DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 24, 2016

Plastiflex Healthcare
Division of Plastiflex Group NV
c/o Patsy J. Trisler
Regulatory Consultant for Plastiflex Group Belgium
Qserve Group, US, Inc.
PO Box 940
Charlestown, New Hampshire 03603

Re: K151461
Trade/Device Name: Hybernite RT
Regulation Number: 21 CFR 868.5270
Regulation Name: Breathing System Heater
Regulatory Class: Class II
Product Code: BZE
Dated: February 15, 2016
Received: February 16, 2016

Dear Patsy J. Trisler:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151461

Device Name

Hybernite RT

Indications for Use *(Describe)*

The Hybernite RT heated breathing circuits are intended to carry warmed/moistened gas from the humidifier to the patient's airways. The Hybernite RT breathing tubes are indicated for patient populations from neonates to adults. They may be used in the home or hospital environments.

They are for single patient use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) Summary **K151461**

Submitter Name:	Plastiflex Healthcare Division of Plastiflex Group NV Frederic.arien@plastiflex.com
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Contact Person:	Frédéric Ariën, Project Manager
Date Prepared:	10 February 2016; updated 23 March 2016
Device Trade Name:	Hybernite RT
Common Name	Heated Breathing Tube
Classification Name, Number & Product Code:	Breathing system heater, 868.5270, BZE
Predicate Device:	**K092129** INTERSURGICAL HEATED WIRE BREATHING SYSTEM
Reference Device:	**K100104** PLASTIFLEX HEALTHCARE HYBERNITE RAINOUT CONTROL SYSTEM
Device Description:	Description: The Hybernite RT is a breathing system heater according to 21 CFR§ 868.5270. A breathing system heater is identified by the Food and Drug Administration (FDA) as a therapeutic device that is intended to warm breathing gases before they enter a patient's airway. The Device family "Hybernite RT" is the name for dual wire passive heated breathing circuits optimized for patient category and application. The Hybernite RT is optimized for 3 patient categories, adult, paediatric and neonatal. Within each patient category there is a dual limb and single limb version to accommodate the specific clinical application as tabulated below; the device is is intended to act as a conduit for the breathing gasses delivered from the ventilator to the humidifier, from the humidifier to the patient and if applicable from the patient to the ventilator. The product family of Hybernite RT is defined as the combination of non- heated and heated breathing tubes intended to deliver the desire air temperature at the patient port when used in combination with a Humidifier. The Hybernite RT tubing has a range of tubing dimensions (Internal diameter from 10 mm to 22 mm and length from 0.3 meter to

2.4 meters) depending on the clinical application that can be connected to a humidifier. That means that the performance requirement in terms of desired patient port temperatures is controlled by the Humidifier. The Hybernite RT functions as a heating element.

All members of this device family therefore share the same basic design and performance characteristics as related to the safety and efficacy of the device, the same intended use and function and device classification.

Breathing circuit	Patient category	Application	Components
Hybernite RT 1000	Adult	Dual limb	Non heated connection tube Heated inspiratory limb Heated expiratory limb
Hybernite RT 1100	Adult	Single limb	Non heated connection tube Heated inspiratory limb
Hybernite RT 2000	Paediatric	Dual limb	Non heated connection tube Heated inspiratory limb Heated expiratory limb
Hybernite RT 2100	Paediatric	Single limb	Non heated connection tube Heated inspiratory limb
Hybernite RT 3000	Neonatal	Dual limb	Non heated connection tube Heated inspiratory limb. Build up out an inspiratory heated tube and unheated incubator tube. Heated expiratory limb
Hybernite RT 3100	Neonatal	Single limb	Non heated connection tube Heated inspiratory limb. Build up out an inspiratory heated tube and unheated incubator tube.

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 reducing or eliminating water condensation and/or pooling of water in the breathing circuit and the problems associated with such condensation. The non-heated tubing has the same construction as the heated tubing without the heating wires incorporated.

