an added feature test for wire continuity.

Intended Use

The Salter Labs 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 patient during a sleep study in a sleep laboratory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Duane Kazal
Director of Regulatory Affairs and Quality Assurance
Salter Labs
100 West Sycamore Road
Arvin, California 93203-2300

JUL 25 2008

Re: K080922
Trade/Device Name: Salter Labs Oral/ Nasal Thermal Airflow Sensor
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: BZQ
Dated: July 17, 2008
Received: July 21, 2008

Dear Mr. Kazal:

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 such 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); 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. This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (K080922)

Device Name: Salter Labs Oral/ Nasal Thermal Airflow Sensor

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 **XX** AND/OR Over-The-Counter Use _____
(Part 21CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MH.

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

510(k) Number: K080922