DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

August 25, 2016

CareFusion 2200, Inc.
Erika Fernandez
Regulatory Affairs Manager
75 N. Fairway Dr.
Vernon Hills, Illinois 60061

Re: K160764
Trade/Device Name: AirLife Autofill Humidification Chamber
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: July 25, 2016
Received: July 26, 2016

Dear Erika Fernandez:

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

Tina Kiang, Ph.D.
Acting Division 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)*

K160764

Device Name
AirLife Autofill Humidification Chamber

Indications for Use *(Describe)*

The AirLife Autofill Humidification Chamber is intended to hold water required to humidify breathing gases delivered to any patient using a heated humidifier. The product is single use device, non-sterile and used in professional healthcare environments under a doctor's supervision and by skilled clinician. The AirLife Autofill Humidification Chamber is compatible with the Fisher and Paykel MR850 system.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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75 N. Fairway Dr.
Vernon Hills, IL 60061
Phone: 847 362-8097
Fax: 312 949-0731
carefusion.com

Summary of Safety and Effectiveness

510k summary complying with 21 CFR 807.92.

1. SUBMITTER

CareFusion 2200, Inc.
75 N Fairway Drive, Vernon Hill, IL 60061
Phone: 847-362-8097
Fax: 312 949-0731
Contact Person: Erika Fernandez
Date Prepared: August 24th , 2016

2. Device

Product Name:	AirLife Autofill Humidification Chamber
Device Name:	Humidifier Chamber
Common Name:	Humidifier Chamber
Classification Name:	Humidifier, Respiratory Gas (21 CFR 868.5450)
Regulatory Class:	II
Product Code:	BTT

3. Predicate Device

This submission demonstrates substantial equivalence to the MR290 Humidification Chamber, K934140 cleared on January 24, 1994. This predicate device has not been subject to a design-related recall.

4. Device Description

The AirLife Autofill Humidification Chamber is intended to hold water required to humidify breathing gases delivered to patients.

5. Indication for use

The AirLife Auto Fill Humidification Chamber is intended to hold water required to humidify breathing gases delivered to any patient using a heated humidifier. The product is single use device, non-sterile and used in professional healthcare environments under a doctor's supervision and by skilled clinician. The AirLife Auto Fill Humidification Chamber is compatible with Fisher and Paykel MR850 system.

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Vernon Hills, IL 60061
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Fax: 312 949-0731
carefusion.com

6. Comparison of technological characteristics with the predicate device

The fundamental scientific technology is the same for both the proposed and predicate device. The AirLife Humidification Chamber is substantially equivalent to the predicate device, MR290 Humidification Chamber, regarding safety, effectiveness, design (technology), materials and intended use.

Element of comparison	Proposed Device	Predicate Device
Indications for Use	The AirLife Autofill Humidification Chamber is intended to hold water required to humidify breathing gases delivered to any patient using a heated humidifier. The product is a single use device, non-sterile and used in professional healthcare environments under a doctor's supervision and by skilled clinicians.	The MR290 Humidification Chamber is intended to hold water required to humidify the air being delivered to patients. The MR290 is an auto-fill humidification chamber suitable for all patients and compatible with all F&P MR-series humidifiers
Principal of Operation	The humidification chamber works with a respiratory humidifier (also called a "heater base") that provides the heat source, temperature control system, and alarm system to heat and humidity respiratory gases.	The humidification chamber works with a respiratory humidifier (also called a "heater base") that provides the heat source, temperature control systems, and alarm systems to heat and humidifies respiratory gases.
Characteristics		
Connection	22 mm ISO conical connections for breathing circuit attachment Flexible tubing bonded to close piercing device (spike) and chamber inlet for supplying water	22 mm ISO conical connections for breathing circuit attachment Flexible tubing bonded to close piercing device (spike) and chamber inlet for supplying water
Design	Maximum and minimum waterline marks for visual confirmation of proper water levels	Maximum water line mark for visual confirmation of proper water levels
	Independent primary and secondary floats to regulate water level and to prevent overfill condition if the primary float fails.	Independent primary and secondary floats to regulate water level and prevent overfill condition if the primary float fails open.
	Clear Housing to allow visibility of water level for monitoring	Clear Housing to allow visibility of water level for monitoring
Humidity Output	Invasive mode: 39.0 mg/L Non Invasive mode: 24.3 mg/L	Invasive mode: 39.2 mg/L Non Invasive mode: 24.6 mg/L
Maximum Operating pressure	13.2kPa	13.2kPa

