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 19, 2017

Resmed Ltd
% Larissa D'Andrea
Director, Government & Regulatory Affairs
Resmed Corp.
9001 Spectrum Center Boulevard
San Diego, California 92123

Re: K161492
Trade/Device Name: Juno VPAP ST-A
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: MNS
Dated: December 16, 2016
Received: December 19, 2016

Dear Larissa 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)*
K161492

Device Name
Juno VPAP ST-A

Indications for Use *(Describe)*

The Juno VPAP ST-A is indicated to provide noninvasive ventilation for patients weighing more than 30lbs (13 kg) with respiratory insufficiency or obstructive sleep apnoea (OSA).

The iVAPS mode is indicated for patients weighing more than 66lbs (30 kg).

The Juno VPAP ST-A is intended for home and hospital use.

The humidifier is intended for single patient use in the home environment and re-use in a hospital/institutional 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

1. Date prepared

January 13, 2017

2. Applicant information

Company Name/ Owner	ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia
Submitter Name	Mr. Jean-Nicolas Boudaud Regulatory Affairs Manager +61 2 88841000 (phone) +61 2 88842004 (fax) Jean.boudaud@resmed.com.au
Correspondent Details/ Official Contact	Ms. Larissa D'Andrea Director, Government & Regulatory Affairs 9001 Spectrum Center Blvd San Diego CA 92123 USA (858) 836 6837 (phone) Larissa.D'Andrea@resmed.com Mr. Jean-Nicolas Boudaud Regulatory Affairs Manager +61 2 88841000 (phone) +61 2 88842004 (fax) Jean.boudaud@resmed.com.au

3. Device details and substantial equivalence claim [807.92(a)(3)]

Trade/Device Names	**Juno VPAP ST-A**
Device Common Name	Ventilator, continuous, non-life supporting
Regulation Number	21 CFR §868.5895
Regulation Name	Anesthesiology devices, Continuous Ventilator
Regulatory Class	Class II
Product Code	MNS
Predicate Device	ResMed Juno VPAP ST-A (**K153061)**

4. Device description

The subject device **Juno VPAP ST-A** retains all the same hardware, technologies and manufacturing characteristics as previously cleared in **K153061**. The device is used in a wider breathing circuit which typically comprises patient tubing and a mask (patient interface) to deliver a prescribed positive airway pressure treatment to patients.

Some of the key features of the device include an in-line power supply; fully integrated humidifier; alarms module; heater controller; colour LCD and simple controls for ease of use. The device also allows data transfer/connectivity via an integrated wireless module (When used in a hospital setting, remote changes may not be appropriate for certain patients, as these setting changes may not be communicated to all hospital personnel treating the patient. Hospital staff should liaise with the patient's regular care provider such that the desired therapy outcome is achieved).

Juno VPAP ST-A utilizes a Micro-processor controlled blower system that generates positive airway pressure (CPAP) between 4-20 cmH_2O as required to maintain an "air splint" for effective treatment of OSA and (Bilevel) pressures between 3-30 cmH_2O for the treatment respiratory insufficiency.

The therapy modes available in the **Juno VPAP ST-A** include CPAP, Spontaneous, Spontaneous/Timed, Timed, PAC and iVAPS. In this submission, the subject device now features an optional "AutoEPAP" function on iVAPS mode. AutoEPAP automatically adjusts EPAP pressure (within set values) in response to flow limitations or obstructions of the upper airway.

Juno VPAP ST-A is intended to be used under the conditions and purposes indicated in the labelling provided with the product.

It is a prescription device, supplied non-sterile.

5. Indications For Use

The **Juno VPAP ST-A** is indicated to provide noninvasive ventilation for patients weighing more than 30lbs (13 kg) with respiratory insufficiency or obstructive sleep apnoea (OSA).

The iVAPS mode is indicated for patients weighing more than 66lbs (30 kg).

The **Juno VPAP ST-A** is intended for home and hospital use.

The humidifier is intended for single patient use in the home environment and re-use in a hospital/institutional environment.

