DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 3, 2016

Hamilton Medical AG
Steffen Boden
Quality Engineer/ Regulatory Affairs
Via Crusch 8,
Bonaduz, CH 7402, Grisons
Switzerland

Re: K152029
Trade/Device Name: Hamilton-H900, Hamilton-BC8022, Hamilton-BC4022, Hamilton-BC8010, Hamilton-BC4010
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: Class II
Product Code: BTT, BZE
Dated: March 21, 2016
Received: March 24, 2016

Dear Mr. Boden:

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

INDICATIONS FOR USE STATEMENT

510(k) Number: **K152029**

Device Name: HAMILTON-H900
HAMILTON-BC8022, HAMILTON-BC8010
HAMILTON-BC4022, HAMILTON-BC4010

Intended Use HAMILTON-H900

The HAMILTON-H900 humidifier is intended to add moisture and to warm breathing gases during invasive and non-invasive mechanical ventilation. The intended area of use is the intensive care ward or the recovery room.

The HAMILTON-H900 humidifier is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications for patients > 10 kg.

Intended Use HAMILTON-BC8022

The HAMILTON-BC8022 breathing set is intended to be used together with compatible Hamilton Medical respiratory gas humidifiers during invasive and noninvasive mechanical ventilation of adult and pediatric patients > 10 kg.

Intended Use HAMILTON-BC4022

The HAMILTON-BC4022 breathing set is intended to be used together with compatible Hamilton Medical respiratory gas humidifiers during invasive and noninvasive mechanical ventilation of adult and pediatric patients > 10 kg.

Intended Use HAMILTON-BC8010

The HAMILTON-BC8010 breathing set is intended to be used together with compatible Hamilton Medical respiratory gas humidifiers during invasive and noninvasive mechanical ventilation of infants > 10 kg.

Intended Use HAMILTON-BC4010

The HAMILTON-BC4010 breathing set is intended to be used together with compatible Hamilton Medical respiratory gas humidifiers during invasive and noninvasive mechanical ventilation of infants > 10 kg.

Prescription Use (Part 21 CFR 801 Subpart D)	___X___	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary - K152029

I. Submitter

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Contact person:	Mr. Steffen Boden, Quality Engineer / Regulatory Affairs
Preparation date:	May 03, 2016

II. Device(s)

(Trade) Name of Device(s):	HAMILTON-H900
Common or Usual Name:	Humidifier for Respiratory Gas
Classification Name:	Respiratory gas humidifier (21 CFR § 868.5450)
Regulatory Class:	II
Product Code:	BTT

(Trade) Name of Device(s):	HAMILTON-BC8022, HAMILTON-BC8010 HAMILTON-BC4022, HAMILTON-BC4010
Common or Usual Name:	Heated Breathing Circuit Set, with water chamber
Classification Name:	Breathing system heater (21 CFR § 868.5270)
Regulatory Class:	II
Product Code:	BZE

III. Predicate Device(s)

Predicate Device - for Humidifier

Fisher & Paykel
MR700 / MR720 / MR730 Respiratory Humidifier, **K913368**

Fisher & Paykel
MR850 Respiratory Humidifier, **K983112**

Predicate Devices - for Heated Breathing Circuits

Fisher & Paykel
RT380 and RT385 'Adult Evaqua 2' Dual Heated Breathing Circuits, **K122432**
RT265 and RT266 Dual Heated Infant Breathing Circuits, **K103767**

References Devices - for Heated Breathing Circuits

Plastiflex Healthcare
Hybernite Rainout Control System, **K100104**

IV. Device Description

HAMILTON-H900

The HAMILTON-H900 respiratory gas humidifier is designed to add heat and moisture to respiratory gases, which are then administered to patients who need invasive or noninvasive ventilation. The breathing gas is passed through a humidifier chamber, where the gas is heated and humidified using an external heat source.

The HAMILTON-H900 humidifier uses breathing circuits that are recognized automatically when connected to the humidifier. The humidifier uses two heating systems as heat sources:

- A heating plate that has contact with the metal plate of a special humidifier chamber inserted into the base of the humidifier prior to application, thus heating the water contained inside the chamber.
- The controlled heating within the breathing circuits.

The respiratory gas exiting the humidifier chamber is continuously monitored using temperature sensors that are integrated into the humidifier base. Additionally, a temperature probe inside the breathing tube is used to measure the temperature of the gas delivered to the patient airway.

