December 15, 2016

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

Re: K160836
Trade/Device Name: Menai System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD, MNR
Dated: November 11, 2016
Received: November 15, 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.
Clinical Deputy Director
DAGRID/ODE/CDRH

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
Indications for Use

Menai system

The Menai self-adjusting system is indicated for the treatment of Obstructive Sleep Apnea (OSA) in patients (female patients with mild to moderate OSA when using AfH treatment mode) weighing more than 66 lb (30 kg). It is intended for home and hospital use.

Smart Phone Application (Monte Carlo)

Monte Carlo is a mobile application for patients to remotely operate a prescribed compatible ResMed machine and transfer, analyze and display usage and therapeutic information. Monte Carlo also allows healthcare professionals to remotely configure compatible OSA therapy devices.

Menai Full Face Mask

The Menai FFM is a non-invasive accessory used for channeling airflow to a patient from a compatible ResMed machine such as a continuous positive airway pressure (CPAP) system. The Menai FFM 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 and hospital/institutional environment.

Type of Use (Select one or both, as applicable)

- [x] 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 – Menai system

**Required**
By section 807.92 (c)

**Date Prepared**
15 Dec 2016

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**Product Codes**
73 BZD
73 MNR

**Class**
II

**Classification Reference**
(21 CFR 868.5905 Product code 73 BZD)
(21 CFR 868.2375 Product code 73 MNR)

**Common/Usual Name**
Non continuous ventilator (IPPB)
Breathing Frequency Monitor

**Proprietary Name**
Menai system

**Predicate Device(s)**
S9 Elouera (K140124)
Medtronic® SULLIVAN CPAP System (K905404)

**Reason for submission**
New Device
DEVICE DESCRIPTION

The Menai system CPAP device retains similar hardware and performance features of the predicate device(s). It is provided in a portable smaller footprint than the predicate for user convenience in the home environment. Key features include mask, tubing, humidification system, and software controls. The Menai System contains a Micro-processor controlled blower system that generates Continuous Positive Airway Pressure (CPAP) from 4-20 cmH2O as required to maintain an “air splint” for treatment of OSA. Included is an optional humidifier component for patients who experience dryness in the upper airways such as mouth or nasal areas.

The Menai system flow generator includes CPAP, AutoSet and AutoSet for Her (AfH) modes. These modes and their treatment parameters are only settable by the Clinician via the Clinician accessible menu of the software. In addition to Patient and Clinician settable features, the software can display patient sleep data and treatment pressures, similar to that found on the predicate S9 Elouera (K140124). The Menai system includes Cheynes Stokes Respiration (CSR) breathing pattern recognition and reporting, this feature remains unchanged as cleared S9 Elouera (K140124).

Substantial Equivalence
The new device has the following similarities to the previously cleared predicate devices.

- Same intended use
- Similar operating principle
- Similar technologies

As a result of the Risk Analysis review and design input requirements, Verification activities were performed on the Menai system. All tests confirmed the product met the predetermined acceptance criteria.

INDICATION FOR USE

Menai system

**Indication for Use**
The Menai self-adjusting system is indicated for the treatment of Obstructive Sleep Apnea (OSA) in patients (female patients with mild to moderate OSA when using AfH treatment mode) weighing more than 66 lb (30 kg).
It is intended for home and hospital use.

Software Application (Monte Carlo)

**Indication for Use**
Monte Carlo is a mobile application for patients to remotely operate a prescribed compatible ResMed machine and transfer, analyze and display usage and therapeutic information. Monte Carlo also allows healthcare professionals to remotely configure compatible OSA therapy devices.

Menai Full Face Mask

**Indication for Use**
The Menai FFM is a non-invasive accessory used for channelling airflow to a patient from a compatible ResMed machine such as a continuous positive airway pressure (CPAP) system.
The Menai FFM 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 and hospital/institutional environment.
## COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

### Characteristics between the predicate and new device

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Predicate Device- S9 Elouera (K140124)</th>
<th>New device- Menai System</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication for use</td>
<td>The S9 Elouera self-adjusting device is indicated for the treatment of Obstructive Sleep Apnea (OSA) in patients (female patients with mild to moderate OSA when using AfH treatment mode) weighing more than 66 lb (30 kg). It is intended for home and hospital use.</td>
<td>The Menai self-adjusting system is indicated for the treatment of Obstructive Sleep Apnea (OSA) in patients (female patients with mild to moderate OSA when using AfH treatment mode) weighing more than 66 lb (30 kg). It is intended for home and hospital use.</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Location of use (primary)</td>
<td>Hospital/Home</td>
<td>Hospital/Home</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Indication for use</td>
<td>—</td>
<td>Monte Carlo is a mobile application for patients to remotely operate a prescribed compatible ResMed machine and transfer, analyze and display usage and therapeutic information. Monte Carlo also allows healthcare professionals to remotely configure compatible OSA therapy devices.</td>
<td>Equivalent: <em>Software application - similar functionality to LCD and keypad operation with S9 Elouera (K140124).</em></td>
</tr>
<tr>
<td>Indication for use</td>
<td>FFM Quattro LT</td>
<td>The Menai FFM is a non-invasive accessory used for channelling airflow to a patient from a compatible ResMed machine such as a continuous positive airway pressure (CPAP) system. The Menai FFM 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 and hospital/institutional environment.</td>
<td>Equivalent: <em>Similar intended Use, reduced feature, same patient population and compatibility with a CPAP Machine.</em></td>
</tr>
</tbody>
</table>

