smiths medical
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SECTION 5, 510(k) Summary

Company Information:

Smiths Medical ASD, Inc.
160 Weymouth Street
Rockland, MA 02370
(781) 878-8011, ext 7904
Contact: Christine A. Lloyd
Regulatory Affairs Specialist

Summary Prepared: November 21, 2007

NOV 2 1 2007

Product Name:

Trade Name: **Thera-Heat™ Heated Humidifier and Heated WireVentilator Breathing Circuits**

Common Name: Respiratory Gas Humidifier and Heated Wire Ventilator Breathing Circuits.

Classification Name: Humidifier, Respiratory Gas Heater (21 CFR 868.5450, Product Code BTT) & Breathing System (21 CFR 868.5270, Product Code BZE)

Predicate Device(s):

K913368, (Fisher & Paykel Electronics Ltd.) Models MR700/MR720/MR730 Dual Servo Respiratory Humidifier ACC

K000697, [Cardinal Health (formerly Allegiance Healthcare Corp)], Airlife® Heated Ventilator and Anesthesia Breathing Circuits

Device Description:

Thera-Heat™ Heated Humidifier

The Thera-Heat™ Heated Humidifier system is a respiratory gas humidifier according to 21 CFR §868.5450. A respiratory gas humidifier is identified by the Food and Drug Administration (FDA) as a therapeutic device that is intended to add moisture and if applicable, heat to breathing gases prior to administration to a patient. Indirect heating is used by the Thera-Heat™ to provide an evaporated water content to dry breathing gases.

Respiratory gas humidifiers are used by clinicians to raise the water content of gases delivered to patients. Gases available for medical use do not always have sufficient moisture and may damage or irritate the respiratory tract or desiccate tracheobronchial secretions of patients whose airways have been bypassed. The Thera-Heat™ Heated Humidifier system warms and adds

water vapor to the inspired gas by heating water within the humidification chamber as the dry gas passes over the warmed water.

The humidification chamber is an auto-fill style that contains an integral float valve at the water filling port. The float valve regulates the water level inside the chamber to maintain a constant water level. The water supply (liquid reservoir) is a pre-filled sterile water reservoir that connects to a filling port on the humidification chamber. When the liquid reservoir is empty, the caregiver will exchange it with a new one. After the gas is warmed and humidified it is channeled to the breathing tube for delivery to the patient.

The system can be operated using a conventional breathing tube (non-heated) in both limbs, or a heated breathing tube in the inspiratory limb only, or a heated breathing tube in both limbs. The heating of the humidification chamber and the power supplied to the heated breathing tube is provided by the controller unit. The purpose of the heated breathing tube is to regulate the gas temperature from the humidification chamber to the patient, reducing condensation and pooling of water, and the means of controlling the relative humidity by maintaining a temperature gradient between the humidification chamber and the delivered airway temperature. The caregiver sets the controller unit to the desired patient airway temperature, and then sets a humidity index value, which is limited in range by the controller based on the desired patient airway temperature. The control unit will maintain the selected temperature for the patient airway and the humidification chamber output temperature based on the humidity index value.

Accessories for the Thera-Heat™ Heated Humidifier include the humidification (water) chambers, temperature probes, interface cables and brackets.

Heated Wire Ventilator Breathing Circuits

A heated Wire Ventilator Breathing Circuit is a disposable device compromised of 22mm corrugated plastic tubing, 22 mm plastic tube connectors, and an electrical heater-wire harness subassembly. After the gas is warmed and humidified in the humidification chamber it is delivered through the inspiratory limb of the breathing circuit to the patient. Heating of the breathing tube is provided and controlled by the heated humidifier. The heated wire breathing circuits may be comprised of a dual limb or single limb circuit. The purpose of the heated wire ventilator breathing circuits is to maintain or raise the gas temperature to or above the dew point reducing or eliminating water condensation and/or pooling of water in the breathing circuit. Other accessories such as exhalation valves, water traps, etc. can be added in to the overall assembly creating different product variations.

Indications for Use:

Thera-Heat™ Heated Humidifier

The Smiths Medical Thera-Heat™ Heated Humidifier device is intended to warm and add humidity to the breathing gases that are administered to the patient. The humidifier is indicated for patients requiring mechanical ventilation, positive pressure breathing assistance of general medical gases

The Smiths Medical Thera-Heat™ Heated Humidifier device is intended for use in hospitals and alternate sites by medically trained healthcare providers.

Inspiratory heated limb

An adult ventilator Heated Breathing Circuit is intended to warm breathing gases before they enter a patient's airway when used with the Thera-Heat™ Heated Humidifier. The circuit acts as a conduit to warm the gases between the humidification chamber and the patient during mechanical ventilation or positive pressure breathing assistance for use with invasive and non-invasive breathing systems.

