5 510(k) Summary

K122432

DEC 0 6 2012

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Contact person	Robert Petry
Date prepared	06 August 2012
Trade name	RT380 and RT385 'Adult Evaqua 2' Dual Heated Breathing Circuits [1]
Common name	Heated Breathing Circuit
Classification name	Breathing System Heater Class II (21 CFR § 868.5270), product code BZE
Predicate device	K103767 Fisher & Paykel Healthcare RT265 and RT266 Dual Heated Infant Breathing Circuit [2]

[1] Referred to throughout this document as RT380/RT385

[2] Referred to throughout this document as RT265/RT266

5.1 Description

The RT380/RT385 'Adult Evaqua 2' dual heated breathing circuits are classified as 'Breathing System Heater' according to 21 CFR §868.5270.

The RT380/RT385 breathing circuits form part of a 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 limbs minimise the formation of condensate.

5.2 Intended use

The RT380/RT385 'Adult Evaqua 2' dual-heated breathing circuits are intended to deliver humidified breathing gases for administration to an adult patient. The RT385 differs only from the RT380 in that the RT385 is supplied with a ventilator pressure line and connector port. 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. Thus humidified gases via a heated breathing circuit may be indicated for patients requiring mechanical ventilation, positive pressure breathing assistance, or general medical gases. These gases may be delivered by facemask or through bypassing the upper airways via an endotracheal tube.

5.3 Indications for use

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.

5.4 Technological characteristics comparison

The new adult breathing circuits (RT380/RT385) have been developed based on the cleared RT265/RT266 infant breathing circuit device. The RT380/RT385 are dual-heated adult breathing circuits that, like the predicate device (RT265/RT266), utilize corrugated polymer tubing, with a heater wire in both the inspiratory and expiratory limb.

The intended use of the RT380/RT385 is the same as that of the predicate device, differing only in the population indicated.

The RT380 and RT385 have a water vapor permeable expiratory limb. Permeability allows water vapor to pass into the environment, minimizing the amount of condensate that might form within the expiratory limb and also minimizing the amount of humidity delivered to a ventilator.

The inspiratory and expiratory limbs of the RT380/RT385 are made using a foaming technique that creates tiny air bubbles in the tube wall. In the case of the inspiratory limb the air bubbles improve the limb thermal insulation properties and thus reduce condensate formation. In the case of the expiratory limb, the air bubbles allow a thick tube wall for robustness against physical damage without compromising the water vapor permeability.

The RT380 and RT385 use the same expiratory limb technology and construction ('Evaqua 2') as the RT265/RT266 expiratory limb, but in an adult sized circuit.

Duration of use for the RT380/RT385 has been verified and labeled for 14 days continuous use, compared with 7 days for the predicate device.

Both the RT380/RT385 and the RT265/RT266 predicate device have been verified and labeled for a shelf life of 5 years.

5.5 Non-clinical tests

Verification tests were performed to establish the safety and efficacy of the RT380 and RT385. These included condensate performance, humidity performance, pneumatic testing, single fault conditions, patient leakage current, enthalpy, connector strength, duration of use testing, shelf life verification and biocompatibility. Testing was performed to the same standards as used for the predicate device.

5.6 Conclusion

The RT380 and RT385 are considered to be substantially equivalent to the RT265/RT266 breathing circuit. The comparison of features, performance, materials and intended use demonstrate that the RT380 and RT385 'Adult Evaqua 2' dual-heated breathing circuits are safe and effective for their intended purpose.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 6, 2012

Mr. Robert Petry
Regulatory Affairs Specialist
Fisher & Paykel Healthcare Limited
15 Maurice Paykel Place, East Tamaki
Auckland, New Zealand 2013

Re: K122432
Trade/Device Name: RT380 and RT385 'Adult Evaqua 2' Dual Heated Breathing Circuits
Regulation Number: 21 CFR 868.5270
Regulation Name: Breathing System Heater
Regulatory Class: II
Product Code: BZE
Dated: November 5, 2012
Received: November 6, 2012

Dear Mr. Petry:

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,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number K122432

Device Name Fisher & Paykel Healthcare
RT380 and RT385 'Adult Evaqua 2' Dual Heated Breathing Circuits

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.

Prescription Use ✓
(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)

Albert E. Moyal

Digitally signed by Albert E. Moyal
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Albert E. Moyal, 0.9.2342.19200300.100.1.1=1300059331
Date: 2012.12.06 08:29:26 -05'00'

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

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