APR 1 6 2012

5 510(k) Summary K103767

Fisher & Paykel Healthcare Limited
15 Maurice Paykel Place, East Tamaki
P O Box 14 348, Panmure
Telephone: +64 9 574 0100
Facsimile: +64 9 574 0158
Website: www.fphcare.com

Contact person	Stéphanie Elvin
Date prepared	21 December 2010
Trade name	RT265 and RT266 Dual Heated Infant Breathing Circuits [1]
Common name	Heated Breathing Circuit
Classification name	Breathing System Heater Class II (21 CFR § 868.5270), product code BZE
Predicate device	K034026 Fisher & Paykel Healthcare RT235 and RT236 Dual Heated Neonatal Breathing Circuits [2]

1 Referred to throughout this document as RT265 and RT266

2 Referred to throughout this document as RT235 and RT236

5.1 Description

The RT265 and RT266 dual heated infant breathing circuits are classified as 'Breathing System Heater' according to 21 CFR §868.5270.

Infant 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 minimise the formation of condensate.

5.2 Intended use

The RT265 and RT266 infant breathing circuits are intended to deliver humidified breathing gases for administration to an infant 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. Thus humidifies gases via 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, for example use of an endotracheal tube.

5.3 Indications for use

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.

5.4 Technological characteristics comparison

The RT265 and RT266 are dual-heated breathing circuits, unchanged from the predicate devices (RT235 and RT236). This means that there is a heater wire in both the inspiratory and expiratory limb.

The inspiratory limb is identical in all aspects to that of the predicate device. The expiratory limb is of a different design to that of the predicate, reflecting the change in material.

The intended use of the RT265 and RT266 is the same as the predicate devices.

5.5 Non-clinical tests

Comparative performance testing of the RT265 and RT266 with the predicate breathing circuits RT235 and RT236, such as pneumatic testing, single fault and fire prevention, patient leakage current, performance and duration of use testing were performed. Testing showed that the relevant features of each predicate are substantially equivalent.

5.6 Conclusion

The RT265 and RT266 are substantially equivalent to the RT235 and RT236 breathing circuits. The comparison of features, performance, materials and intended use demonstrate that the RT265 and RT266 are at least as 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 Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Robert Petry
Fisher & Paykel Healthcare Limited
15 Maurice Paykel Place
PO Box 14648
Auckland, New Zealand 1071

APR 16 2012

Re: K103767
Trade/Device Name: RT265 and RT266 Dual Heated Infant Breathing Circuits
Regulation Number: 21 CFR 868.5270
Regulation Name: Breathing system heater.
Regulatory Class: II
Product Code: BZE
Dated: April 10, 2012
Received: April 11, 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,

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

4 Indications for Use Statement

510(k) Number

Device Name Fisher & Paykel Healthcare RT265 and RT266 Dual Heated Infant Breathing Circuits

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

L Schultz

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

510(k) Number: K103767