October 19, 2023

ResMed Pty Ltd (Registration Number: 3004604967)
% Sheila Bruschi
Senior Director, Regulatory Affairs
ResMed Corp (Registration Number: 3007573469)
9001 Spectrum Center Boulevard
San Diego, California 92123

Re: K230476
Trade/Device Name: Oran Park Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: September 22, 2023
Received: September 22, 2023

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 (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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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.

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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthesia Devices
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K230476

Device Name
Oran Park Mask

Indications for Use *(Describe)*
The Oran Park mask is intended for use in the home or hospital/institutional environment on patients weighing more than 66lb (30kg), who have been prescribed non-invasive CPAP or bi-level positive airway pressure (PAP) therapy.

Only the Sleep Lab Mask (SLM) variant is intended and validated for multi-patient reuse and must be reprocessed if reused between patients.

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 807.921(c)]

Date of Submission:	22 February 2023
Company Name/Owner:	ResMed Pty Ltd 1 Elizabeth Macarthur Drive Bella Vista, NSW, 2153 Australia
Prepared and Submitted by:	Ms Daniellia Chan Regulatory Affairs Specialist Tel: +65 65727166 daniellia.chan@resmed.com.sg
Official Contact:	Ms Sheila Bruschi Senior Director, Regulatory Affairs ResMed Corp 9001 Spectrum Center Blvd San Diego CA 92123 USA Tel: +1 858 922 1803 sheila.bruschi@resmed.com
Device Trade Name:	Oran Park Mask
Device Common Name:	Vented Full Face Mask
Classification and Classification Name:	21 CFR 868.5905, 73 BZD (Class II) Accessory to Noncontinuous Ventilator (IPPB)
Product Code:	BZD
Legally Marketed Predicate Device:	AirFit F20 (K153563)
Reference Device:	Moore Park (K183512)
Submission Reason:	New Device

Device Description

The Oran Park Mask is an accessory to deliver air flow and positive air pressure generated by positive airway pressure (PAP) devices such as CPAP or bi-level flow generator systems to the patient's airway, for the treatment of Obstructive Sleep Apnea (OSA) or ventilator support (non-life support). It delivers the treatment pressure from the source device to the patient's upper airway by providing an air seal between the PAP device and under the patient's nose and mouth.

There are 2 variants to the Oran Park Mask:

- Oran Park Mask (Home Use)
  Intended for single patient re-use (SPMU) for home use. It is configured with a diffused venting port located on the elbow, known as the QuietAir elbow.
- Oran Park SLM (Sleep Lab Mask)

  Intended for multi-patient re-use (MPMU) and must be reprocessed if reused between patients. It is configured with a non-diffused venting port located on the elbow, known as the Multihole elbow.

The Oran Park mask comprises of 4 sub-assemblies: headgear, frame, cushion and elbow. The venting ports and anti-asphyxia valve are incorporated into the elbow assembly. There are four magnets incorporated in the Oran Park mask – two magnets in the frame assembly and 2 magnets in the lower headgear clips – with a magnetic field strength up to 400 mT. The magnets in the mask help facilitate attaching and detaching the headgear to the mask frame when regularly fitting the mask for use. The cushion and headgear are available in various sizes to fit a wide patient population. Soft wraps, which are attached to the Oran Park mask frame, are available as an optional accessory for patient's comfort.

The Oran Park mask is a prescription device and is supplied non-sterile.

Indication For Use

The Oran Park full face mask is intended for use in the home or hospital/institutional environment on patients weighing more than 66lb (30kg), who have been prescribed non-invasive CPAP or bi-level positive airway pressure (PAP) therapy.

Only the Sleep Lab Mask (SLM) variant is intended and validated for multi-patient reuse and must be reprocessed if reused between patients.

Comparison table

Design Parameter or feature	Predicate Device AirFit F20 K153563	Subject Device Oran Park Mask System K230476	Comments
Indication for Use	The AirFit F20 is to be used by patients weighing more than 66lb (30kg) for whom positive airway pressure therapy (non-invasive CPAP or bi-level positive airway pressure (PAP) therapy) has been prescribed. It is intended for single-patient reuse in the home environment and multi-patient reuse in the hospital/institutional environment.	The Oran Park mask is intended for use in the home or hospital/institutional environment on patients weighing more than 66lb (30kg), who have been prescribed non-invasive CPAP or bi-level positive airway pressure (PAP) therapy. Only the Sleep Lab Mask (SLM) variant is intended and validated for multi-patient reuse and must be reprocessed if reused between patients.	Equivalent
FDA Product Code	BZD	BZD	Identical
Reprocessing	Single patient re-use or multi-patient re-use	Single patient re-use (Oran Park Mask) or multi-patient re-use (Oran Park SLM)	Identical

