DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 21, 2015

ResMed Ltd
c/o Larissa D'Andrea
Manager, Regulatory Affairs
Resmed Corp.
9001 Spectrum Center Boulevard
San Diego, CA 92123

Re: K143603

Trade/Device Name: Darlinghurst Vented
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator (IPPB)
Regulatory Class: II
Product Code: BZD

Trade/Device Name: Darlinghurst NV-AAV
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator (IPPB)
Regulatory Class: II
Product Code: BZD, CBK

Dated: April 17, 2015
Received: April 20, 2015

Dear Ms. 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): **K143603**

Device Name: **Darlinghurst Vented**

Indication for Use

The **Darlinghurst Vented** mask is a non-invasive accessory used for channeling airflow to a patient from positive airway pressure (PAP) devices.

The mask is:

- to be used on patients weighing >66 lb (30 kg), for whom non-invasive positive airway pressure therapy has been prescribed
- disposable devices, intended for short-term treatment (up to 7 days) of a single patient, in the hospital environment only.

Prescription Use ____**X**_____ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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Concurrence of CDRH; Office of Device Evaluation (ODE)

Indication for Use

510(k) Number (if known): **K143603**

Device Name: **Darlinghurst NV-AAV**

Indication for Use

The **Darlinghurst NV-AAV** mask is a non-invasive accessory used for channeling airflow to a patient from a positive airway pressure (PAP) device.

The mask is:

- to be used on patients weighing >66 lb (30 kg), for whom non-invasive positive airway pressure therapy has been prescribed
- a disposable device, intended for short-term treatment (up to 7 days) of a single patient, in the hospital environment only
- intended to be used with breathing circuits or positive pressure ventilation (PPV) devices that provide their own method of venting expired or supplemental gases.

Prescription Use ____**X**_____ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

1. Date prepared

May 21st, 2015

2. Applicant information

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3. Device details and substantial equivalence claim [807.92(a)(3)]

Trade/Device Names	***Darlinghurst Vented***	***Darlinghurst NV-AAV***
Device Common Name	Hospital Full Face Mask	Hospital Full Face Mask
Regulation Number	21 CFR 868.5905	21 CFR 868.5905
Regulation Name	Noncontinuous Ventilator (IPPB)	Noncontinuous Ventilator (IPPB)
Regulatory Class	Class 2	Class 2
Classification Product Code	BZD	BZD
Subsequent Product Code	N/A	CBK
Predicate Devices	Hans Rudolph 6600 Series V2 (K071149)	Hans Rudolph 6700 Series V2 (K071149)

4. General device description

The ***Darlinghurst*** masks are externally placed masks covering the mouth and the nose of the patient. They provide a seal such that positive pressure from a positive pressure source is directed to the patient's nose and/or mouth. The masks connect via a standard (female ISO5356-1) conical connector to a conventional air delivery hose between the mask elbow and the positive airway-pressure source.
They are held in place with a common adjustable headgear that straps the mask to the face.

Darlinghurst masks are disposable devices that can be used for a maximum period of 7 days, on a single-patient and in the hospital/institutional environment only.

Both *Darlinghurst* mask variants are very similar in design and function. The only difference between the *Darlinghurst* 'Vented' and the Darlinghurst 'NV-AAV' is in the elbow component.

Whilst both variants of the mask include a built-in Anti-Asphyxia Valve (AAV) to allow the patient to continue to breathe fresh air in the event of a positive air-pressure supply failure or impediment,

- The *Darlinghurst Vented* mask includes additional built-in diffuse exhaust ports to provide a continuous air leak that flushes out CO_2 and prevent it from being re-breathed by the patient
- The *Darlinghurst NV-AAV* design does **not** incorporate built-in passive exhaust ports. This non-vented variant of the mask requires a separate part of the breathing circuit (e.g. an active exhaust valve in the ventilator or an additional leak valve) to vent the expired air (including CO_2).

All other components of the masks are common to both *Darlinghurst* variants.

Darlinghurst masks are intended to be used under the conditions and purposes indicated in the labelling provided with the product.

Darlinghurst masks are prescription devices, supplied non-sterile.

5. Intended use for "Darlinghurst Vented" mask

The **Darlinghurst Vented** mask is a non-invasive accessory used for channeling airflow to a patient from positive airway pressure (PAP) devices.

The mask is:

- to be used on patients weighing >66 lb (30 kg), for whom non-invasive positive airway pressure therapy has been prescribed
- disposable devices, intended for short-term treatment (up to 7 days) of a single patient, in the hospital environment only.

