K110398

JUN - 1 2011

Section 5.0 510(k) Summary

Administrative Information and Device Identification

Name and address of the submitter, contract manufacturer and sponsor of the 510(k) submission:	Submitter: Respironics, Inc. 1740 Golden Mile Highway Monroeville, PA 15146 Fax: 724-387-7490 Contract Manufacturer: WILAmed GMBH Aurachhoehe 5 7 Kammerstein, Bayern, 91126, Germany Fax: 049- 9178-996778 United States Agent: Regulatory Insight, Inc. Kevin Walls 5401 S. Cottonwood CT Greenwood Village, CO 80121 USA Office: 720-962-5412 Fax: 720-962-5413 Email: kevin@reginsight.com
FDA registration number of the manufacturer of the new device:	Submitter: 2518422 (Establishment Registration Number) Contract Manufacturer: 9615827 (Establishment Registration Number) 10033146 (Owner/Operator Number)
Official contact person for all correspondence:	Joseph E. Olsavsky Sr. Regulatory Affairs Manager Philips Respironics 1740 Golden Mile Highway Monroeville, PA 15146 Office: 724-387-7562 Fax: 724-387-7490 Email: joseph.olsavsky@philips.com
Date Prepared:	February 10, 2011
Device Name:	Respironics Disposable Heated Wire Circuits
Trade or Proprietary name of new	Disposable Pediatric, Heated Wire Active Circuit USA

device:	Disposable Adult, Heated Wire Active Circuit USA Disposable Pediatric, Heated Wire Passive Circuit USA Disposable Adult, Heated Wire Passive Circuit USA
Common or usual name of the device:	Heated Breathing Tube
Philips/Respironics model number:	1076043, 1076044, 1076045, 1076046
Classification of new device:	Class II
Classification of the predicate device:	Class II
Classification Panel:	Anesthesiology
Panel Code:	BZE – Breathing system, heater
CFR Regulation Number:	21 CFR 868.5270 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.* (b) *Classification.* Class II (performance standards).
Predicate Device Name(s) and 510(k) numbers:	1. Plastiflex Healthcare Hybernite Rainout Control System - K100104 date of concurrence 04/14/2010) 2. Intersurgical Heated Wire Breathing System - K092129 (date of concurrence 05/18/2010) 3. Fisher & Paykel Respiratory Humidifier - K983112 (date of concurrence 11/10/1996)
Reason for submission:	New Device

Description of Device:

The Respironics heated wire breathing circuit is a disposable device compromised of 15 or 22 mm corrugated plastic tubing, and 22 mm plastic tube connectors, and an electrical heater wire harness subassembly. The Respironics disposable heated wire circuit consists of a single limb single lumen smooth interior tube (15 or 22 mm diameter) containing 2 heater wires that are located 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. After the gas is warmed and humidified in the water chamber it is delivered through the breathing circuit to the patient. Heating of the breathing tube is provided and controlled by a compatible heated humidifier. This disposable heated wire circuit is designed to be used with the HC500 Fisher and Paykel humidifier. 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. 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.

There are four types of disposable breathing circuits:

1. Disposable Pediatric, Heated Wire Active Circuit
2. Disposable Adult, Heated Wire Active Circuit
3. Disposable Pediatric, Heated Wire Passive Circuit
4. Disposable Adult, Heated Wire Passive Circuit

The purpose of the heated wire breathing circuits is to maintain or raise the gas temperature to or above the dew point thus reducing or eliminating water condensation and/or pooling of water in the breathing circuit.

The Respironics disposable heated wire breathing circuit has standard cuffs on both the machine-end cuff and mask-end cuff. As such, the disposable heated wire breathing circuit can be connected to heated humidifiers and flow generators that have standard male outlet connectors. The Respironics disposable heated wire breathing circuit is intended for incorporation into ventilator devices and is intended to act as a conduit for the breathing gasses delivered from the humidifier to the patient. It can also be used in conjunction with supplemental Oxygen.

The environment of use for the disposable heated wire breathing circuit will be for in the home, institutional, nursing, extended care, and clinical sleep lab settings.