The design of the breathing tubes offers heating performance over the entire length by providing constant heating of the entire tube wall, from the chamber exit to the patient connection. A float mechanism, together with detection of the water level inside the humidifier chamber and the auto-fill mechanism, keeps a constant water level.

HAMILTON-BC8022 / HAMILTON-BC8010

The HAMILTON-BC8022 and HAMILTON-BC8010 are single-use, dual-limb breathing circuits comprising heated inspiratory and heated expiratory tubes. The humidifier chamber uses a float mechanism to keep a constant water level inside the auto-feed chamber.

HAMILTON-BC4022 / HAMILTON-BC4010

The HAMILTON-BC4022 and HAMILTON-BC4010 are single-use, single-limb breathing circuits comprising a heated inspiratory tube. The humidifier chamber uses a float mechanism to keep a constant water level inside the auto-feed chamber.

V. Indications for Use / Intended Use

Intended Use HAMILTON-H900

The HAMILTON-H900 humidifier is intended to add moisture and to warm breathing gases during invasive and non-invasive mechanical ventilation. The intended area of use is the intensive care ward or the recovery room.

The HAMILTON-H900 humidifier is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications for patients > 10 kg.

Intended Use HAMILTON-BC8022

The HAMILTON-BC8022 breathing set is intended to be used together with compatible Hamilton Medical respiratory gas humidifiers during invasive and noninvasive mechanical ventilation of adult and pediatric patients > 10 kg.

Intended Use HAMILTON-BC4022

The HAMILTON-BC4022 breathing set is intended to be used together with compatible Hamilton Medical respiratory gas humidifiers during invasive and noninvasive mechanical ventilation of adult and pediatric patients > 10 kg.

Intended Use HAMILTON-BC8010

The HAMILTON-BC8010 breathing set is intended to be used together with compatible Hamilton Medical respiratory gas humidifiers during invasive and noninvasive mechanical ventilation of infants > 10 kg.

Intended Use HAMILTON-BC4010

The HAMILTON-BC4010 breathing set is intended to be used together with compatible Hamilton Medical respiratory gas humidifiers during invasive and noninvasive mechanical ventilation of infants > 10 kg.

VI. Comparison of Technological Characteristics with the Predicate Device(s)

The Intended Use statements for the HAMILTON-H900 and HAMILTON-BC-series breathing circuits are substantially equivalent to the predicate devices; the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicates. Both the subject and predicate devices have the same Indications for use for respiratory gas conditioning.

The proposed devices and the predicates were evaluated against selected applicable standards, and the technological characteristics and performance specifications of the HAMILTON-H900 humidifier and the HAMILTON-BC-series breathing circuits are substantially equivalent to those of the predicate devices. The differences do not alter the intended therapeutic use of the devices nor do they affect the safety and effectiveness of the devices relative to the predicates.

Hamilton Medical has demonstrated the HAMILTON-H900 humidifier and the HAMILTON-BC-series breathing circuits to have adequate performance. The HAMILTON-H900 humidifier and HAMILTON-BC-series breathing circuits are considered to be substantially equivalent to currently marketed predicate devices that have been previously cleared by the FDA.

