DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 20, 2017

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

Re: K163283
Trade/Device Name: Hamilton-H900, Hamilton-BC8010, Hamilton-BC4010
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: Class II
Product Code: BTT, BZE
Dated: August 17, 2017
Received: August 21, 2017

Dear Steffen 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,

Tara A. Ryan -S

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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)*

K163283

Device Name

HAMILTON-H900

HAMILTON-BC8010; HAMILTON-BC4010

Indications for Use *(Describe)*

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.

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 pediatric and neonatal patients.

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 pediatric and neonatal patients.

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.

510(k) Summary - K163283

I. Submitter

Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

Establishment registration number:	3001421318
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Contact person:	Mr. Steffen Boden, Quality Engineer / Regulatory Affairs
Preparation date:	September 18, 2017

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-BC8010** **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

Hamilton Medical AG
HAMILTON-H900, respiratory gas humidifier, **K152029**

Predicate Devices for Heated Breathing Circuits

Hamilton Medical AG
HAMILTON-BC8010 and HAMILTON-BC4010 heated breathing circuits, **K152029**

References Devices

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

Fisher & Paykel
RT265 and RT266 Dual Heated Infant Breathing Circuits, **K103767**

CareFusion Inc.
AirLife Infant Single Limb Heated Wire Circuit, **K151959**

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-BC8010

The HAMILTON-BC8010 is a single-use, dual-limb breathing circuit 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-BC4010

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

HAMILTON-HC322/HC310

The HAMILTON-HC322/HC310 are single-use humidifier chambers with a float mechanism to keep a constant water level inside the auto-feed chamber. The HAMILTON-HC322 humidifier chamber is part of the HAMILTON-BC8022/BC4022 breathing sets and the HAMILTON-HC310 humidifier chamber is part of the HAMILTON-BC8010/BC4010 breathing sets, as cleared in K152029.

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.

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 pediatric and neonatal patients.

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 pediatric and neonatal patients.

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, including humidifier chambers 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 (Predicate device)	HAMILTON-H900 (Subject device)
510(k) No.	K152029	K163283
Device Name	HAMILTON-H900 Respiratory Gas Humidifier	HAMILTON-H900 Respiratory Gas Humidifier
Classification No. & Product code	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.	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.
Patient Population	Patients > 10 kg	Adult, pediatric and neonatal patients
Environment	Hospital use by trained personnel	Hospital use by trained personnel
Type of ventilation	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	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	Non-invasive - up to 120 L/min Invasive – up to 60 L/min
Maximum operating duration	Continuously	Continuously
Accuracy displayed temperature	Displayed Range: 10°C to 60°C Chamber exit: - 10°C to 60°C ± 1°C - 30°C to 41°C ± 0.5°C Y-piece: - 28°C to 43°C ± 0.5°C	Displayed Range: 10°C to 60°C Chamber exit: - 10°C to 60°C ± 1°C - 30°C to 41°C ± 0.5°C Y-piece: - 28°C to 43°C ± 0.5°C
Resolution of displayed temperature	0.1 °C	0.1 °C
Temperature Control Setting: Airway	Airway Temperature Setting: - invasive: 33°C to 42°C - noninvasive: 28°C to 38°C - in steps of 0.5 °C (manually)	Airway Temperature Setting: - invasive: 33°C to 42°C - noninvasive: 28°C to 38°C - in steps of 0.5 °C (manually)
Temperature Control Setting: Chamber	Chamber outlet temperature - invasive: 35°C - 41°C - Noninvasive: 30°C - 35°C - in steps of 0.5°C (manually)	Chamber outlet temperature - invasive: 35°C - 41°C - Noninvasive: 30°C - 35°C - in steps of 0.5°C (manually)
Disabling heater wires	Yes; - expiratory tube is disabled when using Single Limb Circuits - temperature alarm can disable all heating wires	Yes; - expiratory tube is disabled when using Single Limb Circuits - temperature alarm can disable all heating wires

Characteristic used for comparison	HAMILTON-H900 (Predicate device)	HAMILTON-H900 (Subject device)
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	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
Invasive / noninvasive mode	Invasive / Noninvasive mode - auto mode and - manual mode available	Invasive / Noninvasive mode - auto mode and - manual 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	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
Maximum power	283 VA (230 V version) / 293 VA (115 V version) / 268 VA (100 V version)	283 VA (230 V version) / 293 VA (115 V version) / 268 VA (100 V version)
Power heated tube	at 22V 60 W (dual limb) 30 W (single limb)	at 22V 60 W (dual limb) 30 W (single limb)
Power heating plate	150 W ± 5 %	150 W ± 5 %
Heating plate overheat protector	130°C ± 4°C	130°C ± 4°C
Chamber insertion detection	HAMILTON-H900 is able to detect if a chamber is inserted	HAMILTON-H900 is able to detect if a chamber is inserted
Water level detection	High and Low water level can be detected via optical sensors reaching into the water.	High and Low water level can be detected via optical sensors reaching into the water.
Breathing circuit recognition	Via electrical connectors inside the breathing tubes	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
Classification	Class I (in accordance with IEC 60601-1)	Class I (in accordance with IEC 60601-1)
Applied part	Type BF	Type BF
Standards / Performance	- IEC 60601-1:2012 - IEC 60601-1-2:2007 - IEC 60601-1-8:2005+Amd1: 2012 - ISO 8185:2007 - MIL-STD-461F:2007 - IEC 62304:2006 - IEC 62366:2007+Amd1:2014	- IEC 60601-1:2012 - IEC 60601-1-2:2007 - IEC 60601-1-8:2005+Amd1: 2012 - ISO 8185:2007 - MIL-STD-461F:2007 - IEC 62304:2006 - IEC 62366:2007+Amd1:2014