Operators of the disposable heated wire breathing circuit are expected to be: Patients, Lay caregivers (includes family members of patients and aides), Nurses, Respiratory therapists, Physicians and Home care providers.

The disposable heated wire breathing circuit is intended to be used with ventilators that provide both pressure support and volume modes of therapy.

Other accessories such as water traps, etc. can be added in to the overall assembly creating different product variations.

Comparison of Device Technological Characteristics to Predicate Devices:

The Respironics Disposable Heated Wire Circuits have the following similarities to those predicate devices listed in this submission which previously received 510(k) concurrence; the Respironics Disposable Heated Wire Circuits:

- Has the same intended use,
- Uses the same operating principle,

- Incorporates the same basic heated wire breathing circuit design elements for use with ventilator devices including physical interfaces; and performance characteristics;
- Incorporates similar materials & is ISO 10993 compliant;
- Is manufactured utilizing similar manufacturing processes; and
- Complies with similar electrical, mechanical, chemical and performance standards

According to FDA's Draft Reviewer Guidance for Premarket Notification Submissions - Anesthesiology and Respiratory Devices Branch; Division of Cardiovascular, Respiratory, and Neurological Devices (November 1993), the following characteristics for the submitted device and consistent with the predicate devices are identified below:

- The Respironics disposable heated wire breathing circuit is not an implantable device.
- The Respironics disposable heated wire breathing circuit is intended for life support or life sustaining applications.
- The Respironics disposable heated wire breathing circuit is not sold as sterile.
- The Respironics disposable heated wire breathing circuit is a single-patient-use device.
- The Respironics disposable heated wire breathing circuit must be prescribed by a physician.
- The Respironics disposable heated wire breathing circuit does not contain a drug or biological as a component.
- The Respironics disposable heated wire breathing circuit is not a kit.
- The Respironics disposable heated wire breathing circuit is not software driven.
- The Respironics disposable heated wire breathing circuit is electrically operated.

The intended use of the Respironics heated wire breathing circuit is comparable to the referenced predicate devices. The comparison of the data shows similar values for the key performance characteristics. The Respironics disposable heated wire circuit shows similar values for compliance, volume, resistance to flow, wire resistance and tube length and connectivity.

The reason for the Abbreviated 510(k) premarket notification submission for Respironics Disposable Heated Wire circuit is that this is a new device.

The new device as designed and manufactured does not raise any new issues of safety and effectiveness.

The following table compares the Respironics Disposable Heated Wire Circuits with the legally marketed predicate devices.

Table 12-1 Comparison of Respironics Disposable Heated Circuits with Plastiflex Group NV Hybernite Rainout Control System (K100104); Intersurgical Heated Wire Breathing System (K092129); and Fisher & Paykel Respiratory Humidifier (K983112):

Feature/Function	**New device: Respironics Disposable Heated Wire Circuits**	**Predicate Device: Plastiflex Healthcare Hybernite Rainout Control System (K100104)**	**Predicate Device: Intersurgical Heated Wire Breathing System (K092129)**	**Fisher & Paykel Respiratory Humidifier (K983112)**	**Similarity/ Difference**	**Impact on safety and effectiveness**
Common or usual name of the device	Heated Breathing Tube, Breathing system heater	Heated Breathing Tube, Breathing system heater	Heated Breathing Tube, Breathing system heater	Respiratory humidifier with accessories (including heated wire circuits)	Similar. F&P clearance covers a system (humidifier + heated wire circuit)	No impact on safety and effectiveness
Classification	Class II	Class II	Class II	Class II	Same	No impact on safety and effectiveness
Classification Panel	Anesthesiology	Anesthesiology	Anesthesiology	Anesthesiology	Same	No impact on safety and effectiveness
Product Code:	BZE- heater, breathing system w/wo controller	BZE- heater, breathing system w/wo controller	BZE- heater, breathing system w/wo controller	BTT – humidifier, respiratory gas BZE - heater, breathing system w/wo controller	Same	No impact on safety and effectiveness
CFR Regulation Number	21 CFR 868.5270 a) *Identification.* A breathing system heater is a device that is intended to warm breathing gases before they enter a patient's	21 CFR 868.5270 a) *Identification.* A breathing system heater is a device that is intended to warm breathing gases before they enter a patient's airway. The	21 CFR 868.5270 a) *Identification.* A breathing system heater is a device that is intended to warm breathing gases before they enter a patient's	21 CFR 868.5270 a) *Identification.* A breathing system heater is a device that is intended to warm breathing gases before they enter a patient's	Same	No impact on safety and effectiveness

