K140124

MAY 1 2 2014

510(k) Summary – S9 Elouera

Required	By section 807.92 (c)
Date Prepared	12th May, 2014
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Product Codes	73 BZD 73 MNR
Class	II
Classification Reference	(21 CFR 868.5905 Product code 73 BZD) (21 CFR 868.2375 Product code 73 MNR)
Common/Usual Name	Non continuous ventilator (IPPB) Breathing Frequency Monitor
Proprietary Name	S9 Elouera
Predicate Device(s)	S8 Aspen (K091947) ApneaLink Plus (K083575)
Reason for submission	New Device

Indication for Use
The S9 Elouera self-adjusting device is indicated for the treatment of Obstructive Sleep Apnea (OSA) in patients (female patients with mild to moderate OSA when using AfH treatment mode) weighing more than 66 lb (30 kg).

It is intended for home and hospital use.

Substantial Equivalence
The new device has the following similarities to the previously cleared predicate devices.

- Similar intended use Same
- operating principle Similar
- technologies
- Same manufacturing process

The S9 Elouera retains all the same operating/technologies/manufacturing characteristics cleared in the S8 Aspen (K091947). The S9 Elouera includes an additional treatment mode called AutoSet for Her (AfH). AutoSet for Her mode is based on key aspects of ResMed's AutoSet algorithm and delivers therapeutic responses tailored to the characteristics of female OSA patients. These include modified responses to Flow Limitations resulting in a slower pressure rise and decay when compared to standard AutoSet algorithm.

These changes have been fully tested within the clinical trial as shown in the "Clinical Testing" section of this 510(k) summary.

The S9 Elouera includes Cheyne-Stokes Respiration (CSR) breathing pattern recognition and reporting, this feature is equivalent to ResMed's ApneaLink Plus (K083575).

Design and Verification activities were performed on the S9 Elouera device as a result of the risk analysis and design requirements. All tests confirmed the product met the predetermined acceptance criteria. ResMed has determined that the new device has not altered the safety and effectiveness of CPAP treatment. The S9 Elouera complies with the applicable requirements referenced in the FDA guidance documents:

- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
- FDA Draft Guidance for Industry and FDA Staff - Design Considerations for Devices Intended for Home Use- Document Issued on: December 12, 2012
- FDA Draft Guidance for Industry and FDA Staff - Radio Frequency Wireless Technology in Medical Devices - Document Issued on: August 13, 2013
- Reviewer Guidance for Premarket Notification Submissions, ARDB, CDRH, FDA, November 1993.

Clinical Testing:
A clinical trial demonstrated that the modified AutoSet algorithm performed as expected in treating female patients in a single-blind, randomised, cross-over non-inferiority study comparing the efficacy of the new AfH algorithm when compared to the standard AutoSet algorithm cleared in the S8 Aspen (K091947).
The trial showed that the AfH algorithm effectively treated female OSA patients as reflected by the apnea-hypopnea index (AHI) and oxygen desaturation index (ODI) outcomes.

No adverse event or complications occurred as a result of the trial.

Non-Clinical Testing:

Side-by-Side bench testing was performed to verify that the S9 Elouera met the requirements of the S9 Elouera System Specification when compared to the predicate devices (S8 Aspen (K091947) and ApneaLink Plus (K083575)).

This bench testing included testing the performance of each therapy mode which included:

- Pressure stability
- Response to apneas
- Response to flow limitations and snore.
- Reporting of Closed Airway Detection (CAD)

A breathing machine simulates patient breathing patterns, which results in the Flow Generator responding in a manner consistent with maintaining the CPAP treatment pressure (CPAP mode) or adjusting the CPAP pressure based upon the patient's condition in real-time (self-adjusting mode). The clinical Pass/Fail requirements are traced to the S9 Elouera System Specification and to the predicate device's performance.

The S9 Elouera also includes an optional pulse oximeter accessory which is typically is used to confirm apneas when linked with the apnea events.

Bench testing for the S9 Elouera includes Cheynes Stokes Respiration (CSR) breathing pattern recognition and reporting, this feature is equivalent to ResMed's ApneaLink Plus (K083575). Side-by-side testing using the same digitised breathing patterns was used. This test executes patient script files. Each patient script file is treated as an individual scenario, which the S9 Elouera reports either:

- No CSR CSR
- CSR + OSA
- OSA

The S9 Elouera CSR detector results are then compared to human scoring where sensitivity and specificity are assessed. The S9 Elouera met the predefined Clinical Pass/Fail criteria.

In this test, a patient is reported as having CSR once the CSR duration on the FG reaches a value of 15 mins. Once the CSR duration of 15 mins is met, the scenario is complete and the next scenario in the feature file can begin. Should the CSR duration fail to reach 15 mins, the patient script file will run to completion, before the scenario is completed and moves on to the next one.
The S9 Elouera met the predefined Clinical Pass/Fail criteria.

Materials used in the construction of components that contact the heated humidified gas pathway are classified as permanent "external communicating devices" (with tissue/bone/dentin). The appropriate biological tests conducted and passed for these components, in accordance with FDA guidance #G95-1 were:

- ISO 10993-3 Genotoxicity,
- ISO 10993-5 Cytotoxicity,
- ISO 10993-6 Implantation and
- ISO 10993-10 Sensitization & Irritation.