Table 1: Comparison table of humidifier characteristics and specifications

Characteristic used for comparison	HAMILTON-H900	F&P MR730 (Primary predicate device)	F&P MR850 (Secondary predicate device)
510(k) No.	K152029	K913368	K983112
Device Name	HAMILTON-H900 Respiratory Gas Humidifier	MR700 / MR720 / MR730 Respiratory Humidifier	MR850 Respiratory Humidifier
Classification No. & Product code	868.5450 BTT	868.5450 BTT	868.5450 BTT
Indication for Use	The HAMILTON- H900 humidifier is intended to add moisture and to warm breathing gases during invasive and non-invasive mechanical ventilation. The intended area of use is the intensive care ward or the recovery room. The HAMILTON- H900 humidifier is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications for patients > 10 kg.	To warm and add moisture to gases delivered to patients requiring mechanical ventilation or positive pressure breathing assistance via an endotracheal tube or face mask.	The MR850 humidifier is intended to add moisture to, and to warm, the breathing gases for administration to a patient. 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. This may be indicated for patients requiring mechanical ventilation, positive pressure breathing assistance, or general medical gases. These gases may be delivered by face mask or through bypassing the upper airways, for example use of an endotracheal tube.
Environment	Hospital use by trained personnel	Hospital use by trained personnel	Hospital use by trained personnel
Type of ventilation	invasive and noninvasive	invasive and noninvasive	invasive and noninvasive
Modes Of operation	Automatic Mode: - Invasive & Noninvasive Manual Mode: - Invasive & Noninvasive Standby Mode Default mode: - Invasive mode after power on	Manual Mode Standby Mode	Automatic Mode: - Invasive & Noninvasive Manual Mode: - Invasive & Noninvasive Standby Mode Default mode: - Invasive mode after power on
Flow range	Non-invasive - up to 120 L/min Invasive – up to 60 L/min	Up to 80 L/min	Non-invasive - up to 120 L/min Invasive – up to 60 L/min
Maximum operating duration	Continuously	Continuously	Continuously
Accuracy displayed temperature	Displayed Range: 10°C to 60°C - Accuracy Range: 10°C to 60°C (±1°C) - Accuracy Range: 30°C to 41°C (±0.5°C)	Displayed Range: 5.0°C to 80.0 °C Accuracy Range: 25°C to 45°C (± 0.3°C)	Displayed Range: 10°C to 70 °C Accuracy Range: 25°C to 45°C (±0.3°C)
Resolution of displayed temperature	0.1 °C	0.1 °C	0.1 °C
Airway temperature	Invasive mode: 33°C - 43°C Noninvasive mode: 28°C - 38°C	29.5 °C to max 41 °C	Invasive mode: 33°C - 43°C Noninvasive mode: 28°C - 38°C

Characteristic used for comparison	HAMILTON-H900	F&P MR730 (Primary predicate device)	F&P MR850 (Secondary predicate device)
Disabling heater wires	Yes; - expiratory tube is disabled when using Single Limb Circuits - temperature alarm can disable all heating wires	Yes; can be disabled manually - temperature alarm can disable all heating wires	Yes; can be disabled manually - temperature alarm can disable all heating wires
Humidity performance	invasive mode: - humidity of >33 mg H2O/L is reached with a gas flow of up to 60 L/min and an ambient temperature of 26°C noninvasive mode: - humidity of > 10 mg H2O/L with a gas flow of up to 120 L/min and an ambient temperature of 26°C	- humidity of > 33 mg/L with a gas flow of up to 60 L/min	invasive mode: - humidity of > 33 mg/L with a gas flow of up to 60 L/min Noninvasive mode: - humidity of > 10 mg/L with a gas flow of up to 120 L/min
Invasive / noninvasive mode	Invasive / Noninvasive mode - auto mode and - manual mode available	Mode cannot be selected - only manual mode available	Invasive / Noninvasive mode - only auto mode available
Alarm display	Indicators for: - Chamber Temperature - Heater Wire - Humidity Alarm - Patient-end Probe (Y-Piece) - water level (Low / High) - device inclination - tube detection / recognition / connection, - chamber insertion	Amber LED indicators for: - Temperature Probe - Heater Wire - Humidity Alarm - Chamber Probe - Patient-end Probe Red LED indicator for: - See Manual (red LED).	Amber LED indicators for: - Temperature Probe, - Heater Wire - Humidity Alarm - Chamber Probe - Patient-end Probe - Water Out
Maximum power	283 VA (230 V version) / 293 VA (115 V version) / 268 VA (100 V version)	230 V / 1.0 A max 127 V / 1.9 A max 115 V / 2.0 A max 100 V / 2.4 A max	230 V / 1.0 A max 127 V / 1.8 A max 115 V / 2.0 A max 100 V / 2.4 A max
Power heated tube	at 22V 60 W (dual limb) 30 W (single limb)	Internal voltage not specified 60 W	at 22 V 60 W
Power heating plate	150 W ± 5 %	150 W	150 W
Heating plate overheat protector	130°C ± 4°C	118 ± 6 °C	118 ± 6 °C
Max gas input temperature	31°C	29.5°C	31°C
Max water input temperature	37°C	37°C	37°C
Chamber insertion detection	HAMILTON-H900 is able to detect if a chamber is inserted	No chamber detection available	No chamber detection available
Water level detection	High and Low water level can be detected via optical sensors reaching into the water. - Low water level: 5 minutes alarm delay - high water level: immediate alarm	No water level detection available	Only insufficient water in the chamber is detected by measuring the amount of power used to obtain the chamber temperature - Up to 15 minutes to generate an alarm
Breathing circuit recognition	Via electrical connectors inside the breathing tubes	No breathing circuit recognition	Via electrical connectors inside the breathing tubes
Single use / Reuse	Compatible with single use and reusable breathing circuits	Compatible with single use and reusable breathing circuits	Compatible with single use and reusable breathing circuits
Classification	Class I (in accordance with IEC 60601-1)	Class I (in accordance with IEC 60601-1)	Class I (in accordance with IEC 60601-1)
Applied part	Type BF	Type B	Type BF

