Appendix C. 510(k) Summary of Safety and Effectiveness Page1

K092129

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Date: 05/18/2010
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MAY 18 2010

Description of Device:

The 2026 and 2026-CH dual heated wire breathing circuits are classified as "Breathing System Heater" according to 21 CFR 868.5270. The breathing circuits form part of the respiratory humidification system in which the inspiratory limb delivers humidified gas to the patient and the expiratory limb carries the expired gas away from the patient. Heater wires in the inspiratory and expiratory limb minimizes the formation of condensate.

The 2310 Auto-Fill Humidification Chamber, 2320 Manual Fill Humidification Chamber and the 2330 Low Volume Manual Fill Humidification Chamber are classified as accessories to "Breathing System Heater" according to 21 CFR 868.5270. Chambers are an integral part of the breathing system and allow the system to interface with the heated humidifier base. Chambers are commonly used with heated wire breathing systems. The chamber simply slides into position on the hot plate of the base controller allowing the inspiratory gas to pass over the heated water. This provides optimum humidification to the patient.
The 2310 Auto-Fill Chamber offers a fixed level of water within the chamber, ensuring a constant system volume. The float mechanism along with the webs inside the chamber and baffles at the base of the 22mm male connectors, ensure that the chamber gives maximum humidity output without compromising resistance to flow.
The 2320 Manual-Fill Chamber is supplied with a complete fill set and clamp in order to manually control the water level in the chamber.
The 2330 Low-Volume Chamber is suitable for use with high frequency ventilation and many neonatal applications. The chamber is supplied with a fill set and clamp in order to manually control the water level in the chamber.

Predicate Devices:

The 2026 dual wire heated breathing circuit is substantially equivalent to the Fisher & Paykel RT210 dual wire heated breathing circuit. The 2310 Auto-Fill Humidification Chamber is substantially equivalent to the Fisher & Paykel MR 290 Autofeed Humidification Chamber. The 2320 Manual Fill Humidification Chamber is substantially equivalent to the Fisher & Paykel MR 210 Manual Feed Adult Chamber. The 2330 Low Volume Manual Fill Humidification Chamber is substantially equivalent to the Fisher & Paykel MR 225 Manual Feed Infant Chamber.

Intended Use:

Breathing system heaters are defined as a device that is intended to warm breathing gases before they enter a patient's airway.

Humidification Chambers are intended for use to hold water required to humidify the air being delivered to patients.

Technological Characteristics Summary:

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

Characteristic Compared	[510(k) DEVICE] 2026	[PREDICATE DEVICE] F & P RT 210
510K		K983112
Intended use:	Breathing system heaters are defined as a device that is intended to warm breathing gases before they enter a patient's airway.	Breathing system heaters are defined as a device that is intended to warm breathing gases before they enter a patient's airway.
Target Population	Any patient using a heated humidifier	Any patient using a heated humidifier
Indications for use	Instruction leaflet	Instruction leaflet
Where used	Hospital	Hospital
Product Labelling	Heated Wire Breathing Circuit	Heated Wire Breathing Circuit
Design & Performance:	Standards Used: ISO 5367 / ISO 9360	Test Report 30889 located in Appendix F of initial submission
Volume (ml)	1106	1460
Tube Length (m)	2.27 Ins & 1.46 Exp	1.93 Ins & 1.48 Exp
Wire Resistance (ohms)	14.7 Ins & 11.9 Exp	17.2 Ins & 12.2 Exp
Tube material and designated diameter	Flex tube 22mm	Flex tube 22mm
Compliance (ml/Kpa)	11.2	13.3
Resistance to Flow (mb)	2.9 Ins & 2.6 Exp	3.1 Ins & 3.3 Exp

