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

November 24, 2014

ResMed Corp
Mr. Jim Cassi
Vice President-Quality Assurance
9001 Spectrum Center Boulevard
San Diego, California 92123

Re: K133766
Trade/Device Name: HUMICARE D900
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory gas humidifier
Regulatory Class: II
Product Code: BTT
Dated: October 24, 2014
Received: October 27, 2014

Dear Mr. Jim Cassi:

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" (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 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,

Erin I. Keith -S

Erin I. Keith, M.S
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name
HumiCare D900

Indications for Use *(Describe)*
The Gründler's HumiCare D900 system is intended to heat and humidify medical respiratory gases for patients. The device is for use during artificial ventilation or ventilatory support (e.g. invasive ventilation via tracheal tube or cannula), non-invasive ventilation, or respiratory therapy by means of a mask or other patient interface.
Heated breathing circuits are intended to provide warmed and/or humidified breathing gases before entering the patient airway reducing or eliminating water. They are accessories for the Gründler's HumiCare D900. The heated breathing circuits are used for flow rates greater than 3L/min.
The system is for use in hospital/institutional environment or in the home environment by medically trained healthcare users.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

6 510(k) Summary

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

Date Prepared	*December 6th, 2013, updated at November 20th, 2014*
Submitter Name *]*	Dr. Christoph Gründler
Official Contact	Mr. Jim Cassi Vice President – Quality Assurance Americas ResMed Corp. 9001 Spectrum Center Boulevard San Diego CA 92123 USA Tel: (858) 836-5984
Device Trade Name	HumiCare D900
Device Common Name/	Respiratory Gas Humidifier
Classification	21 CFR 868.5450
Product code	73 BTT
Predicate Device	HumiCare D900 (K122705)
Reason for Submission	Device modified
Intended Use	The Gründler's HumiCare D900 system is intended to heat and humidify medical respiratory gases for patients. The device is for use during artificial ventilation or ventilatory support (e.g. invasive ventilation via tracheal tube or cannula), non-invasive ventilation, or respiratory therapy by means of a mask or other patient interface. Heated breathing circuits are intended to provide warmed and/or humidified breathing gases before entering the patient airway reducing or eliminating water. They are accessories for the Gründler's HumiCare D900. The heated breathing circuits are used for flow rates greater than 3L/min. The system is for use in hospital/institutional environment or in the home environment by medically trained healthcare users.

Description

The HumiCare D900 system is a respiratory gas humidifier according to 21 CFR §868.5450. A respiratory gas humidifier is identified by the Food and Drug Administration (FDA) as a therapeutic device that is intended to warm and add humidity.

The HumiCare D900 including heated air tubings is an active heated humidifier which employs a pass-over humidification via an enhanced surface area for gas/water. The huge gas/water surface area is resulting in an output of gas with a temperature almost identical to that of the water with a relative humidity of 100%.

The principle operation of the HumiCare D900 is to direct the gas mixture from the ventilator's outlet into the humidifier's water chamber via air tubing. There it is heated and humidified by means of heated water. A heated inspiratory tube is used to transport the conditioned gas from the water chamber's outlet to the patient.

Depending on the patient interface an inspiratory tube or inspiratory and expiratory tubes can be used for the humidification with HumiCare D900. The inspiratory limb can further include an antibacterial filter with filter heater to reduce condensation. In order to minimize condensation (rain out), both inspiratory and expiratory air tubing can be actively heated. Therefore a temperature sensor is included in the inspiratory air tubing to control the temperature regulation of the air tubing.

