Food and Drug Administration
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May 13, 2016

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

Re: K152068
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 18, 2016
Received: March 23, 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.
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Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Astral 100/150

Indications for Use:

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

The iVAPS mode 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.

Prescription Use ____**X**_____ AND/OR Over-The-Counter Use____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

510(k) Summary – Astral 100/150

Date prepared	22 April, 2016
Submitter	Peter Jennings Senior Regulatory Affairs Manager
Official contact	Larissa D'Andrea Director, Regulatory Government Affairs ResMed Corp. 9001 Spectrum Center Blvd., San Diego CA 92123 USA Tel: +1 858-836-6837 Fax: +1 858-836-5519
Proprietary name	Astral 100/150
Common name	Continuous ventilator
Classification	21 CFR 868.5895 Primary product code CBK Secondary product code NOU Class II Ventilator, continuous, facility use
Predicate Devices	ResMed Astral 100/150 (K133868)
Reference Device	Respironics Trilogy 200 (K093416)
Reason for submission	New device

Indication 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 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.

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

Substantial Equivalence

The Astral has the following similarities to the previously cleared predicate devices:

- Same intended use
- Same scientific technology
- Same operating principle

There is no change to the intended use, scientific technology, operating principle and manufacturing process from the primary predicate device Astral 100/150 (K133868). The main change is the addition of iVAPS therapy mode As with AVAPS mode on the reference device Trilogy 200 (K093416), iVAPS is a Volume Assured Pressure Support therapy mode which adjusts pressure support to meet a preset ventilation target. As with AVAPS mode on Trilogy 200, iVAPS on Astral 100/150 is for a restricted patient weight within the continuous or intermittent ventilator support indication. Otherwise the modified Astral has changes to the main PCBA enabling addition of an alternate external battery and alternate AC power supplies.

A comparative summary of the technological characteristics of the Astral device with the primary predicate and reference devices is presented below.

Characteristic	Astral 100/150 (new device)	Astral 100/150 (K133868)	Trilogy 200 (K093416)	Comparison
Product Code	CBK, NOU	CBK, NOU	CBK	Substantially Equivalent
Intended Use	Continuous or intermittent ventilatory support	Continuous or intermittent ventilatory support	Continuous or intermittent ventilatory support	Substantially Equivalent *Same Intended Use. and equivalent patient population as AVAPS on Trilogy*

	Invasive & non-invasive Adult and Pediatric (>5kg), iVAPS (>30kg) Home, institution/ hospital, & portable	Invasive & non-invasive Adult and Pediatric (>5kg) Home, institution/ hospital, & portable	Invasive & non-invasive Adult and Pediatric (>5kg), AVAPS (adult) Home, institution/ hospital, & portable	
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)	Patients who require mechanical ventilation (Continuous or intermittent ventilatory support) Adult and Pediatric (>5kg), AVAPS (adult)	Substantially Equivalent *Intended Patient Population is the same as the predicate, , and equivalent patient population as AVAPS on Trilogy)*
Therapy Modes				
VC-CMV mode (Volume Control – Continuous Mandatory Ventilation)	ACV *Patient or time triggered.*	ACV *Patient or time triggered.*	CV, AC *Patient or time triggered.*	Substantially Equivalent *Astral implementation is unchanged*
PC-CMV mode (Pressure Control - Continuous Mandatory Ventilation)	PACV *Patient or time triggered.*	PACV *Patient or time triggered.*	T, PC *Patient or time triggered.*	Substantially Equivalent *Astral implementation is unchanged*
V-SIMV (Volume - Intermittent Mandatory Ventilation)	V-SIMV *Mandatory breaths (tidal volume) may be time triggered or patient triggered. Spontaneous breaths are pressure support.*	V-SIMV *Mandatory breaths (tidal volume) may be time triggered or patient triggered. Spontaneous breaths are pressure support.*	SIMV *Mandatory breaths (tidal volume) may be time triggered or patient triggered. Spontaneous breaths are pressure support.*	Substantially Equivalent *Astral implementation is unchanged*
P-SIMV (Pressure - Intermittent Mandatory Ventilation)	P-SIMV *Mandatory breaths (set pressure) may be time triggered or patient triggered. Spontaneous breaths are pressure support.*	P-SIMV *Mandatory breaths (set pressure) may be time triggered or patient triggered. Spontaneous breaths are pressure support.*	PC-SIMV *Mandatory breaths (set pressure) may be time triggered or patient triggered. Spontaneous breaths are pressure support.*	Substantially Equivalent *Astral implementation is unchanged*
CSV (Continuous Spontaneous Ventilation)	PS (*valved*) & ST (*intentional leak*) *Patient (Spontaneous) and Time*	PS (*valved*) & ST (*intentional leak*) *Patient (Spontaneous) and Time*	S, S/T & T *Patient (Spontaneous) and Time (Mandatory via*	Substantially Equivalent *Astral implementation is unchanged*

