MAY 24 1999

K983862

Section 2 - Summary and Certification

COMPANY INFORMATION

Respiratory Support Products, Inc.
division of Smith Industries Medical Systems, Inc.
2552 McGaw Avenue
Irvine, CA 92704
(949) 756-2250
contact: Gordon Shigezawa
Director of Research and Development

PREPARATION DATE OF SUMMARY

October 27, 1998

TRADE NAME

CLOUD 1 Humidification System

COMMON NAME

Humidifier and Breathing Circuit Heater Controller

PRODUCT CLASSIFICATION

Class II, per 868.5450 Product Code: 73BTT

PREDICATE DEVICES

Intertech/Inspiron Vapor Phase Model 009500 "Advanced" Humidifier
Intertech/Inspiron Vapor Phase Model 009300 "Plus" Humidifier
Intertech/Inspiron Vapor Phase Model 009900 Heated Wire Controller
Fisher Paykell Model MR630 Humidifier
Marquest Model SCT 3000 Humidifier
RCI Model 380-88

DESCRIPTION

The Cloud 1 Humidification System is used to deliver heat energy and humidity to a patient's proximal airway in those instances where the patient's natural mechanisms of heat retention and humidification are bypassed by intubation. The system consists of a humidifier that creates water vapor at an elevated temperature and mixes the vapor with air from a ventilator and a specialized breathing circuit including a heating element in either the inspiratory limb or both the inspiratory and expiratory limbs. The water content of the air exiting the humidifier is close to saturation at a desired proximal airway temperature. The breathing circuit heater adds heat energy to the air/vapor mixture as it travels from from the humidifier to the patient's proximal airway and, optionally, from the patient's airway to the ventilator expiratory valve. By reducing the temperature loss in the breathing tube, condensation of water vapor (rainout) is minimized resulting in safer operation and reduced clinical maintenance of the system.

INDICATIONS FOR USE

Humidifiers and heated circuit controllers are intended to be used on intubated patients who require supplemental heat and humidity to prevent hypothermia and drying of the tracheobronchial tract.

CONTRAINDICATIONS, PRECAUTIONS, and WARNINGS

Contraindications, cautions, and warnings are detailed in the product labeling.

TECHNICAL CHARACTERISTICS

The proposed system is a dual microprocessor controlled system with multiple redundant alarm and system check features. The humidification system uses the Vapor Phase transfer chamber concept that provides a physical separation between the water compartment and the vapor compartment by means of a hydrophobic membrane. This separation assures that a large bolus of liquid water cannot enter the patient's breathing circuit due to tipping of the humidifier. The construction of the chamber's membrane and the relatively high operating temperature allows the use of low cost distilled water instead of sterile water as is more commonly used in humidifiers.

The proposed system uses a breathing circuit heater assembly that supports heater elements in the center of the inspiratory air flow with a polymer web. The heater elements are placed such that they cannot touch the wall of the breathing circuit tube, reducing the chance for the heater melting through the tube wall and creating a circuit leak. Locating the heater elements at the center of the tube optimizes heat transfer to the airflow, reducing the operating temperature of the heater elements, further reducing chance of melting the breathing tube. The heater element employs straight wires instead of the more conventional spiral wound wires to reduce the risk of hot spot formation due to uneven spiral pitch winding and subsequent melting of the heater assembly and/or breathing circuit tube.

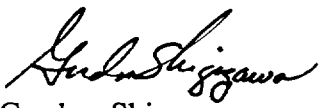
The support web serves as a structure to connect and support temperature sensors (thermistors), two extending to the proximal end of the heater assembly and another at the distal end of the heater assembly. The proximally located sensors measure proximal airway temperature (PAT) while the distally located sensor measures the chamber output temperature (COT). Additional conductive wires are extruded in the assembly support ribbon to electrically connect the PAT sensors to a cable assembly molded in the distal end. The cable assembly plugs into the humidifie/heated wire controller.

NON-CLINICAL DATA

The performance of the system was tested and compared to the performance of the Fisher Paykell and Marquest systems. In most flow/setpoint conditions, the RSP system delivered humidity closer to saturation than either of the competitors' systems. The RSP system provides greater safety by using a dual PAT sensor and tracking error detection, redundant latching high and low PAT alarms, redundant power switches for both the heater platen and the circuit heater, redundant latching platen overtemperature sensing and alarming, and tertiary safety with a platen thermal fuse in addition to the safety benefits of the transfer chamber and improved circuit heater constructions.

CONCLUSION

The testing performed and comparison to predicate devices demonstrate that the proposed device is safe and effective and is substantially equivalent to the predicate devices.



Gordon Shigezawa
Director of Research and Development

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 24 1999

Mr. Gordon Shigezawa
Director of Research and Development
SIMS/Respiratory Support Products, Inc.
2552 McGaw Avenue
Irvine, CA 92614

Re: K983862
Trade Name: Cloud 1 Humidification System
Regulatory Class: II (two)
Product Code: BTT
Dated: March 8, 1999
Received: March 12, 1999

Dear Mr. Shigezawa:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification

submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K983862

Device Name: Cloud 1 Humidification System

Indications For Use:

The Cloud 1 Humidification System is intended to warm and humidify gas before it is delivered to the airway of a patient requiring mechanical ventilation or ventilatory assistance.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use___

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K983862