K132606

JAN 13 2014

510(k) Summary – S9 Cronulla for Her

Required	By section 807.92 (c)
Date Prepared	10th Jan, 2014
Owners Name	ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista, NSW 2153, Australia
Submitter	Greg Dockar + 61 2 8884 2157 (Phone) + 61 2 8884 2000 (FAX) GregD@resmed.com.au
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Classification Reference	21 CFR 868.5905 (Class II)
Product Code	73 BZD
Common/Usual Name	Non continuous ventilator (IPPB).
Proprietary Name	S9 Cronulla for Her
Predicate Device(s)	S8 Aspen (K091947)
Reason for submission	New Device

Indication for Use

The S9 Cronulla for Her self-adjusting system is indicated for the treatment of mild to moderate obstructive sleep apnea (OSA) in female patients weighing more than 66 lb (30 kg).

The S9 Cronulla for Her self-adjusting system 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
- Same technologies
- Same manufacturing process

The S9 Cronulla for Her retains all the same operating/technologies/manufacturing characteristics as the S8 Aspen (K091947). The S9 Cronulla for Her includes an additional treatment mode (software) called AutoSet for Her (AfH) which provides equivalent responses to apneas, snore and flattening breathing events for females in comparison to standard AutoSet mode. The S9 Cronulla for Her is indicated for a subset of the patient population when compared to the predicate S8 Aspen (K091947). Therefore this difference (subset) does not affect safety and effectiveness which remains unchanged from the predicate (K091947).

Design and Verification activities were performed on the S9 Cronulla for Her System 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 Cronulla for Her complies with the applicable requirements referenced in the FDA guidance documents:

- FDA Draft Reviewer Guidance for Ventilators (July 1995)
- 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- FDA Draft Guidance for Industry and FDA Staff - Design Considerations for Devices Intended for Home Use

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 to the standard AutoSet algorithm (K091947).

The primary endpoints were met in the AfH clinical trial. 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. Furthermore, investigation of sleep parameters showed that flow limitation was significantly decreased with the AfH algorithm compared to the standard AutoSet algorithm. Whilst no other statistically significant results were found in these parameters, there were the following improvements:

- REM sleep percentage
- RERAs

Subjective feedback also showed no significant differences between the AfH and standard AutoSet algorithms with all outcomes' median subjective ratings remaining "above average".

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

Non-Clinical Testing:

Verification activities were performed to verify that the software change to include an additional treatment mode ('AutoSet for Her') did not affect the safety and effectiveness of the subject device.

Side-by-Side bench testing was performed to verify that the S9 Cronulla for Her with H5i humidifier and heated tubing met the requirements of the S9 Cronulla System Specification, and compare the results to the predicate device (S8 Aspen with H4i Plus humidifier and heated tubing (K091947)). This bench testing included testing the performance of each therapy mode which included:

- Pressure stability
- Response to apneas
- Response to flow limitations and snore.

A breathing machine was used to simulate patient breathing patterns resulting 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 Cronulla for Her System Specification and to the predicate device's performance. The S9 Cronulla for Her met the predefined Clinical Pass/Fail criteria.

The S9 Cronulla for Her with and without the integrated heated humidifier (H5i) was designed and tested according to:

- 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
- IEC 60601-1:2005, Medical electrical equipment - Part 1: General requirements for safety Medical electrical equipment – General requirements for basic safety and essential performance

Software regression testing was also conducted.

Device Description

The 'S9 Cronulla for Her' contains a Micro-processor controlled blower (flow generator) 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 (standard, or heated), mask (patient interface) and humidifier. The 'S9 Cronulla for Her' System (S9 Cronulla for Her *with* HumidAire 5i) retains all the same hardware and performance features of the predicate device. Key features include in-line power supply, HumidAire 5i, tubing (heated and standard options) and colour LCD for better user interface.

The 'S9 Cronulla for Her' 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 female-specific OSA characteristics.

The functional characteristics of the S9 Cronulla for Her 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 modified device

Characteristic	Predicate Device S8 Aspen (K091947)	Modified device S9 Cronulla for Her	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 Cronulla for Her self-adjusting system is indicated for the treatment of mild to moderate obstructive sleep apnea (OSA) in female patients weighing more than 66 lb (30 kg). The S9 Cronulla for Her self-adjusting system is intended for home and hospital use.	Equivalent *Only name change- and reduced patient population from predicate*
Location of use (primary)	Hospital/Home	Hospital/Home	Equivalent
Performance			
Pressure range	4-20 cm H_2O (CPAP Mode) EPR +3 cm H_2O 4-20 cm H_2O (AutoSet Mode) EPR +3 cm H_2O	4-20 cm H_2O (CPAP Mode) EPR +3 cm H_2O 4-20 cm H_2O (AutoSet Mode) EPR +3 cm H_2O **4-20 cm H_2O (AutoSet AfH Mode) EPR +3 cm H_2O**	Equivalent: *Addition of treatment mode indicated for females*
Ramp	• 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) • **AutoSet for Her (AfH) (maximum to 20cm H_2O with CAD)** • CPAP, AutoSet with EPR(maximum to 20cm H_2O with CAD)	Equivalent: *Addition of treatment mode indicated for females*
System Components	• Flow generator • Integrated humidifier (HumidAire 4i Plus) • Mask, air tubing and heated tubing	• Flow generator • Integrated humidifier (H5i) • Mask, air tubing and heated tubing	Equivalent *Name change only from predicate (K091947)- same performance*

Conclusion

Based on the clinical and non-clinical results, the S9 Cronulla for Her is substantially equivalent to the Predicate device (S8 Aspen K091947).

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

January 13, 2014

ResMed Corporation
Mr. Jim Cassi
Vice President – Quality Assurance Americas
9001 Spectrum Center Boulevard
San Diego, CA 92123

Re: K132606
Trade/Device Name: ResMed™ S9 Cronulla for Her
Regulation Number: 21 CFR 868.5905
Regulation Name: Non-continuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: December 5, 2013
Received: December 9, 2013

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.

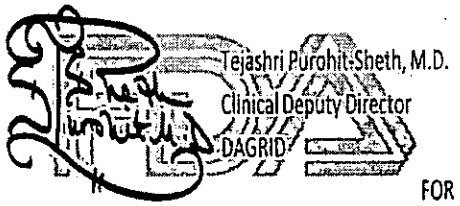
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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" (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,



FOR

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

Enclosure

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)*
K132606

Device Name
S9 Cronulla for Her

Indications for Use *(Describe)*
The S9 Cronulla for Her self-adjusting system is indicated for the treatment of mild to moderate obstructive sleep apnea (OSA) in female patients weighing more than 66 lb (30 kg).

The S9 Cronulla for Her self-adjusting system 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
2014.01.10
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