Physical Dead space (mL)		Small Cushion: 199mL Medium Cushion:219mL Large Cushion: 240mL	Small Cushion: 101.1mL Medium Cushion: 107.6mL Large Cushion: 107.0mL	This is a record-only parameter
Leakage	**Pressure (cmH_2O)**	**Flow (L/min)**	**Flow (L/min)**	Equivalent
	3	19	N/A	
	4	22	20	
	13	42	38	
	22	57	51	
	31	70	62	
	40	82	72	
Use Life		AirFit F20 (single patient, multi-use): Visual inspection per instructions for use AirFit F20 (multi patient, multi-use): 30 validated reprocessing cycles	Oran Park mask: Visual inspection per instructions for use Oran Park SLM: 30 validated reprocessing cycles	Identical
Operating and storage temperature		Operating temperature: 5°C to 40°C Storage temperature: -20°C to +60°C	Operating temperature: 5 to 40 °C Storage temperature: -20 to +60°C	Identical

Sound power level and sound pressure	Tested and declared in accordance with ISO4871 and ISO3744	Tested and declared in accordance with ISO4871 and ISO3744	Equivalent
Cushion assembly design	Seals above the nose and around the mouth	Seals under the nose and around the mouth	Equivalent Both mask systems deliver therapy by providing an air seal at the nose and at the mouth. The 'under the nose' cushion design has been cleared previously in reference device, Moore Park mask (K183512).
Elbow assembly design	The body of the elbow includes a ball joint allowing for flex under the load from tube drag. The elbow can be rotated 360 degrees around the frame connection, it connects to a conventional air delivery hose.	A Short tube and swivel cuff form part of mask's elbow assembly, these features allow for the mask to rotate and move independently of the connected conventional air delivery hose.	Equivalent in terms of decoupling and freedom of movement.
Vent design	Multi-hole Vent array in elbow assembly	Two design variants:	Equivalent

Design Parameter or feature	Predicate Device AirFit F20 K153563	Subject Device Oran Park Mask System	Comments
		• Multi-hole Vent • QuietAir Vent	Both vent variants of the subject mask: • Serves to exhaust patient expired air into the atmosphere • Have been verified to satisfy mask pressure flow and CO_2 rebreathing performance requirement of ISO 17510:2015
AAV design	Two anti-asphyxia valves (AAV)	Single anti-asphyxia valve (AAV)	Equivalent The function of the AAV is the same as the predicate device. Verification testing has been conducted which demonstrated that the AAV of both masks will activate in the event of a single fault condition at a pressure lower than the minimum rated mask pressure.
Patient connection port	ISO 5356-1 (22mm)	ISO 5356-1 (22mm)	Identical

Design Parameter or feature		Predicate Device AirFit F20 K153563	Subject Device Oran Park Mask System	Comments
Flow generator setting on compatible ResMed flow generators		Full Face Mask	Pillows	The ResMed flow generator settings used are different between the subject and predicate device. These are the ResMed flow generator settings indicated when using the respective mask. This sets the appropriate pressure compensation aligned to the mask resistance and exhaust characteristics within the ResMed flow generator to achieve equivalent therapy at the patient's airways.
Pressure Range		3-40cmH_2O	4-40cmH_2O	Pressure range claim is a subset of the predicate device.
Mask exhaust flow (Nominal) ISO 17510:2015 Annex B	**Pressure (cmH_2O)**	**Flow (L/min)**	**Flow (L/min)**	Testing and reporting has been conducted in line with ISO17510: 2015.
	3	19	N/A	
	4	22	20	

Design Parameter or feature		Predicate Device AirFit F20 K153563	Subject Device Oran Park Mask System	Comments
	13	42	38	
	22	57	51	
	31	70	62	
	40	82	72	
Resistance to flow (Pressure drop across mask) ISO 17510:2015 Annex C	**Nom Flow Rate (L/min)**	**Pressure (cmH_2O)**	**Pressure (cmH_2O)**	The pressure drop values have been reported in accordance with ISO17510:2015.
	50	0.2	0.3	
	100	0.9	1.6	
CO_2 re-breathing performance (<20%) ISO 17510:2015 Annex F		Complies with ISO 17510:2015 CO_2 requirements (<20%)	Complies with ISO 17510:2015 CO_2 requirements (<20%)	Equivalent

