K100104

510(k) Summary

APR 14 2010

Submitter Name:	Plastiflex Group NV Division: Plastiflex Healthcare rik.langerock@plastiflex.com
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Contact Person:	Mr. Rik Langerock, Marketing Manager
Date Prepared:	January 2010
Device Trade Name:	Hybernite Rainout Control System
Common Name	Heated Breathing Tube
Classification Name, Number & Product Code:	Breathing system heater, 868.5270, BZE
Predicate Devices:	**K071958** THERA-HEAT HEATED HUMIDIFIER AND ADULT DUAL AND SINGLE LIMB HEATED WIRE VENTILATOR BREATHING CIRCUITS **K041900** F&P HC 600 CPAP HUMIDIFIER including the Thermosmart® heated tubing
Device Description and Statement of Intended Use	Description: The Device family "Hybernite Rainout Control System" is the name for a heated tubing system consisting of a heated tube and power supply. The heated tubing comprises a single limb single lumen smooth bore tube containing 2 heater wires that are embedded in the tubing construction. The heating wires are physically separated from the lumen of the tubing. When a voltage is applied, a current flows through the heating wires. Due to the wire resistance, heat is dissipated through the wall of the tube construction into the air flow in the lumen of the tubing. As a result, the air passing through the tubing is warmed to or above the dew point (of the air exiting the humidifier) reducing or eliminating water condensation and/or pooling of water in the breathing circuit and the problems associated with such condensation. The Hybernite heated breathing tube has standard cuffs on both the machine-end cuff and mask-end cuff. As

such, the Hybernite heated breathing tube can be connected to heated humidifiers and flow generators that have standard male outlet connectors.

Intended Use: The Hybernite Rainout Control System is a heated breathing circuit intended to provide warmed and/or humidified breathing gases before entering the patient airway. The Hybernite device is intended for incorporation into CPAP (continuous positive airway pressure) devices and is intended to act as a conduit for the breathing gasses delivered from the humidifier to the patient. After the gas is warmed and humidified in the humidifier, it is delivered through the heated tubing to the patient. The purpose of the Hybernite Rainout Control System is to maintain or raise the gas temperature to or above the dew point (of the air exiting the humidifier) reducing or eliminating water condensation and/or pooling of water in the breathing circuit, and problems associated with such. The Hybernite is indicated for use in the home or sleep-lab setting by a single adult patient. It can also be used in conjunction with supplemental Oxygen. Hybernite is indicated for non-invasive ventilation.

Summary of Technological Characteristics

The heated tubing consists of a single limb single lumen smooth interior tube containing 2 heater wires that are embedded in the tubing construction of which the tube is formed having a supporting structure; the tube is spiral and the wire has a single loop form. The heating wires are physically separated from the lumen of the tubing. As such, there is no direct contact between the heating wires and the air flow, which contributes significantly to the safety of the device. The device is equipped with an independent power supply i.e. requiring an additional power socket for the lead plug (AC power cord). The power supply is connected to the tube via an integrated connector in the tubing. The lead can be disconnected from the tubing to allow efficient cleaning of the tubing.The device is made of polymeric materials which have been selected on their suitability for medical purpose.

A table comparing the Hybernite Rainout Control System to the predicate devices is attached.

Non-clinical data

Testing carried out on the Hybernite indicates that it meets design and performance functional requirements. It meets the requirements of international electrical standards for safety and performance, IEC 60601-1, and performance and safety requirements from particular standards for heated breathing tubes: ISO 5367, Breathing tubes intended for use with anesthetic apparatus and ventilators, and the universal connectors are in compliance with ISO 5356-1, Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets.

Clinical data

Clinical data was not required for this submission

Conclusion

The information discussed above demonstrates that the Hybernite Rainout Control System is as safe, as effective, and performs as well as or better than the predicate devices.

Declarations

This summary includes only information that is also covered in the body of the 510(k).

- This summary does not contain any puffery or unsubstantiated labeling claims.

- This summary does not contain any raw data, i.e., contains only summary data.
- This summary does not contain any trade secret or confidential commercial information.
- This summary does not contain any patient identification information.