Characteristic used for comparison	HAMILTON-H900	F&P MR730 (Primary predicate device)	F&P MR850 (Secondary predicate device)
Standards / Performance	- IEC 60601-1 - IEC 60601-1-2 - IEC 60601-1-4 - IEC 60601-1-8 - ISO 8185:2007 - ISO 10993 - MILSTD 461F - ISO 14971 - IEC 62304 - IEC 62366 - ISO 5356-1 - ISO 5367	- CSA-C22.2 No.125 - UL2601 - IEC601-1, AS3200.1 - EN 60601-1	- AS/NZS 3200.1.0 - CAN/CSA-22.2 No.601.1 - UL60601-1 - IEC 60601-1 - EN 60601-1

Table 2: HAMILTON-BC8022 and HAMILTON-BC4022 Comparison table of humidifier breathing circuits characteristics and specifications

Characteristic used for comparison	HAMILTON-BC8022 / HAMILTON-BC4022	Predicate Device: F&P RT380
510(k) No.	K152029	**K122432**
Device name	HAMILTON-BC8022 HAMILTON-BC4022	RT380
Description	HAMILTON-BC8022, breathing circuit set, dual limb, heated with water chamber HAMILTON-BC4022, breathing circuit set, single limb, heated with water chamber	Dual Limb Adult Breathing Circuit Kit with Evaqua 2 Technology
Classification No. & Product code	868.5270, BZE	868.5270, BZE
Intended use	The **HAMILTON-BC8022** breathing set is intended to be used together with compatible Hamilton Medical respiratory gas humidifiers during invasive and noninvasive mechanical ventilation of adult and pediatric patients > 10 kg. The **HAMILTON-BC4022** breathing set is intended to be used together with compatible Hamilton Medical respiratory gas humidifiers during invasive and noninvasive mechanical ventilation of adult and pediatric patients > 10 kg	The RT380 and RT385 'Adult Evaqua 2' dual-heated breathing circuits are intended as conduits of breathing gas for ventilation of adult patients, and to maintain the temperature of humidified inspired gas.
Indications for use	invasive and noninvasive ventilation	Patients requiring respiratory support
Compatibility with other devices	Hamilton Medical compatible humidifier such as HAMILTON-H900	Compatible with 700 series and MR 850 humidifiers (specification sheet)
Environment	during invasive and noninvasive mechanical ventilation, hospital use by trained personnel	Intensive Care environment in conjunction with life support equipment
Target / Patient population	Adult and pediatric patients requiring mechanical ventilation or positive pressure breathing assistance	Adult patients requiring respiratory support.
Compressible volume	1600 ml (BC8022) 1000 ml (BC4022)	1600 ml
maximum chamber operating pressure	20 kPa	8 kPa (specification sheet)
Length	- inspiration 1.95m - expiration 1.95m	- inspiration 1.5m - expiration 1.5m
Inner diameter	19 mm	22 mm
Flow range	4 to 120 L/min - invasive max. 60 L/min - noninvasive max. 120 L/min	- invasive 60 L/min - noninvasive 120 L/min (MR850)
Rated flow	2 cmH2O @ 85 L/min (BC8022) 2 cmH2O @ 125 L/min (BC4022)	40 l/ min, ≤ 0.2 kPa
Flow resistance	**BC8022 (@ 30L/min)** **Inspiration:** 0.3 cmH2O **Expiration:** 0.15 cmH2O **BC4022 (@ 30L/min)** **Inspiration:** 0.2 cmH2O (inkl. chamber)	**RT380 @ 30 L/min** **Inspiration:** 0.91 cmH2O **Expiration:** 0.23 cmH2O

