July 6, 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: K223747
Trade/Device Name: Whitsundays Mask System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: December 14, 2022
Received: June 5, 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 (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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223747

Device Name
Whitsundays Mask System

Indications for Use *(Describe)*
The Whitsundays Mask System has two product variants:
• Whitsundays mask
• Whitsundays SLM (Sleep Lab Mask)

Both masks are intended for patients weighing more than 66 lb (30 kg), who have been prescribed non-invasive CPAP or bi-level positive airway pressure (PAP) therapy. The Whitsundays mask is intended for single-patient reuse in the home environment and the Whitsundays SLM is intended for multi-patient reuse in the hospital/institutional environment. The Sleep Lab Mask (SLM) is the only variant that is validated and intended for multi-patient reprocessing 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.

510(k) Summary

[As required by 21 CFR 807.92(c)]

Date Prepared:	July 6, 2023
Company Name/Owner:	ResMed Pty Ltd 1 Elizabeth Macarthur Drive Bella Vista, NSW, 2153 Australia
Prepared and Submitted by:	Ms. Shu-Ying Huang Regulatory Affairs Manager Tel: +65 65727105 Shuying.huang@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:	Whitsundays Mask System
Device Common Name:	Vented Nasal Mask
Classification and Classification Name:	21 CFR 868.5905, 73 BZD (Class II) Accessory to Noncontinuous Ventilator (IPPB)
Product Code:	BZD
Predicate Device:	Scone mask (K180497)

Device Description:

The Whitsundays Mask System is an accessory to deliver airflow 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 ventilatory 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 the bottom of the patient's nose.

The Whitsundays mask system has two product variants:

- Whitsundays mask
  This is the home use variant that is intended for single patient re-use.
- Whitsundays SLM (Sleep Lab Mask)
  This is the SLM variant that is intended for multi-patient re-use and must be reprocessed if reused between patients.

The Whitsundays Mask System mask system is made up of 4 main component assemblies: nasal cushion, conduit frame, elbow, and headgear. The nasal cushion and conduit frame are available in various sizes to allow for adequate mask fit in the intended patient population.

The Whitsundays Mask System is a prescription device supplied non- sterile.

Indications for Use:

The Whitsundays Mask System has two product variants:

- Whitsundays mask
- Whitsundays SLM (Sleep Lab Mask)

Both masks are intended for patients weighing more than 66 lb (30 kg), who have been prescribed non-invasive CPAP or bi-level positive airway pressure (PAP) therapy. The Whitsundays mask is intended for single-patient reuse in the home environment and the Whitsundays SLM is intended for multi-patient reuse in the hospital/institutional environment. The Sleep Lab Mask (SLM) is the only variant that is validated and intended for multi-patient reprocessing and must be reprocessed if reused between patients.

Comparison Table:

Design parameter or feature	**Predicate device:** Error! Reference source not found. Error! Reference source not found.	**Subject device:** Error! Reference source not found.	**Comments**
Indications for Use	The Scone mask is intended to be used by patients weighing more than 66 lb (30 kg) who have been prescribed non-invasive positive airway pressure (PAP) therapy such as CPAP or bi-level therapy. The mask is intended for single patient re-use in the home and multi-patient re-use in the hospital/institutional environment.	The Whitsundays mask system has two product variants: • Whitsundays mask • Whitsundays SLM (Sleep Lab Mask) Both masks are intended for patients weighing more than 66 lb (30 kg), who have been prescribed non-invasive CPAP or bi-level positive airway pressure (PAP) therapy. The Whitsundays mask is intended for single-patient reuse in the home environment and the Whitsundays SLM is intended for multi-patient reuse in the hospital/institutional environment. The Sleep Lab Mask (SLM) is the only variant that is validated and intended for multi-patient reprocessing and must be reprocessed if reused between patients.	Equivalent
Intended Use	The mask is intended to provide an interface for CPAP or bi-level devices.	The mask is intended to provide an interface for CPAP or bi-level devices.	Identical
FDA Product Code	BZD	BZD	Identical
Patient population	Patients weighing more than 66lb (30kg) for whom positive airway pressure therapy has been prescribed.	Patients weighing more than 66lb (30kg) for whom positive airway pressure therapy has been prescribed.	Identical

