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Section 5.

510(k) Summary

SUBMITTER

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510(k) Summary

CLASSIFICATION REFERENCE	21 CFR Subpart C 868.5450
PRODUCT CODE	BTT
TRADE/DEVICE NAME	Humidifier Heater Base, PMH7000 K080149
CLASSIFICATION NAME	Respiratory Gas Humidifier
CLASSIFICATION	Class II
SUBMISSION DATE	December 16, 2008

Description of Device:

The Humidifier Heater Base, PMH7000is a humidifier incorporating with ventilator and provides respiratory humidification through patient breathing circuit for adult at hospital and home.

Humidifier Heater Base, PMH7000 was designed to comply with applicable portions of the following standards.

IEC 60601-1	Medical Electrical Equipment – General Requirements for Safety Requirements for Medical Electrical System
IEC 60601-1-2	Medical electrical Equipment-Part 1: General Requirements for Safety-2. Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
IEC 60601-1-4	Medical Electric Equipment Part 1: General Requirements for Safety 4. Collateral Standard: Programmable Electrical Medical Systems
ISO 8185	Humidifiers for Medical Use-General Requirements for Humidification Systems
ISO 10993-1	Biological evaluation of medical devices Part 1: Evaluation and Testing
ISO 14971	Medical Devices-Application of Risk Management to Medical Devices

Intended Use

The Humidifier Heater Base PMH7000 is intended to add moisture and to warm the breathing gases for administration to a patient.

The Humidifier Heater Base, PMH7000 is intended for use on adult at hospital and home.

Prescription Use : ___x___ (Part 21 CFR 801 Subpart D)

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

Substantial Equivalence to Predicate Device(s)
(Part 1)

The comparison table is provided as a summary of the technological characteristics relative to the predicate devices. This is to demonstrate that Pacific Medico PMH7000 Humidifier Heater Base for respiratory therapy (heater base) has no difference from the predicate device that would adversely affect product safety and effectiveness.

Table 1 Technological Comparison between PMH5000 (predicate device) and PMH7000

Comparison Parameter	**Pegasus Research PMH5000** K020700	**Pacific Medico PMH7000**
Intended Use	Respiratory Humidification	Respiratory Humidification
General Mechanism	(1) Humidification: Heat distilled water in the humidification chamber placed on the heater base. (2) Heater Plate: Using heater plate to heat distilled water. (3) Humidified Gas: Humidified gas generated in the chamber led to patient's breathing circuit through inspiratory tube. (4) Inhaling humidified gas: Patient inhale ventilator supplied gas together with humidified gas. (5) Flow per minute: 5 liters	(1) Humidification: Heat distilled water in the humidification chamber placed on the heater base. (2) Heater Plate: Using heater plate to heat distilled water. (3) Humidified Gas: Humidified gas generated in the chamber led to patient's breathing circuit through inspiratory tube. (4) Inhaling humidified gas: Patient inhale ventilator supplied gas together with humidified gas. (4) Flow per minute 5 liters
Mechanism (Setting) Range Sensor Technology	(1) Temperature – Heater Plate 100°C Thermostat regulated (Normal Operation) 115°C Thermostat limited	(1) Temperature – Heater Plate 100°C Thermostat regulated (Normal Operation) 115°C Thermostat limited

	(AC power disabled)	(AC power disabled)
Population	Adult	Adult
Power Source	AC115V	AC115V
Method of Connection to The Patient	Patient mask through patient breathing circuit	Patient mask through patient breathing circuit
Re-use	(1) Heater Base main unit: Multiple uses with proper care and maintenance in accordance with manual and with all other applicable regulations. (2) Heater Wire – Inspiratory Multiple uses with proper care and maintenance in accordance with manual and with all other applicable regulations. (3) Heater Wire – Expiratory Multiple uses with proper care and maintenance in accordance with manual and with all other applicable regulations. (4) Temperature Probe Multiple uses with proper care and maintenance in accordance with manual and with all other applicable regulations.	(1) Heater Base main unit: Multiple uses with proper care and maintenance in accordance with manual and with all other applicable regulations. (2) Heater Wire – Inspiratory Multiple uses with proper care and maintenance in accordance with manual and with all other applicable regulations. (2) Heater Wire – Expiratory Multiple uses with proper care and maintenance in accordance with manual and with all other applicable regulations. (4) Temperature Probe Multiple uses with proper care and maintenance in accordance with manual and with all other applicable regulations.

