SEP 15 2005

7.0 510(k) Summary

Salter Labs Bi-NAPS Airflow Pressure Transducer

510(k) Summary

K 05 1313 **(Not yet received)**

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	MNR
Common or Usual Name	Airflow Pressure Transducer
Proprietary Name	BI-NAPS Nasal Airflow and Snore Transducer
Predicate Device	Pro-Tech Pressure Transducer 510(k) #K982293
Reason for Submission	Initial Introduction into Interstate Commerce

Substantial Equivalence

The Salter Labs Airflow Pressure Transducer is substantially equivalent to the Pro-Tech Pressure Transducer 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 Airflow Pressure Transducer is a two output channel device used to acquire respiratory low pressure waves and low air flow that are sensed through a Nasal Cannula typically worn by a subject during a sleep diagnostic session. It is used to convert changes in air pressure and flow, occurring during sleep, into electrical signals that can be measured by polysomnography equipment. The Nasal Cannula directs the airflow and pressure waves generated by breathing and snoring from the nares and mouth of a patient through a luer lock fitting and then into a cup shaped plastic cylinder chamber sealed closed at the open end by a piezo-electric ceramic element. The piezo element, when flexed by the impinging air pressure changes, generates a proportional electric voltage. This voltage is attenuated and filtered by

subsequent passive electronic circuitry composing the sensor. The Salter Labs Airflow Pressure Transducer does not require a power source.

The Salter Labs Airflow Pressure Transducer uses equivalent components and design of existing marketed devices such as Pro-Tech Pressure Transducer Airflow Sensor (K982293). The Salter Labs Airflow Pressure Transducer is designed with equivalent circuitry and parts to that of the predicate device, demonstrates equivalent performance, and is substantially equivalent to it.

Intended Use

The Salter Labs Airflow Pressure Transducer is a reusable device intended for use during sleep disorder studies to detect respiratory airflow and snoring for recording onto a polysomnography recorder via nasal pressure changes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 2005

Mr. Duane Kazal
Director, RA/QA
Salter Labs
100 West Sycamore Road
Arvin, California 93203

Re: K051313
Trade/Device Name: Salter Labs BiNAPS
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: September 8, 2005
Received: September 12, 2005

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 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 (if known): Unknown

Device Name: Salter Labs BiNAPS

Indications for Use:

The Salter Labs BiNAPS Airflow Pressure Transducer is an accessory intended for use with polysomnography equipment during sleep disorder studies for the purpose of detecting and amplifying breathing signals and detection of snoring of a sleeping patient through a Salter Labs nasal cannula.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Posted November 13, 2003)

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

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