	airway. The device may include a temperature controller. (b) *Classification.* Class II (performance standards).	device may include a temperature controller. (b) *Classification.* Class II (performance standards).	airway. The device may include a temperature controller. (b) *Classification.* Class II (performance standards).	airway. The device may include a temperature controller. (b) *Classification.* Class II (performance standards). 21 CFR 868.5450 Respiratory gas humidifier. (a)*Identification.* A respiratory gas humidifier is a device that is intended to add moisture to, and sometimes to warm, the breathing gases for administration to a patient. Cascade, gas, heated, and prefilled humidifiers are included in this generic type of device. (b)*Classification.* Class II (*per*formance standards.		
510(k) numbers:	Not yet assigned	K100104	K092129	K983112	N/A	N/A
Intended Use	The disposable heated wire circuit is a heated wire breathing circuit intended to provide warmed and/or humidified breathing gases before they enter a patient's airway. The disposable heated wire circuit is indicated for use by a single adult or pediatric patient in the home, hospital and/or institutional settings. It may	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	Breathing system heaters are defined as a device that is intended to warm breathing gases before they enter the patient's airway.	The Fisher & Paykel Healthcare MR 850 Humidifier is a Respiratory Gas Humidifier as per 73 BTT, 21 CFR 868.5450. It is intended to add moisture to and warm breathing gases for administration to a patient. The MR850 is intended to be used to warm and add humidity to gases delivered to patients	Similar	No impact on safety and effectiveness

	be used for both invasive and non-invasive ventilation.	gasses delivered form 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.		requiring mechanical ventilation, positive pressure breathing assistance or general medical gases. Gases available for medical use do not contain sufficient moisture and may damage or irritate the respiratory tract, or desiccate secretions of patients whose supraglottic airways have been bypassed. Heat is used to increase the water output of the humidifier. Heated breathing tubes are also utilized in order to increase operating efficiency and reduce excessive water and heat loss.		
Anatomical Sites	Invasive & Non-invasive	Non-invasive	Not Specified (intended use includes any patient using a heated humidifier which would be inclusive of Invasive patients)	Invasive & Non-invasive	Same	No impact on safety and effectiveness
Target Patient Population	Pediatric (>= 5kg) to Adult	Adult	Any patient using a heated humidifier	Any patient using a heated humidifier	Same	No impact on safety and effectiveness
Environment of Use	Home, Institution/Hospital Setting, Extended Care and Clinical Sleep settings	Home or Sleep Lab Setting	Hospital Setting	Home, Institution/Hospital Setting, Extended Care and Clinical Sleep settings	Same	No impact on safety and effectiveness
Mode of Action	Applied voltage through	When a voltage is applied, a	Applied voltage through	Applied voltage through	Same	No impact on

	heating wires	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 existing the humidifier) reducing or eliminating water condensation and /or pooling of water in the breathing circuit.	heating wires	heating wires		safety and effectiveness
Energy used and or 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. As a result, the air passing through the tubing is warmed to or above the dew point (of the air existing 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 41C.	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 existing 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 40C.	Rising of the delivered gas temperature from 37 to 40C 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 existing 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 41C.	Same	No impact on safety and effectiveness
Reusable	Single Patient Use – Reusable	Single Patient Use – Reusable Cleaning Regime: Mild soap and water after use.	Not Specified	Single Patient Use – Reusable	Similar	No impact on safety and effectiveness
Sterility	Non-Sterile	Non-Sterile	Not Specified	Non-Sterile	Similar	No impact on safety and effectiveness

