April 26, 2018

ResMed Ltd
% Sheila Bruschi
Senior Manager, Regulatory Affairs, ResMed Corp
Resmed Corp (Registration Number: 3007573469)
9001 Spectrum Center Boulevard
San Diego, California 92123

Re: K172875
Trade/Device Name: Astral 100/150
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK, NOU
Dated: March 29, 2018
Received: March 30, 2018

Dear Sheila Bruschi:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

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)*
K172875

Device Name
Astral 100/150

Indications for Use *(Describe)*
The Astral 100/150 provides continuous or intermittent ventilatory support for patients weighing more than 11lb (5kg) who require mechanical ventilation.
The iVAPS mode with optional AutoEPAP is intended for patients weighing more than 66lb (30kg).
The Astral device is intended to be used in home, institution/hospital and portable applications for both invasive and non-invasive ventilation.

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.

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510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

1. Date prepared

April 26, 2018

2. Applicant information

Company Name/ Owner	ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia
Submitter Name	Peter Jennings Senior Regulatory Affairs Manager **Tel:** + 61 2 8884 2232 **Fax:** + 61 2 8884 2004 peter.jennings@resmed.com.au
Correspondent Details/ Official Contact	Miss Sheila Bruschi Director, Regulatory Affairs ResMed Corp. 9001 Spectrum Center Blvd San Diego CA 92123 USA **Tel:** +1 858 836 5934 **Fax:** +1 858 836 5519 sheila.bruschi@resmed.com

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

Trade/Device Names	**Astral 100/150**
Device Common Name	Continuous ventilator
Regulation Number	21 CFR 868.5895
Regulation Name	Anesthesiology devices, Continuous Ventilator
Regulatory Class	Class II
Product Code	Primary product code CBK Secondary product code NOU
Predicate Device	ResMed Astral 100/150 (K152068)
Reference Device	ResMed Juno VPAP ST-A (K161492)

4. Indications For Use

The Astral 100/150 provides continuous or intermittent ventilatory support for patients weighing more than 11lb (5kg) who require mechanical ventilation.

The iVAPS mode with optional AutoEPAP is intended for patients weighing more than 66lb (30kg).

The Astral device is intended to be used in home, institution/hospital and portable applications for both invasive and non-invasive ventilation.

5. Device description

The Astral ventilator system uses a micro-processor controlled blower, which, along with valves and pressure and flow sensors, achieves pressure, flow and time regulation of air delivery. Air is directed to the patient via one of three ventilator breathing circuits; double circuit, single circuit with expiratory valve, or single circuit with intentional leak. Supplemental oxygen can be entrained at the inlet to the main turbine. The device provides both therapeutic alarms (e.g. tidal volume) and technical alarms (e.g. system fault), and a user interface allowing adjustment of clinical parameters and display of monitored clinical data. The Astral can use external AC or DC power supply and contains an integrated battery.

The Astral is capable of providing the following types of ventilatory support:

- Assist/Control and SIMV with either volume or pressure control
- Continuous Spontaneous Ventilation in either Pressure Support or CPAP
- Volume Assurance and Apnea Ventilation

6. Predicate Comparison

The Astral 100/150 has the same intended use and similar indications, technological characteristics, and principles of operation as the previously cleared predicate Astral 100/150 (K152068).
The main change to the subject 510(k) is the addition of the optional AutoEPAP feature to the iVAPS therapy mode. The purpose of EPAP (Expiratory Positive Airway Pressure) is to maintain upper airway patency. The iVAPS mode in the predicate device includes an EPAP feature which is a manually titrated fixed EPAP. The optional AutoEPAP feature automatically adjusts the EPAP pressure in response to flow limitation (partial obstruction of the upper airway) or apnea (complete obstruction of the upper airway), within pre-set limits determined by the prescribing physician. Whether EPAP is set to manual or automatic, the operating range of EPAP is the same, and the therapeutic effect is the same, i.e. maintenance of an open upper airway. The AutoEPAP feature has been previously cleared on the reference device Juno VPAP ST-A (K161492). The AutoEPAP feature is not intended for invasive use. Other technological differences between the subject device and the predicate device are:

1) Extending the Safety Volume supplementary feature to leak circuits (cleared in K152068 on valved circuits)
2) Duplication of ST mode as PS mode (with leak circuit) to enable clinician preference on PEEP/EPAP terminology

