DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 9, 2016

ResMed Ltd
c/o Ms. Larissa D'andrea
Director, Government Regulatory Affairs
ReMed Corps
9001 Spectrum Center Boulevard
San Diego, California 92123

Re: K161487
Trade/Device Name: VPAP Adapt SV, VPAP Tx, S9 VPAP Tx
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: MNS
Dated: August 10, 2016
Received: August 11, 2016

Dear Ms. D'andrea:

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" (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 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.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Tina Kiang, Ph.D.
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 below.

510(k) Number *(if known)*

Device Name
VPAP Adapt SV

Indications for Use *(Describe)*
The VPAP ADAPT SV is intended to provide non-invasive ventilatory support to treat adult patients with obstructive sleep apnea (OSA) and Respiratory Insufficiency caused by central and/or mixed apneas and periodic breathing.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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 below.

510(k) Number *(if known)*

Device Name
VPAP Tx

Indications for Use *(Describe)*
The VPAP TX is indicated for the treatment of patients weighing more than 66 lb (> 30 kg) with obstructive sleep apnea (OSA), respiratory insufficiency, central or mixed apneas, or periodic breathing.
The VPAP TX is intended to be used in a clinical environment.

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)

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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 below.

510(k) Number *(if known)*

Device Name
S9 VPAP Tx

Indications for Use *(Describe)*
The S9 VPAP Tx is indicated for the treatment and titration of patients with obstructive sleep apnea (OSA), respiratory insufficiency, central or mixed apneas, or periodic breathing. CPAP, S, ST, T and PAC modes are indicated for patients weighing more than 30lb (13 kg); all other modes are indicated for patients weighing more than 66lb (30 kg).
The S9 VPAP Tx is intended to be used in a clinical environment.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary – VPAP Adapt SV

Required	By Section 807.92 (c)
Date Prepared	18 May, 2016
Owners Name	ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista, NSW 2153, Australia
Submitter	Jasjit Baveja + 61 2 8884 1518 (Phone) + 61 2 8884 2000 (FAX) Jasjit.baveja@resmed.com.au
Official Contact	Larissa D'Andrea Director, Government & Regulatory Affairs ResMed Corp 9001 Spectrum Center Boulevard San Diego, CA 92123 +1 858 836 6837 (Phone) +1 858 836 5519 (Fax) Larissa.D'Andrea@resmed.com
Product codes	73 MNS
Class	II
Classification Reference	21 CFR 868.5895, Product Code 73 MNS
Common/Usual Name	Ventilator, Continuous, Non-Life Supporting
Proprietary Name	VPAP Adapt SV
Predicate device(s)	VPAP Adapt SV (K051364)

Reason for submission

This 510(k) is being submitted as a labelling change for the addition of the following contraindication:

ASV therapy is contraindicated in patients with chronic, symptomatic heart failure (NYHA 2-4) with reduced left ventricular ejection fraction (LVEF ≤ 45%) and moderate to severe predominant central sleep apnea.

This contraindication is supported by SERVE-HF, which was a randomized, parallel, event-driven, international multi-center study in 1325 patients with chronic, symptomatic heart failure (NYHA 2-4) with reduced left ventricular ejection fraction (LVEF≤45%) and moderate to severe predominant central sleep apnea. The study investigated the effects of adding ASV to guideline-based medical management on survival and cardiovascular outcomes. The addition of ASV did not improve outcomes and showed an increased risk of cardiovascular mortality despite effective control of central sleep apnea.

Intended Use

The VPAP ADAPT SV is intended to provide non-invasive ventilatory support to treat adult patients with obstructive sleep apnea (OSA) and Respiratory Insufficiency caused by central and/or mixed apneas and periodic breathing.

Substantial Equivalence

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

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

ResMed has determined that the new device has not altered the safety and effectiveness of providing non- invasive ventilatory support for treatment for patients with Obstructive Sleep Apnoea (OSA) and respiratory insufficiency caused by central and/or mixed apneas, and periodic breathing. The new device complies with the applicable requirements referenced in the FDA guidance documents:

- FDA Draft Reviewer Guidance for Ventilators (July 1995)
- FDA Reviewer Guidance for Premarket Notification Submissions (November 1993)
- FDA Reviewer's and Industry, Guidance for the content of premarket submissions for software contained in medical devices, May 1998

As this was a labelling change only, no further clinical or non-clinical testing was required to show substantial equivalence to the predicate device VPAP Adapt SV (K051364)

The new device is as safe and effective as the predicate device.