Characteristic used for comparison	HAMILTON-BC8022 / HAMILTON-BC4022	Predicate Device: F&P RT380
Gas leakage	< 50 mL/min @ 60 cmH20 (BC8022) < 25 mL/min @ 60 cmH20 (BC4022)	< 11 mL/min
Compliance	<1 ml/cmH2O/m	2.10 ml/cmH20
Wire resistance	- Inspiration: 15.35 ±1.23 Ω - expiration: 16.45 ±1.23 Ω	- Inspiratory 17.5 Ω - Expiratory 22.6 Ω
Connector	- Interface connections conical according to ISO 5356-1 - Electrical connector part of breathing tube	- Interface connections conical according to ISO 5356-1 - Electrical connector part of breathing tube
Breathing circuit recognition	Tubes can be recognized with a Hamilton Medical Humidifier	No tube recognition
Sterility	Non Sterile, Ready for use	Non Sterile, Ready for use
Single use / Reuse	Single Use	Single Use
Power heated tube	- 31.53W inspiratory tube @100% power (BC8022/BC4022) - 29.39W expiratory tube @100% power (BC8022)	- 27.66W inspiratory tube @100% power - 21.42W expiratory tube @100% power
Standards / Performance	- IEC 60601-1 - IEC 60601-1-2 - IEC 60601-1-8 - ISO 8185 - ISO 10993 - IEC 62304 - IEC 62366 - ISO 5356-1 - ISO 5367	- ISO 5367 - ISO 5356 - ISO 8185 - IEC 60601-1 - ISO 10993

Table 3: HAMILTON-BC8010 and HAMILTON-BC4010 comparison table of humidifier breathing circuits characteristics and specifications

Characteristic used for comparison	HAMILTON-BC8010 / HAMILTON-BC4010	Predicate Device: F&P RT265
510(k) No.	K152029	**K103767**
Device name	HAMILTON-BC8010 HAMILTON-BC4010	RT265
Description	HAMILTON-BC8010, breathing circuit set, dual limb, heated with water chamber HAMILTON-BC4010, breathing circuit set, single limb, heated, with water chamber	Dual Limb Infant Breathing Circuit Kit with Evaqua 2 Technology and Pressure Line (/Flow > 4L/min)
Classification No. & Product code	868.5270, BZE	868.5270, BZE
Intended use	The **HAMILTON-BC8010** breathing set is intended to be used together with compatible Hamilton Medical respiratory gas humidifiers during invasive and noninvasive mechanical ventilation of infants > 10 kg. The **HAMILTON-BC4010** breathing set is intended to be used together with compatible Hamilton Medical respiratory gas humidifiers during invasive and noninvasive mechanical ventilation of infants > 10 kg.	The dual-heated breathing circuits are intended as conduits of breathing gas for ventilation of infant patients, and to maintain the temperature of humidified inspired gas. The RT265 is used for flow rates greater than 4 L/min, and the RT266 is for flow rates between 0.3 and 4 L/min.
Indications for use	invasive and noninvasive ventilation	facemask or through bypassing the upper airways
Compatibility with other devices	Hamilton Medical compatible humidifier such as HAMILTON-H900	Compatible with MR 850 humidifiers, not compatible with MR810 humidifiers
Where used	during invasive and noninvasive mechanical ventilation, hospital use by trained personnel	Intensive Care environment in conjunction with life support equipment
Target / Patient population	Infants > 10 kg requiring mechanical ventilation or positive pressure breathing assistance	Infant
Compressible volume	800 ml (BC8010) 600 ml (BC4010)	760 ml
Maximum chamber operating pressure	20 kPa	8 kPa