### Performance

<table>
<thead>
<tr>
<th>Performance</th>
<th>Predicate Device- S9 Elouera (K140124)</th>
<th>New device- Menai System</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressure range</td>
<td>4-20 cm H₂O (CPAP Mode)</td>
<td>4-20 cm H₂O (CPAP Mode)</td>
<td>Equivalent: <em>These features are enabled when using the software- similar functionality to LCD and keypad operation with S9 Elouera (K140124).</em></td>
</tr>
<tr>
<td></td>
<td>4-20 cm H₂O (AutoSet Mode)</td>
<td>4-20 cm H₂O (AutoSet Mode)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4-20 cm H₂O (AutoSet AfH Mode)</td>
<td>4-20 cm H₂O (AutoSet AfH Mode)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EPR +3 cm H₂O (all modes)</td>
<td>EPR +3 cm H₂O (all modes)</td>
<td></td>
</tr>
<tr>
<td>Ramp features</td>
<td>User selected as “Off” to 45 minutes in 5 minute increments</td>
<td>User selected as “Off” to 45 minutes in 5 minute increments</td>
<td>Equivalent: <em>These features are enabled when using the software- similar functionality to LCD and keypad operation with S9 Elouera (K140124).</em></td>
</tr>
</tbody>
</table>
### PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

**Biocompatibility Testing**


**Tests Selected**

Component classifications for materials used according to #G95-1 are:

- **Wet Air Path**
  - Device Category: “External communicating devices, Tissue/bone/dentin,”
  - Contact Duration: “C – Permanent (>30d).”

- **Skin Contact**
  - Device Category “Surface devices, skin”
  - Contact Duration “C – Permanent (>30d)”

Biocompatibility evaluation used according to #G95-1 are:

- **Wet Air Path**
  - Cytotoxicity (MEM Elution) (ISO 10993-5)
  - Sensitisation (Polar & Non-polar) (ISO 10993-10)
  - Irritation (Polar & Non-polar) (ISO 10993-10) – additional test as per #G95-1
  - Genotoxicity (Polar & Non-polar) (ISO 10993-3)
  - Implantation (ISO 10993-6)

- **Skin Contact**
  - Cytotoxicity (MEM Elution) (ISO 10993-5)
  - Irritation (Polar & Non-polar) (ISO 10993-10)
  - Sensitisation (Polar & Non-polar) (ISO 10993-10)

Electrical Safety and Electromagnetic Compatibility (EMC)
The Menai system has been tested to appropriate standards and other applicable requirements. The Menai system with integrated tubing and dedicated mask was designed and tested according to:

- **IEC 60601-1:2005 amd 1 (3.1)**, Medical electrical equipment - Part 1: General requirements for safety
  Medical electrical equipment – General requirements for basic safety and essential performance

- **IEC 60601-1-2:2013** Ed. 4.0 Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests


- **ISO 17510-2:2007** Sleep apnoea breathing therapy Part 2: Masks and application accessories

- **IEC 62304:2006** Medical device software - Software life cycle processes

Software Verification and Validation Testing
Software verification and validation testing were conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Guidance for Industry and FDA Staff, May 2005.”

The software for this device was considered as a “Moderate” level of concern, since prior to mitigation of hazards, failure of the Software Device result in Minor Injury, either to a patient or to a user of the device since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Mechanical and Acoustic Testing
Mechanical testing was carried out in accordance with mechanical and environmental requirements as set down in Environmental Testing Section (e) (6) in Reference 4.4 Reviewer Guidance for Premarket Notification Submissions, Anesthesiology and Respiratory Devices Branch, FDA, November 1993.

Acoustic testing was carried out in accordance with ISO 80601-2-70: 2015 Sleep apnoea breathing therapy -- Part 1: Sleep apnoea breathing therapy equipment and found to be compliant with these requirements.

Animal Studies
No animal studies were performed for the Menai system.

Clinical Studies:
The key aims of the clinical study are to characterise the rate of bacterial accumulation and/or proliferation, characterize the change in impedance, and establish the replacement interval. Bio-burden outcomes showed that the humidifier component was relatively stable over the study period with no observation of unstable bioburden proliferation or accumulation. Furthermore, colony identification indicated common microbial presence to that of users and their environment with low risk pathogenicity. The impedance was shown to be relatively stable over the study duration. The clinical trial results demonstrated that the humidifier component of the Menai system performed as expected, and can be used as a single patient reuse item with a standard replacement interval.

Non-Clinical Testing:
Side-by-Side bench testing was performed to verify that the Menai system met the requirements of the Menai system Specification when compared to the predicate device S9 Elouera (K140124).
The bench testing included performance for each therapy mode which covered:

- Pressure stability
- Response to apneas
- Response to flow limitations and snore.
- Reporting of Closed Airway Detection (CAD)

A breathing machine simulates patient breathing patterns, which results in the Flow Generator responding in a manner consistent with maintaining the CPAP treatment pressure (CPAP mode) or adjusting the CPAP pressure based upon the patient’s condition in real-time (self-adjusting mode). The clinical Pass/Fail requirements are traced to the Menai system Specification and to the predicate device’s performance.

Bench testing for the Menai system includes Cheynes Stokes Respiration (CSR) breathing pattern recognition and reporting. Side-by-side testing using the same digitised breathing patterns was used for both predicate and Menai system. This test executes patient script files. Each patient script file is treated as an individual scenario, which the Menai reports either:

- No CSR
- CSR
- CSR + OSA
- OSA

The Menai CSR detection results are then compared to the predicate S9 Elouera (K140124). The Menai system met the predefined Clinical Pass/Fail criteria.

**CONCLUSION**

The Menai system is substantially equivalent to the predicate devices S9 Elouera (K140124) and Medtronic® SULLIVAN CPAP System (K905404) and is as safe and as effective as the predicate device.