1/12/05
K034026

Fisher & Paykel HEALTHCARE

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1.3 Summary of safety and effectiveness

Contact person	Adele Bindon
Date prepared	22 December 2003
Trade name	RT138 Dual Heated Neonatal Breathing Circuit RT141 Dual Heated Neonatal Breathing Circuit
Common name	Heated Breathing Circuit
Classification name	Breathing System Heater (21 CFR 868.5270)
Predicate device	RT130 Neonatal Breathing Circuit K020332 RT131 Neonatal Breathing Circuit K020332

Description of device:

The RT138 and RT141 dual heated neonatal 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 minimises the formation of condensate.

The RT138 is for gas flows of 0.3 – 4 L/min and the RT141 is for gas flows greater than 4 L/min.

Intended use:

The RT138 and RT141 neonatal 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.

This 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.

Technological characteristics summary:

The RT138 and RT141 are dual-heated breathing circuits, compared to the predicate devices (RT130 and RT131) which are single-heated breathing circuits. 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 has different performance characteristics to that of the predicate, reflecting the addition of a heater wire.

The intended use of the RT138 and RT141 is the same as the predicate devices.

Summary of testing:

The following testing has been performed on the RT138 and RT141:

- Materials

All materials used in the RT138 and RT141 have either been evaluated according to tests outlined in ISO 10993-1; or have been previously used in a predicate device; or a justification for minimal testing has been provided

- Inspiratory and expiratory limb performance
- Electrical and thermal safety

Conclusions demonstrating safety, effectiveness and performance:

The testing carried out for the RT138 and RT141 indicates that it meets design and performance functional requirements.

This information indicates that the RT138 and RT141 are equivalent to or better than the predicate devices in terms of safety, effectiveness and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2005

Ms. Adele Bindon
Regulatory Affairs Engineer
Fisher & Paykel Healthcare, Limited
15 Maurice Paykel Place, East Tamaki
PO Box 14 348, Panmure
Auckland, New Zealand

Re: K034026
Trade/Device Name: RT236 and RT235 Dual Heated Neonatal Breathing Circuits
Regulation Number: 868.5270
Regulation Name: Breathing System Heater
Regulatory Class: II
Product Code: BZE
Dated: December 23, 2004
Received: December 28, 2004

Dear Ms. Bindon:

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.

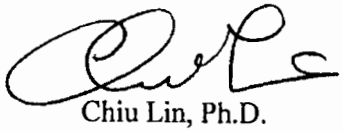
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.2 Indications for use statement

510(k) Number K034026

Device Name Respiratory Humidifier

The dual-heated breathing circuits are intended as conduits of breathing gas for ventilation of patients, and to maintain the temperature of humidified inspired gas. The RT236 is used for flow rates between 0.3 and 4 L/min, and the RT235 is for flow rates greater than 4 L/min, for infant patients.

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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