K060105

APR 7 2006

510(k) Summary – AutoSet CS2
[As required by §807.92 (c)]

Submitter Name:	ResMed Corp.
Submitter Address:	14040 Danielson Street, Poway CA 92064-6857, USA
Contact Person:	David D'Cruz, VP Regulatory & Clinical Affairs US
Phone Number:	(858) 746 2238
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Date Prepared:	December 22, 2005
Device Trade Name	VPAP III ST-A/KIDSTA MASK SYSTEM
Device Common Name/ Classification Reference	Bi level Positive Pressure Ventilator/ Continuous Ventilator, Passive Exhalation Port, Non-Critical Care. 21 CFR868.5895
Product Code	73MNS
Predicate Devices:	VPAP III ST-A (K033276) Mirage VISTA Mask (K031047)
Reason for submission	Include pediatric (7 years and older, > 40 lbs) indication.
Intended Use:	The VPAP III ST-A/Kidsta Mask system is intended to provide non-invasive ventilation for pediatric patients aged 7 years or older (>40lbs) with respiratory insufficiency or obstructive sleep apnea (OSA). The device is intended for use in the hospital or home.

Substantial Equivalence

The VPAP III ST-A / Kidsta system has the following similarities to the previously cleared predicate device.

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

The VPAP III ST-A was cleared in K033276. The Mirage Kidsta is a simple modification of its predicate device (Mirage VISTA) cleared in K031047. ResMed has performed a risk analysis to identify the additional considerations of using the VPAP III ST-A / Kidsta system on pediatric patients (>7 years and >40lbs). Additional testing based on the VPAP III ST-A / Kidsta risk analysis was performed to ensure the safety and efficacy of the VPAP III ST-A / Kidsta system when used on the pediatric patient (>7 years and > 40lbs). Testing confirms that the unmodified VPAP III ST-A when used with the Mirage Kidsta mask can be safely and effectively used to treat the pediatric patient (>7 years and >40lbs).

ResMed has followed the FDA's Guidance for Industry and FDA Staff document "Pre-market Assessment of Pediatric Medical devices" and applied the principle of FDA's Least Burdensome Approach to demonstrate the Substantial Equivalence of the VPAP III ST-A / Kidsta system to its predicate devices (VPAP III ST-A and Mirage Vista). We conclude that the existing and cleared adult indications for use can be safely and effectively applied to pediatric patients (>7 yrs and >40lbs).

ResMed has modified the Mirage Vista and developed the Mirage Kidsta. The development realized slight changes to the headgear and the adoption of a smaller cushion size. Human factors considerations and usability trials demonstrate that the Mirage Kidsta can be safely and effectively applied to the pediatric patient (>7yrs and > 40lbs).

Intended Use

The Indications for Use (IFU) proposed for the VPAP III ST-A / Kidsta System is

> The VPAP III ST-A / Kidsta System is intended to provide non-invasive ventilation for pediatric patients 7 years or older (>40 lb) with respiratory insufficiency or obstructive sleep apnea (OSA), in the hospital or home.

Device Description

The VPAP III ST-A is a flow-cycled, pressure-limited ventilator. A blower assembly generates airway pressure. A flow sensor and a pressure sensor in the patient airway feed data on measured flow and pressure into a microprocessor controller, which in turn regulates the blower assembly. A user interface displays clinical data and enables the operator to set and adjust certain clinical parameters.

The VPAP III ST-A has a CPAP mode in which a fixed pressure is delivered, and three bi-level operating modes which determine how the changes between IPAP (Inspiratory Positive Airway Pressure) and EPAP (Expiratory Positive Airway Pressure) pressures are made: Spontaneous, Spontaneous/Timed and Timed.

The VPAP III ST-A is fitted with alarms to alert the user to changes that will affect the treatment. Some of the alarms are pre-set (fixed), others are user adjustable.

The Mirage Kidsta cushion size and headgear has been modified from the Mirage Vista to meet the requirements of the pediatric population. The Kidsta mask provides therapy through the nose only. The Mirage Kidsta comprises the following

- Mask frame, with two ports for connection to pressure sensor tubing. A 2-ports cap can cover one or both ports.
- Mask elbow, connected to short air tubing, with a swivel, which allows a 360° rotation of the air tube. The elbow has an integral exhaust vent for flushing CO_2 in order to prevent re-breathing.
- Mask cushion, for patient comfort and adequate sealing between mask and face.
- Headgear, a three-layered fabric attached to the mask frame by means of clips to enable fast release of the mask. The mask can be tilted at five different angles by pressing on the tabs and changing the slot position on the headgear clips. The headgear side straps, connected to the headgear clips, are reinforced for increased stability.

The Mirage Kidsta mask comes in one frame size and cushion.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 2006

Mr. David D'Cruz
ResMed Limited
14040 Danielson Street
Poway, California 92064-6857

Re: K060105
Trade/Device Name: VPAP III ST-A/Kidsta Mask System
Regulation Number: 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: II
Product Code: MNS
Dated: December 22, 2005
Received: January 13, 2006

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 (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 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 continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

Indications for Use

510(k) Number (if known): K060105

Device Name:_____VPAP III ST-A/KIDSTA MASK SYSTEM

Indications For Use:

The VPAP III ST-A/Kidsta Mask system is intended to provide non-invasive ventilation for pediatric patients aged 7 years or older (>40lbs) with respiratory insufficiency or obstructive sleep apnea (OSA). The device is intended for use in the hospital or home.

Prescription Use __X_____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (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)

K060105

...ology, General Hosp...
...Dental Devices