DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 2, 2016

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

Re: K153673
Trade/Device Name: AirFit N20
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: March 23, 2016
Received: March 25, 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.
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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)*
K153673

Device Name:
AirFit N20

Indications for Use *(Describe)*

The AirFit N20 channels airflow non-invasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel device.

The AirFit N20 is:

- to be used by patients weighing more than 66 lb (30 kg) for whom positive airway pressure has been prescribed
- intended for single patient re-use in the home environment 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 (Part 21 CFR 807 Subpart C)

CONTINUE ON ANOTHER PAGE IF NEEDED)

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510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

Date Prepared
December 17th, 2015

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Device Trade Name
AirFit N20

Device Common Name
Vented Nasal Mask

Classification & Classification Name
21 CFR 868.5905, 73 BZD (Class II)
Accessory to Noncontinuous Ventilator (IPPB)

Legally Marketed Predicate Devices
AirFit N10 (K132887)

Device Description
The ResMed AirFit N20 is a non-invasive vented respiratory mask that provides a silicone air seal around the patient's nose and upper lip. The mask is held in place with adjustable head straps. Air flow from a positive air pressure (PAP) source is directed to the patient's airway non-invasively. It connects to a conventional PAP device air delivery hose via a standard 22mm swivel.

The AirFit N20 comprises 4 subassemblies: headgear, frame, cushion and elbow/short tube. The exhaust port is incorporated into the elbow/short tube assembly. For home use, the mask may be cleaned in warm soapy water.

The AirFit N20 is a prescription device supplied non-sterile.

Intended Use
The AirFit N20 channels airflow non-invasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel device.
The AirFit N20 is:

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

Submission reason

New Device

Similarities and differences with the predicate device

The AirFit N20 has the following similarities to the previously cleared predicate AirFit N10 (K132887):

- same intended use
- same operating principle
- similar construction materials and design that incorporate:
    a. A silicone elastomer cushion interface that provides air seal around the patient's nose and upper lip.
    b. The use of a multi-hole vent array to continuously flush out and minimize the amount of CO_2 rebreathed by the patient.
    c. A multiple size offering to ensure adequate mask fit over the extended patient population.
    d. Use of a 4 attachment point head strap that employ self-aligning tactile magnetic clips.
    e. A flexible and extensible short tube to mechanically decouple the mask from the conventional PAP device air delivery hose to enhance stability and air seal.
    f. A 22 mm diameter ISO 5356-1 fully rotatable (360^o) conical swivel for connection to the delivery hose.
    g. The use of molded polymeric plastic and silicone air seal components and foam padded fabric headgear deemed safe (ref: ISO 10993-1).
- similar performance i.e. both masks have similar operating pressure range, pressure flow and flow impedance characteristics and operate on the same "*Pillows*, *Mirage* or *Swift"* ResMed flow generator settings.
- same operating environments i.e. reuse in the home and hospital / institution environments
- similar manufacturing processes

The main differences between the AirFit N20 and the previously cleared predicate AirFit N10 (K132887) include mask component design and geometry:

- The AirFit N20 design incorporates an integrated elbow/short tube that is detachable from the frame to enhance usability; the AirFit N10 short tube is permanently moulded to the frame.
- The AirFit N20 plastic frame arms incorporate permanently over-moulded foam padded soft fabrics to enhance patient comfort and usability; the AirFit N10 mask is supplied with fabric soft sleeves that can be fitted to the plastic arms.
- For sealing performance, the AirFit N20 silicone cushions employ a novel feature to anchor and stabilise the interface; the AirFit N10 cushions employ the traditional dual wall design.
- The AirFit N20 exhaust port is located on the elbow component whereas the AirFit N10 exhaust port is located on the frame component.

Verification and validation testing has demonstrated that these differences do not affect intended performance of the mask nor raise new questions of safety or effectiveness.

Non-clinical data

The AirFit N20 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 N20 to the predicate device included:

- CO2 rebreathing
- Total mask flow
- Flow resistance
- Through impedance

Mechanical integrity performance of the new device was verified by testing to simulated normal use and reasonable abuse scenarios including:

- home cleaning for single patient reuse
- reprocessing for multi-patient reuse
- transportation
- 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 N20 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 N20 is substantially equivalent to the predicate AirFit N10 (K132887).

Clinical Data

Clinical data was not relied upon to demonstrate Substantial Equivalence to predicate devices. Bench testing demonstrates that the new AirFit N20 mask device performs in an equivalent manner and is as safe and as effective as the predicate device.

Substantial Equivalence Conclusion

The new AirFit N20 is substantially equivalent to the predicate device:

- it has the same 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 at least as safe and as effective as the predicate device