Characteristic Compared	[510(k) DEVICE] 2026	[PREDICATE DEVICE] F & P RT 210
Compatibility with the environment and other devices. See Pages 9 to 14 for Compatibility Study.	**To be used with 2310 humidification chamber and F&P MR850 heater bases. Product compatible with F & P MR 850.**	**To be used with F&P MR290 humidification chamber and F&P MR850 heater bases.**
Energy used and or delivered	The raising of the delivered gas temperature from 37 to 40C increases its enthalpy.	The raising of the delivered gas temperature from 37 to 40C increases its enthalpy.
Sterility	NON STERILE	NON STERILE
Standards met:	ISO 5367 ISO 10993 ISO 8185 ISO 5356 EN 12342	ISO 5367 ISO 10993 ISO 8185 ISO 5356 EN 12342
Biocompatibility	Compliant with ISO 10993 The materials all met the requirements of the biological tests for Cytotoxicity, Sensitization, Irritation, Genotoxicity - Ames Test, Gene Mutation - In Vitro Mouse Lymphoma and Implantation as described in the biocompatibility tests performed by Nelson Laboratories in Appendix G.	Compliant with ISO 10993
Test Results:	**See Pages 19 to 44 for Summary Conformance.**	**See Pages 45 to 86 for test reports.**
Electrical safety	Compliant with ISO 8185 See page 16B, pp 52 -55, 56, 57-60 & 64-66 for electrical testing.	Compliant with ISO 8185
Mechanical safety	Compliant with ISO 8185 See page 16B and pp 78 -80 for mechanical testing.	Compliant with ISO 8185
Chemical Safety	Compliant with ISO 8185	Compliant with ISO 8185
Thermal safety	Compliant with ISO 8185	Compliant with ISO 8185
Radiation safety	Compliant with ISO 8185	Compliant with ISO 8185

The intended use of the humidification chambers are comparable to the referenced predicate devices. The comparison of the data shows similar values for the key performance characteristics. Proposed humidification chambers show similar values for fill volume, compressible volume, compliance, leakage, weight, moisture output, resistance to flow and evaluation of maximum flows.

Characteristic Compared	[510(k) DEVICE] 2310	[PREDICATE DEVICE] F & P MR 290
510K		**K934140**
Intended use:	**Humidification Chambers are intended for use to hold water required to humidify the air being delivered to patients.**	**Humidification Chambers are intended for use to hold water required to humidify the air being delivered to patients.**
Target Population	Any patient using a heated humidifier	Any patient using a heated humidifier
Indications for use	Instruction leaflet	Instruction leaflet
Where used	Hospital	Hospital
Product Labelling	Auto Fill Humidification Chamber	Auto Fill Humidification Chamber
Design & Performance:	**Standards Used: ISO 8185 / ISO 9360 BS EN 12342**	**Standards Used: ISO 8185 / ISO 9360 BS EN 12342**
Fill Volume (ml)	Full 369.9/ Max Line 147.1/ Min Line 51.1 [3]	355 But no fill lines [3]
Weight (g)	126 [3]	94 [3]
Leakage (ml/min)	<0.5 [2]	<0.5 [2]
Compliance at empty (ml/mb)	0.60 [2]	0.56 [2]
Resistance to Flow (mb)	0.6 [2]	0.4 [2]
Moisture Output (mg/l) at 10 l/min	46.6 [2]	47.4 [2]
Evaluation of Maximum Flows (l/min) Horizontal/10 degrees	194 / 171 [2]	165 / 157 [2]
Compatibility with the environment and other devices	To be used with I/S breathing circuit and F&P MR850 heater bases.	To be used with F&P breathing circuits and F&P MR850 heater bases.
Energy used and or delivered	Electrical energy is used to raise the temperature and humidity of the gas delivered to the patient.	Electrical energy is used to raise the temperature and humidity of the gas delivered to the patient.
Sterility	NON STERILE	NON STERILE

Characteristic Compared	**[510(k) Device] 2310**	**[Predicate Device] F & P MR 290**
Standards met:	ISO 10993 ISO 8185 ISO 5356	ISO 10993 ISO 8185 ISO 5356
Biocompatibility	Compliant with ISO 10993 The materials all met the requirements of the biological tests for Cytotoxicity, Sensitization, Irritation, Genotoxicity - Ames Test, Gene Mutation - In Vitro Mouse Lymphoma and Implantation as described in the biocompatibility tests performed by Nelson Laboratories in Appendix G.	Compliant with ISO 10993
Test Results:	**See Pages 19 to 44 for Summary Conformance.**	**See Pages 45 to 86 for test reports.**
Electrical safety	Compliant with ISO 8185	Compliant with ISO 8185
Mechanical safety	Compliant with ISO 8185	Compliant with ISO 8185
Chemical Safety	Compliant with ISO 8185	Compliant with ISO 8185
Thermal safety	Compliant with ISO 8185	Compliant with ISO 8185
Radiation safety	Compliant with ISO 8185	Compliant with ISO 8185