Device description

The VPAP Adapt SV is identical to the predicate device VPAP Adapt SV (K051364), using a blower based positive pressure system. The device platform is identical to the VPAP Adapt SV (K051364) and contains a blower (motor/fan assembly), flow and pressure sensors, and processing electronics. The blower supplies pressurized air to the patient via a mask and air tubing.

The VPAP Adapt SV is a non-invasive flow generator device designed to provide adaptive servo-ventilation therapy to stabilize a patient's ventilation. The device continually measures the patient's instantaneous ventilation, and calculates a target ventilation equal to 90% of the patient's recent average ventilation (time constant 100 seconds). It then adjusts the degree of support to servo-control the patient's ventilation to at least equal the target ventilation.

Therapy modes contained in the VPAP Adapt SV are

- CPAP mode;
- Auto Servo Ventilation (ASV)

Therapy modes come from the predicate VPAP Adapt SV (K051364).

Characteristic	VPAP Adapt SV (K051364)	New Device (VPAP Adapt SV)	Comments
Indication for use	The VPAP ADAPT is intended to provide non-invasive ventilatory support to treat adult patients with obstructive sleep apnea (OSA) and Respiratory Insufficiency caused by central and/or mixed apneas and periodic breathing.	The VPAP ADAPT is intended to provide non-invasive ventilatory support to treat adult patients with obstructive sleep apnea (OSA) and Respiratory Insufficiency caused by central and/or mixed apneas and periodic breathing.	Equivalent *Only labeling change to include contraindication*
Location of use	Hospital/Home	Hospital/Home	Equivalent
Pressure Range and Treatment Modes			
	4-13 cm H_2O (CPAP) 4-25 cm H_2O (ASV)	4-13 cm H_2O (CPAP) 4-25 cm H_2O (ASV)	Equivalent
RAMP Settings	Feature enables a slow increase in the patient airflow to allow the patient to fall asleep before the device delivers the full pressure; the timer may be set to 0 – 45 minute delay periods, in 5-minutes increments	Feature enables a slow increase in the patient airflow to allow the patient to fall asleep before the device delivers the full pressure; the timer may be set to 0 – 45 minute delay periods, in 5-minutes increments	Equivalent
Flow generator operating system	Nucleus Plus	Nucleus Plus	Equivalent
Motor Type	Brush-less low voltage DC	Brush-less low voltage DC	Equivalent
Fan Type	Centrifugal	Centrifugal	Equivalent
Electronic Controller	Servo-control loop	Servo-control loop	
Power supply	100-240V, 50-60Hz	100-240V, 50-60Hz	Equivalent

Conclusion

The VPAP Adapt SV is substantially equivalent to the predicate device, VPAP Adapt SV (K051364).

510(k) Summary –VPAP Tx

Required	By Section 807.92 (c)
Date Prepared	18 May, 2016
Owners Name	ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista, NSW 2153, Australia
Submitter	Jasjit Baveja + 61 2 8884 1518 (Phone) + 61 2 8884 2000 (FAX) Jasjit.baveja@resmed.com.au
Official Contact	Larissa D'Andrea Director, Government & Regulatory Affairs ResMed Corp 9001 Spectrum Center Boulevard San Diego, CA 92123 +1 858 836 6837 (Phone) +1 858 836 5519 (Fax) Larissa.D'Andrea@resmed.com
Product codes	73 MNS
Class	II
Classification Reference	21 CFR 868.5895, Product Code 73 MNS
Common/Usual Name	Ventilator, Continuous, Non-Life Supporting
Proprietary Name	VPAP Tx
Predicate device(s)	VPAP Tx (K092186)

Reason for submission

This 510(k) is being submitted as a labelling change for the addition of the following contraindication:

ASV therapy is contraindicated in patients with chronic, symptomatic heart failure (NYHA 2-4) with reduced left ventricular ejection fraction (LVEF ≤ 45%) and moderate to severe predominant central sleep apnea.

This contraindication is supported by SERVE-HF, which was a randomized, parallel, event-driven, international multi-center study in 1325 patients with chronic, symptomatic heart failure (NYHA 2-4) with reduced left ventricular ejection fraction (LVEF≤45%) and moderate to severe predominant central sleep apnea. The study investigated the effects of adding ASV to guideline-based medical management on survival and cardiovascular outcomes. The addition of ASV did not improve outcomes and showed an increased risk of cardiovascular mortality despite effective control of central sleep apnea.

