K 050314

510(k) Summary

FEB 18 2005

December 2, 2004

Submitter:
Smiths Medical ASD, Inc.
One Madison Street
Wampsville, NY 13163

Contact: David Geary, Regulatory Affairs Manager
Phone: 315-363-2330 x267
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Device Name:

Product Code Name:	DRIP
Trade name:	AquinOx
Common Name:	Humidifier
Classification Name:	Respiratory Gas Humidifier – 868.5450

Predicate Devices:

Thera-Mist P35000 Humidifier
K894000
Pegasus Research Corporation
1714 South Lyon St.
Santa Ana, CA 92705

Vapotherm 2000i
K000401
Vapotherm Inc.
107 Ridgely Ave. Suite 9
Annapolis, MD 21401

Device Description:
The AquinOx Humidifier is a single patient use device. The device attaches to a compressed air or oxygen source. The input air or oxygen is warmed and humidified before leaving the device. AquinOx attaches to the P20000 heater manufactured by Pegasus Research Corporation and is compatible with multiple commercially available water bottles.

Intended Use:
AquinOx is designed for use to add moisture to and to warm breathing gases for administration to a patient.

Technological Characteristics Compared to Predicate:
AquinOx uses the same technology as the Thera-Mist P35000 for heating and humidifying the breathing gases for introduction to the patient. The water is drawn into the chamber and onto the heating surface. Like the P35000, AquinOx will not heat the delivery gases without water and proper gas flow and is therefore inherently unable to generate an unsafe delivery temperature. As is the case with the Vapotherm predicate, AquinOx delivers high flows of warmed and humidified gases via nasal cannula.

Summary of Studies:
No clinical studies were necessary to demonstrate the safety, effectiveness, and performance of the device.

Non-clinical studies were performed covering thermal safety, environmental, and functional performance.

Conclusion Drawn from Studies
For the indication for use, the AquinOx humidifier performs substantially equivalent to the predicate devices. In the opinion of Smiths Medical ASD, Inc., it is substantially equivalent to the predicate devices and does not adversely affect safety and effectiveness compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2005

Smiths Medical ASD, Incorporated
C/O Mr. Ned Devine
Senior Staff Engineer
ENTELA, Incorporated
3033 Madison Avenue. SE
Grand Rapids, Michigan 49548

Re: K050314
Trade/Device Name: AquinOx
Regulation Number: 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: February 7, 2005
Received: February 9, 2005

Dear Mr. Devine:

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.

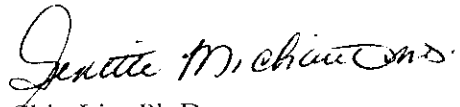
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K050314

Device Name: AquinOx

Indications For Use

AquinOx is designed for use to add moisture to and to warm breathing gases for administration to a patient.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 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: K050314