

FEB 2 2000

K992322

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  
July 9, 1999

510(k) Summary of Safety and Effectiveness

1. Identification of the Device  
Proprietary-Trade Name: "Snap Model 5™"  
Classification Name: 73MNR 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 "Digi-Snap™" Testing Device, "K984169, and incorporates a the same Pulse Oximeter, Nonin Model Xpod, K893221.
3. The intended use of the "Snap Model 5™" device is to screen patients for apnea and snoring and to provide quantitative and qualitative analysis of apnea and snoring. The "Snap Model 5™" 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 "Snap Model 5™" device.
4. Description of the Device: This notification is for a modification to the existing device, the "Digi-Snap™" Testing Device. The modified device is called the "Snap Model 5™" The modification involves the use of a personal computer with certain options installed instead of the specialized microcomputer and Zip drive system.
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. If the patient's own personal computer was used, only a disk is returned to the analysis center for evaluation.

## 6. Substantial Equivalence Chart

Characteristic	Predicate device: Digi-SNAP™ testing device K984169	Modified device: "Snap Model 5™"
Labeling:	(Original submission)	The User's Manual has been updated to show the new configuration, with new operation instructions. Certain instructions will now appear on the computer monitor screen instead of on the equipment.
Intended Use:	Recording and analysis of snoring and apnea	Same
Physical characteristics:		
Recording device:	100 MB "Zip" Drive and proprietary interface.	Personal computer hard disk and floppy disk
Channels acquired:	Snoring sounds, Oximetry level, and pulse	Snoring sounds, Oximetry level, pulse rate, and pulse value.
User equipment:	Zip unit, Zip Disk, cannula, microphone, and Oximeter, Nonin OEM II or Xpod.	Personal computer, cannula, microphone, and Oximeter: Nonin Xpod only.
Energy Source:	90-240 V, 50/60~ internal Medical grade power supply	120 V, 50/60~ (Personal computer)
Anatomical sites:	Upper lip and finger probe	Same
Performance testing:	Summarized above	
Safety characteristics:		
Electrical safety:	Per applicable sections of UL-2601	UL listed personal computer
EMI:	Per FCC part 15 Class A	FCC part 15 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 "Snap Model 5™" 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.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K992322  
Device: Snap Model 5™  
Regulatory Class: II  
Product Code: 73 MNR 74 DQA  
Dated: July 09, 1999  
Received: July 12, 1999

Dr. Gil 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.

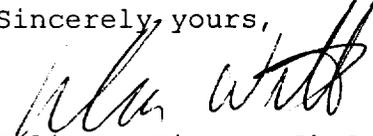
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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" (21CFR 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,



Celia M. Witten, Ph.D., M.D.  
Acting 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 \_\_\_\_\_

Device Name: "Snap Model 5™" Snoring and Apnea recording and analysis system

Indications for Use:

The intended use of the "Snap Model 5™" device is to screen patients for apnea and snoring and to provide quantitative and qualitative analysis of apnea and snoring.

The "Snap Model 5™" 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 "Snap Model 5™" device.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K992322

Prescription Use  OR Over the Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)