Characteristic used for comparison	HAMILTON-BC8010 / HAMILTON-BC4010	Predicate Device: F&P RT265
Length	- Inspiration total length: 1.65 m (heated section 1.3m, unheated section 0.35m) - Expiration: 1.65m	- Inspiration total length: 1.5 m (heated section 1.1m , unheated section 0.4m) - Expiration: 1.5m (IFU)
Inner diameter	12 mm	11.0mm
Flow Range	1 to 30 L/min	For flow rates > 4 L/min
Rated flow	2 cmH2O @ 16 L/min (BC8010) 2 cmH2O @ 29 L/min (BC4010)	2 cmH2O @ 13 L/min
Flow resistance	**BC8010 (@ 15 L/min)** **Inspiration:** 1.0 cmH2O **Expiration:** 0.8 cmH2O **BC8010 (@ 2.5 L/min)** **Inspiration** 0.05 cmH2O **Expiration** 0.04 cmH2O **BC4010 (@ 15 L/min)** Inspiration 0.75 cmH2O **BC4010 (@ 2.5 L/min)** Inspiration 0.05 cmH2O	**RT265 @ 15 L/min** **Inspiration** 2.42 cmH2O **Expiration** 1.32 cmH2O **RT265 @ 2.5 L/min** **Inspiration** 0.11 cmH2O **Expiration** 0.08 cmH2O
Gas leakage	- 15 mL/min (BC8010) - 4.0 mL/min (BC4010)	< 75 mL/min @ 60 cmH20
Compliance	< 1 ml/cmH2O/m	0.81 mL/cmH20
Wire resistance	- inspiration 14.6±0.9Ω - expiration: 18.2±1.2Ω	- inspiration 21.3±0.3Ω - expiration: 21.9±0.3Ω
Connector	- Interface connections conical according to ISO 5356-1 - electrical connector part of breathing tube	- Interface connections conical according to ISO 5356-1 - electrical connector part of breathing tube
Breathing circuit recognition	Tubes can be recognized with a Hamilton Medical Humidifier	No tube recognition
Sterility	Non Sterile, Ready for use	Non Sterile, Ready for use
Single Use / Reuse	Single Use	Single Use
Power heated tube	- 33.15W inspiratory tube @100% power (BC8010/BC4010) - 26.59W expiratory tube @100% power (BC8010)	- 22.72W inspiratory tube @100% power - 22.10W expiratory tube @100% power
Standards / Performance	- IEC 60601-1 - IEC 60601-1-2 - IEC 60601-1-8 - ISO 8185 - ISO 10993 - IEC 62304 - IEC 62366 - ISO 5356-1 - ISO 5367	- ISO 5367 - ISO 5356 - ISO 8185 - IEC 60601-1 - ISO 10993

VII. Performance data

The following performance and nonclinical data were provided in support of the substantial equivalence determination.

Electrical Safety and Electromagnetic Compatibility

Electrical safety and EMC testing were conducted on the HAMILTON-H900 and HAMILTON-BC-series breathing circuits. The devices comply with the IEC 60601-1 standard for safety, the IEC 60601-1-2 standard for EMC, and the ISO 8185 standard for respiratory gas humidifiers.

Mechanical Testing

Mechanical safety testing was conducted on the HAMILTON-H900. The system complies with the IEC 60601-1 standard for safety. Additional mechanical tests were conducted on the HAMILTON-BC-series breathing circuits. The breathing circuits comply with the ISO 5367 standard for breathing tubes intended for use with anaesthetic apparatus and ventilators, and the ISO 5356-1 standard for conical connectors.

Software Verification and Validation Testing

Software verification and validation testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

The results of the software verification and validation testing demonstrate that all specified requirements have been implemented correctly and completely.

Biocompatibility

Biocompatibility testing and evaluation was performed on relevant parts of the breathing circuit. The evaluation was performed in accordance with ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process", and the FDA guidance document "Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, 2013." The battery of tests included the following tests:

- Cytotoxicity
- Sensitization & Irritation
- Systemic Toxicity
- Genotoxicity Testing
- Implantation Testing
- Extractables and Leachables

Additional Testing

A Human Factors / Usability Study was conducted and the HAMILTON-H900 humidifier was found to be in conformance with the Guidance for Industry and FDA Staff "Applying Human Factors and Usability Engineering to Medical Devices, 2016". Additional testing on the HAMILTON-H900 device was conducted according to IEC 60601-1-8, IEC 62366, IEC 60601-1-6, and IEC 62304 standards. The test results show that the device performs adequately for its intended use.

Summary

Based on the nonclinical performance as documented, the HAMILTON-H900 and the HAMILTON-BC breathing circuits were found to have an adequate performance profile that is similar to the predicate devices.

VIII. Conclusion

In comparison to the predicates, the HAMILTON-H900 and the HAMILTON-BC breathing circuits are substantially equivalent to the predicates based on patient population, intended uses, comparison of the technological characteristics and performance. The hardware and software verification and validation support a determination of substantial equivalence. In addition, the conclusions drawn from the nonclinical tests demonstrate that the devices are substantially equivalent to the predicate devices.