6. Predicate comparison

Characteristics	**Juno VPAP ST-A** (Subject device)	**Juno VPAP ST-A** (Predicate device - **K153061**)	Comments
Intended Use			
Indications for use	The **Juno VPAP ST-A** is indicated to provide noninvasive ventilation for patients weighing more than 30lbs (13 kg) with respiratory insufficiency or obstructive sleep apnoea (OSA). The iVAPS mode is indicated for patients weighing more than 66lbs (30 kg). The **Juno VPAP ST-A** is intended for home and hospital use. The Humidifier is intended for single patient use in the home environment and re-use in a hospital/institutional environment	The **Juno VPAP ST-A** is indicated to provide noninvasive ventilation for patients weighing more than 30lbs (13 kg) with respiratory insufficiency or obstructive sleep apnoea (OSA). The iVAPS mode is indicated for patients weighing more than 66lbs (30 kg). The **Juno VPAP ST-A** is intended for home and hospital use. The Humidifier is intended for single patient use in the home environment and re-use in a hospital/institutional environment	Same intended use - **Equivalent**
Environment of use	Hospital/Home	Hospital/Home	Same environment of use - **Equivalent**
Prescription status	Prescription only	Prescription only	Same prescription status - **Equivalent**
Therapies			
Modes available	• CPAP • S, ST, T • PAC • iVAPS with optional AutoEPAP	• CPAP • S, ST, T • PAC • iVAPS with fixed EPAP only	The subject device includes the same therapy modes as the predicate. An optional “AutoEPAP” function is added on the iVAPS mode. The role of AutoEPAP is to automatically adjust EPAP pressure (within a set min-max range) in order to maintain upper airway patency. Data is provided to demonstrate that the new algorithm

			provides equivalent therapy to set fixed EPAP. **Equivalent**
Pressure ranges	• 4-20 cmH_2O (CPAP) • 3-30 cmH_2O (bi-level) o AutoEPAP: 3-25 cmH_2O	• 4-20 cmH_2O (CPAP) • 3-30 cmH_2O (bi-level) o Fixed EPAP: 3-25 cmH_2O	The subject device operates within the same pressure ranges as the predicate in all modes. On the iVAPS (Bi-level mode), the range of adjustment for the new AutoEPAP feature is the same as with fixed EPAP, hence the same as the predicate. **Equivalent**
Ramp settings	• 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	Same ramp settings - **Equivalent**
Features			
Alarms module	Yes	Yes	Same integrated alarms module - **Equivalent**
Humidifier	Yes	Yes	Same integrated humidifier - **Equivalent**
Motor type	Brush-less low voltage DC	Brush-less low voltage DC	Same motor - **Equivalent**
Operating system	Microchip STM32F405ZG micro–controller with ARM32-bit Cortex™-M4 CPU	Microchip STM32F405ZG micro–controller with ARM32-bit Cortex™-M4 CPU	Same operating system - **Equivalent**
Supplemental oxygen	Labeled for use with Supplemental Oxygen	Labeled for use with Supplemental Oxygen	Same use with supplemental oxygen - **Equivalent**
Data transfer medium	• SD Card • Fully integrated wireless module	• SD Card • Fully integrated wireless module	Same data transfer and connectivity mediums - **Equivalent**
Hardware platform	• Gen 10	• Gen 10	Same hardware - **Equivalent**

7. Non Clinical data submitted

Bench test data is presented to demonstrate that the subject device meets all requirements of the Juno VPAP ST-A System Specification. For the new AutoEPAP algorithm, this includes characterization of the ventilator's response to a breathing machine that simulates patients flow limitations and apnoeas.

The **Juno VPAP ST-A** has also been tested to the relevant FDA consensus standards and other applicable requirements passing all test protocols. The **Juno VPAP ST-A** with and without the integrated heated humidifier (HumidAir) was designed and tested according to:

- IEC 60601-1:2005+AMD1:2012, Medical electrical equipment - Part 1: General requirements for safety Medical electrical equipment – General requirements for basic safety and essential performance
- IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-8:2006, Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance -- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-1-11:2010, Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

The 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)

8. Clinical data

Clinical trial data is provided to demonstrate that the added AutoEPAP iVAPS algorithm performed as expected in maintaining upper airway patency in patients with respiratory insufficiency. The data relates to a double-blinded, randomised, crossover study comparing the efficacy of the AutoEPAP iVAPS therapy mode with the fixed EPAP iVAPS mode (as previously used on the predicate).

In patients with respiratory insufficiency, the trial demonstrated that therapy with AutoEPAP iVAPS was as efficacious as iVAPS with fixed EPAP in terms of AHI, ODI, SPO_2, $PtcCO_2$ and sleep quality.

No serious adverse events or complications related to the study device were recorded.

9. Substantial Equivalence Conclusion

This submission demonstrates that the subject device is substantially equivalent to the predicate Juno VPAP ST-A (**K153061**).