AUG 30 2004

K042245

3.1 Summary of Safety and Effectiveness

Non-Confidential Summary of Safety and Effectiveness

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August 16, 2004

Vapotherm, Inc.
108 Log Canoe Circle
Stevensville, MD 21666

Tel – (410) 604-3977
Fax – (410) 974-9707

Official Contact: William Niland, Chairman

Proprietary or Trade Name: Vapotherm™ 2000h and 2000i

Common/Usual Name: Humidifier, Respiratory Gas (Direct Patient Interface)

Classification Name: Humidifier, Respiratory Gas (Direct Patient Interface)

Device: Vapotherm™ 2000h and 2000i

Predicate Devices: Vapotherm™ 2000h, K000401, and 2000i – K013486
Caradyne Guardian – K040862

Device Description:

The Vapotherm 2000i and Vapotherm 2000h are identical and share the concept of humidification by transpiration of water vapor across a membrane by the use of a low or high flow cartridge with membrane bundles. The difference in the cartridges is only the number of membrane bundles included, fewer in the low flow. Both units and cartridges produce a highly humidified air (relative humidity >95%), virtually free of droplets, at body temperature or above at flow rates from 1 to 40 lpm via a nasal cannula. The water content at 41°C is 40-50 mg/liter, about fourfold higher than can be achieved by humidification at room temperature. The unique combination of high flow and high vapor-phase humidity allow an unusually wide range of clinical applications. Applications previously considered impractical because of limited patient tolerance for high nasal flow can now be routine because of the comfort provided by warmth and high humidity.

Indications:

Indicated Use -- To add moisture to and to warm breathing gases for administration to patients, including neonates/infant, pediatrics, and adults. The environment of use include – home, hospital or sub-acute institutional settings

Patient Population -- For use with neonate/infant, pediatric and adult patients utilizing high flow supplemental air, air/oxygen, or gas mixtures in which humidification would be beneficial.

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Indications: (continued)

Environment of Use -- Home, Hospital, Sub-acute Institutions

Contraindications -- None

Comparison to Predicate Devices:

	Vapotherm 2000h and 2000i Predicate	Clarification
Attributes		
Indications for use	To add moisture to and to warm breathing gases at high flows with an air or air/oxygen mixture for administration to a patient	Same
Environments of use	Home, Hospital, Sub-acute Institutions, not specified.	Same
Patient Population	For use with any patient utilizing supplemental oxygen in which humidification would be beneficial and with an air or air/oxygen mixture. All patients, non population specific. **Caradyne – Guardian K040862** Neonate / infant	Neonate/infant, pediatric and adult
Contraindications	None	Same
Equipment Design		
No changes		
Technology of humidification		
Membrane type	Basic membrane type humidifier, hollow fiber cartridge	Low flow – 1 - 8 lpm High flow – 5 - 40 lpm

Differences Between Other Legally Marketed Predicate Devices

There are no differences, only clarification of the indicated populations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2004

Vapotherm, Incorporated
C/O Mr. Paul E. Dryden
President
ProMedic, Incorporated
6329 West Waterview Court
McCordsville, Indiana 46055-9501

Re: K042245
Trade/Device Name: Vapotherm Model# 2000h and 2000i
Regulation Number: 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: August 18, 2004
Received: August 19, 2004

Dear Mr. Dryden:

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) 594-4646. 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

3.3 Indications for Use

510(k) Number: K042245 (To be assigned)

Device Name: Vapotherm 2000h and 2000i

Indications for Use: The Vapotherm™ 2000h and 2000i are designed to add moisture to and to warm breathing gases for administration to patients, including neonates/infant, pediatrics, and adults. The flow rates may be from 1 to 40 liters per minute via nasal cannula.

Environments of use - Home, Hospital, Sub-acute Institutions

Prescription Use XX **or** **Over-the-counter use __**
(Per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K042245