

K100011

Fisher & Paykel

HEALTHCARE

510(k) Summary

510(k) Owner: Fisher & Paykel Healthcare Ltd

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East Tamaki
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New Zealand.

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Establishment Registration Number: 9611451

Owner/Operator Number: 8040217

Contact Person: Robert Petry,
Regulatory Affairs Manager – Neonatal

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Summary Preparation Date: 23 December 2009

Trade Name: Fisher & Paykel Healthcare Bubble CPAP System.

Common Name: Bubble CPAP

Device Classification: Device Name: Noncontinuous ventilator (IPPB)
Product Code: 73 BZD
Regulation: 21 CFR 868.5905
Device Class: Class 2

Predicate Device: Product Name: Babylog 8000 plus ventilator (CPAP mode)
510(k) Number: K974176
Manufacturer: Dräger Medical
Product Code: 73 CBK
Device Class: Class 2

OCT 8 2010

Device Description:

The Fisher & Paykel Healthcare (F&P) Bubble CPAP (continuous positive airway pressure) System provides respiratory support to spontaneously breathing infants. The F&P Bubble CPAP System delivers heated and humidified respiratory gas through an inspiratory breathing circuit to the infant via a nasal interface. An expiratory circuit connects to a water column threshold resistor which pressurizes the circuit. The F&P Bubble CPAP System consists of an in-line pressure relief valve, a humidification chamber, a heated breathing circuit, patient nasal interface and CPAP generator (water column threshold resistor). The System is intended to be operated at input gas flows of 4 - 15 L/min with available CPAP levels of 3 - 10 cmH₂O.

Indications for Use:

The F&P Bubble CPAP System is intended to provide CPAP to spontaneously breathing neonates and infants who require breathing support due to conditions associated with prematurity (such as Respiratory Distress Syndrome) or other conditions where CPAP is required or desired and is prescribed by a physician.

Contra-indications:

Contra-indicated in non-spontaneously breathing infants, infants not requiring CPAP support, gas flows over 15 L/min and in non-hospital environments.

Patient Population:

The intended patient population is premature and full term neonates up to a weight of 10 kg.

Environment of Use:

Hospital.

Comparison of Technological Characteristics:

The F&P Bubble CPAP System is substantially equivalent in indications for use, environment of use, intended patient population and function of the predicate device. Both devices use an expiratory threshold resistor although the type of resistor differs. The F&P Bubble CPAP System uses a water column threshold resistor and the Dräger device uses an electronically regulated valve. Bench tests show that both expiratory resistors provide substantially equivalent CPAP. That is, the CPAP level delivered to the patient and the work of breathing associated with both devices are substantially equivalent.

Pre-clinical Testing:

The single heated breathing circuit of the F&P Bubble CPAP System has been designed and tested to work specifically with F&P Respiratory Humidifiers and the F&P Bubble CPAP System. The breathing circuit meets the requirements of *ISO 8185:2007 (E) Respiratory tract humidifiers for medical use – Particular requirements for respiratory humidification systems* (Surface Temperature; Humidification System Output; Protection Against Hazardous Output) and *ISO 5367:2000 (E) Breathing tubes intended for use with anaesthetic apparatus and ventilators* (Occlusion Resistance).

The CPAP level delivered to the patient has been shown to be very close to the intended pressure set at the CPAP generator. In addition, the auto-leveling mechanism of the CPAP generator compensates for accumulated condensate from the expiratory limb and allows the mean CPAP level to remain stable over time.

The work of breathing of the F&P Bubble CPAP System and the predicate Dräger device has been compared. The results show that the work of breathing of the F&P Bubble CPAP System is significantly less than the predicate device in all measurements.

Biocompatibility assessment and testing of the F&P Bubble CPAP System as per ISO 10993-1, has been undertaken and shows that all materials that contact the patient, either directly or indirectly, are suitable for patient contact.

Clinical Performance:

Gas bubbling out of the water threshold resistor of the F&P Bubble CPAP System creates pressure oscillations about a mean CPAP level, in the expiratory breathing circuit. These pressure oscillations do not adversely affect the performance or safety of the device. Eight peer reviewed and published reports using the F&P Bubble CPAP System, including three randomized controlled trials, show that the device has been widely and successfully used around the world. The device has been compared with other forms of respiratory support in a variety of settings. The outcomes in all of these reports are positive towards the F&P Bubble CPAP System.

Conclusion:

The F&P Bubble CPAP System is intended to be used for spontaneously breathing infants requiring continuous positive airway pressure support and is substantially equivalent to the predicate device. The two devices have substantially equivalent indications for use, environment of use and intended patient population. Both devices use an expiratory threshold resistor and although the type of resistor differs, the performance is substantially equivalent. Pressure oscillations in the expiratory air path of the F&P Bubble CPAP System do not adversely affect performance or safety. The performance testing of the F&P Bubble CPAP System shows that it is safe and effective, and substantially equivalent to the predicate Dräger Babylog 8000 Plus device in CPAP mode.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room - WO66-G609
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OCT 08 2010

Re: K100011
Trade/Device Name: Bubble CPAP System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: September 20, 2010
Received: September 23, 2010

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.

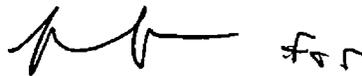
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



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

Indications for Use Statement

510(k) Number (if known): K100011

Device Name: Fisher & Paykel Healthcare Bubble CPAP System.

Indications For Use:

The Fisher & Paykel Healthcare Bubble CPAP System is intended to provide CPAP to spontaneously breathing neonates and infants who require breathing support due to conditions associated with prematurity (such as Respiratory Distress Syndrome) or other conditions where CPAP is required or desired and is prescribed by a physician.

The Bubble CPAP System is for use in the hospital clinical environment such as the NICU (Neonatal Intensive Care Unit) and PICU (Pediatric Intensive Care Unit).

The intended patient population is premature and full term neonates up to a weight of 10 kg.

All components of the Bubble CPAP System are single use only.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)

Division of Anesthesiology, General Hospital
infection Control, Dental Devices

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