December 18, 2020

ResMed Pty Ltd
℅ Sheila Bruschi
Director, Regulatory Affairs
ResMed Corp
9001 Spectrum Center Boulevard
San Diego, California 92123

Re: K203126
Trade/Device Name: S10 Kirra
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: October 16, 2020
Received: October 19, 2020

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

for Malvina B. Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203126

Device Name
S10 Kirra

Indications for Use *(Describe)*

The S10 Kirra is indicated to provide CPAP and Bi-level therapy for the treatment of obstructive sleep apnea (OSA) in patients (female patients with mild to moderate OSA when using AfH treatment mode) weighing more than 66 lb (30 kg). ASV and ASVAuto modes are also indicated for the treatment of central and/or mixed apneas, or periodic breathing. 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.

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510(k) Summary

[As required by 21 CFR 807.92(c)]

Date Prepared:	16 December 2020
Company Name/Owner:	ResMed Pty Ltd 1 Elizabeth Macarthur Drive Bella Vista, NSW, 2153 Australia
Prepared and Submitted by:	Mr Peter Jennings Senior Regulatory Affairs Manager Tel: +612 8884 1000 Fax: +612 8884 2004 peter.jennings@resmed.com.au
Official Contact:	Ms 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
Device Trade Name:	S10 Kirra
Device Common Name:	Non continuous ventilator (IPPB)
Classification:	21 CFR 868.5905, BZD (Class II)
Product Code:	BZD
Predicate Device(s):	S9 Greenhills (K140279) S9 Wanda (K140159) S9 Elouera (K140124)
Reference Device(s):	VPAP Adapt (K133801)
Reason for Submission:	New Device

Device Description:

The S10 Kirra is a prescription only Positive Airway Pressure (PAP) ventilator device intended to treat individuals that are diagnosed with sleep apnea conditions. The S10 Kirra uses a micro-processor controlled blower, along with pressure and flow sensors, to achieve pressure, flow and time regulation of air delivery. It includes optional humidification, with air delivery to the patient via

heated or non-heated breathing circuits. The device provides both therapeutic (e.g. tidal volume) and technical data (e.g. system fault), and a user interface allowing adjustment of device parameters. The device uses an external AC power supply, and allows the addition of low flow supplemental oxygen.

Indications for Use:

The S10 Kirra is indicated to provide CPAP and Bi-level therapy for the treatment of obstructive sleep apnea (OSA) in patients (female patients with mild to moderate OSA when using AfH treatment mode) weighing more than 66 lb (30 kg). ASV and ASVAuto modes are also indicated for the treatment of central and/or mixed apneas, or periodic breathing.

It is intended for home and hospital use.

Substantial Equivalence:

The subject and predicate devices have the same intended use and the following similarities:

- Similar Indications for Use
- Same operating principle
- Similar technological characteristics

The S10 Kirra combines the PAP therapy modes of the predicate devices S9 Greenhills (K140279), S9 Elouera (K140124) and S9 Wanda (K140159) in a new flow generator system. There are only minor differences between the S10 Kirra and the predicate devices including new materials and the addition of Bluetooth technology.

Characteristic	**Predicate device: S9 Greenhills K140279**	**Predicate device: S9 Wanda K140159**	**Predicate device: S9 Elouera K140124**	**Subject device: S10 Kirra**	**Substantially Equivalent?**
Intended Use	Positive airway pressure support for sleep apnea Patients >66 lb (>30kg) Home and Hospital	Positive airway pressure support for sleep apnea Patients >66 lb (>30kg) Home and Hospital	Positive airway pressure support for sleep apnea Patients >66 lb (>30kg) Home and Hospital	Positive airway pressure support for sleep apnea Patients >66 lb (>30kg) Home and Hospital	YES
Indications for Use Statement	The S9 Greenhills is indicated for the treatment of patients weighing more than 66 lb (30 kg) with obstructive sleep apnea (OSA), central and/or mixed apneas, or periodic breathing. It is intended for home and hospital use.	The S9 WANDA VPAP ST 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	The S9 Elouera self-adjusting device is indicated for the treatment of Obstructive Sleep Apnea (OSA) in patients (female patients with mild to moderate OSA when using AfH treatment mode) weighing more than 66 lb (30 kg).	The S10 Kirra is indicated to provide CPAP and Bi-level therapy for the treatment of obstructive sleep apnea (OSA) in patients (female patients with mild to moderate OSA when using AfH treatment mode) weighing more than	YES *S10 Kirra includes a combined IFU statement within the Intended Use of the predicate devices. Disease states treated by each therapy mode are unchanged*

