DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 30, 2015

SOMNOmedics GmbH
Mr. Matthias Broenner
Am Sonnenstuhl 63
97236 Randersacker
GERMANY

Re: K140861
Trade/Device Name: SOMNOtouch™ RESP Ventilatory Effort Recorder
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing frequency monitor
Regulatory Class: II
Product Code: MNR
Dated: December 31, 2014
Received: January 29, 2015

Dear Mr. Broenner:

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 Industry and Consumer Education 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" (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 Industry and Consumer Education 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.

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Enclosure

Indications for Use

510(k) Number (if known): K140861

Device Name: SOMNOtouch™ RESP

Indications For Use:

The SOMNOtouch RESP is a portable physiological signal recorder. It is indicated for use in the recording, displaying, monitoring, printing, and storage of biophysical parameters for the purpose of assisting in the diagnosis of sleep disorders and sleep related respiratory disorders of adult patients. The device is intended to be prescribed for use by a physician in the office, sleep laboratory or patient's home.

This device is NOT designed to be used in life support situations.

Prescription Use ___**X**____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (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)

Section 5: 510(k) Summary of Safety and Effectiveness

The following information is in conformance with 21 CFR 807.92.

Submitter's Information: 21 CFR 807.92(a)(1)

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Date Prepared:	April, 1st 2014

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	SOMNOtouch™ RESP
Common Name:	Ventilatory Effort Recorder
Classification Name:	Breathing frequency monitor
Product code:	MNR
Regulation Number:	21 CFR 868.2375

Predicate Device: 21 CFR 807. 92(a)(3)

FDA has classified the predicate device (K060708) as Class II, CFR 868.2375, MNR. It is our understanding that SOMNOtouch™ RESP device falls under the same classification as the predicate device. Predicate device details are as follows:

Device Classification Name:	Breathing frequency monitor
510(k) Number:	K060708
Regulation Number:	21 CFR 868.2375
Device Name:	SOMNOscreen
Applicant:	SOMNOmedics GmbH Am Sonnenstuhl 63 97236 Randersacker Germany
Classification Product Code:	MNR
Decision Date:	01/24/2007
Classification Advisory Committee:	Anesthesiology

Device Description: 21 CFR 807 92(a)(4)

The SOMNOtouch™ RESP is a small, portable physiological signal recording system intended to be used to record, display, monitor, print and store biophysical parameters to aid in the diagnosis of sleep disorders. The device is intended to be prescribed for use by a physician in the office, sleep laboratory or patient's home.

The SOMNOtouch™ RESP consists of the following:

1. The recording device (worn on the thorax),
2. the finger probe, which is used to detect SpO2,
3. the external effort sensor,
4. two effort belts to measure thoracic and abdominal expansion,
5. the nasal cannula,
6. the Software DOMINOlight for visualization of the recorded data.

The SOMNOtouch™ RESP typically will be worn at the thorax, attached by a thorax belt. It contains a sensor to measure the respiratory effort signal of the thorax. The device has an internal accelerometer, measuring body position and motion activity. It provides a connector to attach a nasal cannula, which allows the recording of respiratory flow and snore signals with the internal pressure sensor. Arterial oxygen saturation (SpO2) and pulse rate can be determined via a pulse oximetric finger sensor. Abdominal respiratory effort is measured with an external sensor, attached with a belt to the abdomen. This information is stored in the internal memory of the device.

The system provides up to 10 internal channels for data acquisition, Pressure/Flow, Thoracic Effort, SpO2, Pulserate, Snoring, Finger Plethysmogram, Body Position, Movement, Patient Marker, CPAP, and 1 external Abdominal Effort Sensor. The data from all channels can be recorded separately or in any combination with the other channels.

Information is stored on an internal 512 MB flash memory and can be transferred to a PC via a USB docking station. The DOMINOlight software retrieves the data from the SOMNOtouch™ RESP, displays and analyzes the data, and can store data for future reference and comparison. The SOMNOtouch RESP does not provide automatic diagnosis and is not designed to be used in Life Support situations.

Indications for Use: 21 CFR 807 92(a)(5)

"The SOMNOtouch RESP is a portable physiological signal recorder. It is indicated for use in the recording, displaying, monitoring, printing, and storage of biophysical parameters for the purpose of assisting in the diagnosis of sleep disorders and sleep related respiratory disorders of adult patients. The device is intended to be prescribed for use by a physician in the office, sleep laboratory or patient's home.

