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OCT 20 2010

510(k) Summary

Company Information:

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

Summary Prepared: October 13, 2010

Product Name:

Trade Name: Thera-Heat™ Heated Humidifier and Neonate Heated Wire Ventilator 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):

- K071958, Thera-Heat™ Heated Humidifier, model RC70000, and Adult Heated Wire Ventilator Breathing Circuits, models, RC70050 and RC70052
- K073706, (Fisher & Paykel Healthcare) models RT130 and RT131 High Performance Circuits
- K913368, (Fisher & Paykel Electronics Ltd.) models MR700/MR720/MR730 Dual Servo Respiratory Humidifier ACC
- K000697, Allegiance Healthcare Corporation a subsidiary of Cardinal Health, Inc, Airlife® Heated Ventilator and Anesthesia Breathing Circuits, model 7582-452.

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 warm and add humidity

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. 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 Adult versions only) in both limbs, or a heated breathing tube in the inspiratory limb only (Adult and Neonate versions), or a heated breathing tube in both limbs (Adult and Neonate versions). The purpose of the heated breathing tube is to regulate the gas temperature from the humidification chamber to the patient thereby reducing condensation and pooling of water and controlling the relative humidity. Thera-Heat™ Heated Humidifier sets and controls the heating of the humidification chamber and the breathing tube. The caregiver first sets the unit to the desired patient temperature and then sets a humidity value that is scaled by the controller based on the desired patient temperature. Thera-Heat™ Heated Humidifier will maintain the selected temperature at the patient and the humidification chamber output temperature based on the humidity value.

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

Neonate Heated Wire Ventilator Breathing Circuits

A Heated Wire Ventilator Breathing Circuit is a disposable device compromised of 10 mm corrugated plastic tubing, 22 mm plastic tube connectors, and an electrical heater-wire harness subassembly. After the gas is warmed and humidified in the water 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 Thera-Heat™ Heated Humidifier. The breathing circuits may be comprised of a dual limb (Adult and Neonate versions) or single limb circuit (Adult versions only). 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 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

A Neonate 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

A Neonate 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 Thera-Heat™ Heated Humidifier and Neonate Heated Wire Ventilator Breathing Circuit is an active heated humidifier which employs passover humidification to the breathing gases that are administered to the patient. The Thera-Heat™ Heated Humidifier system consists of a humidification chamber, heated wire (Adult and Neonate versions) or non-heated breathing circuits (Adult versions only), and a dual sensor temperature probe to monitor the humidification chamber output temperature and temperature of the airway proximal to the patient connection port. Temperature and humidity is controlled over the comparable range. Software is controlled using a microcontroller.

The characteristics of the Thera-Heat™ Heated Humidifier and Neonate Heated Wire Ventilator Breathing Circuit are substantially equivalent to the above specified predicate devices based on intended use, indications for use, operational characteristics, fundamental technological characteristics, and performance characteristics. A detailed side-by-side comparison of the Thera-Heat™ Heated Humidifier and Neonate Heated Wire Ventilator Breathing Circuit is included in this premarket notification.

Non-Clinical Data:

Non-clinical testing of the Thera-Heat™ Heated Humidifier and Neonate Heated Wire Ventilator Breathing Circuits have been conducted including mechanical, electrical, and software for functional performance, temperature accuracy under environmental conditions, and test standards for electromagnetic immunity.

The Thera-Heat™ Heated Humidifier meets the safety requirements of UL60601-1/IEC 60601-1, and CAN/CSA C22.2 No. 60601.1. The device also meets the electromagnetic compliance requirements of IEC60601-1-2, and software compliance requirement of IEC60601-1-4 to the acceptance of Underwriters Laboratories and complies with the performance and safety standards including ASTM F1690 (USA) and ISO8185 for active humidification with the following exception. 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. This event does cause the Thera-Heat™ to generate an alarm and stops the heating of the humidification chamber and the heated circuit. We have described this behavior in the operator's manual Alarm section.

Clinical Data:

Not required

Conclusion:

Based on the similarities in indication for use, design features, and functional features the Thera-Heat™ Heated Humidifier and Neonate Heated Wire Ventilator Breathing Circuits have been shown to be substantially equivalent to the current legally marketed predicate devices.

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

Ms. Christine Lloyd, RAC
Regulatory Affairs Specialist
Smiths Medical North Carolina
160 Weymouth Street
Rockland, MA 02370

OCT 20 2010

Re: K092256
Trade/Device Name: Thera-Heat™ Heated Humidifier and Neonate Heated Wire Ventilator Breathing Circuits
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT, BZE
Dated: October 14, 2010
Received: October 18, 2010

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. 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,

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

K092256

OCT 2 0 2010

510(k) Number (if known): K092256

Device Name: Thera-Heat™ Heated Humidifier

Indications for Use:

The Smiths Medical Thera-Heat™ Heated Humidifier 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.

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

510(k) Number: K092256

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)

K092256

OCT 20 2010

Indications for Use

510(k) Number (if known): K092256

Device Name: Neonate Heated Wire Ventilator Breathing Circuits

Indications for Use:

Inspiratory heated limb

A Neonate 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

A Neonate Heated Wire Ventilator 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.

L Schultz

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

510(k) Number: K092256

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)