



Food and Drug Administration
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September 28, 2017

ResMed Ltd
% Sheila Bruschi
Senior Manager, Regulatory Affairs. ResMed CORP.
ResMed Corp (Registration Number: 3007573469)
9001 Spectrum Center Boulevard
San Diego, California 92123

Re: K171212
Trade/Device Name: AirFit N20
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: August 28, 2017
Received: August 30, 2017

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 (DICE) 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 (DICE) 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,

Tara A. Ryan -S

for

Tina Kiang, PhD

Acting 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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K171212

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.

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510(k) SUMMARY*[As required by 21 CFR 807.92(c)]*

Date Prepared	September 28, 2017
Company Name / Owner	ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista, NSW, 2153 Australia
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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 (K161978)
Device Description	<p>The AirFit N20 is an externally placed vented respiratory mask covering the patient's nose. It provides a seal such that pressure from a positive air pressure (PAP) source is directed to the patient's airway non-invasively via the nose. The mask connects to the positive pressure source through a conventional air tubing via a standard conical connector. The mask is held in place with adjustable head straps.</p> <p>The AirFit N20 comprises 4 subassemblies: headgear, frame, cushion and elbow/short tube. The exhaust port is incorporated into the elbow/short tube assembly. The cushion and headgear are available in various sizes to fit a wide patient population.</p> <p>The AirFit N20 is a prescription device supplied non-sterile.</p>
Intended Use	<p>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.</p> <p>The AirFit N20 is:</p> <ul style="list-style-type: none">• 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 Expansion of reprocessing claims

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 subject AirFit N20 and the previously cleared predicate AirFitN20 (K161978) device.

The subject and predicate devices have identical intended use and are based on the same technological elements as follows:

- Silicone elastomer cushions 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 foam padded fabric headgear and clips.
- An elbow and short tube assembly delivers the treatment pressure from the PAP device tubing to the cushion and the patient's airway.
- Exhaust ports flush out CO₂.
- 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 swivel for connection to the PAP delivery hose.
- Multiple size offerings to allow for adequate mask fit over the intended 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

The main difference between the subject AirFit N20 and the previously cleared predicated device AirFit N20 (K161978) is:

- High level chemical disinfection claims (Alconox cleaning followed by Cidex OPA disinfection) were added to the diffused elbow and diffused short tube assemblies.
- High level thermal disinfection claims (Alconox cleaning followed by Hot Water disinfection (90°C, 1 min) were added to the multi-hole elbow and short tube assembly.

These differences do not affect substantial equivalence claim to the predicate device because non-clinical testing below demonstrates that the subject device has equivalent performance to and is as safe as the predicate device.

Non-clinical data Verification and validation testing has demonstrated that the expansion of the multi-patient reuse reprocessing claims do not affect intended performance of the mask nor raise new questions of safety or effectiveness.

Non clinical testing included:

- Bioburden efficacy tests which demonstrated that the subject device meets the same cleaning and microbicidal bioburden efficacy performance as the predicate device.
- Performance tests before and after the additional reprocessing claims to demonstrate that the subject device continues to meet the same performance specifications as the predicate device. These included Mask Pressure-Flow tests per ISO 17510:2015 and relevant mask mechanical integrity tests such as visual inspection, assembly integrity, headgear connection integrity, simulated body weight crush test and free fall drop test.
- Residual toxicity testing which demonstrated that the subject device remains safe after reprocessing. This was demonstrated using the appropriate Cytotoxicity biocompatibility tests, performed in accordance with ISO 10993-5:2009.

Substantial Equivalence Conclusion The subject AirFit N20 is substantially equivalent to the previously predicate AirFit N20 device (K161978):

- it has the same intended use
- it has the same technological characteristics
- it has the same 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