K013486

MAY 3 0 2003

Vapotherm, Inc.
107 Ridgely Ave. Suite # 9
Annapolis, MD 21401

Summary of Safety and Effectiveness

Non-Confidential Summary of Safety and Effectiveness

21-May-03

Vapotherm, Inc.
107 Ridgely Ave., Suite # 9
Annapolis, MD 21401

Tel – (410) 974-9255
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Official Contact: Robert Storey - President and CEO

Proprietary or Trade Name: Vapotherm 2000h (5000)

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

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

Device: Vapotherm 2000h (5000)

Predicate Devices: Vapotherm 2000i – K000401

Device Description:

The Vapotherm 2000i, predicate, and the Vapotherm 2000h (5000) are identical and share the concept of humidification by transpiration of water vapor across a membrane. Both produce a high flow of highly humidified air (relative humidity >95%), virtually free of droplets, at body temperature or above. 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.

The Vapotherm 2000h (5000) is an unmodified Vapotherm 2000i but with an internal air compressor and external oxygen source, wall or cylinder oxygen. There is a single inlet fitting, like the 2000i for connection to an external oxygen source, if desired.

Intended Use:

Indicated Use -- The Vapotherm 2000h (5000) can mix air with oxygen from an external source and adds heat and moisture to the gas.

Patient Population -- For use with any patient utilizing high flow supplemental air or air/oxygen mixtures in which humidification would be beneficial.

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

Contraindications -- None

Comparison to Predicate Devices:

	Vapotherm 2000i Predicate	**Vapotherm 2000h (5000) Proposed**
Attributes		
Indications for use	To add moisture to and to warm breathing gases for administration to a patient	Same
Environments of use	Home, Hospital, Sub-acute Institutions, not specified.	The same
Patient Population	For use with any patient utilizing supplemental oxygen in which humidification would be beneficial	Add – " with an air or air/oxygen mixture" Otherwise the same.
Contraindications	None	The same
Equipment Design		
Dimensions	11" x 5.5" x 4.5"	12" x 15" x 10"
Weight	Vapotherm - < 6 lbs without water	25 lbs. without water
Power max.	Vapotherm - 250 VA (warm-up), 80 VA (continuous)	Vapotherm - The same Compressor – 49 watts
Input power	115 VAC, 60 Hz	The same
Gas Source Pressure	4-50 psi, wall source or cylinder	Internal compressor – 8 psi
Gas Source	Wall source or Cylinder	Internal AC compressor or wall or cylinder oxygen

	Vapotherm 2000i Predicate	**Vapotherm 2000h (5000) Proposed**
Equipment Design		
Gas fittings	One	One
Method to regulate flow from source	Flow meter at wall or cylinder	Flow meter on device for compressor, plus flow meter at oxygen source.
Capable of variable FiO_2	No – set at wall if practitioner desires	No – set at wall if practitioner desires
Monitoring of FiO_2	None	Instructs to verify with an in-line oxygen analyzer
Technology of humidification		
Membrane type	Basic membrane type humidifier, hollow fiber cartridge	The same
Method of humidifying	Warmed water is circulated over the outside of the cartridges hollow fibers while air is pumped through the center of the fibers. These fibers are permeable to water and allow water to transpire into the air stream in the form of gaseous water vapor. Water temperature is software-controlled	The same
Water type	Common tap water	The same

Compressor	**DeVilbiss K963349**	**Proposed Thomas**
Meets UL 544	Yes	Yes
Portable	Yes	Yes
Max. Compressor pressure	90 psi	8.3 psi
Max liter flow	30 lpm	25 lpm in this application

Differences Between Other Legally Marketed Predicate Devices

The Vapotherm 2000h (5000) system is viewed as substantially equivalent to the following predicate device – Vapotherm 2000i cleared under K000401.

The differences between the Vapotherm 2000h (5000) and the Vapotherm 2000i, the predicate devices, are minimal. There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices. They are viewed as substantially equivalent to the predicate devices since they:

1. Have the substantially equivalent intended uses
2. Have the same environments for use
3. Are similar in design
4. They employ the same technology

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2003

Vapotherm, Inc.
c/o Mr. Paul E. Dryden
ProMedic, Inc.
6329 West Waterview Ct.
McCordsville, IN 46055-9501

Re: K013486
Trade/Device Name: Vapotherm 2000h
Regulation Numbers: 21 CFR 868.5450
Regulation Name: Respiratory gas humidifier
Regulatory Class: Class II (two)
Product Code: 73 BTT; 73 BTI; 73 BZR
Dated: March 6, 2003
Received: March 11, 2003

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,

Susan Runner, DDS, MA
Interim 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: K013486 (To be assigned)

Device Name: Vapotherm 2000 h (5000)

Intended Use: The Vapotherm 2000h (5000) can mix air with oxygen from an external source and adds heat and moisture to the gas. The Vapotherm 2000h (5000) is for use in home, hospital or sub-acute institutional settings.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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

510(k) Number: K013486