K971184

APPENDIX 3

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Contact Name:
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March 28, 1997

OCT - 1 1997

510(k) Summary of Safety and Effectiveness

1. **Identification of the Device**
Proprietary-Trade Name: "Oxi-Snap"
Classification Name: Apnea/Snoring Recording and Analysis Device and Oximeter.
Common/Usual Name: Snoring and Apnea Recording and Analysis Device.

2. **Equivalent legally marketed devices** This product is similar in design and function to the "Snap Testing Device" K944524, and incorporates a Pulse Oximeter, Palco Model 305, K943842 and "Mesam IV device" K901466.

3. **Indications for Use:** The intended use of the "Oxi-Snap" device is to screen patients for apnea and snoring and to provide quantitative and qualitative analysis of apnea and snoring.

   The Oxi-SNAP testing system is only intended for short term monitoring such as to record the oximetry level continuously during the night.

   The "Oxi-SNAP" system is not intended as a substitute for full polysomnography when additional parameters such as sleep stages, limb movements or EEG activity are required.

   The target population is patients who are suspected of apnea and/or complain about snoring. The majority of the screenings are going to take place at the patient's home, although some may take place in a sleep laboratory. Both pediatric and adult patients may be tested.

4. **Description of the Device:** This notification is for a modification to the existing device, the "Snap Testing Device" the modified device is called the "Oxi-Snap" The modification involves the addition of the ability to record and analyze, (along with snoring sounds) the oxygen saturation level of the patient being monitored. An FDA cleared oximeter (Palco Model 305, K943842) is connected to the currently used DAT tape recorder, and the oxygen saturation is recorded while the patient is under test. Later, during the analysis phase, O2 SAT levels appear on the playback analysis screen, thereby allowing an additional criterion of apnea to be used.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and user testing indicates that the modified device is as safe and effective as the predicate device and provides the additional benefit of giving the clinician more information about the patient's snoring and apnea condition. The additional information is the patient's oxygen saturation level. The modified device is easy for the user to set up at home or in the sleep laboratory. The modification involves the addition of a portable oximeter to the patient setup. The oximeter is connected to the DAT tape recorder along with the usual microphone/cannula apparatus and the oximeter sensor is slipped over the patient's finger in the usual manner. The patient turns on the tape recorder, then goes to sleep. Apnea and snoring events are then recorded. After awakening, the patient returns the tape and the equipment to the analysis service center, where the tape is analyzed.

6. Substantial Equivalence Chart - Appendix 2

7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of SNAP Laboratories that the "Oxi-Snap" testing snoring and apnea testing device is as safe and effective as the predicate device and has no new indications for use, thus rendering it substantially equivalent to the predicate Snap Testing Device.

Substantial Equivalence Chart

Characteristic	Predicate device: SNAP testing device (K944524)	Modified device: "Oxi-SNAP"	Palco (k943842)	Mesam IV (K901466)
Labeling:	(Original submission)	The User's manual has been updated to include a description of the oximetry device	Oximetry diagnostics	Apnea & Snoring Diagnostics
Intended Use:	Recording and analysis of snoring and apnea	Recording and analysis of snoring and apnea	Recording & Analysis of oximetry	Recording and analysis of snoring & apnea
Physical Characteristics:				
Recording device:	Sony TDC-D7 DAT digital audio tape recorder	Sony TDC-D7 DAT digital audio tape recorder	Oximeter	Recorder (solid state)
Channels acquired:	One: snoring sounds recorded by microphone	Two: snoring sounds on one channel, Oximetry level on the other channel	Oximetry and pulse rate	Snoring Oxygen Saturation Body Position Event Marking Heart rate
User equipment:	DAT recorder, tape, cannula, microphone	DAT recorder, tape, cannula, microphone, and Oximeter, Palco Model 305	Oximeter Finger Probe	Recorder Sensors
Energy Source:	120 V 60-wall mount AC-DC converter 12W (recommended) or batteries	120 V 60-wall mount AC-DC converter 12W (recommended) or batteries Plus	Battery or 120V 60 V wall mount	Battery

Characteristic	Predicate device: SNAP testing device (K944524)	Modified device: "Oxi-SNAP"	Palco (k943842)	Mesam IV (K901466)
		NiCad rechargeable batteries for the oximeter (12 hour life per charge) Charger is UL list		
Anatomical Sites:	Upper lip	Upper lip and finger probe	Finger probe	Finger probe - Microphone attached to patient neck - Chest sensors for body position and EKG.
Performance Testing	Original submission	Summarized above	Clinical Evaluation	Unknown to us
Safety Characteristics:	ETL Listed	ETL Listed	CSA - tested for UL 544	Unknown to us
Electrical Safety:	Per applicable sections of UL-2601	Per applicable sections of UL-2601	CSA for UL.544 & IEC601-1	Unknown to us
EMI:	Per FCC Part 15 Class A	Per FCC Part 15 Class A	Yes, EN55011B Group EN60601-1-2	Unknown to us
Oximetry	Not included	Included	Included	Included
Intended Population	Older than 3 yrs. old	Adults and pediatrics	Adults and pediatrics	Believe that adults and pediatrics
Home Use	Yes	Yes	Yes (by Healthcare Professional)	Yes

NOTE: As the Palco Part List [redacted] indicated, the Palco sensors list (an accessory to the Palco Oximeter) includes a Pediatric Sensor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

OCT - 1 1997

Gil Raviv, Ph.D.
SNAP Laboratories, L.L.C.
3633 West Lake Avenue, Suite 406
Glenview, Illinois 60025

Re: K971184
"OXI-SNAP™"
Regulatory Class: II (two)
Product Code: 73 MNR
Dated: July 1 1997
Received: July 8 1997

Dear Dr. Raviv:

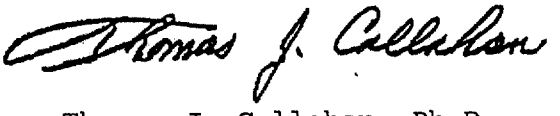
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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/dsmamain.html".

Sincerely yours,



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

Enclosure

I) Indications for Use

510(k) Number K971184.

Device Name: "Oxi-Snap" Snoring and Apnea recording and analysis system.

Indications for Use:

The intended use of the "Oxi-Snap" device is to screen patients for apnea and snoring and to provide quantitative and qualitative analysis of apnea and snoring.

The Oxi-SNAP testing system is only intended for short term monitoring such as to record the oximetry level continuously during the night.

The "Oxi-SNAP" system is not intended as a substitute for full polysomnography when additional parameters such as sleep stages, limb movements or EEG activity are required.

The target population is patients who are suspected of apnea and/or complain about snoring. The majority of the screenings are going to take place at the patient's home, although some may take place in a sleep laboratory. Both pediatric and adult patients may be tested.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Use of this device must be under the direct supervision of a qualified adult (parent or guardian) or health care practitioner trained in the use of the Oxi-Snap device.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Arth A. Carbonski

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

510(k) Number

Prescription Use ✓ OR Over-the-Counter Use

(Per 21 CFR 801.109)