Inspiratory and Expiratory heated limbs)

An adult ventilator Heated Breathing Circuit is intended to warm breathing gases before they enter a patient's airway and to warm the breathing gases on return from the patient to the ventilator when used with the Thera-Heat™ Heated Humidifier. The circuit acts as a conduit to warm the gases between the humidification chamber and the patient during mechanical ventilation or positive pressure breathing assistance for use with invasive and non-invasive breathing systems.

Technological Characteristics:

The technological characteristics of the Thera-Heat™ Heated Humidifier are equivalent to the predicate device; Fisher & Paykel Electronics Ltd, Models MR700/MR720/MR730 Dual Servo Respiratory Humidifier ACC per K913368. The Thera-Heat™ is equivalent to the Fisher & Paykel humidifiers in terms of:

Type:	Active Heated Humidifier
Humidification method:	Passover humidification
Configuration:	Humidification chamber, heated wire or non-heated breathing circuits, and a dual sensor temperature probe to monitor the humidification chamber output temperature and temperature of the airway proximal to the patient connection port.
Control:	Comparable range of temperature and humidity adjustments
Control method:	Software controlled using a microcontroller

Non-Clinical Data:

Non-clinical testing of the Thera-Heat™ Heated Humidifier has been carried out covering mechanical, electrical, and software for functional performance and temperature accuracy under environmental conditions and tests standards for electromagnetic immunity.

The Thera-Heat™ Heated Humidifier meets the safety requirements of IEC60601-1, UL60601-1, and CAN/CSA 22.2 No.60601.1. It meets the electromagnetic compliance requirements of IEC60601-1-2 and the software compliance of IEC60601-1-4 to the acceptance of Underwriters Laboratories. The Thera-Heat™ Heated Humidifier complies with the performance and safety

standards ASTM F1690 (USA) and ISO 8185 for active humidification with the following two exceptions. Clause 51.6.2 the Thera-Heat™ generates a high priority alarm in the event that the airway temperature is at or above 41°C. Clause 51.8 part C, the Thera-Heat™ cannot reduce the airway temperature sufficiently when the air flow is increased (instantaneously) from the minimum rated flow to the maximum rated flow and the airway temperature is being regulated through a non-heated (non-wire) breathing circuit. This event does cause the Thera-Heat™ to generate an alarm and stops the heating of the humidification chamber however it cannot prevent the airway temperature from exceeding 43°C for 30 seconds (ISO8185 clause 51.8); this is because energy in the water was created for the lower flow. We have placed a warning label on the outside of the device and in the operator's manual to provide some risk control over this situation for the user.

Clinical Data:
Not required

Conclusion:
The standards compliance and product performance testing conducted demonstrates that the proposed device is safe and effective and is substantially equivalent to the predicate device.

Very truly yours,

SMITHS MEDICAL ASD, INC.

Christine A. Lloyd
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 1 2007

Ms. Christine Lloyd
Regulatory Affairs Specialist
Smiths Medical ASD, Incorporated
160 Weymouth Street
Rockland, Massachusetts 02370

Re: K071958
Trade/Device Name: Thera-Heat™ Heated Humidifier and Heated Wire Ventilator Breathing Circuits
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT, BZE
Dated: November 16, 2007
Received: November 19, 2007

Dear Ms. Lloyd:

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.

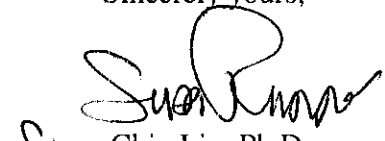
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0120. 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

SECTION 4, Indications for Use Statement

Indications for Use

510(k) Number (if known): K071958

Device Name: **Thera-Heat™ Heated Humidifier**

Indications for Use:

The Smiths Medical Thera-Heat™ Heated Humidifier device is intended to warm and add humidity to the breathing gases that are administered to the patient. The humidifier is indicated for patients requiring mechanical ventilation, positive pressure breathing assistance of general medical gases

The Smiths Medical Thera-Heat™ Heated Humidifier device is intended for use in hospitals and alternate sites by medically trained healthcare providers.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

(acting B.C.)

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

510(k) Number: K071958

SECTION 4, Indications for Use Statement

Indications for Use

510(k) Number (if known): K071958

Device Name: **Heated Wire Ventilator Breathing Circuits**

Indications for Use:

Inspiratory heated limb

An adult ventilator Heated Breathing Circuit is intended to warm breathing gases before they enter a patient's airway when used with the Thera-Heat™ Heated Humidifier. The circuit acts as a conduit to warm the gases between the humidification chamber and the patient during mechanical ventilation or positive pressure breathing assistance for use with invasive and non-invasive breathing systems.

Inspiratory and Expiratory heated limb

An adult ventilator Heated Breathing Circuit is intended to warm breathing gases before they enter a patient's airway and to warm the breathing gases on return from the patient to the ventilator when used with the Thera-Heat™ Heated Humidifier. The circuit acts as a conduit to warm the gases between the humidification chamber and the patient during mechanical ventilation or positive pressure breathing assistance for use with invasive and non-invasive breathing systems.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

(Acting B.C.)

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

510(k) Number: K071958