Characteristic	Predicate device: S9 Greenhills K140279	Predicate device: S9 Wanda K140159	Predicate device: S9 Elouera K140124	Subject device: S10 Kirra	Substantially Equivalent?
	The humidifier is intended for single patient use in the home environment and re-use in a hospital / institutional environment.		It is intended for home and hospital use	66 lb (30 kg). ASV and ASVAuto modes are also indicated for the treatment of central and/or mixed apneas, or periodic breathing. It is intended for home and hospital use.	*from the predicates.*
Environment of Use	Home Healthcare Environment, Professional Healthcare Facilities	Home Healthcare Environment, Professional Healthcare Facilities	Home Healthcare Environment, Professional Healthcare Facilities	Home Healthcare Environment (including aircraft), Professional Healthcare Facilities	YES *S10 Kirra and predicate devices for use in same environments. Specific use on aircraft based on reference device K133801 testing methods.*
Therapies					
Therapy Modes	CPAP ASV ASVAuto	CPAP - - - - VAuto S, ST, T	CPAP - - AutoSet AutoSet for Her (AfH)	CPAP ASV ASVAuto AutoSet AutoSet for Her (AfH) VAuto S, ST, T	YES *S10 Kirra has same therapy modes as predicates*
Pressure Range	4-20 cm H2O (CPAP) 3-25 cm H2O (ASV, ASVAuto)	4-20 cm H2O (CPAP) 4-25 cm H2O (VAuto) 3-25 cm H2O (S, ST, T)	4-20 cm H2O (CPAP, AutoSet, AutoSet for Her)	4-20 cm H2O (CPAP, AutoSet, AutoSet for Her) 4-25 cm H2O (VAuto) 3-25 cm H2O (S, ST, T, ASV, ASVAuto)	YES *S10 Kirra has identical pressure range for corresponding modes.*
Comfort Features		Expiratory Pressure Relief (EPR) Easybreathe	Expiratory Pressure Relief (EPR)	Expiratory Pressure Relief (EPR) Easybreathe	YES
Technology & Design					
System Components	Flow Generator Integrated Humidifier Air Tubing Mask	Flow Generator Integrated Humidifier Air Tubing Mask	Flow Generator Integrated Humidifier Air Tubing Mask	Flow Generator Integrated Humidifier Air Tubing Mask	YES

Characteristic	Predicate device: S9 Greenhills K140279	Predicate device: S9 Wanda K140159	Predicate device: S9 Elouera K140124	Subject device: S10 Kirra	Substantially Equivalent?
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	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: Polymers Plastics Stainless steel	Various materials, including: Polymers Plastics Stainless steel	Various materials, including: Polymers Plastics Stainless steel	Various materials, including: Polymers Plastics Stainless steel	YES *Substantially equivalent materials verified for reprocessing and BioC. Same base material.*
Data Connectivity	SD card, Cellular Wireless	SD card, Cellular Wireless	SD card, Cellular Wireless	SD card, Cellular Wireless, Bluetooth Wireless	YES *Bluetooth is an alternate wireless technology option to provide the same data transfer capabilities as cellular.*
Humidification					
Humidifier	Integrated thermostatically controlled heated humidifier with detachable water chamber	Integrated thermostatically controlled heated humidifier with detachable water chamber	Integrated thermostatically controlled heated humidifier with detachable water chamber	Integrated thermostatically controlled heated humidifier with detachable water chamber	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.	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	12.0mg/L @ 20cm H2O (50 L/min)	12.0mg/L @ 20cm H2O (50 L/min)	12.0mg/L @ 20cm H2O (50 L/min)	12.6mg/L @ 20cm H2O (50 L/min)	YES
Heated Tube temperature settings	60-86 °F (16-30 °C)	60-86 °F (16-30 °C)	60-86 °F (16-30 °C)	60-86 °F (16-30 °C)	YES

Characteristic	Predicate device: S9 Greenhills K140279	Predicate device: S9 Wanda K140159	Predicate device: S9 Elouera K140124	Subject device: S10 Kirra	Substantially Equivalent?
Heated Tube temperature cutout	106 °F (41 °C)	106 °F (41 °C)	106 °F (41 °C)	106 °F (41 °C)	YES

Non-Clinical Data:

- Verification bench testing for S10 Kirra comprises system verification and comparative side-by-side predicate testing. Verification confirmed the S10 Kirra 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 S10 Kirra is substantially equivalent to the predicate devices (S9 Greenhills (K140279), S9 Wanda (K140159), S9 Elouera (K140124)). Verification bench testing included testing the performance of the therapy modes and therapy functions including:
    - Pressure performance
    - Breath events including flow limitations, snore and apneas
    - Response to periodic breathing
    - Humidification

The S10 Kirra was designed and tested in accordance with the applicable requirements in relevant FDA consensus standards including:

- 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: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-11:2015, 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 10993-1:2018 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 18562-1:2017 – 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 device uses established therapeutic technology and bench testing is sufficient to demonstrate substantial equivalence.

Substantial Equivalence Conclusion:

The S10 Kirra has the same intended use and similar indications and technological characteristics as the predicate devices. The differences in the technological characteristics between the predicate devices and subject device do not impact or raise new questions of safety or efficacy. Non-clinical performance data supports the determination that the subject device is substantially equivalent to the predicate devices.