K111640

510(k) SUMMARY

Vapotherm, Inc.'s Precision Flow® - Heliox

OCT - 7 2011

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

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

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Contact Person: Gregory A. Whitney

Date Prepared: September 26, 2011

Name of Device and Name/Address of Sponsor

Precision Flow® - Heliox

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

Common or Usual Name

Humidifier, Respiratory Gas (Direct Patient Interface)

Classification Name

Humidifier, Respiratory Gas (Direct Patient Interface)

Predicate Device

Primary Device: Precision Medical, Inc. Heliox/Oxygen Blender, K090781
Secondary Device: Precision Flow® - Air, K072845

The Precision Medical device is a mechanical device and the Precision Flow® device is electronic/mechanical device. The Precision Medical predicate device is compared to the Precision Flow® device for mechanical aspects and the Precision Flow® - Heliox is compared to the Precision Flow® - Air for electronic functions. The Precision Medical

device depends on adding external stand alone devices (i.e. flowmeter, oxygen analyzer) to it for some functions. The Precision Flow® - Heliox has the same functions residing in the unit.

Intended Use / Indications for Use

The Precision Flow® - Heliox is intended to warm and add moisture to breathing gases from an external source for administration to neonate/infant, pediatric and adult patients in the hospital and sub-acute institutions. It adds heat and moisture to a blended medical heliox (79% helium, 21% oxygen)/oxygen mixture and assures the integrity of the precise heliox (79% helium, 21% oxygen)/oxygen mixture via an integral oxygen analyzer. The flow rates may be from 1 to 40 liters per minute via nasal cannula.

Technological Characteristics

The Precision Flow® - Heliox 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 heliox and oxygen is measured by mass flow sensors. The mass flow sensors are configured for the specific gravity of the type of breathing gas. The blending function is independent from the type of gas. 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). 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.

2. Disposable components:

- Vapor Transfer Cartridge. In the cartridge blended gas passes through membrane made of a specially developed polymer. Warm water circulates and diffuses as vapor through the membrane material into the gas stream. 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.

  The device front panel has a LCD display which performs the following functions:

  - Displays
    - Gas flow
    - Delivered oxygen concentration
    - Temperature of gas delivered
  - Alarms for
    - Water level for humidifier
    - General fault
    - Blocked tube (water for humidifier)
    - Battery charging status
    - Cartridge fault (humidifier cartridge)

    - Cartridge type (2 are available for lower flows and higher flow)
    - Supply gas fault
- Encoder knob
    - For selecting settings
- Run / Standby button
- Status LED
- Alarm mute

Performance Data:

In all instances, the Precision Flow® - Heliox functioned as intended and the results observed were as expected.

The Precision Flow® - Heliox met the following standards with exceptions:

#	Document Number	Title
1	ISO 62304	Medical Device Software - Software Life Cycle Process
2	ISO 8185:2007	Respiratory tract humidifiers for medical use
3	ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity
4	ISO 10993-10:2010	Tests for Irritation and Sensitization
5	ISO 11195:1995	Gas mixers for medical use – Stand-alone gas mixers
6	ISO 14971:2007	Medical devices – Application of risk management to medical devices
7	ANSI/AAMI/ISO 15223-1:2007/A1:2008	Medical Devices – Symbols to be used with Medical Device Labels, Labeling and information to be supplied – Part 1: General Requirements
8	ANSI/AAMI ES60601-1:2005	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
9	ANSI/AAMI/IEC 60601-1-2:2007 3rd edition	Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and tests General Requirements for Safety with exceptions: Section 5: Device can not produce hazardous radiation Section 6: Anesthetic mixtures not applicable
9	ANSI/AAMI/IEC 60601-1-2:2007 3rd edition	Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and tests General Requirements for Safety with exceptions: Section 5: Device can not produce hazardous radiation Section 6: Anesthetic mixtures not applicable

#	Document Number	Title
10	EN60601-1-4:1999	Medical Electrical Equipment: Part 1: General Requirements for Safety 4. Collateral Standard: Programmable Electrical Medical Systems
11	IEC 60601-1-8 2006-10	General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
12	IEC 60529 IPX1	Drip Proof
13	AAMI TIR 32:2004	Software Risk Management
14	AAMI TIR 36:2007	Validation of Software
15	ISTA -1A:2001	Procedure 1A: Packaged-Products weighing 150 LB (68 KG) or Less
16	EPA/625/R-96/010b (VOC) Method TO-15 (1999)	Compendium Method TO-15 Determination of Volatile Organic Compounds (VOCs) in Air collected in specially-Prepared canisters and analyzed by chromatography/mass spectrometry (GC/MS)
17	NIOSH Method 0500 (1994)	NIOSH manual of Analytical methods (NMNM) fourth edition August 1994 (Particulate Matter Testing)

Design Verification Plan:

Listing of all Required Tests

- Functional Performance Test
- Alarms & Fault Conditions Test
- Patient Connector Attachment Test
- Water Connector Attachment Test
- Extended Life Test
- Membrane Switch and Adjustment Dial Test
- Software Verification Test
- Fluid & Gas Pathways Leak Test
- Cartridge Insertion Test
- Door Test
- IPX Test
- Environmental Temperature/Humidity Extremes Test

Substantial Equivalence

The Precision Flow® - Heliox is as safe and effective as the predicate and the Precision Medical Heliox/Oxygen Blender (K090781).