	(Mandatory via Breathing Frequency) triggered. All breaths can be patient or time terminated.	*(Mandatory via Breathing Frequency) triggered. All breaths can be patient or time terminated.*	*Breath Rate) triggered. Breaths can be patient or time (Mandatory breath duration is set inspiratory time) cycled.*	
	CPAP *Constant positive pressure*	CPAP *Constant positive pressure*	CPAP *Constant positive pressure*	Substantially Equivalent *Astral implementation is unchanged*
	PAC *Patient (Spontaneous) and Time (Mandatory via Breathing Frequency) triggered. All breaths time cycled.*	PAC *Patient (Spontaneous) and Time (Mandatory via Breathing Frequency) triggered. All breaths time cycled.*	PC, S & T *Patient (Spontaneous or "assist") and Time (Mandatory via Breath Rate) triggered. All breaths time cycled (or can be configured to be).*	Substantially Equivalent *Astral implementation is unchanged*
Volume Assurance (*Adaptive control mechanism that can introduce a degree of volume assurance to pressure-control/ pressure-support modes*)	iVAPS *Breath by breath control of pressure support within given limits, to achieve an alveolar minute volume target. Indications: Patients > 66 lbs (30 kg).* SV (Safety Volume) *Breath by breath control of pressure support within given limits, to achieve a tidal volume target.*	SV (Safety Volume) *Breath by breath control of pressure support within given limits, to achieve a tidal volume target.*	AVAPS *Breath by breath control of pressure support within given limits, to achieve a tidal volume target. Indications: Adult patients*	Substantially Equivalent to Trilogy K093416 for iVAPS implementation. *All modes adjust the pressure support, within practitioner-determined limits, to meet the preset ventilation target.*
Supplementary Features	Sigh Apnea Ventilation Manual Breath	Sigh Apnea Ventilation Manual Breath	Sigh Apnea Ventilation	Substantially Equivalent *Astral implementation is unchanged*
Ventilation Control Parameters				
Pressure Range [cmH20]	IPAP: 4-50 EPAP: 2-25 s CPAP: 3-20 PEEP: Off, 3 to 20 *Accuracy: ±(0.5*	IPAP: 4-50 EPAP: 2-25 s CPAP: 3-20 PEEP: Off, 3 to 20 *Accuracy: ±(0.5*	IPAP: 4-50 EPAP: 0-25 CPAP: 4-20 *Accuracy: greater*	Substantially Equivalent

