510(k) Summary – TxControl

K072615
page 1 of 2

Date Prepared	10th September 2007
Official Contact	Dr Lionel King V.P., Quality Assurance & Regulatory Affairs ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista, NSW 2153 Australia Tel: +61 (2) 8884 1000 Fax: +61 (2) 8884 2021
Classification Reference	21 CFR 868.5905
Product Code	73 BZD
Common/Usual Name	Noncontinuous ventilator (IPPB).
Proprietary Name	TxControl
Predicate Device(s)	ResControl II (K040944)
Reason for submission	New Device

JAN - 4 2008

Intended Use

The TxControl™ is a software application intended to be used by clinicians with ResMed flow generators that incorporate ResMed's proprietary communication protocol. TxControl provides real-time data display directly from the flow generator or via ResControl II™.

TxControl can also provide flow generator setting changes, remotely within a clinical environment.

Device Description

ResMed's TxControl™ is a PC-based software application that enables clinicians to monitor real-time patient and flow generator information and adjust flow generator settings as required from the control room within the sleep lab clinical setting.

TxControl is also designed to transfer data from a CPAP or bilevel flow generator to a polysomnograph (PSG) display system such as Somnologica (K971813) when used in conjunction with a ResControl II device. The performance and functional characteristics of the TxControl includes similar user friendly features of the predicate device, ResControl II (K040944).

Substantial Equivalence

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

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

Design and Verification activities were performed on the TxControl as a result of the risk analysis and product requirements. All tests confirmed the product met the predetermined acceptance criteria. ResMed has determined that the new device is Substantially Equivalent to the predicate device. The transfer of ResControl II hardware features to the TxControl software application has not altered the safety and effectiveness when used primarily in the management of patients with Obstructive Sleep Apnea (OSA). The new device complies with the applicable standards and 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)
- FDA Off-the-Shelf Software Use in Medical Devices (September 9,1999)
- FDA Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software (January 14, 2005)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 4 2008

ResMed, Limited
C/O Mr. David D'Cruz
Vice President Clinical & Regulatory Affairs
ResMed Corporation
14040 Danielson Street
Poway, California 92064-6857

Re: K072615
Trade/Device Name: TxControl™
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: December 18, 2007
Received: December 26, 2007

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.

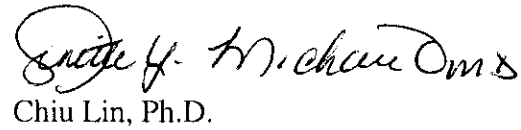
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: TxControl™

Indication for Use

The TxControl™ is a software application intended to be used by clinicians with ResMed flow generators that incorporate ResMed's proprietary communication protocol. TxControl provides real-time data display directly from the flow generator or via ResControl II™.

TxControl can also provide flow generator setting changes, remotely within a clinical environment.

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) acting BS
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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