Indication for Use

The VPAP Tx is indicated for the treatment of patients weighing more than 66 lb (> 30 kg) with obstructive sleep apnea (OSA), respiratory insufficiency, central or mixed apneas, or periodic breathing.
The VPAP Tx is intended to be used in a clinical environment.

Substantial Equivalence

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

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

ResMed has determined that the new device has not altered the safety and effectiveness of treatment for patients with obstructive Sleep Apnoea (OSA), respiratory insufficiency central and/or mixed apneas, or periodic breathing who weigh more than 66 lb (>30 kg). The new device 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 Off-the-Shelf Software Use in Medical Devices (September 9,1999)

As this was a labelling change only, no further clinical or non-clinical testing was required to show substantial equivalence to the predicate device VPAP Tx (K092186).

The new device is as safe and effective as the predicate device.

Device Description

The VPAP Tx is identical to the predicate device VPAP Tx (K092186), using a blower based positive pressure system. The device platform is identical to the VPAP Tx (K092186) and contains a Micro- processor controlled blower system that generates airway pressures as required to maintain an “air splint” for effective treatment of OSA and/or respiratory insufficiency.

The VPAP Tx system comprises the flow generator, patient tubing, mask (patient interface) and optional humidifier.

Therapy modes contained in the VPAP Tx are:

- CPAP
- Auto-titrating
- Bi-level
- VAuto
- ASV

These modes come from the VPAP Tx (K092186).

Characteristic	VPAP Tx (K092186)	New Device (VPAP Tx)	Comments
Indication for use	The VPAP Tx is indicated for the treatment of patients weighing more than 66 lb (> 30 kg) with obstructive sleep apnea (OSA), respiratory insufficiency, central or mixed apneas, or periodic breathing. The VPAP Tx is intended to be used in a clinical environment.	The VPAP Tx is indicated for the treatment of patients weighing more than 66 lb (> 30 kg) with obstructive sleep apnea (OSA), respiratory insufficiency, central or mixed apneas, or periodic breathing. The VPAP Tx is intended to be used in a clinical environment.	Equivalent *Only labeling change to include contraindication*
Location of use	Hospital/Home	Hospital/Home	Equivalent
Pressure Range and Treatment Modes			
	4-20 cm H_2O (CPAP) 4-20 cm H_2O (Autoset) 3-30 cm H_2O (Bilevel) 4-25 cm H_2O (VAuto) 4-25 cm H_2O (ASV)	4-20 cm H_2O (CPAP) 4-20 cm H_2O (Autoset) 3-30 cm H_2O (Bilevel) 4-25 cm H_2O (VAuto) 4-25 cm H_2O (ASV)	Equivalent:
Flow generator operating system	ResMed proprietary 'FG Engine' using Diamond architecture	ResMed proprietary 'FG Engine' using Diamond architecture	Equivalent
Motor Type	Brush-less low voltage DC	Brush-less low voltage DC	Equivalent
Fan Type	Centrifugal	Centrifugal	Equivalent
Electronic Controller	Servo-control loop	Servo-control loop	
Power supply	100-240V, 50-60Hz	100-240V, 50-60Hz	Equivalent

Conclusion

The VPAP Tx is substantially equivalent to the predicate device, VPAP Tx (K092186).

510(k) Summary – S9 VPAP Tx

Required	By Section 807.92 (c)
Date Prepared	18 May, 2016
Owners Name	ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista, NSW 2153, Australia
Submitter	Jasjit Baveja + 61 2 8884 1518 (Phone) + 61 2 8884 2000 (FAX) Jasjit.baveja@resmed.com.au
Official Contact	Larissa D'Andrea Director, Government & Regulatory Affairs ResMed Corp 9001 Spectrum Center Boulevard San Diego, CA 92123 +1 858 836 6837 (Phone) +1 858 836 5519 (Fax) Larissa.D'Andrea@resmed.com
Product codes	73 MNS
Class	II
Classification Reference	21 CFR 868.5895, Product Code 73 MNS
Common/Usual Name	Ventilator, Continuous, Non-Life Supporting
Proprietary Name	S9 VPAP Tx
Predicate device(s)	S9 VPAP Tx (K123511)

Reason for submission

This 510(k) is being submitted as a labelling change for the addition of the following contraindication:

ASV therapy is contraindicated in patients with chronic, symptomatic heart failure (NYHA 2-4) with reduced left ventricular ejection fraction (LVEF ≤ 45%) and moderate to severe predominant central sleep apnea.