Design parameter or feature		Predicate device: Error! Reference source not found. Error! Reference source not found.	Subject device: Error! Reference source not found.	Comments
Environment of Use		Home or hospital/institutional environment.	Home or hospital/institutional environment.	Identical
Reprocessing claims		Single patient re-use or multi-patient re-use.	Single patient re-use or multi-patient re-use.	Identical
Sterility state as provided		Non-sterile	Non-sterile	Identical
Validated reprocessing methods		High-Level Thermal disinfection	High-Level Thermal disinfection	Identical
Materials		Materials include silicone, polycarbonate, polybutylene terephthalate and nylon elastane polyurethane laminate.	Whitsundays mask system has new materials for the nasal cushion and for the sleeve on the the conduit frame. Device materials include silicone, nylon elastane, polycarbonate, polybutylene terephthalate, polyurethane and nylon elastane polyurethane laminate	Equivalent. All of the materials used in the subject device have been included in previously cleared submissions or have undergone biological evaluation as per ISO 10993-1 and ISO 18562-1.
Cushion type		Cradles patient's nose and seals under the nose	Cradles patient's nose and seals under the nose	Identical. The cushion is designed to seal in the same way.
Frame type		Tubular conduit	Tubular conduit	Identical.
PAP tubing connection point		22mm conical connector as per ISO 5356-1 over the head connection	22mm conical connector as per ISO 5356-1 over the head connection	Identical.
Exhaust port location		Elbow and cushion	Elbow and cushion	Identical.
Sizes		Cushion available in four sizes Frame available in two sizes Headgear available in one size	Cushion available three sizes Frame available in two sizes Headgear available in one size	Equivalent
Mask exhaust flow (Nominal) ISO 17510:2015 Annex B	**Pressure (cm H_2O)**	**Flow (L/min) 'Pillows' curve**	**Flow (L/min) 'Pillows' curve**	Identical
	4	20	20	
	9	31	31	
	15	41	41	
	20	49	49	
	25	55	55	

Design parameter or feature	Predicate device: Error! Reference source not found. Error! Reference source not found.	Subject device: Error! Reference source not found.	Comments
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%)	Identical
Physical Dead space (mL)	**Frame size** / **SML** / **STD** **Cushion size** S: 109 / 116 SW: 105 / 112 M: 113 / 120 W: 112 / 119	**Frame size** / **SML** / **STD** **Cushion Size** SW: 116 / 124 M: 119 / 127 L: 123 / 130	Equivalent. This is a record-only parameter.
Resistance to flow (Pressure drop across mask in cmH_2O) ISO 17510:2015 Annex C	**@50 L/min**: 0.5 **@100 L/min**: 2.3	**@50 L/min**: 0.4 **@100 L/min**: 1.6	Resistance to flow values is reported in the instructions for use in accordance with ISO 17510:2015.
Flow generator setting on compatible ResMed CPAP and Bi-level flow generators.	"Pillows"	"Pillows"	Identical
Operating pressure range (cmH_2O)	4 - 25	4 – 25	Identical
Sound	Sound power level: 21 dBA Sound pressure level: 14 dBA	Sound power level: 24 dBA Sound pressure level: 17 dBA	Equivalent
Operating and storage temperature	Operating temperature: 5°C to 40°C Storage temperature: -20°C to +60°C	Operating temperature: 5°C to 40°C Storage temperature: -20°C to +60°C	Identical
Use life	Scone mask: Visual inspection per instructions for use Scone SLM: 30 validated reprocessing cycles	Whitsundays mask: Visual inspection per instructions for use Whitsundays SLM: 30 validated reprocessing cycles	Identical

Non-Clinical Data Submitted:

Non-clinical verification and validation testing completed for the new device demonstrated that Whitsundays Mask System 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:

- CO_2 rebreathing
- Mask exhaust flow
- Resistance to flow

Other bench tests:

- Physical dead space
- Pressure accuracy and pressure swing performance
- Mechanical Integrity of the mask system before and after the following environmental tests:
    - Home cleaning
    - Transportation and Storage
    - Operation environment
    - Free fall and sit test
    - Cleaning and Reprocessing

Biocompatibility evaluation was conducted in accordance with ISO 18562-1 and ISO 10993-1. This evaluation was conducted on components that had patient exposure classifications of long-term external communicating device (tissue) and /or long-term skin contact.

Validation of reprocessing claims (in accordance with ISO 17664-1 and ISO 17664-2) included a combination of cleaning efficacy, disinfection efficacy, residual toxicity, and mechanical integrity testing.

Whitsundays 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*
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- *Part 1: Evaluation and testing within a risk management process*
ISO 18562-2:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter
ISO 18562-3:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds (VOCs)
ISO 18562-4:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 4: Tests for leachables in condensate
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Test for in vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation of medical devices – Part 10: Tests for skin sensitization
ISO 10993-17:2002	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
ISO 10993-18:2021	Biological evaluation of medical devices – Part 18: Chemical characterization of materials

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
ISO17664-2:2021	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
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer

Substantial Equivalence Conclusion:

The Whitsundays mask system is substantially equivalent to the predicate Scone mask (K180497):

- It has equivalent intended use
- It has similar technological characteristics
- It has similar performance characteristics
- The differences do not raise any new questions of safety or effectiveness
- It is as safe and as effective as the predicate device