MAY 26 1999

K984169

EXHIBIT 2

Snap Laboratories, LLC
3633 West Lake Avenue Suite 406
Glenview, IL 60025 USA
847-657-8100
Fax: 847-657-8105
Contact Name:
Gil Raviv, President
February 21 1999

510(k) Summary of Safety and Effectiveness

1. Identification of the Device
   Proprietary-Trade Name: "Digi-Snap ™"
   Classification Name: **73 MNR** Apnea/Snoring Recording and analysis Device and 74DQA, 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 "Oxi-Snap ™" Testing Device," K971184, and incorporates a different Pulse Oximeter, Nonin Model 8500 (OEM II Module or the Xpod Module), **K893221.**

3. The intended use of the "Digi-Snap ™" device is to screen patients for apnea and snoring and to provide quantitative and qualitative analysis of apnea and snoring. The Digi-Snap testing system is only intended for short term monitoring such as to record the oximetry and snoring sounds continuously during the night. The 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: US Federal law 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 "Digi-Snap™" device.

4. Description of the Device: This notification is for a modification to the existing device, the "Oxi-Snap™" Testing Device. The modified device is called the "Digi-Snap.™" The modification involves the use of a 100 MB "Zip" drive in place of the DAT tape recorder. This eliminates one A/D-D/A conversion because the snoring sounds are digitized at the first opportunity, in the unit at the patient's bedside.

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. The modified device is easy for the user to set up at home or in the sleep laboratory. The modification involves the use of a fully digital recording technique. The oximeter is connected to the unit 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 unit, then goes to sleep. Apnea and snoring events are then recorded. After awakening, the patient returns the disk and the equipment to the analysis service center, where the disk is analyzed.

6. Substantial Equivalence Chart

Characteristic	Predicate device: Oxi-SNAP™ testing device K971184	Modified device: "Digi-Snap ™"
Labeling:	(Original submission)	The User's Manual has been updated to show the new configuration, with new operation instructions.
Intended Use:	Recording and analysis of snoring and apnea	Same
Physical characteristics:		
Recording device:	Sony TDC-D7 DAT digital audio tape recorder	100 MB "Zip" Drive and proprietary interface.
Channels acquired:	Two: snoring sounds on one channel, Oximetry level on the other channel.	Three: snoring sounds, Oximetry level, and Heart Rate
User equipment:	DAT recorder, tape, cannula, microphone, and Oximeter, Palco Model 305	Zip unit, Zip Disk, cannula, microphone, and Oxmieter, Nonin OEM II or Xpod.
Energy Source:	120 V 60~ wall mount AC-DC converter 12W (recommended) or batteries Plus NiCad rechargeable batteries for the oximeter (12 hour life per charge) Charger is UL listed	90-240 V, 50/60~ internal Medical grade power supply
Anatomical sites:	Upper lip and finger probe	Same
Performance testing:	Summarized above	
Safety characteristics:		
Electrical safety:	Per applicable sections of UL-2601	Same
EMI:	Per FCC part 15 Class A	FCC class B, CISPR 11 Class B
Oximetry	Included	Same
Intended population	Adults and pediatrics	Same
Home use	Yes	Same

7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of Snap Laboratories that the "Digi-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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 6 1999

Gil Raviv, Ph.D.
Snap Laboratories
3633 West Lake Avenue, Suite 406
Glenview, IL 60025

Re: K984169
"Digi-Snap™" Snoring and Apnea Recording and Analysis Device
Regulatory Class: II (two)
Product Code: 73 MNR
Dated: February 23, 1999
Received: February 26, 1999

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 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). 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/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

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

Enclosure

j) Indications for Use

510(k) Number K984169

Device Name: "Digi-Snap ™" Snoring and Apnea recording and analysis system

Indications for Use:

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

The Digi-Snap testing system is only intended for short term monitoring such as to record the oximetry and snoring sounds continuously during the night. The 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: US Federal law 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 "Digi-Snap ™" device.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K984169

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)