This device is NOT designed to be used in life support situations."

Technological Characteristics: 21 CFR 807 92(a)(6)

CHANNELS	10 Internal Channels: (Body Position, Movement, Patient Marker, Thoracic Effort, SpO2, Plethysmography, Pulse Rate, Pressure/Flow sensor (CPAP) Snoring) 1 External Channel: (Abdominal Effort)
DATA PROCESSING	12 Bit ADC Different Sampling Rates Adjustable (1/60s - 512/s)

Technological Characteristics: Comparison/Discussion Table:

Features/Technical Information	**SOMNOmedics SOMNOtouch™ RESP**	**SOMNOmedics SOMNOscreen**	**Discussion of differences**
510(k) number	Not assigned	K060708	n/a
Product code	MNR	MNR	n/a
Indications for Use	The SOMNOtouch RESP is a portable physiological signal recorder. It is indicated for use in the recording, displaying, monitoring, printing, and storage of biophysical parameters for the purpose of assisting in the diagnosis of sleep disorders and sleep related respiratory disorders of adult patients. The device is intended to be prescribed for use by a physician in the office, sleep laboratory or patient's home. This device is NOT designed to be used in life support situations.	The SOMNOscreen is a non-life-supporting portable physiological signal recording device intended to be used for testing adult patients suspected of having sleep-related breathing disorders.	Indications for use and Intended Use sections have been merged. The use in life support situations was clarified. The differences do not raise concerns in safety or effectiveness.

Features/Technical Information	SOMNOmedics SOMNOtouch™ RESP	SOMNOmedics SOMNOscreen	Discussion of differences
Intended Use	The SOMNOtouch RESP is a portable physiological signal recorder. It is indicated for use in the recording, displaying, monitoring, printing, and storage of biophysical parameters for the purpose of assisting in the diagnosis of sleep disorders and sleep related respiratory disorders of adult patients. The device is intended to be prescribed for use by a physician in the office, sleep laboratory or patient's home. This device is NOT designed to be used in life support situations.	The SOMNOscreen is indicated for use in the recording, displaying, monitoring, printing, and storage of biophysical parameters for the purpose of assisting in the diagnosis of Neurological and Sleep Disorders.	Indications for use and Intended Use sections have been merged. The SOMNOscreen provides sensors for additional neurological measurement. The use in life support situations was clarified. The differences do not raise concerns in safety or effectiveness.
Intended Patient Population	Adult Patients	Adult Patients	n/a
Intended Environment	The intended environment are the physician's office, a sleep laboratory or the patient's home	The intended environment are the physician's office, a sleep laboratory or the patient's home	n/a
Prescription Use	Yes	Yes	n/a
Number of patients monitored simultaneously	1 per Unit	1 per Unit	n/a
Number of Channels	11 Channels	28 Channels	The 11 channels are sufficient to fulfill the intended use.

Features/Technical Information	SOMNOmedics SOMNOtouch™ RESP	SOMNOmedics SOMNOscreen	Discussion of differences
Functions	Recording and processing of Pressure Flow, Thorax/Abdominal Respiratory Effort, SPO2, Snore, Pulse Rate, Plethysmogram, Body Position, Movement and Patient Marker for basic respiration screening or CPAP-titration.	Recording and processing of Pressure Flow, Thorax/Abdominal Respiratory Effort, SPO2, Snore, Pulse Rate, Plethysmogram, Body Position, Brightness and Patient Marker for basic respiration screening or CPAP-titration. Optional: Additional signals for full PSG recording with or without video, 24-hour ambulatory **EEG** recording, stationary EEG-monitoring with video control or 24-hour **ECG** and pulse oximetry.	The 11 channels of the SOMNOtouch RESP are sufficient to fulfill the intended use and already extend the basic requirements for a Type III or Type IV Home Sleep Testing device The additional channels are not required for the diagnosis of sleep-related respiratory disorders. The differences do not raise concerns in safety or effectiveness.
Portable Design	Yes	Yes	n/a
Size	84 x 55 x 18 mm³ (3.3″ x 2.2″ x 0.7″)	140 x 70 x 28 mm³ (5.5″ x 2.8″ x 1.1″)	The SOMNOtouch RESP is smaller, reducing the disturbance of the patient's sleep when using the device. The differences do not raise concerns in safety or effectiveness.
Weight	64 grams including battery (2.26 oz.)	220 grams including battery (7.76 oz.)	The reduced weight does not raise concerns in safety or effectiveness.
Device Application	Attachment to patient's thorax using an effort belt	Attachment to patient's thorax or waist using an effort belt	Application on the thorax is the preferred application position. The restriction to this position does not raise concerns in safety or effectiveness.
Device User Interface	Power and control buttons Color Touch Display Status Indication LEDs	Power and control buttons Dot Matrix display Status Indication LEDs	The touch display allows a more intuitive interaction with the user interface. The differences do not raise concerns in safety or effectiveness.
Data collection	Yes	Yes	n/a

