510(k) SUMMARY K070056

Vapotherm's 2000i Respiratory Gas Humidifier

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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

APR 13 2007

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Contact Person: Robert Storey, President and CEO

Date Prepared: 13 December 2006

Name of Device and Name/Address of Sponsor

Vapotherm™ 2000i and 2000h

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

Common or Usual Name: Respiratory Gas Humidifier

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

Predicate Devices: Vapotherm™ 2000i and 2000h

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

Purpose of the Special 510(k) Corrective Action Being Effected

The Vapotherm 2000i device is a modification to cleared Vapotherm 2000i device.

Intended Use

Both the modified Vapotherm 2000i device and the predicate 2000i device are indicated for use to add moisture to and to warm breathing gases for administration to a patient.

Technological Characteristics

The base device of the modified Vapotherm 2000i device has the same technological characteristic as the predicate Vapotherm 2000i device. The software contained in the modified device has not been modified as a result of the corrections being effected and remains identical to the software resident in the predicate device. The modifications that have been made to the device, which are the subject of this Special 510(k) Corrective Action Being Effected, do not raise any new issues of safety or effectiveness.

Performance Data

Vapotherm has conducted extensive testing to verify and validate the changes to the previously marketed Vapotherm 2000i device.

Substantial Equivalence

The company's Vapotherm 2000i respiratory gas humidifier that is the subject of this Special 510(k) Corrective Actions Being Effected notice is a modification to the previously marketed Vapotherm 2000i (K042245). The modified Vapotherm 2000i device has the same intended use and indications for use, similar principles of operation, and similar technological characteristics as the previously cleared predicate Vapotherm 2000i device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vapotherm, Incorporated
C/O Mr. Johnathan Kahan
Regulatory Counsel
Hogan & Hartson, L.L.P
555 Thirteenth Street, NW
Washington, DC 20004

APR 13 2007

Re: K070056
Trade/Device Name: Vapotherm Model #2000i and 2000h
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: March 15, 2007
Received: March 16, 2007

Dear Mr. Kahan:

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 (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 (if known): K070056

Device Name: Vapotherm Model # 2000i and 2000h

Indications for Use: The Vapotherm 2000i and 2000h are designed to add moisture to and to warm breathing gases for administration to patients, including neonates/infants, pediatrics, and adults. The flow rates may be from 1 to 40 liters per minute via nasal cannula. Environments for use -- Home, Hospital, Sub-acute Institutions.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Division Sign-Off
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K070056