Compatible with multiple humidifiers (standard connectors)	For use with F&P 500	Universal	For use with Intersurgical model humidifiers	For use with F&P model humidifiers	Similar	No impact on safety and effectiveness
Breathing Gases Specified	Air & Supplemental Oxygen	Air & Supplemental Oxygen	No t Specified	Air & Supplemental Oxygen	Similar	No impact on safety and effectiveness
Standard Breathing Circuit Polymeric materials	Yes	Yes	Yes	Yes	Similar	No impact on safety and effectiveness
Tube Diameter	15 and 22 mm configurations	15 and 22 mm configurations	22mm	15 and 22 mm configurations	Similar	No impact on safety and effectiveness
Tube Length	1.83 m	~1.5 m	~1.5 m	1.5 m	Same	No impact on safety and effectiveness
Power Source	Incorporated (humidifier controlled)	Separate	Incorporated (humidifier controlled)	Incorporated (humidifier controlled)	Similar	No impact on safety and effectiveness
Heating Wire	Encased	Encased	Encased	Encased	Same	No impact on safety and effectiveness
Wire Resistance (ohms)	30 +/- 5%	Not specified	14.7 Ins & 11.9 Exp	Not specified	Similar	No impact on safety and effectiveness
Active Controller	No – Humidifier Controlled	No – Power source controlled	No – Humidifier Controlled	No – Humidifier Controlled	Similar	No impact on safety and effectiveness
Standards of Conformity/Performance	ISO 5367 – Breathing tubes intended for use with anesthetic apparatus and ventilators ISO 5356-1 – Anesthetic and respiratory equipment – Conical connectors: Part 1: Cones and sockets.	ISO 5367 – Breathing tubes intended for use with anesthetic apparatus and ventilators ISO 5356-1 – Anesthetic and respiratory equipment – Conical connectors: Part 1: Cones and sockets.	ISO 5367 – Breathing tubes intended for use with anesthetic apparatus and ventilators ISO 5356-1 – Anesthetic and respiratory equipment – Conical connectors: Part 1: Cones and sockets.	ISO 5367 – Breathing tubes intended for use with anesthetic apparatus and ventilators ISO 5356-1 – Anesthetic and respiratory equipment – Conical connectors: Part 1: Cones and sockets.	Similar	No impact on safety and effectiveness

	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 IEC 60601-1-2 Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests AAMI/ANSI/ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing ISO 14971 Medical devices - Application of risk management to medical devices.	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 AAMI/ANSI/ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing	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 IEC 60601-1-2 Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests AAMI/ANSI/ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing	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 IEC 60601-1-2 Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests AAMI/ANSI/ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing ISO 14971 Medical devices - Application of risk management to medical devices.		
Compliance (mlpa) **Resistance to Flow (mb)[2]** **Tube Volume (ml)**	ISO 5367 compliant	ISO 5367 compliant	ISO 5367 compliant	ISO 5367 compliant	Same	No impact on safety and effectiveness
Biocompatibility	ISO 10993 compliant	ISO 10993	ISO 10993	ISO 10993	Same	No impact on safety and effectiveness

Electrical Safety	IEC 60601-1 compliant	IEC 60601-1 compliant	IEC 60601-1 compliant	IEC 60601-1compliant	Same	No impact on safety and effectiveness

Conclusion of Comparison of Device Technological Characteristics to Predicate Devices

The Respironics Disposable Heated Circuits are substantially equivalent to the predicate devices listed in this Summary and the new device does not raise any new issues of safety and effectiveness.

All items addressed by the Reviewer's Checklist are unchanged from the predicate devices identified in this submittal. Also, see Section 12.0 – Substantial Equivalence Discussion.