Features/Technical Information	SOMNOmedics SOMNOtouch™ RESP	SOMNOmedics SOMNOscreen	Discussion of differences
Selectable Montage Configuration	Yes	Yes	n/a
Calibration Check	No calibration required. Signal quality check on device display possible.	No calibration required. Signal quality check on device display possible.	n/a
Sampling method	Analogue to digital conversation, 12 Bit	Analogue to digital conversation, 16 Bit	The 12-Bit A/D-converter used to transform the analogue signals from effort sensors and the pressure sensor is sufficient to fulfill all specifications and allows a smaller device size, as it is integrated in the microcontroller housing. The change does not affect the measurement quality compared with the predicate device, as also confirmed within the validation described in section 20: Performance Testing – Clinical.
Sampling rates	Up to 512 Hz	Up to 512 Hz	n/a
Raw Data Storage	Internal 512MB flash-memory	Compact Flash Card with a capacity up to 512 MB	The integrated memory card, allows a reduced size, minimizes errors in handling with the card and is an improved protection against unauthorized access to data stored on the memory card. The differences do not raise concerns in safety or effectiveness.
Radio LAN Capabilities for Remote Live View of Data	No	Yes	The Live View of Data is required for fully attended sleep testing in the sleep lab. For basic home sleep testing the live view is not required and not relevant for the predicate device in that field of usage as well. The differences do not raise concerns in safety or effectiveness.

Features/Technical Information	SOMNOmedics SOMNOtouch™ RESP	SOMNOmedics SOMNOscreen	Discussion of differences
Data interface	Serial data transfer	Serial data transfer	n/a
Transfer method	Docking station	External card reader on PC	The docking station allows a direct communication with the device, prevents handling errors with the memory card, allows to check correct transfer of montage and patient data to the SOMNOtouch RESP and allows status indication (i.e. battery state) directly during device initialization. The differences do not raise concerns in safety or effectiveness.
Data Review Device	Personal computer	Personal computer	n/a
Operating System for PC Software	Windows 7	PC Windows 2000, XP and Windows 7	Windows 2000 and Windows XP are not supported by Microsoft anymore and should not be used in fields with confidential data (i.e. patient data). The differences do not raise concerns in safety or effectiveness.
Software	DOMINO light	DOMINO	DOMINO provides additional features needed for the additional SOMNOscreen channels and options. DOMINO light is optimized for the functionality of the SOMNOtouch within the intended use. The differences do not raise concerns in safety or effectiveness.
Operating Voltage	3.7 V	3.7V	n/a
Power Source	Li Ion rechargeable battery	Li Ion rechargeable battery	n/a

Features/Technical Information	SOMNOmedics SOMNOtouch™ RESP	SOMNOmedics SOMNOscreen	Discussion of differences
Patient isolation	Device has no galvanic connection to mains, as it is battery operated Device has no galvanic connection to patient Device has no galvanic connection to auxiliary devices	Device has no galvanic connection to mains, as it is battery operated	Reduced connectivity of the device minimizes the risk of unintended patient currents. The differences do not raise concerns in safety or effectiveness.
Sensors	Abdomen and thorax effort sensor SpO2 Sensor (NONIN-type) Solid state pressure sensor Solid state activity/position sensor	Abdomen and thorax effort sensor SpO2 Sensor (NONIN-type) Solid state pressure sensor Solid state position sensor Optional: EEG, EOG, EMG, ECG, Microphone, Thermistor, Activity, Oesophageal pressure	The available sensors of the SOMNOtouch RESP are sufficient to fulfill the intended use. The additional sensors are not required to be used for basic home sleep testing (Type IV or Type II) with the SOMNOscreen. The differences do not raise concerns in safety or effectiveness.
Control	Data acquisition and data storage are microprocessor controlled	Data acquisition and data storage are microprocessor controlled	n/a
Reusable / Disposable Components with skin contact	Nasal Cannula (Disposable) SpO2 Sensor (Reusable)	Nasal Cannula (Disposable) SpO2 Sensor (Reusable) For PSG Options: Electrodes for EEG/EOG/EMG/ECG (Disposable) Cup Electrodes (reusable) Microphone (reusable)	n/a, same materials/reuse type
Ingress Protection Rating Device	IP22	IP20	The SOMNOtouch RESP provides an improved Ingress Protection Rating. The differences do not raise concerns in safety or effectiveness.