Characteristic Compared	**[510(k) DEVICE] 2320**	**[PREDICATE DEVICE] F & P MR 210**
510K		**K850647**
Intended use:	**Humidification Chambers are intended for use to hold water required to humidify the air being delivered to patients.**	**Humidification Chambers are intended for use to hold water required to humidify the air being delivered to patients.**
Target Population	Any patient using a heated humidifier	Any patient using a heated humidifier
Indications for use	Instruction leaflet	Instruction leaflet
Where used	Hospital	Hospital
Product Labelling	Manual Fill Humidification Chamber	Manual Fill Humidification Chamber
Design & Performance:	**Standards Used: ISO 8185 / ISO 9360 BS EN 12342**	**Standards Used: ISO 8185 / ISO 9360 BS EN 12342**
Fill Volume (ml)	Full 457.7/ Max Line 243.2/ Min Line 66 [6]	Full 445.3/Max 252.4 [6]
Weight (g)	93.4 [1]	55.9 [1]
Leakage (ml/min)	< 0.5 [6]	0.7 [1]

Characteristic Compared	[510(k) DEVICE] 2320	[PREDICATE DEVICE] F & P MR 210
Compliance at empty (ml/mb)	0.44 [1]	0.49 [1]
Resistance to Flow mb at (60 l/min)	0.1 [1]	0.1 [1]
Moisture Output mg/l at (10 l/min)	47.1 [1]	46.4 [1]
Evaluation of Maximum Flows (l/min) Horizontal/10 degrees	200/200 [1]	200/200 [1]
Compatibility with the environment and other devices:	To be used with I/S breathing circuit and F&P MR850 heater bases.	To be used with F&P breathing circuits and F&P MR850 heater bases.
Energy used and or delivered	Electrical energy is used to raise the temperature and humidity of the gas delivered to the patient.	Electrical energy is used to raise the temperature and humidity of the gas delivered to the patient.
Sterility	NON STERILE	NON STERILE
Standards met:	ISO 10993 ISO 8185 ISO 5356	ISO 10993 ISO 8185 ISO 5356
Biocompatibility	Compliant with ISO 10993 The materials all met the requirements of the biological tests for Cytotoxicity, Sensitization, Irritation, Genotoxicity - Ames Test, Gene Mutation - In Vitro Mouse Lymphoma and Implantation as described in the biocompatibility tests performed by Nelson Laboratories in Appendix G.	Compliant with ISO 10993
Test Results:	**See Pages 19 to 44 for Summary Conformance.**	**See Pages 45 to 86 for test reports.**
Electrical safety	Compliant with ISO 8185	Compliant with ISO 8185
Mechanical safety	Compliant with ISO 8185	Compliant with ISO 8185
Chemical Safety	Compliant with ISO 8185	Compliant with ISO 8185
Thermal safety	Compliant with ISO 8185	Compliant with ISO 8185
Radiation safety	Compliant with ISO 8185	Compliant with ISO 8185

Characteristic Compared	[510(k) DEVICE] 2330	[PREDICATE DEVICE] F & P MR 225
510K		**K862923**
Intended use:	**Humidification Chambers are intended for use to hold water required to humidify the air being delivered to patients.**	**Humidification Chambers are intended for use to hold water required to humidify the air being delivered to patients.**
Target Population	Any patient using a heated humidifier	Any patient using a heated humidifier
Indications for use	Instruction leaflet	Instruction leaflet
Where used	Hospital	Hospital
Product Labelling	Low Volume Manual Fill Humidification Chamber	Low Volume Manual Fill Humidification Chamber
Design & Performance:	**Standards Used: ISO 8185 / ISO 9360 BS EN 12342**	**Standards Used: ISO 8185 / ISO 9360 BS EN 12342**
Fill Volume (ml)	Full 307.4/ Max Line 190.6/ Min Line 62.5 [7]	Full 308.1/ Max Line 193.5 [7]
Weight (g)	82.9 [4]	51.1 [1]
Leakage (ml/min)	0.5 [1]	3 [1]
Compliance at empty (ml/mb)	0.31 [5]	0.31 [5]
Resistance to Flow mb at (60 l/min)	0.1 [7]	0.2 [6]
Moisture Output (mg/l) at 10 l/min	46.4 [1]	46.3 [1]
Evaluation of Maximum Flows (l/min) Horizontal/10 degrees	130/140 [1]	130/140 [1]
Compatibility with the environment and other devices	To be used with I/S breathing circuit and F&P MR850 heater bases.	To be used with F&P breathing circuits and F&P MR850 heater bases.
Energy used and or delivered	Electrical energy is used to raise the temperature and humidity of the gas delivered to the patient.	Electrical energy is used to raise the temperature and humidity of the gas delivered to the patient.

