DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 13, 2016

ResMed Ltd.
% Larissa D'Andrea
Director, Government & Regulatory Affairs
ResMed Corp.
9001 Spectrum Center Boulevard
San Diego, California 92123

Re: K153563
Trade/Device Name: AirFit F20
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (Ippb)
Regulatory Class: Class II
Product Code: BZD
Dated: April 8, 2016
Received: April 11, 2016

Dear Larissa D'Andrea:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K153563

Device Name
AirFit F20

Indications for Use *(Describe)*

The AirFit F20 is a non-invasive accessory used for channeling airflow (with or without supplemental oxygen) to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel system.

The AirFit F20 is:
• to be used by patients weighing more than 66 lb (30 kg) for whom positive airway pressure therapy has been prescribed
• intended for single-patient reuse in the home environment and multi-patient reuse 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

Date Prepared May 4, 2016

Company Name / Owner
ResMed Ltd
1 Elizabeth Macarthur Drive
Bella Vista NSW 2153 Australia

Submitter Name
Ms. Johanna Wright
Senior Regulatory Affairs Manager
ResMed Ltd
Tel: +612 8884 1000
Fax: +612 8884 2004
johanna.wright@resmed.com.au

Official Contact
Ms Larissa D'Andrea
Director, Government & Regulatory Affairs
ResMed Corp
9001 Spectrum Center Blvd
San Diego CA 92123 USA
Tel: +1 858 836 6837
Fax: +1 858 836 5519
Larissa.D'Andrea@resmed.com

Device Trade Name AirFit F20

Device Common Name Vented Full Face Mask

Classification Name Noncontinuous Ventilator (IPPB) (21 CFR 868.5905, Product Code BZD)

Predicate Device Quattro Air (K123979)

Reference Device AirFit N10 (K132887)

Device Description

The AirFit F20 is an externally placed vented mask covering the mouth and the nose of the patient. It provides a seal such that pressure from a positive pressure source is directed to the patient's nose and/or mouth. The mask connects via a standard conical connector to a conventional air delivery hose, which in turn connects to the positive pressure source. The mask is held in place with an adjustable headgear that straps the mask to the face.

The AirFit F20 mask system comprises four subassemblies: cushion, frame, elbow and headgear. The elbow incorporates the vent array and anti-asphyxia valve safety features. The cushion and headgear are available in various sizes to fit a wide patient population.

AirFit F20 is a prescription device supplied non-sterile.

Intended Use

The AirFit F20 is a non-invasive accessory used for channeling airflow (with or without supplemental oxygen) to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel system.

The AirFit F20 is:

- to be used by patients weighing more than 66lb (30kg) for whom positive airway pressure therapy has been prescribed
- intended for single-patient reuse in the home environment and multi-patient reuse in the hospital/institutional environment.

Similarities and Differences with the Predicate Device

The AirFit F20 device has the following similarities to the previously cleared predicated device (Quattro Air (K123979):

- same intended use
- same operating principle
- similar design and materials which incorporates:
  - a silicone interface providing a seal around the nose and the mouth;
  - vent holes providing continuous air leak to flush out and minimize the amount of CO_2 re-breathed by the patient;
  - anti-asphyxia valves (AAV) to enable the patient to breathe fresh air in the event that airflow from the flow generator is impeded;
  - elbow which connects to a conventional air delivery hose via standard conical connector;
  - molded plastic and silicone components and polyamide/polyurethane/polyester headgear – all deemed biologically safe (ref: ISO 10993-1);
  - Both masks are offered in various sizes to ensure adequate fit over the extended patient population.
- similar performance i.e both masks operate on the same flow generator settings and have similar pressure-flow characteristics and flow impedance.
- same operating environments i.e reuse in the home and hospital / institution environments
- similar manufacturing processes

The main differences between the AirFit F20 and the previously cleared predicated device (Quattro Air (K123979)) include mask component design and geometry:

- The AirFit F20 frame incorporates an upper arm positioned under the eyes whilst the Quattro Air frame includes a forehead support.
- The AirFit F20 vent array is located on the elbow assembly, whereas the Quattro Air vent array is located on the cushion assembly.
- For sealing performance, the AirFit F20 silicone cushion employs a novel feature to anchor and stabilise the interface compared with the traditional Quattro Air silicone cushion design.

Verification and validation testing has demonstrated that these

differences do not raise new questions of safety or effectiveness.

Non-Clinical Data

The AirFit F20 was designed and tested in accordance with *ISO 17510-2: Sleep apnoea breathing therapy - Part 2: Masks and application accessories.*

The scope of non-clinical testing conducted to support the substantial equivalence claim of AirFit F20 with the predicate device included:

- CO2 rebreathing
- AAV performance (activation/deactivation, inspiratory /expiratory resistance, inadvertent activation/deactivation, response to extreme humidification)
- Total mask flow
- Flow resistance
- Through impedance

Mechanical integrity and performance of the new device was also verified to simulated normal and reasonable abuse scenarios including: home cleaning; multi-patient reuse; transportation and storage.

Biocompatibility testing was conducted in accordance with *ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-12* and *ISO 10993-17* on new materials used in the manufacture of the AirFit F20 with patient exposure classifications permanent external communicating device (tissue) and /or permanent skin contact.

Testing confirmed that the new device met the predetermined acceptance criteria and the performance of the AirFit F20 is substantially equivalent to Quattro Air (K123979).

Clinical Data

Clinical data was not relied upon to demonstrate substantial equivalence to the predicate device. Bench testing demonstrates that the new AirFit F20 device performs in an equivalent manner and is as safe and as effective as the predicate device.

Substantial Equivalence Conclusion

The new AirFit F20 is substantially equivalent to the predicate device:

- it has the same intended use
- it has similar technological characteristics
- it has similar performance characteristics
- the difference do not raise any new questions of safety or effectiveness
- it is at least as safe and as effective as the predicate device.