June 15, 2018

ResMed Ltd
Ms. Kim Kuan Lee
Senior Regulatory Affairs Manager
1 Elizabeth Macarthur Drive
Bella Vista, 2153 Au

Re: K180497
  Trade/Device Name: Scone Mask
  Regulation Number: 21 CFR 868.5905
  Regulation Name: Noncontinuous ventilator (IPPB)
  Regulatory Class: Class II
  Product Code: BZD
  Dated: May 16, 2018
  Received: May 18, 2018

Dear Ms. Lee:

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 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,

James J. Lee -S

for 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
Indications for Use

The Scone Mask is intended to be used by patients weighing more than 66 lb (30 kg) who have been prescribed non-invasive positive airway pressure (PAP) therapy such as CPAP or bi-level therapy. The mask is intended for single patient re-use in the home 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)*

<table>
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<tr>
<th>Date Prepared</th>
<th>February 23, 2018</th>
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| Device Trade Name  | Scone Mask |
| 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 Device | AirFit N20 (K171212) |
| Device Description | The Scone Mask is an externally placed vented respiratory mask. Positive air pressure (PAP) source is directed to the patient's airway non-invasively, via the nose. The mask connects to the positive pressure flow source through conventional air tubing via an industry standard conical connector. The mask is held in place with adjustable head straps.  
The Scone Mask comprises 4 subassemblies: headgear, frame, cushion and elbow. The exhaust ports are incorporated into the elbow and cushion assemblies. The cushion and frame are available in various sizes to fit a wide patient population.  
The Scone Mask is a prescription device supplied non-sterile. |
| Intended Use | The Scone mask is intended to be used by patients weighing more than 66 lb (30 kg) who have been prescribed non-invasive positive airway pressure (PAP) therapy such as CPAP or bi-level therapy. The mask is intended for single patient re-use in the home and multi-patient re-use in the hospital/institutional environment. |
| Submission reason | New Device |
Delivering treatment pressure generated from a positive airway pressure (PAP) device to the patient’s airway is the technological principle of both the subject Scone Mask and the previously cleared predicate AirFit N20 (K171212) device.

The subject and predicate device have an identical intended use and the following similarities:

- A silicone elastomer cushion to achieve an air seal at the patient’s nose.
- The cushion is held in place via the mask frame
- The frame is strapped to the patient’s head and sits along the sides of the face, held in place via head straps.
- An elbow assembly connects to the PAP device tubing.
- Exhaust ports flush out CO₂.
- The mask can be disassembled for cleaning and reprocessing in accordance with the labelling.
- Polymeric materials are used for the construction of the pneumatic and structural components. Foam padded fabric materials are used for the construction of the head strap.
- A port compliant to ISO 5356-1 is used to connect to the PAP delivery hose.
- Multiple cushion and frame sizes are available to allow for adequate mask fit over the intended patient population.
- Similar performance i.e. both masks have similar operating pressure range and pressure flow characteristics and operate on the same “Pillows” ResMed flow generator settings.
- Same operating environments i.e. re-use in the home and hospital / institution environments

The main differences between the subject Scone Mask and the previously cleared predicate device AirFit N20 (K171212) are:

- The PAP device tubing is connected to the Scone device at the top of the patient’s head, whereas the predicate device is connected near the nose.
- The new device is labelled for a smaller operating pressure range compared to the predicate AirFit N20 device.

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

Non-clinical data

Non-clinical verification and validation testing completed for the new device demonstrated that the Scone device met all intended performance requirements. These included:

Applicable performance and safety tests in accordance with ISO 17510:2015: Medical devices – Sleep apnoea breathing therapy – Masks and application accessories:

- CO₂ rebreathing
- Total mask flow
- Flow resistance
Other bench tests:
- Physical dead space
- Functional tests
- Mechanical integrity performance following relevant environmental exposure
  - Home cleaning
  - Transportation
  - Operation environment
  - Relevant abuse use case tests

Biocompatibility evaluation was conducted in accordance with ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-12, ISO 10993-17 and ISO 10993-18 on components that were manufactured using new materials with patient exposure classifications of permanent external communicating device (tissue) and/or permanent skin contact.

Validation of reprocessing claims included a combination of cleaning efficacy, disinfection efficacy, residual toxicity and mechanical integrity testing.

Verification confirmed that the new device met the predetermined acceptance criteria and the performance is substantially equivalent to the previously cleared predicate AirFit N20 (K171212).

**Substantial Equivalence Conclusion**

The Scone Mask is substantially equivalent to the predicate AirFit N20 device (K171212):
- 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