Characteristic	Predicate Device: Astral 100/150 (K152068)	Subject Device: Astral 100/150	Substantially Equivalent?
Product code	CBK, NOU	CBK, NOU	YES
Intended Use	Continuous or intermittent ventilatory support Invasive & non-invasive Adult and Pediatric (>5kg) Home, institution/hospital, & portable	Continuous or intermittent ventilatory support Invasive & non-invasive Adult and Pediatric (>5kg) Home, institution/hospital, & portable	YES
Intended Patient Population	Patients who require mechanical ventilation (Continuous or intermittent ventilatory support) Adult and Pediatric (>5kg), iVAPS (>30kg)	Patients who require mechanical ventilation (Continuous or intermittent ventilatory support) Adult and Pediatric (>5kg), iVAPS (>30kg)	YES
Therapies			
Modes	ACV PACV V-SIMV P-SIMV PS & ST CPAP PAC iVAPS (fixed manual EPAP)	ACV PACV V-SIMV P-SIMV PS & ST CPAP PAC iVAPS (optional AutoEPAP)	YES *Clinical and bench data for AutoEPAP on the subject Astral device demonstrate it is substantially equivalent to manual EPAP.* *Moreover, AutoEPAP in iVAPS mode has been cleared in the reference device K161492.* *PS & ST with intentional leak have the same functionality and clinical intent.*
Supplementary Therapy Features	SV (Safety Volume) Sigh Apnea Ventilation Manual Breath	SV (Safety Volume) Sigh Apnea Ventilation Manual Breath	YES *SV on therapy modes with leak circuits has the same clinical intent and functional implementation as SV on equivalent therapy modes with valved circuits.*
Ventilation Control Parameters			
Pressure Range [cmH20]	IPAP: 4-50 EPAP: 2-25 s CPAP: 3-20 PEEP: Off, 3 to 20 Accuracy: ±(0.5 + 5% of target)	IPAP: 4-50 EPAP: 2-25 s CPAP: 3-20 PEEP: Off, 3 to 20 Accuracy: ±(0.5 + 5% of target)	YES
Tidal Volume [mL]	100-2500 (adult) 50-500 (pediatric) Accuracy ± 12 ml or 10% whichever is greater. (Valved Circuits)	100-2500 (adult) 50-500 (pediatric) Accuracy ± 12 ml or 10% whichever is greater. (Valved Circuits)	YES
Respiratory Rate (Breathing Frequency) [bpm]	2-50 (adult) 5-80 (pediatric) Accuracy ±2%	2-50 (adult) 5-80 (pediatric) Accuracy ±2%	YES

Characteristic	Predicate Device: Astral 100/150 (K152068)	Subject Device: Astral 100/150	Substantially Equivalent?
Rise Time	Min-900 msec	Min-900 msec	YES
Timed Inspiration	0.2 to 5 seconds Accuracy ±(20 ms +5% of setting)	0.2 to 5 seconds Accuracy ±(20 ms +5% of setting)	YES
Sensitivity	Inspiratory Flow controlled 0.5 to 15l/min	Inspiratory Flow controlled 0.5 to 15l/min	YES
Technology & Design			
Operating Principle	Micro-processor controlled blower as air source	Micro-processor controlled blower as air source	YES
Technology	Software based pressure, flow and time regulation with secondary volume target	Software based pressure, flow and time regulation with secondary volume target	YES
Material contact status	Permanent contact duration, indirect dry airpath patientcontacting materials	Permanent contact duration, indirect dry airpath patientcontacting materials	YES
Circuit Interfaces	Vented & Non-vented Invasive & Non-invasive	Vented & Non-vented Invasive & Non-invasive	YES
Circuit Types	Double limb Single limb with expiratory valve Single limb with intentional leak	Double limb Single limb with expiratory valve Single limb with intentional leak	YES
User Interface	LCD screen, soft keys, mute button & LED indicators.	LCD screen, soft keys, mute button & LED indicators.	YES
System Components	Ventilator Mask, invasive patient interface Air tubing, air filter, optional antibacterial filter Optional humidifier/ HME, oximeter, nebuliser	Ventilator Mask, invasive patient interface Air tubing, air filter, optional antibacterial filter Optional humidifier/ HME, oximeter, nebuliser	YES
Power	AC, DC and Internal Battery	AC, DC and Internal Battery	YES
Supplemental Oxygen	Labeled for use with supplemental oxygen Optional oxygen sensor	Labeled for use with supplemental oxygen Optional oxygen sensor	YES

7. ***Non Clinical data***

Design and Verification activities were performed on the Astral as a result of the risk analysis and product requirements. Performance testing included:

- accuracy of ventilation,
- volume & pressure controls and monitoring,
- waveform performance (flow, pressure, volume),
- alarms verification.

All tests confirmed the product met the predetermined acceptance criteria. In particular bench testing for the AutoEPAP feature included characterization of the ventilator's response to a breathing machine that simulates patients flow limitations and apneas.

The Astral was designed and tested in accordance with the applicable requirements in relevant FDA guidance documents and international standards including:

- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
- ISO 80601-2-72:2015, Medical Electrical Equipment – Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients
- IEC 60601-1:2005+AMD1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: Electromagnetic compatibility - Requirements and tests

8. Clinical data

Clinical trial data is provided to demonstrate that the AutoEPAP algorithm performed as expected in maintaining upper airway patency in patients with respiratory failure or respiratory insufficiency. The data relates to a multi-center, single-blind, randomized, cross-over clinical trial comparing AutoEPAP algorithm in iVAPS therapy mode with manual EPAP titration in iVAPS therapy mode.

The trial demonstrated that for the primary outcome Oxygen Desaturation Index (ODI4%) as a measure of upper airway obstruction, the iVAPS with AutoEPAP algorithm is non-inferior to iVAPS with manual EPAP.

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

9. Substantial Equivalence Conclusion

The indications for use, technological characteristics, and principles of operation are similar to the predicate device. Clinical data and non-clinical performance data supports that the subject device is substantially equivalent to the predicate device.