From the above technological comparison, there is no difference in the technology applied in both PMH5000 and PMH7000 which may which may affect the safety and effectiveness of the subjective devices.

Substantial Equivalence to Predicate Device(s)

(Part 2)

The comparison table is provided as a summary of the technological characteristics relative to the predicate devices. This is to demonstrate that Pacific Medico PMH7000 has no difference from the predicate device (Pegasus Research, PMH5000) that would adversely affect product safety and effectiveness.

Table 2 Discussions on Substantial Equivalence

Comparison Parameter	**Pegasus Research** PMH5000 K020700	**Pacific Medico** PMH7000	Discussion of Differences and Similarities
Intended Use	The Humidifier Heater Base PMH5000 is intended to add moisture and to warm the breathing gases for administration to a patient. The humidifier is intended for use with flows of 5 liters per Minute or more through the humidifier.	The Humidifier Heater Base PMH7000 is intended to add moisture and to warm the breathing gases for administration to a patient. The Humidifier Heater Base, PMH7000 is intended for use on adult at hospital and home.	No difference
Temperature Setting	Patient Side : 30 to 40 ℃ Chamber Side: 23 to 34℃	Patient Side : 30 to 40 ℃ Chamber Side: 23 to 34℃	No difference

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Temperature Probe	Platinum Resistance RTD	Platinum Resistance RTD	No difference
Temperature Control	Dual Servo Control	Dual Servo Control	No Difference
Control Panel	Front Panel	Front Panel	No difference
Setting Function	Manual Mode: Temperature can be set manually. Patient Side: 30–40℃ Chamber Side: Patient side temperature -4 to + 3℃ (26 – 43℃)	Manual Mode: same as in PMH5000 IPPV Mode: Patient side & Chamber side temperature can be pre-set. Patient side: 40℃ Chamber side: 37℃ NPPV Mode: Patient side & Chamber side temperature can be pre-set. Patient side: 34℃ Chamber side: 37℃ Both IPPV and NPPV mode are controlled on front touch panel.	Differences do not affect safety or effectiveness
Alarm	All alarms : displayed by LED	All alarms: displayed by LED at the illustrated portion on the front touch panel. *** Refer below note for alarm details**	Differences do not affect safety or effectiveness
Humidity Control	Using heater wire	Using heater wire	No difference
Population	Adult	Adult	No difference
Power Source	AC 115V	AC 115V	No difference
Method of Connection to	Using patient breathing circuit	Using patient breathing circuit	No difference

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The Patient			
Re-use	Multiple Use	Multiple Use	No difference
Heater Wire Control Power Supply	Controlled by an internal transformer	Controlled by Switching Power Supply Total weight reduced almost half.	Differences do not affect safety or effectiveness

NOTE: * Details of alarm display on PMH7000 front touch panel at the illustrated portion.

Patient side temperature over-increasing: color of LED becomes Red

Patient side temperature over-decreasing: color of LED becomes Orange

Chamber side temperature over-increasing: color of LED becomes Red

Chamber side temperature over-decreasing: color of LED becomes Orange

Abnormal temperature of Thermo-probe: color of LED becomes Red

Abnormal temperature of Heater Wire: color of LED becomes Red

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Conclusion:

1) Based on the results of the comparison and reproducibility studies described in this 510(k) submission, it is concluded that the Humidifier Heater Base, PMH7000 is as safe and effective (therefore substantially equivalent) as the predicate device as an aid for mitigation of dryness of airway.
2) Under the above technological comparison, discussion on substantial equivalence, it is demonstrated that the subjective device is as safe and effective, performs as well as the predicate device.
3) It is determined that the Performance Testing – Clinical is not required because of the above comparison.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2008

Mr. Yoshio Toyama
Manager of Regulatory Affairs
Pacific Medico Company, Limited
2-6-4 Hongo, Bunkyo-ku
Tokyo
JAPAN 113-0033

Re: K080149
Trade/Device Name: Humidifier Heater Base: PMH7000
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: November 26, 2008
Received: December 1, 2008

Dear Mr. Toyama:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Indications for Use

510(k) Number : K080149
Device Name : Humidifier Heater Base: PMH7000

Indication for Use:

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Prescription Use : ____×____ (Part 21 CFR 801 Subpart D)

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)

Judy Y. Michaels DMD

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

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