K072982

PARI Hydrate V
510(k) Submission
510(k) Summary

Submitter Information

Name:	PARI Innovative Manufacturers, Inc.
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Date Prepared:	June 15, 2007

NOV 2 9 2007

Device Name

Common Name:	Humidifier
Proprietary Name:	PARI Hydrate V
Classification Name:	Humidifier, Respiratory Gas (Direct Patient Interface), 21 CFR 868.5450, Product Code BTT

Legally Marketed Predicate Device(s)

Manufacturer	Device	510(k) Number
PARI Innovative Manufacturers, Inc.	PARI Hydrate G	K071707
Fisher & Paykel Healthcare, Ltd.	MR 850 Heated Humidifier	K033710

Device Description

The Hydrate V is a Respiratory Gas Humidifier which provides heated evaporated water content to dry breathing gases using Capillary Force Vaporization technology. A breathing circuit is used to deliver the heated and humidified gas to the patient.

Indications For Use

The PARI Hydrate V is intended to warm and add moisture to breathing gases to patients requiring mechanical ventilation, positive pressure breathing assistance of general medical gases for administration to infant, pediatric, and adult patients. The Hydrate V is intended for use in homes, hospitals, and sub-acute institutions.

Technological Characteristics Compared to Predicate Device

PARI Hydrate V, PARI Hydrate G and Fisher & Paykel MR 850 are all Active Gas Humidification systems, used to add moisture and warmth to breathing gases for administration to patients.

PARI Hydrate V employs similar materials, similar air, water, and power inputs, and delivers similar outputs compared to the predicate devices. The Capillary Force Vaporization technology used in the Hydrate V, although slightly different than the heated plate concept used by the predicate MR 850, is identical to that used in the PARI Hydrate G and uses a heater to draw liquid through a porous medium resulting in comparable humidification output to the predicate devices.

Non-Clinical Test Summary

PARI Hydrate V was tested to compare performance to the predicate devices and ISO 8185, using a gravimetric test standard for humidifier output across the range of flows. The output of the subject device is comparable to the predicates.

Clinical Performance Summary

Clinical testing was not completed and is not required to show substantial equivalence.

Conclusions from Testing

PARI Hydrate V meets performance requirements and raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 9 2007

PARI Innovative Manufacturers, Incorporated
C/O Daniel W. Lehtonen
Senior Staff Engineer- Medical Devices
Intertek Testing Services NA, Incorporated
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K072982
Trade/Device Name: PARI Hydrate V
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: November 14, 2007
Received: November 15, 2007

Dear Mr. Lehtonen:

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 (240) 276-0120. 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/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 (if known): N/A

Device Name: PARI Hydrate V

Indications for Use:

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Prescription Use XXX
(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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K072982