DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 17, 2016

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

Re: K161978
Trade/Device Name: AirFit N20
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: October 17, 2016
Received: October 18, 2016

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. 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

Tina Kiang, Ph.D.
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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)*

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 (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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510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

Date Prepared

Nov 16th, 2016

Company Name / Owner

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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 N20 (K153673)

Device Description

The modified 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 modified 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

Device modifications

Comparison of technological characteristics with the previously cleared predicate AirFit N20 device

Delivering treatment pressure generated from a positive airway device (PAP) device to the patient's airway is the technological principle of both the modified AirFit N20 and the previously cleared predicate AirFitN20 (K153673) device.

The modified and predicate devices are based on the following same technological elements:

- Soft silicone elastomer cushions are used to achieve an air seal around the patient's nose and upper lip.
- The cushion is held in place using a polymeric frame
- The frame is strapped to the patient's head using a four point foam padded fabric headgear that employ self- aligning tactile magnetic clips.
- A flexible and extensible elbow and short tube assembly delivers the treatment pressure from the PAP device tubing to the cushion and the patient's airway.
- Exhaust ports are built into the elbow to continuously flush out and minimize the amount of CO_2 rebreathed by the patient.
- The masks can be disassembled for cleaning and reprocessing in accordance with the labelling.
- Use of polymeric construction materials for the pneumatic and structural components and foam padded fabrics for the head strap.
- Use of ISO 5356-1 compliant 22mm diameter swivel for connection to the PAP delivery hose.
- Multiple size offering to ensure adequate mask fit over the extended patient population.
- 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 following technological differences exist between the modified AirFit N20 and the previously cleared predicate AirFit N20 (K153673) are:

- The modified AirFit N20 design incorporates an optional multi-hole integrated elbow/short tube; the previously cleared AirFit N20 only has a diffused elbow/short tube assembly.
- Headgear fabric materials were modified.
- Exhaust port vent geometries modifications were made to the diffused elbow.
- Reprocessing claims expanded to include other components. In the predicate device only the cushion was labelled for reprocessing.

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

Non-clinical data

The modified AirFit N20 was designed and tested in accordance with *ISO 17510:2015: Medical devices – Sleep apnoea breathing therapy – Masks and application accessories.*
The scope of non-clinical testing conducted to support the substantial equivalence claim of modified AirFit N20 to the previously cleared predicate AirFit N20 device included:

- CO_2 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 evaluation was conducted in accordance with *ISO 10993-1, ISO 10993-5, ISO 10993-10 and ISO 10993-12* on modified components that were manufactured using new materials with patient exposure classifications of permanent external communicating device (tissue) and /or permanent skin contact. Predication on the predicate AifFit N20 device (K153673) and other reference devices was relied upon where the modified components were manufactured using previously cleared predicate materials. Reference devices include Mirage Vista Mask (K031047), Mirage Swift (K032433), AirFit P10 (K132013) and AirFit N10 (K132887).

Validation of reprocessing included a combination of cleaning efficacy testing, disinfection efficacy testing and predication based on previously validated Master Components. Post disinfection and sterilization performance testing and residual toxicity evaluation were also completed to demonstrate functional performance of the modified device.

Verification confirmed that the modified device met the predetermined acceptance criteria and the performance is substantially equivalent to the previously cleared predicate AirFit N20 (K153673).

Clinical Data

Clinical data was not relied upon to demonstrate Substantial Equivalence to the predicate device. Bench testing demonstrates that the modified AirFit N20 mask device performs in an equivalent manner and is as safe and as effective as the previously cleared predicate AirFit N20 device (K153673).

Substantial Equivalence Conclusion

The modified AirFit N20 is substantially equivalent to the previously predicate AirFit N20 device (K153673):

- 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