K131994

TAB 5

510(K) SUMMARY

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724-387-7954 t

OCT 17 2013

Date of Preparation	June 27, 2013
Classification Reference	21 CFR 868.2375
Product Code	MNR—Ventilatory Effort Recorder
Common/Usual Name	Sleep Analysis System
Proprietary Name	Somnolyzer 24x7
Predicate Device(s)	Somnolyzer 24x7 (K083620)
Reason for submission	Modified Device

Substantial Equivalence

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

- ❑ Same intended use.
- ❑ Same operating principle.
- ❑ Same technology.

Design verification tests were performed on Somnolyzer 24x7 as a result of the product requirements. Respironics has determined that the modifications have no impact on the safety and effectiveness of the device. In summary, the device described in this submission is substantially equivalent to the predicate device.

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.

Indications for Use

Somnolyzer 24x7 is a computer program (software) intended for use as an aid for the diagnosis of sleep and respiratory disorders.

Somnolyzer 24x7 is intended to be used for analysis (automatic scoring and manual re-scoring), display, redisplay (retrieve), summarize, reports generation and networking of data received from monitoring devices typically used to evaluate sleep and respiratory related sleep disorders.

This device is to be used under the supervision of a physician.

The indications for use remain unchanged from K083620.

Device Description

Somnolyzer is a polysomnography scoring application that provides automated analysis of sleep, respiratory and movement information recorded during sleep studies. It processes information recorded during sleep by electrodes and sensors attached to the body. It then generates results that include quantitative sleep, breathing and motion parameters, used to evaluate sleep and respiratory-related disorders. Somnolyzer 24x7 scoring is applicable to adult patient populations only.

Somnolyzer 24x7 version 2.5 provides an update to the currently released Somnolyzer 24x7 (K083620), which enables Somnolyzer to score sleep recordings according to the American Academy of Sleep Medicine (AASM) Manual 2007 and 2012 editions.

Description of Modifications:

The fundamental scientific technology of Somnolyzer 24x7 is unchanged from the predicate device (K083620). Respironics has made the following changes to the previously cleared Somnolyzer 24x7 to be considered for this submission:

- **Modifications to accommodate the AASM rules up to the 2012 edition:**

  To accommodate the American Academy of Sleep Medicine (AASM) scoring rules, various algorithms in the Somnolyzer 24x7 software were updated to add inputs. The use of additional EEG leads in the AASM recommended EEG montage were built into the software for detecting

sleep staging and arousals. A CPAP flow sensor and pressure transducer air flow channel were added as valid inputs into the software. In sleep studies where the primary air flow channels are absent or have produced unreliable data, the respiratory effort belt signal can now be used to derive an air flow signal, known as RIPflow. RIPflow was added as an optional flow channel in the AASM 2012 manual.

Sleep staging and respiratory event scoring rules were also updated to incorporate new rules with the AASM 2012 edition. Somnolyzer has the ability to support the sub-classification of hypopneas, as well as detect Cheyne Stokes breathing patterns.

- **Other improvements**:

  In addition to the AASM updates, Somnolyzer 24x7 was modified to provide clinician configurability of several scoring parameters, accept ECG input for signal processing (allow for removal of ECG electrical interference in the EEG/EOG/EMG data, use the ECG signal in respiratory event detection as part of the scoring consideration for hypopneas), and identify and select the EMG channel with the most viable data for scoring.

Non-Clinical Tests

Verification activities were performed to verify that the software modifications performed as intended and did not affect safety and effectiveness. Two types of testing were conducted: verification tests and automated validation tests. The verification testing involved verifying the validity of the results from the autoscoring algorithms. The automated validation testing compared the performance of human manual scoring against Somnolyzer 24x7 version 2.5 and previous versions of Somnolyzer. Testing included software code reviews, bench verification testing and user manual inspection. The verification and validation testing demonstrates that all new requirements have been satisfied and safety and effectiveness has not been inadvertently affected by modifications to the system.

Testing confirmed that the Somnolyzer 24x7 software version 2.5 performs equivalently to the device predicate Somnolyzer 24x7 software (K083620). All tests had passing results or minor resolved defects.

Clinical Tests

Clinical tests were not required to demonstrate the safety and effectiveness of Somnolyzer 24x7. Product functionality has been adequately assessed by non-clinical tests.

Conclusion

Somnolyzer 24x7 software has passed all of the aforementioned non-clinical tests and required no clinical tests in order to demonstrate safety or effectiveness. It is therefore concluded that Somnolyzer 24x7 is substantially equivalent to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 17, 2013

Respironics, Inc.
Daniela Aizpitarte
Regulatory Affairs Engineer
1740 Golden Mile Highway
Monroeville, PA 15146

Re: K131994
Trade/Device Name: Somnolyzer 24x7
Regulation Number: 21 CFR 868.2375
Regulation Name: Ventilatory Effort Recorder
Regulatory Class: Class II
Product Code: MNR
Dated: September 6, 2013
Received: September 9, 2013

Dear Ms. Aizpitarte:

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.

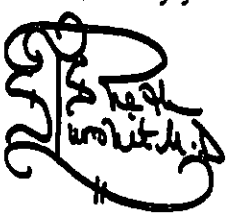
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,



Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: ___Somnolyzer 24x7_

Indications for Use:

Somnolyzer 24x7 is a computer program (software) intended for use as an aid for the diagnosis of sleep and respiratory disorders.

Somnolyzer 24x7 is intended to be used for analysis (automatic scoring and manual re-scoring), display, redisplay (retrieve), summarize, reports generation and networking of data received from monitoring devices typically used to evaluate sleep and respiratory related sleep disorders.

This device is to be used under the supervision of a physician.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K131994 Anya C. Harry -S

Digitally signed by Anya C. Harry -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry -S, 0.9.2342.19200300.100.1.1=0011315590
Date: 2013.10.16 23:25:33 -04'00'