



February 23, 2026

ResMed Pty Ltd
% Nicole Wilson
Director, Regulatory Product Strategy & Delivery Regulatory Affairs
ResMed Pty Ltd
1 Elizabeth Macarthur Drive
Bella Vista NSW 2153, Australia

Re: K251661
Trade/Device Name: Mariana Minerva; Mariana Nimbus
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: MNS, BTT
Dated: January 23, 2026
Received: January 23, 2026

Dear Nicole Wilson:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K251661

Device Name
Mariana Minerva;
Mariana Nimbus

Indications for Use (Describe)

The Mariana Minerva is intended to provide non-invasive ventilation, for patients weighing more than 30 lb (13 kg) or more than 66 lb (30 kg) in iVAPS mode with respiratory impairment or obstructive sleep apnoea (OSA). It is intended for home and hospital use.

The Mariana Nimbus is intended to provide non-invasive ventilation, for patients weighing more than 30 lb (13 kg) or more than 66 lb (30 kg) in iVAPS mode with respiratory impairment or obstructive sleep apnoea (OSA). It is intended for home and hospital use.

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)]

<u>Date Prepared:</u>	February 2026
<u>Company Name/Owner:</u>	ResMed Pty Ltd 1 Elizabeth Macarthur Drive Bella Vista, NSW, 2153 Australia
<u>Prepared and Submitted by:</u>	Ms Nicole Wilson Director, Regulatory Product Strategy & Delivery nicole.wilson@resmed.com.au
<u>Official Contact:</u>	Ms Nicole Wilson Director, Regulatory Product Strategy & Delivery Regulatory Affairs ResMed Pty Ltd 1 Elizabeth Macarthur Drive Bella Vista NSW 2153, Australia Phone: +61 404 820 279 Email: nicole.wilson@resmed.com.au
<u>Device Trade Name:</u>	Mariana
<u>Device Common Name:</u>	Ventilator, continuous, non-life supporting
<u>Classification and Classification Name:</u>	21 CFR §868.5895, 73 MNS (Class II) Continuous Ventilator
<u>Product Code:</u>	MNS
<u>Predicate Device:</u>	Juno VPAP ST-A (K161492)
<u>Reference Device</u>	N/A
<u>Submission Reason:</u>	New device

Device Description:

The Mariana devices, that is Mariana Minerva and Mariana Nimbus, are non-invasive ventilation (NIV) devices that use a microprocessor controlled blower, along with pressure and flow sensors, to achieve pressure, flow and time regulation of air delivery. They have an integrated alarms module. The Mariana devices also include optional humidification, with air delivery to the patient via heated or non-heated breathing circuits. The devices provide both therapeutic (e.g. tidal volume) and technical data (e.g. system fault), and a user interface allowing adjustment of device parameters. The devices use an external AC power supply and allow the addition of low pressure supplemental oxygen.

Indications for Use:

The Mariana Minerva is intended to provide non-invasive ventilation, for patients weighing more than 30 lb (13 kg) or more than 66 lb (30 kg) in iVAPS mode with respiratory impairment or obstructive sleep apnoea (OSA). It is intended for home and hospital use.

The Mariana Nimbus is intended to provide non-invasive ventilation, for patients weighing more than 30 lb (13 kg) or more than 66 lb (30 kg) in iVAPS mode with respiratory impairment or obstructive sleep apnoea (OSA). It is intended for home and hospital use.

Substantial Equivalence:

Characteristic	Predicate device: Juno VPAP ST-A K161492	Subject devices: Mariana Minerva / Mariana Nimbus	Substantially Equivalent?
Regulatory Classification	73MNS Class II 21 CFR 868.5895	73MNS Class II 21 CFR 868.5895	YES
Intended Use	The Juno VPAP ST-A is intended to provide non-invasive ventilation	The Mariana is intended to provide non-invasive ventilation	YES
Indications for Use Statement	The Juno VPAP ST-A is indicated to provide noninvasive ventilation for patients weighing more than 30 lbs (13 kg) with respiratory insufficiency or obstructive sleep apnoea (OSA). The iVAPS mode is indicated for patients weighing more than 66 lbs (30 kg).	The Mariana is indicated to provide non-invasive ventilation for patients weighing more than 30 lb (13 kg) or more than 60 lb (30 kg) in iVAPS mode with respiratory impairment or obstructive sleep apnoea (OSA). The Mariana is intended for home and hospital use.	YES <i>The intended patient population between predicate and subject device is equivalent. Respiratory impairment terminology included in subject device to better reflect patient population, alignment with ISO 80601-2-79</i>