The lead from the heated limb can be connected to the humidifier to supply the heating. The Hybernite RT does not have sensing functionality. However it is equipped with a flow probe port and a temperature probe port which connect with the sensors of the humidifier. Based on these readings the humidifier regulates the power supplied to

the Hybernite RT.

All the cuffs of the Hybernite RT breathing tubes are standard cuffs. As such, the Hybernite RT breathing tubes can be connected to ventilators and masks that have standard male/female outlet connectors

The Hybernite RT can be used in a hospital environment in combination with the Fisher & Paykel MR 850 Heated Humidifier.

Indications for Use Statement:

The Hybernite RT heated breathing circuits are intended to carry warmed/moistened gas from the humidifier to the patient's airways. The Hybernite RT breathing tubes are indicated for patient populations from neonates to adults. They may be used in the home or hospital environments. They are for single patient use only.

Summary of Technological Characteristics and Comparison to Predicate devices

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. 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 RT is to maintain or raise the gas temperature to the desired patient port temperature. The desired patient port temperature is set, monitored and regulated by the humidifier.

A table comparing the Hybernite RT to the Predicate #1 and Reference device is provided below.

The Hybernite RT circuits have the following similarities to the predicate and reference devices:

- Has the same intended use
- Uses the same operating principle
- Incorporates the same basic heated wire breathing circuit design elements for use with ventilators including physical interfaces.
- Has the same basic performance characteristics
- Complies with the applicable electrical, mechanical, chemical and performance standards, and comparison of the data shows similar values for the key performance characteristics.
- Is manufactured using the same manufacturing process (Reference device)
- Incorporates the same materials (Reference device) and is ISO 10993 compliant

The differences between the Hybernite RT and predicate device are:

- The Indications for the Hybernite includes:
  - Use in the patient population to include neonates up to adults,
  - Use in the home, as well as hospital environments, and
  - Single patient use.
- A Usability Study and additional Biocompatibility testing were performed for the Hybernite RT because of the expanded indications (patient population and inclusion of home use).

	The new device as designed and manufactured does not raise any new issues of safety and effectiveness
Non-clinical data	Testing carried out on the Hybernite RT indicates that it meets design and performance functional requirements. The device has been tested according to the appropriate ISO and IEC standards including international electrical standards for safety (IEC 60601-1 Basic safety and essential performance, Electrical, Basic safety and essential performance, Mechanical) and performance and test standards for electromagnetic immunity (IEC 6060-2 Basic safety and essential performance, EMC). Tests include Resistance to flow, Compliance, Compressible Volume, and Wire resistance. 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 ISO 5356-1, Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets have also been conducted. Comparative performance testing has been done for the Hybernite RT and Intersurgical Predicate utilizing the Fisher & Paykel MR 850 Heated Humidifier, for which both devices have demonstrated compatibility; in terms of the specified performance characteristics both devices were considered to be equivalent. All materials utilized in the Hybernite RT circuits have been evaluated according to tests outlined in ISO 10993-1. Further details are provided in the Table below.
Clinical data	Clinical data was not required for this submission.
Usability	The device has been subject to a usability study according to IEC 62366. The Usability study demonstrated the utility of the device, the user interface, for the intended use and in the environment in which it is used.
Conclusion	The information discussed above demonstrates that the new Hybernite RT is substantially equivalent to the predicate device, and the new device does not raise any new issues of safety and effectiveness.

Summary Technical Characteristics Comparison Table the Hybernite RT with the Legally Marketed Predicate

