APR - 5 2012

510(k) Summary – Stellar 150 K113640

Date prepared	February 6, 2012
Submitter	Sandra Grünwald Manager Quality Management & Regulatory Affairs ResMed Germany, Inc.
Official contact	David D'Cruz V.P., Clinical & Regulatory Affairs ResMed Corp. 9001 Spectrum Center Blvd., San Diego CA 92123 USA Tel: +1 858-836-5984 Fax: +1 858-836-5522
Proprietary/Trade name	Stellar 150
Common name	Continuous ventilator
Classification	21 CFR 868.5895 Class II
Product code	MNT Ventilator, continuous, minimal ventilatory support, facility use
Predicate Device	STELLAR 150 (K103167)
Reason for submission	Change of Indication for Use

Indications for Use

The device is intended to provide ventilation for non-dependent, spontaneously breathing adult and pediatric patients (30 lb / 13 kg 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 the use of the ResMed Leak Valve). 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 and is substantially equivalent to the already marketed Stellar 150 device (K103167). For both devices as they are substantial equivalent, it is essential that a microprocessor controlled blower generates the required airway pressure. CPAP and Bi-level modes are implemented. With ongoing technological progress, the device is further suitable to include a population above 30 lbs (13 kg) for CPAP and Bi-level modes. The device also includes a volume assured pressure support mode (iVAPS), indicated for patients above 66 lbs (30 kg). The Stellar 150 in combination with the new developed ResMed Leak Valve supports the invasive use therapy. The ResMed Leak Valve incorporates a leak port as well as an integrated anti-asphyxia valve.

Performance Data

Design and verification activities which were performed on the previously cleared Stellar 150 as a result of the risk analysis and product requirements remain still valid. All tests confirmed the product met the predetermined acceptance criteria.

Performance testing on the Stellar 150 device was performed and cleared in the previous submission of the Stellar 150 (K103167). Within this submission performance testing on the ResMed Leak Valve was accomplished. The ResMed Leak Valve performance tests comprise functionality tests according to:

- ISO 5356-1 Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets
- ASTM F 1246-91 Specification for Electrically Powered Home Care Ventilators, Part 1 – Positive-Pressure Ventilators and Ventilator Circuits

In addition to the performance testing of the new ResMed Leak Valve, system verification testing was performed as well as bench testing. The side-by-side testing demonstrated that there is no significant difference in delivering invasive therapy using the new ResMed Leak Valve (leak port with integrated anti-asphyxia valve) and therefore the Stellar 150 is Substantially Equivalent to the predicate device.

Substantial Equivalence

The Stellar 150 is substantial equivalent to the previously cleared predicate device Stellar 150 (K103167).

- Similar indication for use
- Same operating principle
- Same technologies
- Same manufacturing process

The extension of the indication for use can be realized by combining the Stellar 150 with the new developed ResMed Leak Valve. Especially the ResMed Leak Valve with its integrated anti-asphyxia valve (AAV) ensures that safety and effectiveness of the invasive use therapy is not affected adversely. Performance and side-by-side testing demonstrated that there is no significant difference in delivering invasive therapy using the new ResMed Leak Valve (leak port with integrated anti-asphyxia valve).

As the operating principle, the technology and the manufacturing process of the Stellar 150 device are identical to the Stellar 150 (K103167) design and verification activities which were performed on the previously cleared Stellar 150 as a result of the risk analysis and product requirements remain still valid. All tests confirmed the product met the predetermined acceptance criteria.

Thus the Stellar 150 with the modified indication for use is substantial equivalent to the previous cleared Stellar 150 device (K103167).

Conclusion

The indication for use is similar to the predicated device, whereas the technological characteristics, principles of operation and manufacturing process remain unchanged. Performance data of the new ResMed Leak Valve and side-by-side testing demonstrate that the new combination consisting of the ResMed Leak Valve and the Stellar 150 is as safe and effective as the Stellar 150 device (K103167). The Stellar 150 with modified indication for use is therefore substantially equivalent to the Stellar 150 device (K103167).

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

ResMed Germany, Inc.
C/O Mr. David D'Cruz
Vice President, Clinical & Regulatory Affairs
ResMed Corporation
9001 Spectrum Center Blvd.
San Diego, California 92123

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Re: K113640
Trade/Device Name: Stellar 150
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MNT
Dated: March 14, 2012
Received: March 19, 2012

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,

for

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): **K113640**

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)

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

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