Characteristic	Predicate device: Juno VPAP ST-A K161492	Subject devices: Mariana Minerva / Mariana Nimbus	Substantially Equivalent?
	The Juno VPAP ST-A is intended for home and hospital use.		
Environment of Use	Home Healthcare Environment (including aircraft), Professional Healthcare Facilities	Home Healthcare Environment (including aircraft), Professional Healthcare Facilities	YES
Therapies			
Therapy Modes	<ul style="list-style-type: none"> • CPAP • S, ST, T • PAC • iVAPS with AutoEPAP 	<ul style="list-style-type: none"> • CPAP • S, ST • PAC • iVAPS with AutoEPAP 	<p>YES</p> <p><i>The iVAPS with AutoEPAP therapy algorithm implemented in the subject devices is identical to the algorithm cleared under K161492.</i></p> <p><i>Subject device does not have Timed Mode to better reflect the needs of intended patient population (non-dependent, spontaneously breathing). Removal of Timed Mode does not affect the AutoEPAP algorithm or its clinical functionality and does not impact substantial equivalence.</i></p>
Therapy Features	<ul style="list-style-type: none"> • iBR • Ti Control • Rise time adjustment • VSync 	<ul style="list-style-type: none"> • iBR • Ti Control • Rise time adjustment • VSync 	YES
Vsync	Vsync monitors and compensates for unintentional mask leak, so that patients receive their prescribed therapy pressure. Working in sync with TiControl, Vsync ensures reliable breath detection even in conditions of high leak.	Vsync monitors and compensates for unintentional mask leak, so that patients receive their prescribed therapy pressure. Working in sync with TiControl, Vsync ensures reliable breath detection even in conditions of high leak.	YES
Pressure Range	<ul style="list-style-type: none"> • 4-20 cmH₂O (CPAP) • 3-30 cmH₂O (bi-level) • Fixed EPAP range: 3-25 cmH₂O AutoEPAP range 3-25 cmH₂O 	<ul style="list-style-type: none"> • 4-20 cmH₂O (CPAP) • 3-30 cmH₂O (bi-level) • Fixed EPAP range: 3-25 cmH₂O AutoEPAP range 3-25 cmH₂O 	YES

Characteristic	Predicate device: Juno VPAP ST-A K161492	Subject devices: Mariana Minerva / Mariana Nimbus	Substantially Equivalent?
Other Features	Ramp Ramp Down Smart Start / Smart Stop Learn Targets Mask Fit	Ramp Ramp Down Smart Start / Smart Stop Learn Targets Mask Fit Test Drive Acoustic Signal	YES <i>Test Drive is an optional, non-therapeutic feature intended for patient acclimatisation accessed separately from therapy. It does not modify the patient's prescribed therapy settings and is not required for device function or therapeutic operation. No impact to safety or efficacy.</i> <i>Acoustic signal is an optional non-therapeutic feature that captures a series of short 0.2 second acoustic signals to identify important characteristics about a user's equipment. It is not required for device function or therapeutic operation. No impact to safety or efficacy.</i>
Technology & Design			
System Components	Flow Generator Integrated Humidifier Air Tubing BV filter (optional) Mask	Flow Generator Integrated Humidifier Air Tubing BV filter (optional) Mask	YES
Operating Principle	Micro-processor controlled brush-less centrifugal blower as air source to provide splinting of patient airway	Micro-processor controlled brush-less centrifugal blower as air source to provide splinting of patient airway	YES
Materials	Various materials, including: Polycarbonate (PC) Polyurethane (PU) Polypropylene (PP) Thermoplastic Silicone Stainless steel Copolyester PC/ABS TPE	Various materials, including: Polycarbonate (PC) Polyurethane (PU) Polypropylene (PP) Thermoplastic Silicone Stainless steel Copolyester PC/ABS TPE Polybutylene terephthalate (PBT) Liquid crystal polymer (LCP) Low Density Polyethylene Polyolefin Polymer	YES <i>Substantially equivalent materials verified for device functionality, reprocessing and biocompatibility.</i>



Characteristic	Predicate device: Juno VPAP ST-A K161492	Subject devices: Mariana Minerva / Mariana Nimbus	Substantially Equivalent?
		Non Woven Textile (Mariana Nimbus)	
User Interface	LCD screen, dial & buttons	LCD touch screen & buttons	YES <i>Touch screen has no impact on safety or efficacy</i>
Alarm module	Yes	Yes	YES
Supplemental Oxygen	Labelled for use with supplemental oxygen	Labelled for use with supplemental oxygen	YES
Power Supply	100-240V, 50-60Hz	100-240V, 50-60Hz	YES
DC-DC Converter for Vehicle Use	Yes	Yes	YES
External Battery Compatibility	Yes	No	YES <i>The subject device does not include external battery compatibility, which is appropriate for its intended patient population (non- dependent, spontaneously breathing). Mariana has no Essential Performance requirements related to continuous operation and does not include a Timed Mode; therefore, it is intended only for patients who can tolerate brief interruptions to therapy and who are not ventilator- dependent.</i>
Data Connectivity	SD card, Cellular Wireless	SD card, Cellular Wireless, Bluetooth Wireless	YES <i>Bluetooth is an additional wireless technology option to provide data transfer capabilities. No impact on safety or efficacy.</i>
Humidification			