Design Parameter or feature		Predicate Device AirFit F20 K153563	Subject Device Oran Park Mask System	Comments
CO_2 re-breathing Single Fault use (<60%) ISO 17510:2015 Annex F		Complies with ISO 17510:2015 CO_2 requirements (<60%)	Complies with ISO 17510:2015 CO_2 requirements (<60%)	Equivalent
Breathing Resistance (single fault) (cmH_2O) ISO 17510:2015 Annex E	Inspiratory	<10cmH_2O	<10cmH_2O	Equivalent The expiratory and inspiratory breathing resistances are both <10cmH_2O in accordance with ISO 17510:2015.
	Expiratory	<10cmH_2O	<10cmH_2O	
AAV Operating Pressures (cmH_2O) ISO 17510:2015 Annex D	De-activation	<4.0 cmH_2O	<4.0 cmH_2O	Equivalent
	Activation	<4.0 cmH_2O	<4.0 cmH_2O	

Similarities and differences with the predicate device

The subject Oran Park Mask and the previously cleared predicate AirFit F20 (K153563) devices share the same technological characteristics and principle of operation. They act as a patient interface seal to deliver treatment pressure generated from a positive airway pressure (PAP) device to the patient's airway.

The subject and predicate device have equivalent intended use and the following similarities:

- A silicone elastomer cushion to achieve air seal at the patient's mouth and nose.
- The cushion is held in place via the mask frame.
- The frame is strapped to the patient's head and sits along the sides of the face, held in place via headgear.
- An elbow assembly connects to the PAP device tubing.
- Venting ports/AAV flush out CO2.
- The mask can be disassembled for cleaning and reprocessing in accordance with the labelling.
- A port compliant to ISO 5356-1 is used to connect to the PAP delivery hose.
- Polymeric materials are used for the construction of the pneumatic and structural components.
- Foam padded fabric materials are used for the construction of the head straps.
- Multiple cushion sizes are available to allow for adequate mask fit over the intended patient population.
- Similar performance i.e., both masks have similar operating pressure range and pressure flow characteristics.
- Same operating environments i.e., re-use in the home and hospital/institution environment.

The main difference between the subject Oran Park Mask and the predicate AirFit F20 device (K153563) is:

- Mask component design and geometry
- Different operating ResMed flow generator settings i.e., "Full Face Mask" vs "Pillows"
- Incorporation of new materials for Headgear laminate and elbow assembly vent ring
- Reprocessing claims

These differences do not affect the substantial equivalence claim to the predicate device because non-clinical testing demonstrated that the new device has equivalent performance to and is as safe as the predicate device.

Non-clinical data submitted

Non-clinical verification and validation testing completed for the new device demonstrated that the Oran Park Mask met all intended performance requirements. These included:

Applicable performance and safety tests in accordance with ISO 17510:2015 Medical devices – Sleep apnoea breathing therapy – Masks and application accessories:

- CO2 rebreathing
- Pressure-Flow characteristics
- Resistance to flow
- Anti-Asphyxia valve operating pressures
- Breathing resistance (single fault)
- Through impedance
- Inadvertent anti-asphyxia valve operation

Other Bench tests:

- Mechanical Integrity of the mask system before and after the following environmental tests:
  - Home cleaning
  - Transportation and storage
  - Operation environment
  - Free fall

Biocompatibility evaluation was conducted in accordance with ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-12, ISO 10993-17, ISO 10993-18 and ISO 18562 on components that had patient exposure classifications of permanent external communicating device (tissue) and /or permanent skin contact.

Validation of reprocessing claims included a combination of cleaning efficacy, disinfection efficacy, residual toxicity, and mechanical integrity testing.

Verification confirmed that the new device met the predetermined acceptance criteria, and the performance is substantially equivalent to the previously cleared predicate AirFit F20 (K153563).

Oran Park Mask System was designed and tested in accordance with the applicable requirements in relevant FDA consensus standards including:

Standards	**Title**
ISO 17510:2015	Medical devices -- Sleep apnoea breathing therapy -- Masks and application accessories

Standards	Title
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 17664-1:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices
ISO 17664-2:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices.
ISO 5356-1: 2015	Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets
ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
ISO20417:2021	Medical devices - Information to be supplied by the manufacturer

Substantial Equivalence Conclusion

The Oran Park Masks are substantially equivalent to the AirFit F20 (K153563). The differences described above do not raise new questions of safety and effectiveness.