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Innovative Sleep Solutions

K110486

AUG 12 2011

SECTION 5: 510(k) SUMMARY

510(k) Summary

Date Prepared: August 3, 2011

Submitter: NovaSom, Inc.
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Contact: Roger K. Richardson, V.P., Operations
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Trade/Proprietary Name of Device: ACCUSOM

Common Name of Device: Ventilatory Effort Recorder

Classification: Class II per 21 CFR 868.2375, Ventilatory Effort Recorder, Product Code MNR

Legally Marketed Predicate Device: Silent Night V (K000253), manufactured by NovaSom, Inc. (formerly Sleep Solutions, Inc.)

Description of New ACCUSOM Device:

The ACCUSOM device is a battery and line powered ventilatory effort recorder. The ACCUSOM device is indicated for use in the diagnostic evaluation of adults with possible sleep apnea. The ACCUSOM can score obstructive apneas, which includes mixed apneas. The ACCUSOM device is intended for use in the home and clinic setting.

As with the predicate Silent Night V device, the ACCUSOM is supplied to patients only upon physician order for use in Home Sleep Testing. The ACCUSOM device is positioned on the patient's arm. The sensors are positioned on the patient's body and connect into the ACCUSOM device. The ACCUSOM contains identical functions and the same algorithm as the predicate Silent Night V device (K000253). The indications for use of the ACCUSOM are identical to the Silent Night V (K000253).

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NovaSom, Inc. (formerly Sleep Solutions, Inc.) owns the 510(k) for the predicate Silent Night V (K000253). The Silent Night V device was cleared in 2000 and has been in use since that time with no adverse or reportable events and no issues related to reliability. The ACCUSOM device is the next generation to the Silent Night V (K000253).

NovaSom, Inc. was formerly known as Sleep Solutions, Inc. The name change to NovaSom, Inc. took place on September 10, 2010. NovaSom, Inc. was last inspected by the FDA in December, 2009 while still under its previous name of Sleep Solutions, Inc.

The ACCUSOM device provides physiological measurements that are identical to the predicate Silent Night V device including:

- Arterial oxygen saturation level (SpO2)) – (Sampled every 5 (+/- 0.2 seconds))
- Pulse Rate - (Sampled every 5 (+/- 0.2 seconds))
- Respiration effort signal - (Sampled every 100 (+/- 0.5 mseconds))
- Airflow waveform corrected for ambient room noise - (Sampled at 5.2083 kHz, accurate to 100ppm over the operating temperature range)

As consistent with the predicate Silent Night V device, throughout a typical sleep study, sleep disordered breathing information and statistics are stored into the ACCUSOM memory. The stored information includes time and duration of apneas and hypopneas, blood oxygen saturation levels, pulse rate, respiratory effort level, sound intensity level, epoch numbers, and paused time intervals. The new ACCUSOM device can retain three 8.5-hour sleep studies. Existing software retrieves, scores, displays and prints the collected data on a personal computer platform. A summary report and event log can be provided to the physician to view the sleep data.

The ACCUSOM is a battery-powered device with cables that attach to a nasal sensor, to a respiratory effort sensor, and to a blood oxygen saturation sensor (SpO2). The ACCUSOM contains visual and audible sensor status indicators for the patient's convenience. At the end of each night of testing, the sensors are removed and the ACCUSOM is plugged into a wall outlet to recharge and to upload the previous night's data using the cellular network to NovaSom, Inc. for report preparation. If the cellular network is insufficient in the patient's residence, the ACCUSOM data will be downloaded using the traditional RS232 cable connection upon receipt at NovaSom, Inc.

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Indications for Use of the New Device:

The ACCUSOM device is indicated for use in the diagnostic evaluation of adults with possible sleep apnea. The ACCUSOM can score obstructive apneas, which includes mixed apneas.

The ACCUSOM device is intended for use in the home and clinic setting.

Comparison of the Technological Features of the New (Modified) Device and Predicate Device:

The ACCUSOM device and the lawfully marketed predicate Silent Night V device contain similar materials of construction. Features of the ACCUSOM are comparable to those of the predicate Silent Night V device. The main differences include:

1. Change in power from AC Power: 120 VAC, 50/60 Hz to AC/DC
2. Change in software programming language: From Assembly to C++
3. Change in hardware: Combination of Bedside Unit and Patient Module into a single unit
4. Additional mode of completed test download: Addition of wireless capability

Testing:

Bench performance testing has been conducted to demonstrate that the new ACCUSOM device is substantially equivalent to the predicate Silent Night V device.

NovaSom, Inc. will test to ensure compliance to the requirements of various published standards applicable to this device prior to its introduction to the market.

Because the new ACCUSOM device utilizes the same algorithm as the predicate Silent Night V device, no additional clinical testing has been performed. The clinical studies performed in support of the Silent Night V can be found in the Silent Night V 510(k) submission (K000253) on pages 251 - 275.

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Conclusion:

The conclusions drawn from the specifications and performance testing of the ACCUSOM device demonstrate that the new ACCUSOM device is at least as safe and as effective and performs as well as or better than the NovaSom, Inc. predicate Silent Night V device, (K000253). For these reasons, we believe the ACCUSOM device is substantially equivalent to the predicate device.

Signed,

_____

Roger K. Richardson, RRT-NP, RPFT
Vice President, Operations & Chief Compliance Officer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Roger K. Richardson
Vice President, Operations
NovaSom, Incorporated
801 Cromwell Park Drive, Suite 108
Glen Burnie, Maryland 21061

AUG 12 2011

Re: K110486
Trade/Device Name: ACCUSOM Ventilatory Effort Recorder
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing frequency monitor
Regulatory Class: II
Product Code: MNR
Dated: August 3, 2011
Received: August 10, 2011

Dear Mr. Richardson:

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,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

cc: DMC - 2 copies
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08/11/11 EFW

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SECTION 4: INDICATIONS FOR USE

510(k) Number (if known): K110486

Device Name: ACCUSOM

Indications for Use:

The ACCUSOM device is indicated for use in the diagnostic evaluation of adults with possible sleep apnea. The ACCUSOM can score obstructive apneas, which includes mixed apneas.

The ACCUSOM device is intended for use in the home and clinic setting.

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

Nayak for L Scholtheis

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

510(k) Number: K110486

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