



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

April 13, 2016

ResMed Ltd  
Larissa D'Andrea  
Director, Government & Regulatory Affairs  
9001 Spectrum Center Boulevard  
San Diego, California 92123

Re: K153061  
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: March 9, 2016  
Received: March 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

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

Enclosure

## Indications for Use

510(k) Number (if known)  
K153061

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  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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** April 12<sup>th</sup>, 2016

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)  
(858) 836 5519 (fax)  
Larissa.D'Andrea@resmed.com

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 S9 VPAP ST-A (**K113288**)

Reference Device ResMed S9 WANDA VPAP ST (**K140159**)

#### **4. Device description**

The **Juno VPAP ST-A** System is a positive pressure device which design is based on the previously cleared ResMed S9 WANDA VPAP ST (**K140159**) platform. The device is used in a wider breathing circuit which typically comprises patient tubing and a mask (patient interface) to deliver the prescribed positive pressure treatment to patients.

Some of the key features of the platform include: in-line power supply; fully integrated humidifier; heater controller; colour LCD and simple controls for ease of use.

An integrated wireless module for data transfer/connectivity is also included (note: Remote changes in a hospital setting may not be appropriate, 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** contains a Micro-processor controlled blower system that generates positive airway pressure (CPAP) between 4-20 cmH<sub>2</sub>O as required to maintain an "air splint" for effective treatment of OSA and (Bilevel) pressures between 3-30 cmH<sub>2</sub>O for the treatment respiratory insufficiency.

The device also incorporates an Alarm function as a fully integrated module.

The therapy modes available in the **Juno VPAP ST-A** come from the predicate ResMed S9 VPAP ST-A (**K113288**). These include CPAP, Spontaneous, Spontaneous/Timed, Timed, PAC and iVAPS.

**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. Comparison with previously cleared devices

Characteristics	Juno VPAP ST-A (new device)	S9 VPAP ST-A (K113288) <b>Predicate device</b>	S9 WANDA VPAP ST (K140159) <b>Reference device only</b>	Comments
<b>Intended Use</b>				
Indications for use	<p>The <b>Juno VPAP ST-A</b> is indicated to provide noninvasive ventilation for patients weighing more than 30lbs (13 kg) with respiratory insufficiency or obstructive sleep apnoea (OSA).</p> <p>The iVAPS mode is indicated for patients weighing more than 66lbs (30 kg).</p> <p>The <b>Juno VPAP ST-A</b> is intended for home and hospital use.</p> <p>The Humidifier is intended for single patient use in the home environment and re-use in a hospital/institutional environment</p>	<p>The <b>S9 VPAP ST-A</b> is indicated to provide noninvasive ventilation for patients weighing more than 30lbs (13 kg) or more than 66lbs (30 kg) in iVAPS mode with respiratory insufficiency or obstructive sleep apnoea (OSA). The <b>S9 VPAP ST-A</b> is intended for home and hospital use.</p>	<p>The <b>S9 WANDA VPAP ST</b> is indicated for the treatment of Obstructive Sleep Apnea (OSA) in patients weighing more than 66 lb (30 kg). It is intended for use in the hospital and home.</p>	<p>The new device has the same intended use as the predicate S9 VPAP ST-A (K113288).</p> <p><b>Equivalent</b></p>
Environment of use	Hospital/Home	Hospital/Home	Hospital/Home	<b>Equivalent</b>
Prescription status	Prescription only	Prescription only	Prescription only	<b>Equivalent</b>