A comparison of the devices is as follows:

#	Manufacturer	Precision Medical, Inc. Heliox/Oxygen Blender; K090781	Vapotherm, Inc. Precision Flow® - Oxygen/Heliox, K111640	Comments
1	Indications for Use	The Precision Medical, Inc. Heliox Blender Oxygen System is intended to deliver blended Helium and oxygen in a hospital setting. Oxygen concentrations can be dialed from 20% to 100% for heliox tank mixtures of 20% oxygen/ 80% helium, and 30% to 100% for heliox tank mixtures of 30% oxygen/ 70% helium. The Blender is not intended as a life supporting device.	The Precision Flow® - Heliox is intended to warm and add moisture to breathing gases from an external source for administration to neonate/infant, pediatric and adult patients in the hospital and sub-acute institutions. It adds heat and moisture to a blended medical heliox (79% helium, 21% oxygen)/oxygen mixture and assures the integrity of the precise heliox (79% helium, 21% oxygen)/oxygen mixture via an integral oxygen analyzer. The flow rates may be from 1 to 40 liters per minute via nasal cannula.	Equivalent
2	Patient population	Infant, pediatric, and adult patients.	Neonate/infant, pediatric and adult patients	Equivalent
3	Technology	Mechanical	Electronic/Mechanical	Equivalent
4	Gases Mixed	Heliox & Oxygen	Heliox & Oxygen	Equivalent
5	Heliox/Oxygen Mixtures	79% Heliox, 21% Oxygen	79% Heliox, 21% Oxygen	Equivalent
6	Oxygen % Range	21 to 100%	21 to 100%	Equivalent
7	Oxygen Concentration Monitor	Requires an external oxygen analyzer with alarm. Accuracy requires a gas bleed operation at flow settings below 15 lpm for High Flow and 3 lpm for Low Flow	Internal oxygen analyzer independent of blender function	Equivalent PF-H eliminates user error at set up
8	Oxygen Concentration Range	21 to 100%	21 to 100%	Equivalent
9	Correct Heliox Flow Rates	Manual Oxygen Flowmeter Conversion Chart Needed	Automatically	Equivalent PF-H has less opportunity for error
10	Supply Pressure Range	30 to 75 psi Heliox + Oxygen must be within 10 psi of each other	4 to 70 psi, Device unaffected by input gas pressure differences, Heliox medical grade & certified gas cylinder	Equivalent

#	Manufacturer	Precision Medical, Inc. Heliox/Oxygen Blender, K090781	Vapotherm, Inc. Precision Flow® - Oxygen/Heliox, K111640	Comments
11	Operating Temperature	15° to 40°C	33° to 43° C	Equivalent
12	Environment of use	Institutional environments	Hospital and sub-acute institutions	Equivalent
13	Condition Gas: Warm & Humidify	Need to add auxiliary equipment	Integrated into device	Equivalent PF-H eliminates user error in assembly
14	FiO_2 Accuracy	+/- 3% of full scale @ 50 psi	2 to 40 lpm: +/- 2% 1 to 2 lpm: +/- 5%	Equivalent
15	Alarms	Alarms for Gas Bypass & Oxygen/Heliox Supply Gas Connected	Alarms for General Fault (internal component failure), Blocked Delivery Tube, Water Out, Disposable Water Path function, Battery Charging (AC disconnected), Vapor Transfer Cartridge type & fault, Gas Supply, Gas Temperature	Equivalent PF-H provides alarms for multiple alarm conditions
16	Alarm Sound Level	>/= to 80 db at 1 ft.	Medium Priority 47 db @ 1 m Low Priority 45 db @ 1 m	Equivalent
17	Primary Outlet Flow Range	High Flow 15 to 120 lpm Low Flow 3 to 30 lpm (With both supply pressures at 50 psi with Bleed Closed*)	1 to 40 lpm	Equivalent
18	Auxiliary Outlet Flow Range	High Flow 2 to 100 lpm Low Flow 3 to 30 lpm (With both supply pressures at 50 psi with Bleed Open)	Auxiliary outlet not needed	Equivalent
19	Inlet Fitting	DISS or NIST	DISS or NIST	Equivalent
20	Bleed Flow @50 psi	3 lpm or less	Not required for PF-H functionality	Equivalent PH-H easier to use, no bleed off required to operate
21	No. of Primary Outlet Ports	1	1	Equivalent
22	No. of Auxiliary Outlet Ports	1	0	PF-H for single patient use

* The Precision Medical, Inc. Heliox/Oxygen Blender needs a minimum input flow rate of 30 psi to operate. In order to delivery a lower flow rate to the patient, the excess gas is vented to atmosphere (bleed).

