Section 5 - 510(k) Summary

K110064

MAR 18 2011

SNAP Model 8 – 510(k) Summary

510(k) Owner

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Date Summary Prepared

January 7, 2011

Name of Device

SNAP Model 8 Snoring and Apnea Recording and Analysis System

Common Name

SNAP Model 8

Classification Name

Ventilatory Effort Recorder (21 CFR 868.2375, Product Code MNR)

Predicate Device

510(k): K080321, SNAP MODEL 7 SNORING AND APNEA RECORDING AND ANALYSIS SYSTEM

Section 5 - 510(k) Summary

Description of the Device

The SNAP Model 8 system consists of several components. The Model 8 data recorder and associated sensors and accessories, the SNAP application software which run on a PC in the physician's office, and the SNAP data analysis software located on computers at the SNAP Diagnostics central location.

The SNAP Model 8 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 (SD card). The data on the removable data card is accessed through a USB port on the device, connecting to a PC running the SNAP application software. The recorder is made from flame retardant ABS plastic and has the following specifications.

Respiratory Channels	4
Sample Rate	14 Hz (flow, effort), 2240 Hz (audio)
Measurements	Air Flow, Effort(2), Audio
Oximeter Channels	2
Measurements	SaO2, Pulse (both sampled at 14 Hz)
Body Position Channel (optional)	1 (sampled at 14 Hz)

Height	1.375 inches (34.925 mm)
Width	5.5 inches (139.7 mm)
Depth	4 inches (101.6 mm)
Weight (with power adapter)	15.9 ounces (0.45 kg)
Power	AC 100-240v 50-60Hz
	Battery backup 3.6v Lithium Ion

The SNAP application software consists of a DLL (dynamic link library) and GUI (graphical user interface) and provides the interface for all communication between the recorder and the computer in the doctor's office. 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 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 Diagnostics for analysis and processing. The SNAP data analysis software, which runs on PC computers at the SNAP Diagnostics central location, consists of a GUI and algorithms that allow SNAP to display the recorded

data and mark the recorded events that are characteristic of sleep and respiratory disorders such as apnea. The software summarizes the events and provides the data necessary to generate a report. 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 SNAP Model 8 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 8 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.

Comparison to the Predicate Device

The SNAP Model 8 is an evolutionary design modification to the above-listed predicate device. The technological characteristics (i.e., design, material, electronic circuitry, energy source, software) are essentially the same as the predicate device. It is physically similar to the SNAP Model 7, 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 the predicate device, there are no electrical connections to the patient. In addition, the Model 8 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 8 has been tested and certified to the International Standard EN 60601-1-2:2007, an accepted EMC/EMI standard for medical devices. The Model 8 has added a backup battery to the design that will allow the recorder to continue recording in case of a power outage. The sensors, transducers and accessories used with the Model 8 are similar to those used with the predicate device, 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 8 is via the USB interface and the same as the predicate device. The program running on the PC in the doctor's office (used for Recorder setup and data uploading from the Recorder) is the same as that used with the Model 7 predicate device. The Model 7 predicate device makes use of secure data transmission over the Internet for uploading patient data and demographic information to the SNAP Diagnostics central location for analysis and reporting. The Model 8 uses this same method, basically unchanged from that used with the Model 7, to enable the software running on the doctor's office computer to connect to the central data analysis site via the Internet. The secure https:// method for secure data transmission, using data encryption methods standard with most high-security financial transactions, is employed by the Model 8 software, the same as the Model 7 predicate

device. The SNAP data analysis software, which runs on PC computers at the SNAP Diagnostics central location, has been updated with a new GUI to support Windows (the older software used a DOS interface). The software displays the recorded data and allows manual marking of events. The algorithms are essentially unchanged from that used with the predicate device. Analysis is performed and reports are generated at the SNAP Diagnostics central site, and these reports are faxed to the physician and/or placed onto the SNAP Diagnostics secure web site for access and retrieval by the referring physicians.

Testing and Performance Data

The SNAP Model 8 has undergone medical electromagnetic compatibility (EMC) testing to verify compliance with CISPR 11:2009 and safety testing to verify compliance with IEC 60601-1-2 and any applicable particular standards in this family of international safety standards to ensure that there are no potential hazards to patients, operators, or the surroundings.

It was found that the SNAP Model 8 recorder meets the radio interference Power Line Conducted and Radiated emission requirements of CISPR 11 Group 1, Class B, Industrial, Scientific and Medical (ISM) Radio- Frequency Equipment. It was found that the SNAP Model 8 recorder meets the requirements of European Standard EN 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard Electromagnetic Compatibility Requirements and Tests using the test procedures IEC 61000-4-2; IEC 61000-4-3; IEC 61000-4-4; IEC 61000-4-5; IEC 61000-4-6; IEC 61000-4-8; and IEC 61000-4-11.

No other specific guidance document on performance is required for this type of device.

The data recorded by the Model 8 was compared to data recorded from the predicate device and analyzed by qualified technicians. The result of the comparison is that the signals recorded by the Model 8 are in every respect clinically equivalent to those signals recorded by the predicate device. The presentation, analysis and reports generated by the analysis software were compared to those of the predicate device. The result of the comparison is that the analysis software is in every respect clinically equivalent to the presentation, analysis and reports generated by the predicate device.

Substantial Equivalence

The modified device has the following similarities to the previously cleared predicate device.

- Same intended use
- Same operating principle
- Same technology
- Same manufacturing process

Design verification tests were performed on the SNAP Model 8 as a result of the product requirements and risk analysis. All tests were verified to meet the required acceptance criteria. The results of the

Section 5 - 510(k) Summary

testing and verification lead SNAP Diagnostics to the conclusion that the modifications have no impact on safety and effectiveness. The modified device complies with the applicable standards referenced in the Guidance for FDA Reviewers and Industry "Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices", May 2005. In summary the device described in this submission is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Gil Raviv
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MAR 18 2011

Re: K110064
Trade/Device Name: SNAP Model 8 – 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: February 16, 2011
Received: Febr17, 2011

Dear Mr. 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. 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.

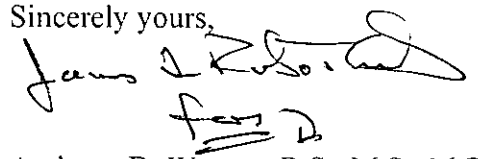
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 – Indications for Use

Indications for Use

510(k) Number (if known):

Device Name: SNAP Model 8 - Snoring and Apnea Recording and Analysis System

Indications for Use:

The SNAP Model 8 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.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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 and Dental Devices
510(k) Number: K110664

Page 1 of 1