Therapies				
Modes available	<ul style="list-style-type: none"> <li>• CPAP</li> <li>• S, ST, T</li> <li>• PAC</li> <li>• iVAPS</li> </ul>	<ul style="list-style-type: none"> <li>• CPAP</li> <li>• S, ST, T</li> <li>• PAC</li> <li>• iVAPS</li> </ul>	<ul style="list-style-type: none"> <li>• CPAP (w/o EPR mode)</li> <li>• S, ST, T</li> <li>• VAuto</li> </ul>	<p>The new device includes the same therapy modes as the predicate S9 VPAP ST-A (<b>K113288</b>).</p> <p><b>Equivalent</b></p>
Pressure ranges	<ul style="list-style-type: none"> <li>• 4-20 cmH2O (CPAP)</li> <li>• 3-30 cmH2O (bi-level)</li> </ul>	<ul style="list-style-type: none"> <li>• 4-20 cmH2O (CPAP)</li> <li>• 3-30 cmH2O (bi-level)</li> </ul>	<ul style="list-style-type: none"> <li>• 4-20 cm H2O (CPAP)</li> <li>• 4-25 cmH2O (VAuto) EPR + 3 cmH2O</li> <li>• 3-25 cmH2O (bi-level)</li> </ul>	<p>The new device operates in the same pressure ranges as the predicate S9 VPAP ST-A (<b>K113288</b>).</p> <p><b>Equivalent</b></p>
Ramp settings	<ul style="list-style-type: none"> <li>• User selected as “Off” to 45 minutes in 5 minute increments</li> <li>• Max Ramp time set at clinician’s discretion</li> </ul>	<ul style="list-style-type: none"> <li>• User selected as “Off” to 45 minutes in 5 minute increments</li> <li>• Max Ramp time set at clinician’s discretion</li> </ul>	<ul style="list-style-type: none"> <li>• User selected as “Off” to 45 minutes in 5 minute increments</li> <li>• Max Ramp time set at clinician’s discretion</li> </ul>	<p><b>Equivalent</b></p>
Features				
Alarms module	Yes	Yes	No	<p>Both the new device and the predicate S9 VPAP ST-A (<b>K113288</b>) include an Alarm module.</p> <p><b>Equivalent</b></p>
Humidifier	Yes - HumidAir	Yes – H5i	Yes - HumidAir	<p>The new device includes the last generation humidifier that was first used in S9 WANDA VPAP ST (<b>K140159</b>). The humidifier function and performance is equivalent to that of the predicate S9 VPAP ST-A (<b>K113288</b>).</p> <p>All humidifiers are intended for single patient use in the home environment and re-use in a hospital/institutional environment</p> <p><b>Equivalent</b></p>



Motor type	Brush-less low voltage DC	Brush-less low voltage DC	Brush-less low voltage DC	<b>Equivalent</b>
Operating system	Microchip STM32F405ZG micro-controller with ARM32-bit Cortex™-M4 CPU	Micrium uC/OS-II Software/digital	Microchip STM32F405ZG micro-controller with ARM32-bit Cortex™-M4 CPU	The new device includes an updated micro and CPU compared to the predicate. Those components are coming from S9 WANDA VPAP ST (K140159).  <b>Equivalent</b>
Supplemental oxygen	Labeled for use with Supplemental Oxygen	Labeled for use with Supplemental Oxygen	Labeled for use with Supplemental Oxygen	<b>Equivalent</b>
Data transfer medium	<ul style="list-style-type: none"> <li>• SD Card</li> <li>• Fully integrated wireless module</li> </ul>	<ul style="list-style-type: none"> <li>• SD Card</li> <li>• Optional wireless module</li> </ul>	<ul style="list-style-type: none"> <li>• SD Card</li> <li>• Fully integrated wireless module</li> </ul>	The new device and the predicate both provide connectivity to ResMed's ECO platform (K132371) however access to ECO is provided via an optional module on the predicate whilst the new device includes the built-in module previously cleared with S9 WANDA VPAP ST (K140159).  <b>Equivalent</b>
Hardware platform	<ul style="list-style-type: none"> <li>• Gen 10</li> </ul>	<ul style="list-style-type: none"> <li>• Gen 9</li> </ul>	<ul style="list-style-type: none"> <li>• Gen 10</li> </ul>	The new device reuses the S9 WANDA VPAP ST (K140159) platform so that numerous hardware components are common with this previously cleared platform.  <b>Equivalent</b>

## **7. Non Clinical data submitted**

Bench test data is presented to demonstrate that the new device meets its published specifications and back-to-back testing shows substantial equivalence to the predicate device S9 VPAP ST-A (K113288).

All bench tests confirmed that the product met the predetermined acceptance criteria, this included Pressure, Flow, Pressure Support, Trigger and Cycling, Hypopnea and Apnea tests against the predicate devices using common protocols for both devices.

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 data for the **Juno VPAP ST-A** is not required as the predicate devices have been subjected to clinical trial requirements or validated patient simulation models have been used during the bench testing phases

## **9. Substantial Equivalence Conclusion**

This submission demonstrates that the new **Juno VPAP ST-A** is substantially equivalent to the predicate S9 VPAP ST-A (K113288).