May 7, 2019

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

Re: K183512
Trade/Device Name: Moore Park Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: April 4, 2019
Received: April 5, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Michael Ryan
Director
DHT1C: Division of ENT, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183512

Device Name
Moore Park Mask

Indications for Use *(Describe)*
The Moore Park 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.

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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1 510(k) Summary

[As required by 21 CFR 807.92(c)]

Date of Submission:	7 May 2019
Company Name/Owner:	ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista, NSW, 2153 Australia
Prepared and Submitted by:	Ms Nerida Hunt Senior Regulatory Affairs Manager Tel: +612 8884 1000 Fax: +612 8884 2004 nerida.hunt@resmed.com
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:	Moore Park Mask
Device Common Name:	Vented Full Face Mask
Classification and Classification Name:	Class II Noncontinuous Ventilator (IPPB) (21 CFR 868.5905)
Product Code:	BZD

Predicate Device:	Mirage Liberty Full Face Mask (K063011)
Reference Device:	Scone Mask (K180497)
Device Description:	The Moore Park mask is an externally placed vented respiratory mask. Positive air pressure (PAP) is directed to the patient's airway non-invasively, via the nose and/or mouth. The mask connects to the positive pressure flow source through conventional air tubing via an industry standard conical connector. The mask is held in place with adjustable headgear straps. The Moore Park mask comprises 4 assemblies: headgear, frame, cushion and elbow. The exhaust ports are incorporated into the elbow and cushion assemblies. The anti-asphyxia valve is incorporated in the frame assembly. The cushion is available in various sizes to fit a wide patient population. The Moore Park mask is a prescription device supplied non-sterile.
Indications For Use:	The Moore Park 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.
Submission Reason:	New device
Similarities and differences with the predicate device:	The subject and predicate device have an identical intended use and the following similarities: • A silicone elastomer cushion to achieve an 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 • Exhaust ports flush out CO_2 • The mask can be disassembled for cleaning and reprocessing in accordance with the labelling • Polymeric materials are used for the construction of the pneumatic and structural components. Foam padded fabric materials are used for the construction of the headgear.

- A port compliant to ISO 5356-1 is used to connect to the PAP delivery hose
- 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 environments

The main difference between the subject Moore Park device and the previously cleared predicate Mirage Liberty Full Face Mask (K063011) is:

- The PAP device tubing is connected to the Moore Park device at the top of the patient's head, whereas the predicate device is connected near the mouth.

Non-clinical data submitted:

Non-clinical verification and validation testing completed for the new device demonstrated that the Moore 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*:

- CO_2 rebreathing
- Pressure-Flow characteristics
- Resistance to flow
- Anti-Asphyxia valve operating pressures
- Breathing resistance

Other bench tests:

- Pressure performance testing
- Mechanical Integrity of the mask system before and after the following environmental tests:
    - Home cleaning
    - Transportation and Storage
    - Operation environment

Biocompatibility evaluation was conducted in accordance with the following standards:

- 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 10993-1:2009 Biological evaluation of medical devices -- *Part 1: Evaluation and testing within a risk management process*
- ISO 10993-3:2014 Biological evaluation of medical devices -- *Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
- ISO 10993-5:2009 Biological evaluation of medical devices -- *Part 5: Tests for in vitro cytotoxicity*
- ISO 10993-10:2010 Biological evaluation of medical devices -- *Part 10: Tests for irritation and skin sensitization*
- ISO 10993-11:2017 Biological evaluation of medical devices -- *Part 11: Tests for systemic toxicity*
- ISO 10993-17:2002 Biological evaluation of medical devices -- *Part 17: Establishment of allowable limits for leachable substances*
- ISO 10993-18:2005 Biological evaluation of medical devices -- *Part 18: Chemical characterization of materials*

This evaluation was conducted on components that were manufactured using new materials with 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 Mirage Liberty Full Face Mask (K063011).

Substantial Equivalence Conclusion:

The Moore Park mask is substantially equivalent to the predicate Mirage Liberty Full Face Mask (K063011).