Characteristic	Predicate device: Juno VPAP ST-A K161492	Subject devices: Mariana Minerva / Mariana Nimbus	Substantially Equivalent?
Humidifier	Integrated thermostatically controlled heated humidifier with detachable water chamber	Integrated thermostatically controlled heated humidifier with detachable water chamber	YES
Usage	Single patient use at home, multi patient multi use in the hospital	Single patient use at home, multi patient multi use in the hospital	YES
Operating Principle	Water is heated by a heater plate to create warm and moist air within the water chamber. Airflow from the device is passed through the heated water chamber, which moistens and warms the air.	Water is heated by a heater plate to create warm and moist air within the water chamber. Airflow from the device is passed through the heated water chamber, which moistens and warms the air.	YES
Humidifier output	> 10 mg/L BTPS	> 10 mg/L BTPS	YES
Heated Tube dimensions	Length 2 m Diameter 15 mm	Length 2 m Diameter 15 mm	YES
Heated Tube maximum power	60 watt	60 watt	YES
Connections	Custom connector to flow generator. Cuff to fit 22mm ISO taper to patient port.	Custom connector to flow generator. Cuff to fit 22mm ISO taper to patient port.	YES
Heated Tube temperature settings	60-86 °F (16-30 °C)	60-86 °F (16-30 °C)	YES
Heated Tube temperature cutout	106 °F (41 °C)	106 °F (41 °C)	YES
Alarm Functions			
Alarm conditions	<ul style="list-style-type: none"> • Non-vented Mask <ul style="list-style-type: none"> • High Leak • Blocked Tube • Tube Disconnected <ul style="list-style-type: none"> • Power Fail • System Fault • Apnea • Low Minute Ventilation 	<ul style="list-style-type: none"> • Non-vented Mask <ul style="list-style-type: none"> • High Leak • Blocked Tube • Tube Disconnected <ul style="list-style-type: none"> • Power Fail • System Fault • Apnea • Low Minute Ventilation 	<p>YES</p> <p><i>Subject device does not monitor or display SpO2 as this is handled by the compatible Bluetooth oximeter.</i></p>



Characteristic	Predicate device: Juno VPAP ST-A K161492	Subject devices: Mariana Minerva / Mariana Nimbus	Substantially Equivalent?
	<ul style="list-style-type: none"> Low SpO2 	<ul style="list-style-type: none"> Tub/End cap disconnected 	
Standards			
Standards Compliance	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-8 IEC 60601-1-11 ISO 8185	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-8 IEC 60601-1-11 ISO 80601-2-70 ISO 80601-2-74 ISO 80601-2-79	YES <i>Updated compliance to FDA recognized performance standards. Bench testing demonstrates device performs to specification.</i>

Non-Clinical Data:

Verification bench testing for the Mariana devices comprises system verification and comparative side-by-side predicate testing. Verification confirmed the Mariana devices met the predetermined acceptance criteria as defined in the relevant compliance standards and as defined in the system verification protocols.

Comparative predicate testing supports the determination that the Mariana devices are substantially equivalent to the predicate device Juno VPAP ST-A (K161492). Verification bench testing included testing the performance of the therapy modes and therapy functions.

The Mariana devices were designed and tested in accordance with the applicable requirements in relevant FDA consensus standards including:

- IEC 60601-1 Edition 3.2:2020, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+AMD1:2021, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-6 Edition 3.2:2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-8:2006+AMD2:2021, 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 60601-1-11:2020, 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

- ISO 80601-2-70, Medical Electrical Equipment – Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment
- ISO 80601-2-74, Medical Electrical Equipment – Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
- ISO 80601-2-79, Medical electrical equipment - Part 2-79: Particular requirements for the basic safety and essential performance of ventilatory support equipment for ventilatory equipment
- ISO 10993-1:2018 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 18562-1:2024 – Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process

Clinical Data:

Clinical performance data is not required as the subject devices use established therapeutic technology and bench testing is sufficient to demonstrate substantial equivalence

Substantial Equivalence Conclusion:

The Mariana devices have the same intended use and similar indications and technological characteristics as the predicate device. The differences in the technological characteristics between the predicate device and subject devices do not impact or raise new questions of safety or efficacy. Non-clinical performance data supports the determination that the subject devices are substantially equivalent to the predicate device.