K072845

510(k) SUMMARY

Vapotherm, Inc.'s Precision Flow™

JUL 17 2008

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

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

Phone: 410-604-3977
Facsimile: 410-604-3978

Contact Person: Gregory A. Whitney

Date Prepared: April 15, 2008

Name of Device and Name/Address of Sponsor

Precision Flow™
Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, Maryland 21666

A. Common or Usual Name

Humidifier, Respiratory Gas (Direct Patient Interface)

B. Classification Name

Humidifier, Respiratory Gas (Direct Patient Interface)
Anesthesiology Panel (868.5450)
Class II

C. Product Code

BTT

D. Predicate Devices

Vapotherm, Inc.	2000i& 2000h	K000401, K0142245, K042245
Medtec	Oxygen Sensor	K063488
Bird Products	Air-Oxygen Blender	K911962

K072845

E. Intended Use / Indications for Use

The Precision Flow™ is intended to be used for adding warm moisture to breathing gases from an external source for administration to a neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer. The flow rates may be from 1 to 40 liters per minute via nasal cannula.

F. Technological Characteristics

The Precision Flow™ consists of two parts:

The **main unit** which contains all the electrical and electronic components including the electronic blender and flow controllers. All the sensors are located in the main unit. The main unit has no water pathways and the gas pathway contains only dry gas at room temperature, and consequently does not need internal cleaning or disinfection.

The **disposable components** comprising the disposable water module, vapor transfer cartridge and heated delivery tube. Conditions in the circulating water and gas streams are sensed remotely via the interface between the main unit and the disposable module.

1. Main unit:

- The flow of oxygen and air are measured by mass flow sensors. The operating software calculates the required flow of each needed to reach the target flow and oxygen percentage set by the operator. The system controls gas flows accordingly by adjusting proportional solenoid valves on the gas lines. An oxygen sensor monitors the gas mixture and signals any discrepancy between target and measured percentage. The oxygen sensor is automatically calibrated with oxygen at power-up and every 24 hours.

- Firmware running in the main unit uses sensors to monitor gas pressure, water level and water temperature, and to detect air leaks into the water circuit (bubble detector) and water leaks into the gas circuit (droplet detector). Alarms are displayed if any parameters are outside the normal range. Other indicators show low charge in the backup battery, and the type of cartridge installed. An internal battery backup will maintain the set flow and oxygen blend for at least 15 minutes without AC power.

K072845

2. Disposable components:

- Vapor Transfer Cartridge. In the cartridge blended gas passes through the lumens of hundreds of parallel hollow fibers made of a specially developed polymer. Warm water circulates around the fibers and diffuses as vapor through the fiber material into the gas stream flowing through each fiber. Unlike most humidifiers, there is no direct contact between the water and gas streams. The gas stream leaves the cartridge essentially saturated with vapor at the set temperature.

- Triple-lumen heated delivery tube. The warmed humidified gas passes through the center lumen. The center lumen is surrounded by two outer lumens carrying warmed water to maintain the temperature of the inner lumen and to minimize rain-out. A proprietary short nasal cannula is connected to the end of the delivery tube and passes the humidified breathing gas to the patient's nose.

- Disposable module. The module houses a water reservoir, pump, connections for the cartridge and delivery tube, and sensor interfaces to the main unit. Water is pumped past a heater plate through the outer lumens of the delivery tube. Returning water passes through the outer jacket of the Vapor Transfer Cartridge where some water is lost as vapor to the gas stream. There is no direct contact between water and gas flows. The water then returns to the pump reservoir. Heater power is adjusted continuously to maintain the set temperature. Water flows into the circuit from the water bag to replace evaporative losses in the Vapor Transfer Cartridge. Air is purged to atmosphere from the circulation via a hydrophobic filter membrane.

3. Summary of Non-Clinical Performance Data

The following table lists the non-clinical Performance Testing Data that was performed on the Precision Flow™:

Number	Test Description
1	Biocompatibility – Murine Local Lymph Node Assay (LLNA) (Sensitization)
2	Biocompatibility – ISO Intracutaneous Reactivity Test (Irritation)
3	Biocompatibility – MEM Elution (Cytotoxcity)
4	Volatile Organic Compounds (VOC), EPA Compendium Method TO-15
5	Particulate Matter, NIOSH Method 0500
6	EMC Test
7	Emissions Test
8	Safety Inspection Test
9	IEC 60601-1, Medical Electrical Equipment Part 1: General Requirements for Safety
10	IEC 60601-1-4, Medical Electrical Equipment Part 1-4 – Collateral Standard: Programmable Electrical Medical Systems

Number	Test Description
11	IEC 60601-1-8, Medical electrical equipment, General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
12	Bio Burden, 30 Day Comparative Use Testing
13	Ximedica TRP 1097, "Vapotherm Precision Flow Hyperthermic Humidification System, System Software Verification & Validation Test Plan"
14	TRP 1071 "System Software Test" (Black Box)
15	Unit Test Case Listing – 3VAP1004/TRP 1092 (White Box)
16	Thermal Stability
17	Blender Comparison Performance

- Bio Burden, 30 Day Comparative Use Testing: After a thirty day comparative use testing, there were no detectible bacteria in any water condensation samples from the Precision Flow® devices either initially (3 days) or after 30 days of operation.
- The Precision Flow™ software was verified and validated in accordance with applicable FDA guidance documents.
- The Volatile Organic Components and Particulate Mater tests were performed to recognized standards.

Substantial Equivalence

The Precision Flow™ is as safe and effective as the Vapotherm 2000i and 2000h, the Bird Mircoblender, and the Medtec Oxygen Sensor. The Precision Flow™ has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Precision Flow™ and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Precision Flow™ is as safe and effective as the predicate devices. Thus, the Precision Flow™ is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUL 17 2008

Re: K072845
Trade/Device Name: Precision Flow™
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: June 27, 2008
Received: June 30, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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~~,

P/H 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): K072845

Device Name: Precision Flow™

Indications for Use:

Precision Flow™ is intended for use to add warm moisture to breathing gases from an external source for administration to a neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer. The flow rates **may be from 1 to 40 liters per minute via nasal cannula**.

Precision Use _X_ (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)

Will Maly for M. Hoiband Page __ of __

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

510(k) Number: K072845