6. Intended use for "Darlinghurst NV-AAV" mask

The **Darlinghurst NV-AAV** mask is a non-invasive accessory used for channeling airflow to a patient from a positive airway pressure (PAP) device.

The mask is:

- to be used on patients weighing >66 lb (30 kg), for whom non-invasive positive airway pressure therapy has been prescribed
- a disposable device, intended for short-term treatment (up to 7 days) of a single patient, in the hospital environment only
- intended to be used with breathing circuits or positive pressure ventilation (PPV) devices that provide their own method of venting expired or supplemental gases.

7. Comparison with the predicates

Intended Use comparison

The ***Darlinghurst*** masks and the predicate Hans Rudolph 6600 Series V2 and 6700 Series V2 intended uses are equivalent. The masks are intended to be used:

- as a non-invasive interface to positive pressure therapy equipment,
- for the same patient population
- for short-term use and on a single patient only.

The non-vented variants of both the new mask (Darlinghurst NV-AAV) and the predicate device (Hans Rudolph 6700 Series V2) must also both be used with a separate exhalation device.

The main difference is that the predicate devices have been cleared for use in both the hospital and in the home environment whereas the new Darlinghurst masks are Hospital-use only devices. The scope of use of the predicate devices is therefore broader than the new masks.

Technological Characteristics comparison

The ***Darlinghurst*** masks and the Hans Rudolph 6600 and 6700 Series V2 have the same operating principle and very similar physical properties and characteristics. The masks all consist of:

- a Full Face (oro-nasal) design that covers the mouth and the nose of the patient
- various sizes and an adjustable headgear that allows fitting on a wide range of patients
- an anti-asphyxia valve (AAV) to enable the patient to breathe fresh air in the event that airflow from the flow generator is impeded
- a headgear quick-release feature
- an elbow component which can rotate through 360 degrees and connects to a conventional air delivery hose between the mask and the positive airway-pressure source via a standard conical connectors (ref: ISO 5356-1:2004).

The predicate **Hans Rudolph 6600 Series V2** (K071149) and the ***Darlinghurst 'Vented'*** variant of the new mask also both include additional built-in diffuse exhaust ports to provide a continuous air leak that flushes out CO_2 and prevent it from being re-breathed by the patient.

The predicate **Hans Rudolph 6700 Series V2** (K071149) and the ***Darlinghurst 'NV-AAV'*** do not include such built-in exhaust ports. These masks rely on another part of the circuit to flush out CO_2.

The main differences between the predicate devices and the new masks are in the component design (e.g. shape, materials used) and how the components interface with one another:

- The number of headgear attachment points to the frame of the mask differs between the predicates and the new masks
- The vented predicate mask (i.e. Hans Rudolph 6600 Series V2) utilizes a male-type ISO5356-1 connector whereas a female-type ISO5356-1 connector was selected for the Non-Vented predicate (Hans Rudolph 6700 Series V2) and both the two (2) ResMed (hospital-only) Darlinghurst masks (i.e. Vented and NV-AAV variants)
- Both predicate devices include an additional rotating swivel component which is attached at the end of the mask elbow. This additional swivel is not supplied with the new ResMed masks but can instead be incorporated in another part of the breathing circuit (e.g. on the air tubing)
- The headgear quick-release is achieved by a slide-clip mechanism on the predicate devices instead of a press-button clip mechanism on the new ResMed Darlinghurst masks
- Certain components of the predicate elbow (e.g. the AAV and the additional swivel) can be dis-assembled from the rest of the mask. The new Darlinghurst device components are permanently assembled together and do not need to be dis-assembled in the seven (7) day, single-patient use indication
- The mask Face Piece, which contacts the patient's skin on the predicate device, is constructed of injection grade thermoplastic elastomer (TPE) whereas the Darlinghurst cushion (also contacting the patient's skin) is made of silicone rubber.
- The anti-asphyxia valves on both the predicate and the new device come into contact with the patient's breathed gases. They are both constructed of a silicone rubber material but their composition/grade may differ.
- The rest of the mask components which comes into contact with the patient's breathed gases (e.g. elbows and cushion clips), are constructed of acrylic-based multipolymer compounds on the predicate while polycarbonates have been used on the Darlinghurst masks .
- The predicate Head Gear materials consist of nylon, polyester straps, and polycarbonate clips. The new device

uses an alternate grade polyester headgear straps with PBT clips.

The data provided in this submission shows that the differences in design of the mask components are substantially equivalent.

