K090781

510(k) Summary

Precision Medical, Inc. Blender

Submitter Information

Submitter	Precision Medical, Inc. 300 Held Drive Northampton, Pa. 18067
Contact	James Parker Quality Assurance Manager
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AUG 1 3 2009

Preparation Date: March 20, 2009

Device Name

Proprietary Name:	HeliO2 Blender
Common Name:	Helium- Oxygen Blender
Classification Name:	Blender, HeliO2 Unit (BZR) as per CFR 868.5330
Two models:	
Low flow Blender	PM 5470/5480 flow, range 2 to 30 liters per minute
High flow blender	PM 5580/5570 flow, range 15 to 120 liters per minute

Predicate Device Equivalence

510K # K053232

Precision Medical, Inc. is claiming substantial to Precision Medical, Inc. oxygen blender same as oxygen blender except air fitting has been replaced with helium male fitting and scale on dial has been altered to add the Helium to the concentration.

Four models will be marketed

1. Low flow HeliO2 uses 70/30 helium to oxygen mixture
2. Low Flow HeliO2 uses 80/20 helium to oxygen mixture
3. Hi Flow HeliO2 uses 70/30 helium to oxygen mixture
4. Hi Flow HeliO2 uses 80/20 helium to oxygen mixture.

Device Description

The Precision Medical, Inc. Heliox/oxygen blender is a restricted medical device intended for use by qualified and trained personnel under the direction of a physician in institutional environments where delivery of Heliox/oxygen mixtures are required.

Intended 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 in 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.

Table of Comparisons to Predicate Device

Manufacturer	Precision Medical, Inc. Heliox/oxygen blender	Precision Medical, Inc. air/oxygen blender
Dimensions	H 3 ½ " W 2 ¼ " 5 ¼ "	H 3 ½ " W 2 ¼ " 5 ¼ "
Weight	2 ¾ lbs	2 ¾ lbs
Oxygen % Range	20 to 100% and 30 to 100%	21 to 100%
Accuracy	± 3% of full scale	± 3% of full scale
Supply Pressure	30-75 psi Heliox + O2 must be within 10 psi of each other	30-75 psi air + O2 must be within 10 psi of each other
Max Flow (High Flow)	≥ 120 lpm @60% setting at 50psi inlet pressures	≥ 120 lpm @60% setting at 50psi inlet pressures
Pressure Drop (high flow)	≤ 3 psi at inlet pressures from 30-90 psi and at 30lpmflow rate at 60% FiO2	≤ 6 psi at 50 psi inlet pressure and 40 lpm flow
Alarm/Bypass Reset	When inlet gas pressure differential is ≤ 6 psi	When inlet gas pressure differential is ≤ 6 psi
Alarm intensity	≥80 db at 1 foot	80 db at 1 foot
Operating temperature	59°F to 104°F	59°F to 104°F

The low flow model has the same characteristics as listed above, with the Max flow and the pressure drop being the only differences.

Manufacturer	Precision Medical, Inc. Heliox/oxygen blender	Precision Medical, Inc. air/oxygen blender
Max Flow (Low Flow)	≥ 30 lpm @60% setting at 50psi inlet pressures	≥ 30 lpm @60% setting at 50psi inlet pressures
Pressure Drop (low flow)	≤ 2 psi at 30-90 psi inlet pressure and 10 lpm flow Rate at 60%FiO2	≤ 6 psi at 50 psi inlet pressure and 10 lpm flow

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. James Parker
Quality Assurance Manager
Precision Medical, Incorporated
300 Held Drive
Northampton, Pennsylvania 18067

AUG 13 2009

Re: K090781
Trade/Device Name: Helium-Oxygen Blender
Regulation Number: 21 CFR 868.5330
Regulation Name: Breathing Gas Mixer
Regulatory Class: II
Product Code: BZR
Dated: August 10, 2009
Received: August 11, 2009

Dear Mr. Parker:

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

510 (k) number K090781
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Indications for use:
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Prescription Use__X__ (Per 21 CFR 801.109) Or Over the counter use_____ (Optional Format 1-2-9)

(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

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