Characteristic Compared	[510(k) DEVICE] 2330	[PREDICATE DEVICE] F & P MR 225
Sterility	NON STERILE	NON STERILE
Standards met:	ISO 10993 ISO 8185 ISO 5356	ISO 10993 ISO 8185 ISO 5356
Biocompatibility	Compliant with ISO 10993 The materials all met the requirements of the biological tests for Cytotoxicity, Sensitization, Irritation, Genotoxicity - Ames Test, Gene Mutation - In Vitro Mouse Lymphoma and Implantation as described in the biocompatibility tests performed by Nelson Laboratories in Appendix G.	Compliant with ISO 10993
Test Results:	**See Pages 19 to 44 for Summary Conformance.**	**See Pages 45 to 86 for test reports.**
Electrical safety	Compliant with ISO 8185	Compliant with ISO 8185
Mechanical safety	Compliant with ISO 8185	Compliant with ISO 8185
Chemical Safety	Compliant with ISO 8185	Compliant with ISO 8185
Thermal safety	Compliant with ISO 8185	Compliant with ISO 8185
Radiation safety	Compliant with ISO 8185	Compliant with ISO 8185

[1] Results taken from MGI_15605_CC_2330, MR225 and 2320, MR210 Comparison_Issue 1
[2] Results taken from 2310_(17.50mm_MAX_line)MK_IV_TR_AR,MS_02_03_2009.doc
[3] Results taken from AW_15731_CC_Fluid and gas volumes for MK2 and MK4 Chambers_issue1.doc [3]
[4] Results taken from AW_ CC_Fill volume of manual fill, low volume humid chamber_issue 1.Book1 (2).xls
[5] Results taken from TO_2002_Compliance chamber.doc
[6] Results taken from CC_AW_31655_MF 2320 & F&P M225 Chamber Testing_issue1.doc
[7] Results taken from MGI_15605_CC_2330, Low volume chamber measurements_Issue 1.doc
Note: See pages 67 to 75C for the attached reports detailing the information for the Humidification Chambers.

Summary of Testing:

Nonclinical tests submitted to demonstrate substantial equivalence for the Heated Wire Breathing Circuit include Resistance to Flow, Compliance, Compressible Volume and Wire Resistance. Tests were performed to calculate the running temperature of the Heated Wire Breathing Circuit.

Nonclinical tests submitted to demonstrate substantial equivalence for the Humidification Chambers include Rates of Fill, Chamber Critical Dimensions, Resistance to Flow, Fill Volume, Compliance, Humidity Output, Overflow, Leakage and Tapers.

All materials used in the heated wire breathing circuit and humidification chambers have been evaluated according to tests outlined in ISO 10993-1. The only exception being the tube hanger and tubing clips on the heated wire breathing circuit. These two components are on the outside of the device and do not contact the patient.

No clinical tests have been performed on the Heated Wire Breathing Circuit or the Humidification Chambers.

Conclusions Demonstrating Safety, Effectiveness and Performance:

Intersurgical Incorporated has demonstrated that the proposed devices are safe and effective. They are considered to be substantially equivalent to the currently marketed predicate devices which have been previously reviewed for market clearance by the FDA.

K092129

Premarket Notification [510(k)] Number

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

Intersurgical, Incorporated
C/O Michael Zalewski
RA/QA Specialist
Sleep & Home Respiratory Group
417 Electronics Parkway
Liverpool, New York 13088

MAY 18 2010

Re: K092129
Trade/Device Name: Intersurgical Heated Wire Breathing System and Humidification Chambers
Regulation Number: 21 CFR 868.5270
Regulation Name: Breathing System Heater
Regulatory Class: II
Product Code: BZE, BTT
Dated: May 10, 2010
Received: May 17, 2010

Dear Michael Zalewski:

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

10. INDICATION FOR USE FORM

510(k) Number (if known): K092129

Device Name: 2026 - Heated Wire Breathing System
2026-CH - Heated Wire Breathing System with Auto-Fill Chamber

Indications For Use: Breathing system heaters are defined as a device that is intended to warm breathing gases before they enter a patient's airway.

Prescription Use XX AND/OR Over-The-Counter Use ____
(Per 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,

L Schuttheis

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

510(k) Number: K092129

10. INDICATION FOR USE FORM

510(k) Number (if known): K092129

Device Name: 2310 - Auto-Fill Humidification Chamber
2320 - Manual Fill Humidification Chamber
2330 - Low Volume Manual Fill Humidification Chamber

Indications For Use: Humidification chambers are intended for use to hold water required to humidify the air being delivered to patients.

Prescription Use XX AND/OR Over-The-Counter Use _____
(Per 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

510(k) K092129

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

510(k) Number: K092129