Summary Comparison with Predicate Devices

Feature	Hybernite Rainout Control System	THERA-HEAT HEATED HUMIDIFIER AND ADULT DUAL AND SINGLE LIMB HEATED WIRE VENTILATOR BREATHING CIRCUITS	F&P HC 600 CPAP HUMIDIFIER including the Thermosmart® heated tubing
510(k) Number	New	K071958	K041900
Manufacturer	Plastiflex Healthcare	Smiths Medical	Fisher & Pykel Healthcare
Classification # & Product Code	868.5270, BZE	868.5270, BZE (for heated tubing)	BZD Tubing not separately coded!
Intended Use	The Hybernite Rainout Control System is a heated breathing circuit intended to provide warmed and/or humidified breathing gases before entering the patient airway. The Hybernite device is intended for incorporation into CPAP (continuous positive airway pressure) devices and is intended to act as a conduit for the breathing gasses delivered from the humidifier to the patient. After the gas is warmed and humidified in the humidifier, it is delivered through the heated tubing to the patient. The purpose of the Hybernite is to maintain or raise the gas temperature to or above the dew point (of the air exiting the humidifier) reducing or eliminating water condensation and/or pooling of water in the breathing circuit, and problems associated with such. The Hybernite is intended to be used in the home or sleep lab by a single patient. It can also be used in conjunction with supplemental Oxygen and is indicated for use in non-invasive ventilation.	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 TM 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	"Includes a heated breathing tube connected to the device, reducing condensation or "rain-out" to form in the tube." The device (humidifier) is used to assist with patient breathing while sleeping for the purpose of treating Obstructive Sleep Apnea (OSA). This is done by the delivery of Continuous Positive Airway Pressure (CPAP) in order to prevent airway obstruction. The addition of heated respiratory humidification to the device relieves the drying and irritating effects on the patient airways which usually arises from use of a CPAP system. The device is for use on adult patients at home or in the sleep lab.
Mode of Action	When a voltage is applied, a current flows through the heating wires. Due to the wire resistance, heat is dissipated through the wall of the tube construction into the air flow in the lumen of the tubing. As a result, the air	After the gas is warmed and humidified in the humidification chamber it is delivered through the breathing circuit to the patient. Heating of the breathing tube is provided and controlled by the heated humidifier. The heated wire breathing	After the gas is warmed and humidified in the humidification chamber it is delivered through the breathing circuit to the patient. Heating of the breathing tube is provided and controlled by the heated

	passing through the tubing is warmed to or above the dew point (of the air exiting the humidifier) reducing or eliminating water condensation and/or pooling of water in the breathing circuit.	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.	humidifier. The purpose of the heated wire 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.
Reusable	Yes Cleaning Regime: Mild soap and water after use	Disposable	Yes Cleaning Regime: Mild soap and water after use
Compatible with multiple humidifiers (standard connectors)	Yes, Universal	For use with the Thera-Heat TM Heated Humidifier	For use with the HC 600 CPAP Humidifier.
Breathing gases specified	Air & Supplemental Oxygen	General Breathing Gases	Air & Supplemental Oxygen
Standard breathing circuit polymeric materials	Yes	Yes	Yes
Power Source	Separate	Incorporated	Incorporated
Heating Wire	Encased	Exposed in the lumen of the tubing	Encased
Active Controller	No	Yes	Yes
Standards of Conformity/ Performance	ISO 5367 Breathing tubes intended for use with anaesthetic apparatus and ventilators ISO 5356-1, Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets. ISO 8185 Respiratory humidification systems- requirements (as applicable to breathing tubes). IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Individual standards for the heated breathing tube not specified. IEC 60601-1, IEC60601-2 EMC Standards IEC 60601-1-4 Software compliance. ISO 8185 Respiratory humidification systems- requirements ASTM 1609 Humidifiers for Medical Use	Individual standards for the heated breathing tube not specified. IEC 60601-1, IEC60601-2 EMC Standards ISO 8185 Respiratory humidification systems- requirements ASTM 1609 Humidifiers for Medical Use

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

Plastiflex Group NV
C/O Mr. William Greenrose
President
Qserve America, Incorporated
220 River Road
Claremont, New Hampshire 03743

APR 14 2010

Re: K100104
Trade/Device Name: Hybernite Rainout Control System
Regulation Number: 21 CFR 868.5270
Regulation Name: Breathing System Heater
Regulatory Class: II
Product Code: BZE
Dated: January 11, 2010
Received: January 14, 2010

Dear: Mr. Greenrose:

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Division 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): Unknown
Device Name: Hybernite Rainout Control System

Indications For Use:

The Hybernite Rainout Control System is a heated breathing circuit intended to provide warmed and/or humidified breathing gases before entering the patient airway. The Hybernite device is intended for incorporation into CPAP (continuous positive airway pressure) devices and is intended to act as a conduit for the breathing gasses delivered from the humidifier to the patient. After the gas is warmed and humidified in the humidifier, it is delivered through the heated tubing to the patient. The purpose of the Hybenite Rainout Control System is to maintain or raise the gas temperature to or above the dew point (of the air exiting the humidifier) reducing or eliminating water condensation and/or pooling of water in the breathing circuit, and problems associated with such. The Hybernite Rainout Control System is indicated for use in the home or sleep-lab setting by a single adult patient. It can also be used in conjunction with supplemental Oxygen. The Hybernite Rainout Control System is indicated for non-invasive ventilation.

Prescription Use YES AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100104