DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 15, 2016

Salter Labs
Mara Caler
Director, Regulatory Affairs
2365 Camino Vida Roble
Carlsbad, California 92011

Re: K151874
Trade/Device Name: BiNAPS Nasal Airflow and Snore Transducer;
ThermiSense Oral/Nasal Thermal AirFlow Sensor with Airflow
Pressure Cannulas, Nasal and Oral/Nasal
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR, BZQ
Dated: March 17, 2016
Received: March 18, 2016

Dear Ms. Caler:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

*Tejashri Purohit-Sheth, M.D.*

**Tejashri Purohit-Sheth, M.D.**
**Clinical Deputy Director**
**DAGRID/ODE/CDRH FOR**

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K151874

Device Name
BiNAPS Nasal Airflow Pressure and Snore Transducer
ThermiSense Oral/Nasal Thermal AirFlow Sensor with Airflow Pressure Cannulas, Nasal and Oral/Nasal

Indications for Use *(Describe)*
The BiNAPS Nasal Airflow Pressure and Snore Transducer (using the 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. This device is intended for adult and pediatric (excluding neonatal and infant) use.

The ThermiSense Oral/Nasal Thermal AirFlow Sensor with Airflow Pressure Cannulas, Nasal and Oral/Nasal is a thermal resistive thermistor designed to monitor oral/ nasal thermal airflow temperature and pressure changes during sleep studies. The ThermiSense is intended for use with a nasal cannula and polysomnography headbox or pressure transducers, such as, BiNAPS Nasal Airflow Transducer. This device is intended for adult and pediatric (excluding neonatal and infant) use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807) is provided:

**510 (k) Summary**

**A. Submitter:**

Salter Labs
2365 Camino Vida Robles
Carlsbad, CA 92011
Telephone: 760-795-7094
Fax: 760-683-6797

**B: Contact Person:**

Mara Caler
Director, Regulatory Affairs

**C: Date Prepared:**

13 April 2016

**D. Device Names:**

| Trade Name | Common Name | Classification Name | Product Code |
|---|---|---|---|
| BiNAPS Nasal Airflow Pressure and Snore Transducer | Airflow Pressure Transducer | Ventilatory Effort Recorder | MNR |
| ThermiSense Oral/Nasal Thermal AirFlow Sensor with Airflow Pressure Cannulas, Nasal and Oral/Nasal | Airflow Sensor | Monitor, Breathing Frequency | BZQ |

**Regulation Number:** 868.2375
**Classification:** II
**Classification Panel:** Anaesthesiology

**Predicate Devices:**
This submission demonstrates substantial equivalence to the predicate devices:
K051313, Airflow Pressure Transducer
K080922, Airflow Sensor

## E. Device Descriptions

The Salter Labs BiNAPS Nasal Airflow Pressure and Snore 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 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.

ThermiSense Oral/Nasal Thermal AirFlow Sensor with Airflow Pressure Cannulas, Nasal and Oral/Nasal 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 is mounted in the Cannula to position the thermistor properly under the nares and in the airflow path of the mouth. The Thermistor is covered with a heat shrink tubing to protect it from moisture from the patient. The Thermistor requires a battery source in order to derive a current flow through the circuit. This battery source is 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.

## F. Intended Use

| **Intended / Indications for Use** |
|---|
| The BiNAPS Nasal Airflow Pressure and Snore Transducer (using the 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. This device is intended for adult and pediatric (excluding neonatal and infant) use. |
| The ThermiSense Oral/Nasal Thermal AirFlow Sensor with Airflow Pressure Cannulas, Nasal and Oral/Nasal is a thermal resistive thermistor designed to monitor oral/nasal thermal airflow temperature and pressure changes during sleep studies. The ThermiSense Oral/Nasal Thermal AirFlow Sensor with Airflow Pressure Cannulas, Nasal and Oral/Nasal is intended for use with a nasal cannula and polysomnography headbox or pressure transducers, such as, BiNAPS Nasal Airflow Pressure and Snore Transducer. This device is intended for adult and pediatric (excluding neonatal and infant) use. |

**G. Substantial Equivalence Table:**

Comparison of Technological Characteristics with the Predicate Device

The proposed BiNAPS Nasal Airflow Pressure and Snore Transducer and ThermiSense Oral/Nasal Thermal AirFlow Sensor with Airflow Pressure Cannulas, Nasal and Oral/Nasal are substantially equivalent to the predicate devices.