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carefusion.com

Element of comparison	Proposed Device	Predicate Device
Maximum Continuous Gas Flow Rate	Maximum continuous gas flow rate of 60 LPM in invasive mode and 120 LPM in non-Invasive mode	Maximum continuous gas flow rate of 60 LPM in invasive mode and 120 LPM in non-Invasive mode
Compliance	6.23 mL/kPa	5.54 mL/kPa
Resistance to Flow @60L/min	0.40 cmH_2O	0.50 cmH_2O
Enthalpy Maximum Value **Enthalpy Averaged Value**	156 kJ/kg Max. 117 kJ/kg Avg.	151 kJ/kg Max. 120 kJ/kg Avg.
Compressible volume	245 mL	255 mL
Material	Uses Noryl for float frame	Uses Polycarbonate for float frame
Gas leakage	<30mL/min	<100 mL/min
Duration for Use	14 days	14 days
Shelf life	24 months	Not Published
Compatibility (1)	Compatible with flexible and rigid inhalation water containers (water feed set contains air vent provision for rigid containers)	Compatible with flexible and rigid inhalation water containers (water feed set contains air vent provision for rigid containers)
Compatibility (2)	Compatible with Fisher and Paykel MR850 Humidifiers	Compatible with Fisher and Paykel MR series Humidifiers

7. Performance Data

The proposed device was tested to ensure compliance to the following standards:

Biocompatibility

Tests for an externally communicating, tissue by way of gas path and direct mucosal contact with prolonged contact (greater than 24 hours but less than 30 days): Cytotoxicity, Sensitization, Irritation, Muscle Implantation, Genotoxicity and Extractables/Leachables

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carefusion.com

Standards

Performance Characteristic	Standard
Biological Evaluation of Medical Devices--Part 1: Evaluation and Testing	AAMI/ANSI/ISO 10993-1:2009
Biological Evaluation of Medical Devices-Part 5: Tests for In Vitro Cytotoxicity	AAMI/ANSI/ISO 10993-5:2009 (R2014)
Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization.	AAMI/ANSI/ISO 10993-10:2010 (R2014)
Biological Evaluation of Medical Devices Part 12: Sample Preparation and Reference Materials	AAMI/ANSI/ISO 10993-12:2012
Biological Evaluation of Medical Devices Part 17: Establishment of allowable limits for leachable substances	AAMI/ANSI/ISO 10993-17:2002
Biological Evaluation of Medical Devices Part 18: Chemical characterization of materials	AAMI/ANSI/ISO 10993-18:2005

Performance

The following tests were performed for the proposed device to support the substantial equivalence decision.

Performance Characteristic	Relevant Standard
Humidity Output Invasive	BS EN ISO 8185:2009
Humidity Output Non-Invasive	
Specific Enthalpy	BS EN ISO 8185:2009
Hazardous Output	BS EN ISO 8185:2009

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Fax: 312 949-0731
carefusion.com

Performance Characteristic	Relevant Standard
Resistance to Flow	BS EN ISO 5367:2014
Maximum Peak Flow	BS EN ISO 8185:2014
Leakage & Maximum Operating Pressure	BS EN ISO 8185:2009 BS EN ISO 5367:2014
Liquid Overflow	BS EN ISO 8185:2009
Compliance	BS EN ISO 8185:2009 BS EN ISO 5367:2014
Compressible Volume	N/A
Accessible Surface Temperature	BS EN ISO 8185:2009 IEC 60601-1:2005
Steady State Noise	BS EN ISO 8185:2009 IEC 60601-1:2005
Shelf Life/Accelerated Aging	N/A
End-use Simulation/Duration of Use	N/A

8. Conclusion

Test results demonstrate that the proposed device is as safe and effective as the predicate device, and therefore, is substantially equivalent to the predicate device.