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K 053232

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
Tel: Fax:	(610)-262-6090 Extensions 228 (610)-262-6080
Preparation Date:	November 17, 2005

Device Name

Proprietary Name:	Precision Blender
Common Name:	Oxygen Blender
Classification Name:	Blender, Oxygen Unit (73 ~~BYJ~~ BZR) as per CFR 868.5330
Two models:	
Low flow Blender	PM 5300 flow, range 0 to 30 liters per minute
High flow blender	PM 5200 flow, range 2 to 120 liters per minute

Predicate Device Equivalence

Precision Medical, Inc. is claiming substantial equivalence to the Bio-Med Blender 510K # K925982

Device Description

The Precision Medical, Inc. Air and 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 air/oxygen mixtures is required.

Intended Use

The Precision Medical Inc. Air and oxygen blender is designed to dispense a continuous and precise blend of Medical Air and Oxygen via outlet ports to infant, pediatric, and adult patients. The exact FIO2 blend of gases corresponds to the dialed in Fractional Concentration of Oxygen (FiO2) setting indicated by the control face.

Table of Comparisons to Predicate Device

Manufacturer	BIO-Med Blender	Precision Medical, Inc.
Dimensions	H 3 ½ "x W 2 ¼" D 2 7/8 "	H 3 ½ " W 2 ¼ " 5 ¼ "
Weight	2 ¾ lbs	2 ¾ lbs
Oxygen % Range	21 to 100%	21 to 100%
Accuracy	± 3% of full scale	± 3% of full scale
Supply Pressure	30-75 psi air + 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)	≤ 6 psi at 50 psi inlet pressure and 40 lpm flow	≤ 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° 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	BIO-Med Blender	Precision Medical, Inc.
Max Flow (Low Flow)	≥ 30 lpm @60% setting at 50psi inlet pressures	≥ 30 lpm @60% setting at 50psi inlet pressures
Pressure Drop (low flow)	≤ 6 psi at 50 psi inlet pressure and 10 lpm flow	≤ 6 psi at 50 psi inlet pressure and 10 lpm flow

Summary of Performance Testing

The Precision Medical, Inc. Blender will successfully pass tests in the following areas;
Mechanical / Climatic
Device Performance

Conclusions

In Summary, Precision Medical, Inc. has demonstrated that the Precision Medical, Inc. oxygen blender is safe and effective. The combined testing and analysis of results provides assurance that the device meets the specifications and is safe and effective for the intended use.

Risk Analysis

Precision Medical, Inc. is using International Standard ISO 14971 Medical Devices Application of Risk management to medical devices
Risk analysis has been completed for this device.
This document will be updated and released as part of design control.

Design control

Precision Medical, Inc. is in compliance with 21 CFR 820.30 for design control. The design inputs/outputs matrix has been developed using form PMF 202.
These documents will be completed before the release of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 10 2006

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

Re: K053232
Trade/Device Name: Precision Medical, Inc Blender
Regulation Number: 868.5330
Regulation Name: Breathing Gas Mixer
Regulatory Class: II
Product Code: BZR
Dated: November 17, 2005
Received: November 18, 2005

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.

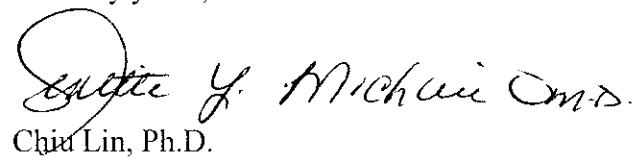
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chin 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

510 (k) number (if known)_____
Device Name: Precision Medical, Inc.Blender
Indications for use:
The Precision Medical, Inc. Blender Oxygen System is intended to deliver blended air and oxygen in a Hospital setting. Oxygen concentrations can be dialed in from 21% to 100%. The blender is not intended as a life supporting device.

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 of Anesthesiology, General Hospital, Infection Control, Dental Devices

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