SECTION 6 – Corrected 510(k) Summary

MAY 23 2008

SAFETY AND EFFECTIVENESS SUMMARY

Safety and effectiveness information concerning the SNAP Model 7 device is summarized below.

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DATE ON WHICH THE SUMMARY WAS PREPARED: March 31, 2008

NAME OF DEVICE: SNAP Model 7™

COMMON NAME: Snoring and Apnea Recording and Analysis Device

CLASSIFICATION NAME: MNR Ventilatory Effort Recorder

PREDICATE DEVICE: There are two predicate devices, both being earlier existing versions Snoring/Apnea Recording Systems designed by SNAP Laboratories. These are: 510(k) #K002095 – SNAP Model 6™.
510(k) #K992322 – SNAP Model 5™.

The new SNAP Model 7™ employs a combination of features from these two devices.

DESCRIPTION OF THE DEVICE: The SNAP Model 7™ system consists of several components, many of them essentially unchanged from the predicate devices. The design modification is for the Model 7 Data Recorder, which is an updated design modification to the Model 6 predicate device. Other major elements of the system are the DLL and GUI software which run on a PC in the physician's office, and the data analysis software located on computers at the SNAP laboratories central location. The DLL consists of a set of low-level routines for setup, control and data transfer, whereas the GUI is a high-level program which provides the interface between the user (doctor's office) and the DLL.

The DLL/GUI software is similar to that of the Model 6 predicate device, except that the data from the recorder is transferred to the computer via USB communication instead of physically moving a Zip drive cartridge. Also, the Model 6 interface was via serial port.

The data analysis software is unchanged from that which is used in the predicate devices.

The SNAP Model 7™ Data Recorder is a small DC powered device designed to be simple and easy to use by a patient. It is self-contained, with integrated microcontroller and LCD display and all necessary interface electronics to perform all system recording functions. It does not require connection to a host computer in order to perform the recording functions. The data recorder consists of the physical hardware and firmware that interfaces to the patient to collect the physiological data. The recorder has sensors to collect sound, pulse oximetry, respiration effort (belt), and body position. The information is digitized and stored on a removable solid state memory card. The data on the removable data card is accessed through a USB port on the device, connecting to a PC running the DLL software.

The DLL software provides the interface for all communication between the recorder and the computer in the doctor's office. This DLL handles the low-level USB communications as well as parsing and storing intermediate files on the connecting computer. The DLL also interacts with a higher-level GUI client application. The GUI calls DLL functions to interact with the data recorder. The GUI also interacts through the Internet with the central website to transfer the patient data, and provides various data entry functions. The GUI calls DLL functions to program the recorder, check status, clear memory, check USB connectivity, retrieve serial number, retrieve patient data, get time, etc.. The GUI interacts with the website to identify the patient for the programming step and to transfer the collected patient data to the web server. The GUI also functions as a dedicated browser to the website, to navigate the website and identify the patient (and optionally enter new patient information). Once the patient is selected, the recorder is programmed with information regarding the patient name and which sensors are required for the test. After the programming is completed, the patient goes home with it and following the instructions for connection and startup prior to going to sleep. After the patient uses the recorder to collect overnight sleep data, the recorder is returned to the doctor's office, connected to the DLL/GUI computer via the USB port, where the patient data record is programmatically matched to the on-line patient record. After a manual confirmation step, the intermediate files are zipped up and uploaded (via secure, encrypted https) to the web server.

The GUI functions as a dedicated web browser to the website. This allows the GUI to be used for the various data entry steps. The website stores patient information, patient reports, and serves as a "way station" for the raw patient data before it get processed by the data analysis component. Demographic information is collected for the patient along with insurance and credit-card information. Contact and identifying information is collected for the patient's referring physicians. The test results are delivered to the referring physician based on this information. Access to the website is login and password protected. Various roles and user types are in place to safeguard inappropriate access to patient information. All pages of the website run in secure mode (https). The data analysis follows a pre-existing procedure that is already in place for earlier recorder models. The patient data from the website is securely downloaded to analysis workstations at SNAP Laboratories for analysis and processing. The resulting report is then securely uploaded back to the website so it can be made available to the referring physician by a transfer mechanism of their choice.