Testing for particulate matter and volatiles demonstrated compliance to EPA requirements.

The S9 Elouera has been tested to appropriate standards and other applicable requirements. The S9 Elouera with integrated heated humidifier was designed and tested according to:

- IEC 60601-1:2005, Medical electrical equipment - Part 1: General requirements for safety Medical electrical equipment – General requirements for basic safety and essential performance
- IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

Device Description

The S9 Elouera retains all the same hardware and performance features of the predicate device(s). Key features include in-line power supply, fully integrated humidifier, tubing, colour LCD and simplified controls which provides improved usability. The S9 Elouera contains a Micro-processor controlled blower system that generates Continuous Positive Airway Pressure (CPAP) from 4-20 cmH_2O as required to maintain an "air splint" for effective treatment of OSA. The system comprises the flow generator, patient tubing, mask (patient interface) and humidifier.

The S9 Elouera flow generator includes three therapy modes. These include:

- CPAP mode – the device delivers a continuous positive airway pressure throughout the entire therapy session
- AutoSet mode – the device automatically adjusts pressure in response to inspiratory flow limitation, snore and apnea.
- AutoSet for Her mode – the device automatically adjusts pressure in response to female-specific OSA characteristics.

The functional characteristics of the S9 Elouera system includes all the clinician and user friendly features of the predicate device which have been verified during usability studies in accordance with IEC 62366 Medical devices - Application of usability engineering to medical devices.

Characteristics between predicate and new device

Characteristic	Predicate Device S8 Aspen (K091947)	New device S9 Elouera	Comments
Indication for use	The S8 Aspen self-adjusting system is indicated for the treatment of obstructive sleep apnea (OSA) in patients weighing more than 66 lb (>30 kg). The S8 Aspen self-adjusting system is intended for home and hospital use.	The S9 Elouera self-adjusting device is indicated for the treatment of Obstructive Sleep Apnea (OSA) in patients **(female patients with mild to moderate OSA when using AfH treatment mode)** weighing more than 66 lb (30 kg). It is intended for home and hospital use.	Equivalent *Name change and reduced patient population from predicate regarding AfH mode.*
Location of use (primary)	Hospital/Home	Hospital/Home	Equivalent
Performance			
Pressure range	• 4-20 cm H_2O (all modes) • EPR +3 cm H_2O (all modes)	• 4-20 cm H_2O (all modes) • EPR +3 cm H_2O (all modes)	Equivalent

Ramp features	• User selected as "Off" to 45 minutes in 5 minute increments • Max Ramp time set at clinician's discretion	• User selected as "Off" to 45 minutes in 5 minute increments • Max Ramp time set at clinician's discretion	Equivalent
Modes of operation	• CPAP Mode (Fixed-pressure) • AutoSet Mode (maximum to 20cm H_2O with CAD) • CPAP and AutoSet with EPR (maximum to 20cm H_2O with CAD)	• CPAP Mode (Fixed-pressure) • AutoSet Mode (maximum to 20cm H_2O with CAD) • CPAP, AutoSet with EPR(maximum to 20cm H_2O with CAD) • **AutoSet for Her (AfH) (maximum to 20cm H_2O with CAD)**	Equivalent: *Addition of AfH treatment mode. Clinical testing demonstrated that this new mode is substantially equivalent to the AutoSet mode.*

Characteristic	Predicate Device S8 Aspen (K091947)	New device S9 Elouera	Comments
System Components	• Flow generator • Integrated humidifier (HumidAire 4i Plus) • Mask, air tubing and heated tubing	• Flow generator • Humidifier • Mask, air tubing and heated tubing	Equivalent

Characteristic	Predicate Device ApneaLink Plus (K083575)	New device S9 Elouera	Comments
CSR Detection and Reporting	Scoring of apnea events such as Obstructive Sleep Apnea (OSA) and Cheyne-Stokes Respiration (CSR).	Scoring of apnea events such as Obstructive Sleep Apnea (OSA) and Cheyne-Stokes Respiration (CSR).	Equivalent

Conclusion

The S9 Elouera is substantially equivalent to the predicate devices (S8 Aspen K091947) and ApneaLink Plus (K083575) and is as safe and as effective as the predicate devices.

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

May 12, 2014

Resmed Corporation
Mr. Jim Cassi
Vice President, Quality Assurance Americas
9001 Spectrum Center Blvd.
San Diego, CA 92123

Re: K140124
Trade/Device Name: S9 Elouera
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD, MNR
Dated: April 7, 2014
Received: April 9, 2014

Dear Mr. Cassi:

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,

Mary S. Runner -S

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140124

Device Name
S9 Elouera

Indications for Use *(Describe)*
The S9 Elouera self-adjusting device is indicated for the treatment of Obstructive Sleep Apnea (OSA) in patients (female patients with mild to moderate OSA when using AfH treatment mode) weighing more than 66 lb (30 kg).

It is intended for home and hospital use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anya C. Harry -S
2014.05.12
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