Feature	**Hybernite RT**	**Intersurgical Heated Wire Breathing System #1 Predicate**	***Hybernite Rainout Control System Reference Device***	**Impact on Safety Effectiveness?**
510(k) Number	K151461	K092129	*K100104*	None
Manufacturer	Plastiflex Healthcare	Intersurgical Incorporated	*Plastiflex Healthcare*	None
CFR Regulation Number	868.5270, Breathing system heater. **(a) *Identification.*** A breathing system heater is a device that is intended to warm breathing gases before they enter a patient's airway. The device may include a temperature controller.	868.5270, Breathing system heater. **(a) *Identification.*** A breathing system heater is a device that is intended to warm breathing gases before they enter a patient's airway. The device may include a temperature controller.	*868.5270, Breathing system heater.* ***(a) Identification.*** *A breathing system heater is a device that is intended to warm breathing gases before they enter a patient's airway. The device may include a temperature controller.*	None
Product Code	BZE – heater breathing system w/wo controller	BZE – heater breathing system w/wo controller	*BZE – heater breathing system w/wo controller*	None
Classification	Class II, performance standards	Class II, performance standards	*Class II, performance standards*	None
Classification Panel	Anesthesiology	Anesthesiology	*Anesthesiology*	None
Intended Use	The Hybernite RT heated breathing circuits are intended to carry warmed/ moistened gas from the humidifier to the patient's airways. The Hybernite RT breathing tubes are indicated for patient populations from neonates to adults. They may be used in the home or hospital environments. They are for single patient use only.	Breathing system heaters are defined as a device that is intended to warm breathing gases before they enter a patient's airways.	*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*	None

			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.	
Anatomical Site	Invasive and Non-invasive	Any patient using a heated humidifier: implies both invasive and non-invasive therapies	*Non-invasive*	None
Patient Population	Neo-natal, pediatric, adult	Any patient using a heated humidifier	*Adult*	None. (Hybernite RT subject to a usability study)
Environment of Use	Home and Hospital	Hospital Setting	*Home, Sleep Lab*	None. (Hybernite RT subject to a usability study).
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 passing through the tubing is warmed reducing or eliminating water condensation and/or pooling of water in the breathing circuit.	Applied voltage through heating wires	*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.*	None

Energy used/delivered	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. The raising of the gas temperature does not exceed 40ºC.	Rising of the delivered gas temperature from 37 to 40ºC increases its enthalpy	*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* *The raising of the gas temperature does not exceed 40ºC*	None
Reusable	No, Disposable. Single patient use only.	Not specified	*Yes* *Cleaning Regime: Mild soap and water after use*	None
Sterility	Not sterile	Not Sterile	*Not Sterile*	None
Compatibility with multiple humidifiers, standard connectors, and humidification chambers	Compatible with F&P MR850 humidifier, standard connectors, F&P MR290 humidification chamber	Compatible with F&P MR850 humidifier, standard connectors, 2310 humidification chamber (substantially equivalent to F&P MR 290 Compatible with MR850 humidifier)	*Yes, Universal*	None
Breathing gases specified	Not specified	Not specified	*Air & Supplemental Oxygen*	None
Standard breathing circuit polymeric materials	Yes	Yes	*Yes*	None
Power Source	Humidifier controlled	Humidifier controlled	*Separate*	None
Heating Wire	Encased	Encased	*Encased*	None
Active Controller	No, humidifier controlled	No, humidifier controlled	*No, humidifier controlled*	None
Standards of Conformity/ Performance	ISO 5367 ISO 5356 ISO 8185 ISO 10993 IEC 60601-1 IEC 60601-1-2 IEC 62366	ISO 5367 ISO 5356 ISO 8185 ISO 10993 IEC 60601-1 IEC 60601-1-2	*ISO 5367* *ISO 5356* *ISO 8185* *ISO 10993* *IEC 60601-1*	None

Compliance (mlpa) Resistance to flow (mb)^2 Tube Volume	ISO 5367 compliant	ISO 5367 compliant	*ISO 5367 Compliant*	None
Biocompatibilty	ISO 10993, tests for: Cytotoxicity, Sensitization, Irritation, Genotoxicity, Implantation, Extractables and leachables	ISO 10993, tests for: Cytotoxicity, Sensitization, Irritation, Genotoxicity, Implantation	*ISO 10993, tests for: Cytotoxicity, Sensitization, Irritation, Genotoxicity, Implantation*	None. Hybernite RT is manufactured under the same conditions and using the same process, and materials as the Reference device. Hybernite RT has also completed E&L testing and risk assessment. No risks identified for any of the patient populations.
Usabilty	Usabilty testing conducted to IEC 62366	None	*None*	None