INTENDED USE:

The Model 7™ device is indicated for use in the diagnostic evaluation of patients for apnea and snoring and to provide quantitative and qualitative analysis of apnea and snoring.

The SNAP Model 7™ testing system is not intended as a substitute for full polysomnography when additional parameters such as sleep stages or EEG activity are required.

The target population consists of patients who are suspected of apnea and/or complain about snoring. The majority of the test procedures will 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 7™ device.

PATIENT POPULATION: Adults and pediatric patients.

SAFETY AND EFFECTIVENESS SUMMARY

The SNAP Model 7™ is an evolutionary design modification to the above-listed predicate devices. It is physically similar to the SNAP Model 6™, in that it is a small, separate recorder located in the general vicinity of the patient, with all sleep sensors connected from the patient to the recorder box. As with all SNAP devices, there are no electrical connections to the patient. In addition, the Model 7 uses a medical grade power supply, and there are no exposed metal connectors or controls, further minimizing any electrical risk to the patient or the user. The Model 7 has been tested and certified to the International Standard EN 60601-1-2:2005, the accepted EMC/EMI standard for medical devices. The sensors, transducers and accessories used with the Model 7 are the same as those used with one or more of the predicate devices, and all instructions for use, for Recorder, oximeter, respiratory effort belt, etc., are appropriate for their intended use.

The PC computer interface to the Model 7 is via the USB interface, the current standard for simple and effective computer accessory connections. The Model 6 predicate device uses a similar (but obsolete) serial port interface. The Model 5 predicate device did not use a separate hardware Recorder. The program running on the PC in the doctor's office (used for Recorder setup and data uploading from the Recorder) is very similar to that used with the Model 6 predicate device, except for changes in communication protocols required because of the change from serial port to USB, and changes as required because of the different Recorder hardware. The Model 5 predicate device introduced the use of secure data transmission over the Internet for uploading patient data and demographic information to the SNAP Laboratories central

location for analysis and reporting. The Model 7 uses this same method, basically unchanged from that used with the Model 5, to enable the software running on the doctor's office computer to connect to the central data analysis site via the Internet. The SNAP data analysis software, which runs on PC computers at the SNAP Laboratories central location, is essentially unchanged from that used with both predicate devices. The secure https:// method for secure data transmission, using data encryption methods standard with most high-security financial transactions, is employed by the Model 7 software. Analysis is performed and reports are generated at the SNAP laboratories central site, and these reports are faxed to the physician and/or placed onto the SNAP Labs web site for access and retrieval by the referring physicians.

Substantial Equivalence Comparison Chart

Characteristic	SNAP Model 7 - Subject of this 510(k)	Predicate Device SNAP Model 5	Predicate Device SNAP Model 6
Labeling	The User's Manual and device labeling has been updated to show new configuration and operational information. Labeling on accessories (oximeter, respiratory effort belt, etc.) are unchanged from predicate devices.	Each SNAP model has labeling appropriate for the features available and the way it is to be used.	Each SNAP model has labeling appropriate for the features available and the way it is to be used.
Intended Use	Recording and analysis of snoring and apnea.	Same as Model 7.	Same as Model 7.
Physical and Technical Characteristics	Small, handheld device with all interfaces necessary for patient connection.	Uses PC for all data recording and patient interface.	Same as Model 7.
Recording Device Memory	Hardware-detectable removable SD flash media card, up to 128 MB, 32K RAM buffer	Personal computer hard disk and floppy disk.	100 MB ZIP drive and proprietary interface.
Data Acquisition	Four A/D channels, 12-bit resolution, up to 2,350 samples per second; for snoring audio, respiratory effort, body position. Oximetry provided via digital interface.	Snoring sound, Oximetry, pulse rate & value.	Same as Model 7.
User Equipment	Cannula, microphone, oximeter, respiratory effort belt, body position monitor.	Same as Model 7, except no respiratory effort & body position.	Same as Model 7, except Model 6 also had limb movement.
Energy Source	External medical grade power supply, 90-240 VAC 50/60 Hz primary, 9 volt secondary.	Personal Computer supply, 120 VAC, 50/60 Hz.	Internal medical grade power supply.
Anatomical Sites	Upper lip, finger probe, respiratory effort belt with body position.	Upper lip and finger probe only.	Same as Model 7, except Model 6 also had limb movement.
Performance Testing	Extensive testing, as summarized in other sections of this document.	Same as Model 7.	Same as Model 7.
Safety Characteristics	No direct electrical connection to patient. Medical grade power supply (IEC 60601-1) used. EMI/EMC testing performed.	Same as Model 7, except PC power supply used for power.	Same as Model 7.
Electrical Safety	Designed to meet IEC 60601-1, power supply is medical grade, and there are no electrical connections to the patient.	Same as Model 7, except PC power supply used for power.	Same as Model 7.