The Darlinghurst mask was developed within a risk management process in accordance to ISO 14971:2007, Medical devices - Application of risk management to medical devices and under ResMed's 21 CFR 820 compliant Quality System.

8. Non Clinical data submitted

Performance / Non-clinical data is relied upon to demonstrate that the design choices adopted for the Darlinghurst masks do not impact the fundamental scientific concept nor the therapeutic effects of the new devices when compared to the predicates.

- The Darlinghurst 'Vented' variant was compared to the vented predicate mask Hans Rudolph 6600 Series V2 (K071149)
- The Darlinghurst 'NV-AAV' variant was compared to the NV-AAV predicate mask Hans Rudolph 6700 Series V2 (K071149)

The masks can operate on the same flow generator settings and are shown to meet their published specifications. The pressure-flow characteristics and flow impedance of the devices are equivalent to the predicates in the labelled performance range for each device (3-40 cmH_2O). Labeling these characteristics ensures that clinicians are able to prescribe the appropriate therapy when using the new device.

CO_2 performance (physical and functional dead space) of the new devices was also tested and where relevant, benchmarked to ISO17510-2:2007. Data demonstrates CO_2 re-breathing to be substantially equivalent to the predicates.

The Darlinghurst component materials were subject to a biocompatibility evaluation program in accordance with ISO 10993-1. Materials used in the construction of components that:

- contact the heated humidified gas pathway have been classified as permanent "external communicating devices" (with tissue/bone/dentin)
- contact the patient during the therapy have been classified as permanent "skin contact"

Where relevant, and to support the biocompatibility evaluation of each mask component, following biological effects (selected in accordance with FDA guidance #G95-1) were assessed:

- Genotoxicity (ISO 10993-3)
- Cytotoxicity (ISO 10993-5)
- Implantation (ISO 10993-6)
- Sensitization (ISO 10993-10)
- Irritation (ISO 10993-10)

Mechanical integrity and performance of the new devices were also verified to simulated normal use and reasonable abuse scenarios. The new masks can withstand the effects of storage temperature, humidity and transportation shock & vibration and met their intended specifications.

A summary of the data included in this submission as well as the overall results (pass/fail) is provided below:

Bench test	Test name	Darlinghurst NV-AAV	Darlinghurst Vented
CO2 flushing	- Functional dead-space measurements **normal use**	**N/A**	**PASS**
	- Functional dead-space measurements **Single fault condition**	**PASS**	**PASS**
	- Physical dead-space measurement	**PASS**	**PASS**
AAV performance	- Activation (Open to Atmosphere)	**PASS**	**PASS**
	- Deactivation (Close to Atmosphere)	**PASS**	**PASS**
	- Inspiratory resistance	**PASS**	**PASS**
	- Expiratory resistance	**PASS**	**PASS**
	- Inadvertent activation	**PASS**	**PASS**
	- Inadvertent de-activation	**PASS**	**PASS**
	- AAV Durability	**PASS**	**PASS**
Mask Characteristics	- Pressure-flow test - Total mask flow	**N/A**	**PASS**
	- Pressure-flow test - Un-intentional leak	**PASS**	**N/A**
	- Mask Impedance	**PASS**	**PASS**
Assembly Integrity (post cleaning)	- Normal use	**PASS**	**PASS**
	- Reasonable abuse	**PASS**	**PASS**
	- Pressure-flow test (post cleaning)	**PASS**	**PASS**
	- AAV Activation/De-activation (post cleaning)	**PASS**	**PASS**
Ease of cleaning	- Ease of cleaning – geometry accessibility	**PASS**	**PASS**
Material Safety	- Biocompatibility of all mask components (ref: ISO 10993-1)	**PASS**	**PASS**
Transportation and Storage	- Performance after storage under simulated extreme environmental conditions	**PASS**	**PASS**
	- Performance after shock and vibration simulating extreme transportation environment	**PASS**	**PASS**

9. Clinical data

Use of Full Face masks as a non-invasive interface to positive airway pressure therapy is proven technology and is well accepted by the medical community. Bench testing was sufficient to demonstrate substantial equivalence to the predicate devices.

10. Substantial Equivalence Conclusion

The new Darlinghurst 'Vented' and 'NV-AAV' mask systems are substantially equivalent to the nominated predicate devices:

- They have equivalent intended uses
- They have the same fundamental operating principle and similar technological characteristics
- They have similar performance characteristics to the predicates
- Data shows that the differences in design are substantially equivalent