A comparison of the Precision Flow® - Oxygen/Heliox to the Precision Flow® - Oxygen/Air is as follows:

#	Item	Vapotherm, Inc. Precision Flow® - Oxygen/Air, K072845	Vapotherm, Inc. Precision Flow® - Oxygen/Heliox, K111640	Comments
1	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 Precision Flow® - Heliox is intended to warm and add moisture to breathing gases from an external source for administration to neonate/infant, pediatric and adult patients in the hospital and sub-acute institutions. It adds heat and moisture to a blended medical heliox (79% helium, 21% oxygen)/oxygen mixture and assures the integrity of the precise heliox (79% helium, 21% oxygen)/oxygen mixture via an integral oxygen analyzer. The flow rates may be from 1 to 40 liters per minute via nasal cannula.	Equivalent
2	Patient population	Neonate/infant, pediatric, and adult patients.	Neonate/infant, pediatric and adult patients	Equivalent
3	Technology	Electronic/Mechanical	Electronic/Mechanical	Equivalent
4	Oxygen % Range	21 to 100%	21 to 100%	Equivalent
5	Oxygen Concentration Monitor	Internal oxygen analyzer	Internal oxygen analyzer	Equivalent
6	Oxygen Concentration Range	21 to 100%	21 to 100%	Equivalent
7	Supply Pressure Range	4 to 70 psi, Air/Oxygen	4 to 70 psi, Heliox medical grade & certified gas cylinder	Equivalent
8	Operating Temperature	33° to 43° C	33° to 43° C	Equivalent
9	Environment of use	Hospital and sub-acute institutions	Hospital and sub-acute institutions	Equivalent
10	Condition Gas: Warm & Humidify	Integrated into device	Integrated into device	Equivalent
11	FiO_2 Accuracy	1 to 40 lpm: +/- 2 %	2 to 40 lpm: +/- 2% 1 to 2 lpm: +/- 5%	Equivalent
12	Max Flow Range	40 lpm	40 lpm	Equivalent

#	Item	Vapotherm, Inc. Precision Flow® - Oxygen/Air, K053232	Vapotherm, Inc. Precision Flow® - Oxygen/Heliox, K111640	Comments
13	Alarms	Alarms for General Fault (internal component failure), Blocked Delivery Tube, Water Out, Disposable Water Path function, Battery Charging (AC disconnected), Vapor Transfer Cartridge type & fault, Gas Supply, Gas Temperature	Alarms for General Fault (internal component failure), Blocked Delivery Tube, Water Out, Disposable Water Path function, Battery Charging (AC disconnected), Vapor Transfer Cartridge type & fault, Gas Supply, Gas Temperature	Equivalent
14	Alarm Sound Level	Medium Priority 47 db @ 1 m Low Priority 45 db @ 1 m.	Medium Priority 47 db @ 1 m Low Priority 45 db @ 1 m.	Equivalent
15	Inlet Fitting	DISS or NIST	DISS or NIST	Equivalent

The Precision Flow® - Heliox has the same intended uses and similar indications, technological characteristics, and principles of operation as the Precision Medical, Inc. Heliox/Oxygen Blender (K090781). The conversion of the mass flow meter from air to Heliox and the minor change for the percentage oxygen range raises no new issues of safety or effectiveness. Performance data of the blending of Heliox and oxygen demonstrate that the Precision Flow® - Heliox is as safe and effective. Thus, the Precision Flow® - Heliox is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Gregory A. Whitney
Vice President Regulatory Affairs
Vapotherm, Incorporated
198 Log Canoe Circle
Stevensville, Maryland 21666

OCT - 7 2011

Re: K111640
Trade/Device Name: Vapotherm Precision Flow®, Heliox
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: September 26, 2011
Received: September 29, 2011

Dear Mr. Whitney:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Indication for Use Statement

510(k) Number (if known): K111640

Device Name: Vapotherm Precision Flow®, Heliox

Indications for Use:

The Precision Flow® - Heliox is intended to warm and add moisture to breathing gases from an external source for administration to neonate/infant, pediatric and adult patients in the hospital and sub-acute institutions. It adds heat and moisture to a blended medical heliox (79% helium, 21% oxygen)/oxygen mixture and assures the integrity of the precise heliox (79% helium, 21% oxygen)/oxygen mixture via an integral oxygen analyzer. The flow rates may be from 1 to 40 liters per minute via nasal cannula.

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 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: K111640