EMI	Tested and certified to meet EN 60601-1-2:2005.	FCC Part 11 Class B.	FCC Part 11 Class B.
Oximetry	Nonin OEM internal oximeter module.	Nonin Xpod Oximeter	Same as Model 7.
Intended population	Adults and pediatrics.	Same as Model 7.	Same as Model 7.
Home Use?	Yes, may be used in home or in laboratory.	Same as Model 7.	Same as Model 7.
Computer Analysis Software	The Model 7 uses the same analysis software as all SNAP devices have used since the original 510(k) submission K984169.	Same as Model 7.	Same as Model 7.
Data quality	A/D is 12-bit resolution, data quality is appropriate for data analysis performed.	Same as Model 7.	Same as Model 7.
Fundamental Scientific Technology	Similar to all predicate devices. No new scientific technology introduced in the Model 7. Does not include sleep staging or EEG.	Same as Model 7.	Same as Model 7.
Data Acquisition Rate	Up to 2,350 samples per second.	Approximately 2 KHz, after low-pass filtering.	Same as Model 7.
Data Reduction Algorithm	Data reduction reduces storage space requirements and data transmission time.	Same as Model 7	Does not use data reduction algorithm.
Connection from Recorder to Computer	The SNAP Model 7 interfaces to the host computer via a USB port.	No separate recorder, sensors interface directly to the computer	Uses a serial port instead of USB port.
Packaging or expiration dating	There are no expiration dates applicable to any parts or accessories of the SNAP Model 7, including the packaging.	Same as Model 7.	Same as Model 7.
Sterilization	Not applicable.	Same as Model 7.	Same as Model 7.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2008

Dr. Gil Raviv
President
SNAP Laboratories International, LLC
5210 Capitol Drive
Wheeling, Illinois 60090

Re: K080321
Trade/Device Name: SNAP Model 7™ Snoring and Apnea Recording and Analysis System
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: May 12, 2008
Received: May 15, 2008

Dear Dr. Raviv:

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.

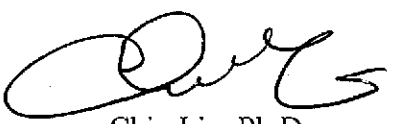
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0120. 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,
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Enclosure

SECTION 5 – Corrected Indications for Use Statement

INDICATIONS FOR USE STATEMENT Page 1 of 1

510(k) Number (if known): K080321

Device Name: SNAP Model 7™ Snoring and Apnea Recording and Analysis System

Indications For Use:

The SNAP Model 7™ device is indicated for use in the diagnostic evaluation of patients for apnea and snoring and to provide quantitative and qualitative analysis of apnea and snoring.

The SNAP Model 7™ testing system is not intended as a substitute for full polysomnography when additional parameters such as sleep stages or EEG activity are required.

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

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Prescription Use X **OR** **Over-The-Counter Use** ____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K080321

(Optional Format 1-2-96)