Features/Technical Information	SOMNOmedics SOMNOtouch™ RESP	SOMNOmedics SOMNOscreen	Discussion of differences
Standards applied during design and performance testing	DIN EN 60601-1 DIN EN 60601-1-2 DIN EN 60601-1-11 DIN EN 62366 DIN EN ISO 14971 DIN EN IEC 62304 ISO 10993-1	DIN EN 60601-1 DIN EN 60601-1-1 DIN EN 60601-1-2 DIN EN 60601-1-4 DIN EN ISO 14971	Since development of SOMNOscreen the structure of the IEC 60601 standard family (which are the underlying standards of the listed DIN EN 60601 standards*) had been revised completely. E.g. DIN EN 60601-1-1 and 60601-1-4 got integrated into DIN EN 60601-1. DIN EN 62366 emerged from DIN 60601-6, which was not listed as an applied standard for SOMNOscreen but it was applied implicitly to ensure usability aspects. During the filing of SOMNOscreen there was no requirement to demonstrate fulfillment of usability aspects. In summary it could be stated that certain standards had been reorganized which explains why DIN EN 60601-1-1 and 60601-1-4 are no longer supported. Other standards had been added as the requirements and common sense of adequate development of safe and effective medical devices rose during the last years. Finally the standard related changes do not lower the requirements in any way but they raise the requirements and therefore ensure a higher level of safety and effectiveness. The extended assessment of standards does not raise concerns regarding safety or effectiveness.

Performance Data from nonclinical Testing: 21 CFR 807 92(b)(1)

A Hazard Analysis, in accordance with DIN EN ISO 14971 was performed to identify and address the design and operation of the SOMNOtouch™ RESP.

Testing included, but was not limited to, verification in accordance following internationally accepted standards for electrical safety and electromagnetic compatibility

- Medical Electrical Equipment, Part 1: General requirements for Safety, DIN EN 60601-1
- Medical Electrical Equipment, Part 1-2: Electromagnetic Compatibility, DIN EN 60601-1-2

The SOMNOtouch™ RESP was found to be compliant with the requirements of these standards, no nonconformities have been detected.

Performance testing was conducted to confirm compliance to device specifications. All functions were verified to operate as designed.

The SOMNOtouch™ RESP was found to be compliant with the requirements of these standards for its intended use. All tests had been passed successfully and did not raise new concerns regarding safety and effectiveness of the device.

Performance Data from clinical Testing: 21 CFR 807 92(b)(2)

For determination of the quality of the acquired data, SOMNOtouch™ RESP was evaluated in a clinical study according to the most recent FDA recommendations and US clinical standards. The aim of this study was to assess SOMNOtouch RESPs ability to detect breathing events like hypopnea and apnea during sleep with comparable quality to the results from the predicate device (SOMNOscreen, K060708). The Apnea–Hypopnea Index (AHI) served as underlying measure for the comparison. The statistical evaluation contained regression analysis as well as sensitivity specificity calculation. Severity classification was defined in accordance with the definition of the American Academy of Sleep Medicine.

The study was performed in a professional sleep lab under the supervision of qualified sleep technicians. Data sets were scored manually by different qualified professionals.

Subjects were recruited out of the regular patient collective of the sleep lab where the study was conducted.

During the study no adverse effects and no complications occurred.

The comparison studies found the subject device can be expected to provide safety and effectiveness outcomes substantially equivalent to the predicates.

Conclusion: 21 CFR 807 92(b)(3)

SOMNOmedics SOMNOtouch™ RESP has the same principles of operation and similar technological characteristics as the predicate device SOMNOscreen from SOMNOmedics GmbH. Clinical testing supports substantial equivalence of the clinical performance of the subject and predicate devices.

Based on performance testing, the SOMNOmedics SOMNOtouch™ RESP is substantially equivalent to devices already on the market and presents no new concerns of safety and effectiveness. Additionally, the device has similar indications to the predicate devices and the labeling of the device is consistent both with FDA's guidance as well as current medical practice.