	+ 5% of target)	*+ 5% of target)*	*of 2cmH2O or 8% of setting*	
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)*	50-2000 *Accuracy: greater of 15mL or 10% of setting (Active Circuits)*	Substantially Equivalent
Respiratory Rate (Breathing Frequency) [bpm]	2-50 (adult) 5-80 (pediatric) *Accuracy ±2%*	2-50 (adult) 5-80 (pediatric) *Accuracy ±2%*	1-60 *Accuracy ±1 bpm or 10% of setting*	Substantially Equivalent
Rise Time	Min-900 msec	Min-900 msec	1-6 (*nominal values*)	Substantially Equivalent
Timed Inspiration	0.2 to 5 seconds *Accuracy ±(20 ms +5% of setting)*	0.2 to 5 seconds *Accuracy ±(20 ms +5% of setting)*	0.3 to 5 seconds *Accuracy ±100ms*	Substantially Equivalent
Sensitivity	Inspiratory Flow controlled 0.5 to 15l/min	Inspiratory Flow controlled 0.5 to 15l/min	Inspiratory & Expiratory Flow controlled	Substantially Equivalent
Technology & Design				
Operating Principle	Micro-processor controlled blower as air source	Micro-processor controlled blower as air source	Micro-processor controlled blower as air source	Substantially Equivalent *Same operating principle*
Technology	Software based pressure, flow and time regulation with secondary volume target	Software based pressure, flow and time regulation with secondary volume target	Software based pressure, flow and time regulation with secondary volume target	Substantially Equivalent *Same technology*
Material contact status	Permanent contact duration, indirect dry air-path patient-contacting materials	Permanent contact duration, indirect dry air-path patient-contacting materials	Permanent contact duration, indirect dry air-path patient-contacting materials	Substantially Equivalent *Status unchanged from K133868*
Materials	Various materials, including: • Thermoplastic Polyurethane (TPU) • Polycarbonate (PC) and PC blends • Polypropylene (PP) • Silicone • Aluminium	Various materials, including: • Thermoplastic Polyurethane (TPU) • Polycarbonate (PC) and PC blends • Polypropylene (PP) • Silicone • Aluminium	Proprietary information	Substantially Equivalent *Materials unchanged from K133868*
Circuit Interfaces	Vented & Non-vented	Vented & Non-vented	Vented & Non-vented	Substantially Equivalent

	Invasive & Non-invasive	Invasive & Non-invasive	Invasive & Non-invasive	
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	Single limb with expiratory valve with proximal flow & pressure sensing Single limb with expiratory valve Single limb with intentional leak	Substantially Equivalent *Same circuit types*
User Interface	LCD screen, keys & LED indicators	LCD screen, keys & LED indicators	LCD screen, hard keys & LED indicators	Substantially Equivalent
Power	AC, DC, & Internal battery	AC, DC, & Internal battery	AC, DC, & Internal battery	Substantially Equivalent
System Components	Ventilator Mask, invasive patient interface Air tubing, air filter, optional antibacterial filter Optional external humidifier or HME	Ventilator Mask, invasive patient interface Air tubing, air filter, optional antibacterial filter Optional external humidifier or HME	Ventilator Mask, invasive patient interface Air tubing, air filter, optional antibacterial filter Optional external humidifier or HME	Substantially Equivalent
Supplemental Oxygen	Labeled for use with supplemental oxygen Optional oxygen sensor	Labeled for use with supplemental oxygen Optional oxygen sensor	Labeled for use with supplemental oxygen	Substantially Equivalent

Non-Clinical Performance 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),
- accuracy and repeatability of triggering and cycling,
- endurance and environmental testing,
- alarms verification.

All tests confirmed the product met the predetermined acceptance criteria. In particular non-clinical side-by-side performance testing was performed for the new therapy mode. Characteristics tested included flow, pressure and volume waveforms, ventilation control parameter accuracy, and patient trigger reliability and synchrony. As the new device included electrical changes, testing included updated third party test reports to IEC 60601-1:2005 and IEC 60601-1-2:2007 (+ additional ESD & EMI to IEC 60601-1-2 Ed 4.0). There was no change to cleaning procedures or materials from the predicate device so no additional testing was conducted in these areas. This suite of tests supports the claim that the Astral is substantially equivalent to the predicate device.

Human Factors/Usability Engineering evaluations were performed on the Astral in order to mitigate risks associated with users performing tasks incorrectly or failing to perform tasks which could result in serious harm. Human Factors/Usability Engineering testing was performed for the clearance of the predicate Astral device (K133868). Additional Human Factors/Usability Engineering testing was performed for iVAPS implementation, disconnection alarm and external battery.

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)
- ASTM F 1246-91 (2005) Standard Specification for Electrically Powered Home Care Ventilators
- ISO 10651-2:2004. Lung ventilators for medical use - Part 2: Home care ventilators for ventilator-dependent patients
- IEC 60601-1:2005 Medical electrical equipment. Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: Electromagnetic compatibility - Requirements and tests

Clinical testing was not required.

Conclusion

The intended use, technological characteristics, and principles of operation are similar to the predicate and reference devices. Non-clinical performance data supports the claim that the new device is substantially equivalent to the predicate and reference devices. The primary modification of the inclusion of iVAPS therapy mode remains within the previously cleared indications for use for VAPS therapy. Thus the data in this submission supports the claim of substantial equivalence to the identified predicate and reference devices.