Table 2: HAMILTON-BC8010 and HAMILTON-BC4010 comparison table of humidifier breathing circuits characteristics and specifications

Characteristic used for comparison	HAMILTON-BC8010 / HAMILTON-BC4010 (Predicate devices)	HAMILTON-BC8010 / HAMILTON-BC4010 (Subject devices)
510(k) No.	K152029	K163283
Device name	HAMILTON-BC8010 HAMILTON-BC4010	HAMILTON-BC8010 HAMILTON-BC4010
Description	HAMILTON-BC8010, breathing circuit set, dual limb, heated with water chamber HAMILTON-BC4010, breathing circuit set, single limb, heated, with water chamber	HAMILTON-BC8010, breathing circuit set, dual limb, heated with water chamber HAMILTON-BC4010, breathing circuit set, single limb, heated, with water chamber
Classification No. & Product code	868.5270, BZE	868.5270, BZE

Characteristic used for comparison	HAMILTON-BC8010 / HAMILTON-BC4010 (Predicate devices)	HAMILTON-BC8010 / HAMILTON-BC4010 (Subject devices)
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 HAMILTON-BC8010 breathing set is intended to be used together with compatible Hamilton Medical respiratory gas humidifiers during invasive and noninvasive mechanical ventilation of pediatric and neonatal patients. 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 pediatric and neonatal patients.
Patient Population	infants > 10 kg	pediatric and neonatal patients
Environment	Hospital use by trained personnel	Hospital use by trained personnel
Indications for use	invasive and noninvasive ventilation	invasive and noninvasive ventilation
Compatibility with other devices	Hamilton Medical compatible humidifier such as HAMILTON-H900	Hamilton Medical compatible humidifier such as HAMILTON-H900
Where used	during invasive and noninvasive mechanical ventilation, hospital use by trained personnel	during invasive and noninvasive mechanical ventilation, hospital use by trained personnel
Target / Patient population	infants > 10 kg requiring mechanical ventilation or positive pressure breathing assistance	pediatric and neonatal patients requiring mechanical ventilation or positive pressure breathing assistance
Compressible volume	800 ml (BC8010) 600 ml (BC4010)	800 ml (BC8010) 600 ml (BC4010)
Maximum chamber operating pressure	20 kPa	20 kPa
Length	- Inspiration total length: 1.65 m (heated section 1.3m, unheated section 0.35m) - Expiration: 1.65m	- Inspiration total length: 1.65 m (heated section 1.3m, unheated section 0.35m) - Expiration: 1.65m
Inner diameter	12 mm	12 mm
Flow Range	1 to 30 L/min	1 to 30 L/min
Flow resistance (at 2.5 l/min	Inspiration: 0.03 cmH2O/(l/min) Expiration: 0.02 cmH2O/(l/min)	Inspiration: 0.03 cmH2O/(l/min) Expiration: 0.02 cmH2O/(l/min)
Flow resistance (at 15 l/min)	Inspiration: 0.06 cmH2O/(l/min) Expiration: 0.04 cmH2O/(l/min	Inspiration: 0.06 cmH2O/(l/min) Expiration: 0.04 cmH2O/(l/min)
Gas leakage	- 15 mL/min (BC8010) - 4.0 mL/min (BC4010)	- 15 mL/min (BC8010) - 4.0 mL/min (BC4010)
Compliance	< 1 ml/cmH2O/m	< 1 ml/cmH2O/m
Wire resistance	- inspiration 14.6±0.9Ω - expiration: 18.2±1.2Ω	- inspiration 14.6±0.9Ω - expiration: 18.2±1.2Ω
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	Tubes can be recognized with a Hamilton Medical Humidifier
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)	- 33.15W inspiratory tube @100% power (BC8010/BC4010) - 26.59W expiratory tube @100% power (BC8010)
Standards / Performance	- IEC 60601-1:2012 - IEC 60601-1-2:2007 - ISO 8185:2007 - ISO 10993-3:2014 - ISO 10993-5:2009 - ISO 10993-6:2007 - ISO 10993-10:2010 - ISO 10993-11:2006 - ISO 10993-17:2002 - ISO 5356-1:2004 - ISO 5367:2014	- IEC 60601-1:2012 - IEC 60601-1-2:2007 - ISO 8185:2007 - ISO 10993-3:2014 - ISO 10993-5:2009 - ISO 10993-6:2007 - ISO 10993-10:2010 - ISO 10993-11:2006 - ISO 10993-17:2002 - ISO 5356-1:2004 - ISO 5367:2014

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 60601-1:2012 standard for safety, the IEC 60601-1-2:2007 standard for EMC, and the ISO 8185:2007 standard for respiratory gas humidifiers.

Mechanical Testing

Mechanical safety testing was conducted on the HAMILTON-H900. The system complies with the IEC 60601-1:2012 standard for safety. Additional mechanical tests were conducted on the HAMILTON-BC-series breathing circuits. The breathing circuits comply with the ISO 5367:2014 standard for breathing tubes intended for use with anaesthetic apparatus and ventilators, and the ISO 5356-1:2004 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 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 60601-1-8:2012, IEC 62366:2014, IEC 60601-1-6:2013, and IEC 62304:2006 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 including humidifier chambers 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.