Characteristics	Predicate	Modified Device	Comments
	HumiCare D900	**HumiCare D900 with the T2 air tubing circuits**	
Intended use including target population and location of use	The Gründler's HumiCare D900 system is intended to heat and humidify medical respiratory gases for patients. The device is for use during artificial ventilation or ventilatory support (e.g. invasive ventilation via tracheal tube or cannula), non-invasive ventilation, or respiratory therapy by means of a mask or other patient interface. Heated breathing circuits are intended to provide warmed and/or humidified breathing gases before entering the patient airway reducing or eliminating water. They are accessories for the Gründler's HumiCare D900. The heated breathing circuits are used for flow rates greater than 3L/min. The system is for use in hospital/ institutional environment or in the home environment by medically trained healthcare users.	The Gründler's HumiCare D900 system is intended to heat and humidify medical respiratory gases for patients. The device is for use during artificial ventilation or ventilatory support (e.g. invasive ventilation via tracheal tube or cannula), non-invasive ventilation, or respiratory therapy by means of a mask or other patient interface. Heated breathing circuits are intended to provide warmed and/or humidified breathing gases before entering the patient airway reducing or eliminating water. They are accessories for the Gründler's HumiCare D900. The heated breathing circuits are used for flow rates greater than 3L/min. The system is for use in hospital/ institutional environment or in the home environment by medically trained healthcare users.	Equivalent
Operating modes	Invasive Mode, Non-invasive Mode Last Setting	Invasive Mode, Non-invasive Mode Last Setting	Equivalent.
Circuit type	Single/ Dual heated Limb system	Single/ Dual heated Limb system	Equivalent

Chamber type	Passover with extended water/respiratory gas interface	Passover with extended water/respiratory gas interface	Equivalent
Humidification	Invasive mode: Flow up to 60 L/min > 33 mg/L Non-invasive mode: Flow up to 100 L/min > 10 mg/L	Invasive mode: Flow up to 60 L/min > 33 mg/L Non-invasive mode: Flow up to 100 L/min > 10 mg/L	Equivalent
Monitoring of values	Temperature (patient) Temperature (chamber) Temperature (expiration tube)	Temperature (patient) Temperature (chamber) Temperature (expiration tube)	Substantially Equivalent Temperature of the expiration tube of the modified device is controlled via the temperature probe of the inspiratory tube. The closed loop temperature regulation has been validated.

Clinical Testing

Clinical testing is not required, bench testing alone is sufficient to demonstrate the product remains substantially equivalent to the predicate device HumiCare D900 (K122705).

Non-Clinical Testing

Side-by-Side bench testing was performed to verify that the HumiCare D900 met the predetermined pass/fail requirements of the HumiCare D900 System Specification when compared to the predicate devices [HumiCare D900 (K122705)].

This bench testing included testing the performance of each therapy mode which included:

- Determination of the accuracy of displayed gas temperature
- Determination of surface temperature of the tubes
- System performance according to ISO 8185
- Absence of condensate formation

As was the case with the predicate, the HumiCare D900 materials not previously cleared by FDA were subject to appropriate biocompatibility evaluations according to ISO 10993-1.
Materials used the construction of components that:

- contact the heated humidified gas pathway have been classified as permanent “external communicating devices” (with tissue/bone/dentin)

As relevant and to support the biocompatibility evaluation of each tube 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)

In addition the device was tested for volatiles, particulates and leachable substances. The device was shown to pass all requirements.

Validation of cleaning and reuse was completed to establish that the T2 plug in sensor can be reused in the home or hospital/institutional environment.

Substantial equivalence

Comparison with previously cleared HumiCare D900

The modified device has the following similarities to the previously cleared HumiCare D900:

- Same intended use
- Similar operating principle
- Similar circuit types
- Same fundamental technological characteristics
- Similar performance characteristics.
- Similar manufacturing process

Design and Verification activities were performed on the modified HumiCare D900 as a result of the risk analysis and product requirements. All tests confirmed that the product met the predetermined acceptance criteria and that the modified HumiCare D900 essential performance specifications (humidification performance, resistance of the humidifier) are substantially equivalent to the predicate device (K122705).

The modified device complies with the applicable requirements referenced in the FDA guidance documents:

- FDA Reviewer Guidance for Premarket Notification Submissions (November 1993)
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
- FDA Heated Humidifier Review Guide (February 1997)

Conclusion

The indications for use, technological characteristics, and principles of operation are similar to the predicate device. Performance data demonstrate that the modified HumiCare D900 system is substantially equivalent to the predicate device.