K103167

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510(k) Summary – Stellar 150

Date prepared	February 15, 2011
Submitter	Sandra Grünwald
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Proprietary/Trade name	Stellar 150
Common name	Continuous ventilator
Classification	21 CFR 868.5895 Class II
Product code	73 MNT
Predicate Devices	BREAS VIVO 40 SYSTEM (K090113) ResMed VPAP III ST-A/KIDSTA MASK SYSTEM (K060105) Draeger Carina Home (K060705).
Reason for submission	New device

Indications for Use

The Stellar 150 is intended to provide ventilation for non-dependent, spontaneously breathing adult and pediatric patients (30 lb / 13kg and above) with respiratory insufficiency or respiratory failure, with or without obstructive sleep apnea. The device is for non-invasive use, or invasive use with an uncuffed or deflated tracheostomy. Operation of the device includes both stationary, such as in hospital or home, or mobile, such as wheelchair usage.

Device Description

The Stellar 150 is a pressure controlled ventilator using a single limb vented circuit, product code MNT. A microprocessor controlled blower generates the required airway pressure between 3-40 cm H_2O. Comparing to previous ResMed devices, CPAP and Bi-level modes are implemented as in VPAP III ST-A / Kidsta mask system, which is indicated for patients above 40 lb (18 kg). With ongoing technological progress, the new device is further suitable to include a population above 30 lb (13 kg) for CPAP and Bi-level modes, which is comparable to Draeger Carina Home. The new device also includes a volume assured pressure support mode, indicated for patients above 66 lb (30 kg), which is substantially equivalent to Breas Vivo 40.

Performance Data

Design and Verification activities were performed on the Stellar 150 as a result of the risk analysis and product design requirements. All tests confirmed the product met the predetermined acceptance criteria. Performance testing comprises pressure performance, trigger and cycling, as well as volume assured pressure support ventilation. In addition to system verification testing, comparative testing was performed using common protocols for Stellar 150 and the predicate device. The side-by-side testing demonstrated that the Stellar 150 is Substantially Equivalent to the predicate devices

This device has been tested to appropriate ISO and IEC standards and other applicable requirements passing all test protocols. The Stellar 150 was designed and tested according to:

- IEC 60601-1:1988, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance and its Amendments A1:1991 and A2:1995
- IEC 60601-1-2:2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- ISO 10651-6:2004, Lung ventilators for medical use - Particular requirements for basic safety and essential performance. Part 6: Home care ventilatory support devices.

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

- FDA Draft Reviewer Guidance for Ventilators (July 1995)
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)

Substantial Equivalence

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

- Same intended use
- Same operating principle
- Similar technologies
- Same manufacturing process

Breas Vivo 40 is the principal predicate for the new therapy options and MNT classification. In particular this comprises volume assured pressure support ventilation for patients above 66 lb (30 kg), treatment of

respiratory failure for non-dependent spontaneously breathing patients, non-invasive and invasive applications in hospital or home environments. Further the new device is substantially equivalent to the VPAP III ST-A / Kidsta Mask System, when looking at CPAP and Bi-level pressure support ventilation including pediatric patients above 40 lb (18 kg). Finally for CPAP and Bi-level modes the extension to patients above 30 lb (13 kg) is comparable to Draeger Carina Home.

Conclusion

The indications for use, technological characteristics, and principles of operation are similar to the predicate devices. Performance data demonstrate that the new device is as safe and effective as the predicate devices. Thus the Stellar 150 is substantially equivalent to BREAS VIVO 40 SYSTEM (K090113), ResMed VPAP III ST-A/KIDSTA MASK SYSTEM (K060105) and Draeger Carina Home (K060705).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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Vice President, Clinical & Regulatory Affairs
ResMed Corporation
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Re: K103167
Trade/Device Name: Stellar 150
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MNT
Dated: February 15, 2011
Received: February 18, 2011

Dear Mr. D'Cruz:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103167

Device Name: Stellar 150

Indications for Use:

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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)

L Schultheiss

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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