Performance Testing Summary:

This device has been tested to appropriate ISO and IEC standards and other applicable requirements passing all test protocols. The Respironics disposable heated wire circuit was designed and tested according to guidance outlined in:

1. FDA's Draft Reviewer Guidance for Premarket Notification Submissions - Anesthesiology and Respiratory Devices Branch; Division of Cardiovascular,Respiratory, and Neurological Devices (November 1993);

2. FDA's Draft Reviewer Guidance for Ventilators July 1995; and

as suggested by FDA's November 1993 publication entitled "Reviewer Guidance for Premarket Notification Submissions - Anesthesiology and Respiratory Devices Branch; Division of Cardiovascular, Respiratory, and Neurological Devices" and "Draft Reviewer Guidance for Ventilators July 1995" the Respironics disposable heated wire circuit was tested in accordance with the applicable voluntary standards. The Respironics disposable heated wire circuit met the required performance criteria and functioned as intended.

Non-clinical testing of the Respironics Disposable Heated Wire Breathing Circuit have been conducted including mechanical, electrical, and temperature accuracy under environmental conditions, and test standards for electromagnetic immunity. These include

Resistance to Flow, Compliance, Compressible Volume and Wire Resistance. All materials used in the heated wire breathing circuit and humidification chambers have been evaluated according to tests outlined in ISO 10993-1.

See Section 9.0 Declarations of Conformity and Summary Reports, Section 17.0 Electromagnetic Compatibility and Electrical Safety and Section 18.0 Performance Testing – Bench.

Clinical data:

Not required. No clinical tests have been performed on the Respironics Disposable Heated Wire Breathing Circuit.

Non-Clinical Testing:

This device has been tested to appropriate ISO and IEC standards and other applicable requirements passing all test protocols. The Respironics disposable heated wire circuit was designed and tested according to guidance outlined in:

1. FDA's Draft Reviewer Guidance for Premarket Notification Submissions - Anesthesiology and Respiratory Devices Branch; Division of Cardiovascular, Respiratory, and Neurological Devices (November 1993);

2. FDA's Draft Reviewer Guidance for Ventilators July 1995; and

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See Section 9.0 Declarations of Conformity and Summary Reports, Section 17.0 Electromagnetic Compatibility and Electrical Safety and Section 18.0 Performance Testing – Bench.

Statement of Safety and Effectiveness:

Analysis of comparison of design, function and features of the Respironics Disposable Heated Wire Breathing Circuit to the Plastiflex Healthcare Hybernite Rainout Control System - K100104 date of concurrence 04/14/2010); Intersurgical Heated Wire Breathing System - K092129 (date of concurrence 05/18/2010) and Fisher & Paykel Respiratory Humidifier - K983112 (date of concurrence 11/10/1996), together with the results of testing demonstrates the new device to be substantially equivalent to the predicate devices in terms of meeting performance criteria and functioning as intended.

Statement of Intended Use:

The disposable heated wire circuit is a heated wire breathing circuit intended to provide warmed and/or humidified breathing gases before they enter a patient's airway. The disposable

heated wire circuit is indicated for use by a single adult or pediatric patient in the home, hospital and/or institutional settings. It may be used for both invasive and non-invasive ventilation.

Conclusion:

The Respironics Disposable Heated Circuits are substantially equivalent to the predicate devices listed in this Summary and the new device does not raise any new issues of safety and effectiveness.

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

Mr. Joseph E. Olsavsky
Senior Manager-HRC Regulatory Affairs
Respironics, Incorporated
Sleep & Home Respiratory Group
1740 Golden Mile Highway
Monroeville, Pennsylvania 15146

JUN - 1 2011

Re: K110398
Trade/Device Name: Respironics Disposable Heated Wire Circuits
Regulation Number: 21 CFR 868.5270
Regulation Name: Breathing System Heater
Regulatory Class: II
Product Code: BZE
Dated: May 11, 2011
Received: May12, 2011

Dear Mr. Olsavsky:

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.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4.0 Indications for Use

Indications for Use

510(k) Number (if known): _____

Device Name: Disposable Heated Wire Circuits

The disposable heated wire circuit is a heated wire breathing circuit intended to provide warmed and/or humidified breathing gases before they enter a patient's airway. The disposable heated wire circuit is indicated for use by a single adult or pediatric patient in the home, hospital and/or institutional settings. It may be used for both invasive and non-invasive ventilation.

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)

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

510(k) Number: K110398