| Characteristic | Predicate device | Modified device |
|---|---|---|
| Intended use | The BiNAPS Nasal Airflow Pressure and Snore 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.<br><br>The ThermiSense Oral/Nasal Thermal AirFlow Sensor with Airflow Pressure Cannulas, Nasal and Oral/Nasal 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. | Unchanged |
| Intended use population | Patients undergoing sleep diagnosis studies | Unchanged |
| Principles of operation | The detection and amplification of breathing signals and detection of snoring of a sleeping patient through a Salter Labs nasal cannula. | Unchanged |
| Airflow output | Output is a nasal pressure airflow waveform. Output is connected to a polygraph's AC jackbox with 1.5mm safety connectors. Snoring can also be superimposed onto the airflow waveform as shown in the example on the next page. This is accomplished by setting higher values for the high frequency filter and the sampling rate for the airflow channel. | Unchanged |
| Snore output | Output is a snoring waveform derived from | Unchanged |

| Characteristic | Predicate device | Modified device |
|---|---|---|
| | snore vibrations on the nasal pressure signal. The channel has internal low frequency filter to remove the airflow signal and to provide a flat baseline between snores. Output is connected to a polygraph's AC jackbox with 1.5mm safety connectors. | |
| Clinical setting | Prescription use sleep diagnosis study | Unchanged |
| Device characteristics | Non-sterile | Unchanged |

The only difference between the modified BiNAPS Nasal Airflow Pressure and Snore Transducer and the modified ThermiSense Oral/Nasal Thermal AirFlow Sensor with Airflow Pressure Cannulas, Nasal and Oral/Nasal and predicate devices is a material modification used in the cannulas from PVC (DEHP and DIDP) to (DINCH and DOPT). The materials used in the remainder of the devices are unchanged.

| **Features** | **Predicate Airflow Pressure Transducer & Airflow Sensor** | **Modified Airflow Pressure Transducer & modified Airflow Sensor** | **Performance Testing** |
|---|---|---|---|
| Material Formulation | PVC, DIDP | PVC, DINCH | Biocompatibility and Performance |
| | PVC, DEHP | PVC, DOTP | |

## H. Performance Data

The BiNAPS Nasal Airflow Pressure and Snore Transducer and the ThermiSense Oral/Nasal Thermal AirFlow Sensor with Airflow Pressure Cannulas, Nasal and Oral/Nasal were tested to verify that the new material bond and performance characteristics of flow rate, back pressure, and tubing bond strength did not impact the strength or performance of the modified Airflo w Pressure Transducer and the modified Airflow Sensor after the material change.

The test results demonstrate that the BiNAPS Nasal Airflow Pressure and Snore Transducer and the ThermiSense Oral/Nasal Thermal AirFlow Sensor with Airflow Pressure Cannulas, Nasal and Oral/Nasal are substantially equivalent to the predicate devices

**Performance Testing Summary**

| Criteria | Predicate specifications | Modified devices | Comments |
|---|---|---|---|
| Back pressure (flow rates): | Shall not have a back pressure that exceeds 3 psi at a maximum flow rate in ambient of 5°C, 20°C, and 40°C. | Maximum back pressure was found to be less than 2 psi. | The modified devices passed all specifications |
| Bond Strength (tensile strength): | The bonded components of the set will have a bond strength that is ≥ 2 lbs. when pulled at a rate of 5 inches per minute. | The bond strength test achieved over 2 times the minimum allowable value. | The modified devices passed all specifications |
| Device dimensions: | Unchanged. | Unchanged. | The modified devices use the same molds and are unchanged from the predicate devices |
| Aging (shelf life) | Not included | 3 years | The modified devices meet all specifications at the 3 year test point |

The modified Sleep Diagnostics Cannulas meet established Salter Labs performance specifications.

| Characteristic | Predicate | New Device | Result |
|---|---|---|---|
| *Performance* | | | |
| Sampling flow rate (max) | .5 lpm | .5 lpm | Same |
| Sampling backpressure @ max flow | < .64 psi | < .64 psi | Same |

## I. Clinical / Non-Clinical

No clinical patient testing was required for this submission.

The following biocompatibility testing was performed. The materials passed all parameters:

- Irritation
- Sensitization
- Cytotoxicity

## J. Conclusions

The BiNAPS Nasal Airflow Pressure and Snore Transducer and the ThermiSense Oral/Nasal Thermal AirFlow Sensor with Airflow Pressure Cannulas, Nasal and Oral/Nasal data and test results demonstrate that the devices are substantially equivalent to the predicate devices.