This contraindication is supported by SERVE-HF, which was a randomized, parallel, event-driven, international multi-center study in 1325 patients with chronic, symptomatic heart failure (NYHA 2-4) with reduced left ventricular ejection fraction (LVEF≤45%) and moderate to severe predominant central sleep apnea. The study investigated the effects of adding ASV to guideline-based medical management on survival and cardiovascular outcomes. The addition of ASV did not improve outcomes and showed an increased risk of cardiovascular mortality despite effective control of central sleep apnea.

Indication for Use

The S9 VPAP Tx is indicated for the treatment and titration of patients with obstructive sleep apnea (OSA), respiratory insufficiency, central or mixed apneas, or periodic breathing. CPAP, S, ST, T and PAC modes are indicated for patients weighing more than 30lb (13 kg); all other modes are indicated for patients weighing more than 66lb (30 kg).

The S9 VPAP Tx is intended to be used in a clinical environment.

Substantial Equivalence

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

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

ResMed has determined that the new device has not altered the safety and effectiveness of treatment for patients with Obstructive Sleep Apnoea (OSA), central and/or mixed apneas, or periodic breathing who weigh more than 66 lb (>30 kg).

The new device 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)

As this was a labelling change only, no further clinical or non-clinical testing was required to show substantial equivalence to the predicate device S9 VPAP Tx (K123511).

The new device is as safe and effective as the predicate device.

Device Description

The S9 VPAP Tx is identical to the predicate device S9 VPAP Tx (K123511), using a blower based positive pressure system. The device platform is identical to the S9 VPAP Tx (K092186) and contains a Micro- processor controlled blower system that generates airway pressures as required to maintain an “air splint” for effective treatment of OSA and/or respiratory insufficiency.

The S9 VPAP Tx comprises the flow generator, patient tubing, mask (patient interface) and optional humidifier.

Therapy modes contained in the VPAP Tx are

- CPAP
- Auto-titrating
- Bi-level
- VAuto
- ASV

These modes come from the S9 VPAP Tx (K123511).

Characteristic	S9 VPAP Tx (K123511)	New Device (S9 VPAP Tx)	Comments
Indication for use	The S9 VPAP Tx is indicated for the treatment and titration of patients with obstructive sleep apnea (OSA), respiratory insufficiency, central or mixed apneas, or periodic breathing. CPAP, S, ST, T and PAC modes are indicated for patients weighing more than 30lb (13 kg); all other modes are indicated for patients weighing more than 66lb (30 kg). The S9 VPAP Tx is intended to be used in a clinical environment.	The S9 VPAP Tx is indicated for the treatment and titration of patients with obstructive sleep apnea (OSA), respiratory insufficiency, central or mixed apneas, or periodic breathing. CPAP, S, ST, T and PAC modes are indicated for patients weighing more than 30lb (13 kg); all other modes are indicated for patients weighing more than 66lb (30 kg). The S9 VPAP Tx is intended to be used in a clinical environment.	Equivalent *Only labeling change to include contraindication*
Location of use	Hospital/Home	Hospital/Home	Equivalent
Pressure Range and Treatment Modes			
	4-20 cm H_2O (CPAP) 3-30 cm H_2O (Bi-level) 3-25 cm H_2O (VAuto) 3-30 cm H_2O (ASV) 3-30 cm H_2O (ASVAuto)	4-20 cm H_2O (CPAP) 3-30 cm H_2O (Bi-level) 3-25 cm H_2O (VAuto) 3-30 cm H_2O (ASV) 3-30 cm H_2O (ASVAuto)	Equivalent:
Flow generator operating system	Micrium uC/OS-II Software/digital	Micrium uC/OS-II Software/digital	Equivalent
Motor Type	Brush-less low voltage DC	Brush-less low voltage DC	Equivalent
Fan Type	Multiple impeller axial motor	Multiple impeller axial motor	Equivalent
Electronic Controller	Servo-control loop	Servo-control loop	
Power supply	100-240V, 50-60Hz	100-240V, 50-60Hz	Equivalent

Conclusion

The S9 VPAP Tx is substantially equivalent to the predicate device, S9 VPAP Tx (K123511).