January 3, 2018

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

Re: K170924
Trade/Device Name: AirFit F20
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: December 1, 2017
Received: December 4, 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.

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.

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,

Tina Kiang, Ph.D.
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

Indications for Use

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

510(k) Number *(if known)*
K170924

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.

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510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

Date Prepared December 29, 2017

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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 AirFit F20 (K153563)

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 AirFit F20 (K153563):

- 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 fabric/foam 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 following are the main differences between the subject AirFit F20 and the previously cleared predicated device (AirFit 20 (K153563)):

- all components of the mask system can be reprocessed:
  - In the predicate device, the cushion can be reprocessed via high level thermal disinfection, high level chemical disinfection, and STERRAD sterilization, while the elbow can be reprocessed via STERRAD sterilization.
  - In the subject device, the elbow, frame and headgear can all be processed via high-level thermal disinfection. The cushion maintains the same reprocessing methods as the predicate device.
- Material changes to the elbow, frame, and headgear assemblies

Non-Clinical Data

Validation testing has demonstrated that the material changes and expansion of the multi-patient reuse reprocessing claims does not raise new questions of safety or effectiveness.

Non clinical testing included:

- Bioburden efficacy tests which demonstrated that the modified 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 modified device continues to meet the same performance specifications as the predicate device, including:
  - Visual inspection
  - Total mask flow
  - AAV activation / deactivation
  - Assembly integrity
  - Mask to headgear connections
- Residual toxicity tests, including cytotoxicity testing per ISO 10993-5, which demonstrated that the modified device remains as safe as the predicate device if the reprocessing steps provided in the labelling are followed
- For the material changes requiring additional testing, the following biocompatibility tests were conducted:
  - Cytotoxicity testing per ISO 10993-5
  - Sensitization testing per ISO 10993-10
  - Irritation testing per ISO 10993-10
  - Genotoxicity per ISO 10993-3
  - Acute systemic toxicity per ISO 10993-11
  - Material-mediated Pyrogenicity per ISO 10993-11
  - Implantation per ISO 10993-6
  - Leachables testing per ISO 10993-17

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.