OCT 4 - 2004

K041122

510(k) Summary

Precision Medical, Inc. Portable Liquid Oxygen System

Submitter Information

Submitter	Precision Medical, Inc. 300 Held Drive Northampton, Pa. 18067
FDA registration number:	2523148
Contact	James Parker Quality Assurance Manager
Tel: Fax:	(610)-262-6090 Extensions 228 (610)-262-6080

Preparation Date: April 22, 2004

Device Name

Proprietary Name:	Precision Liquid Oxygen System
Common Name:	Portable Liquid Oxygen Unit
Classification Name:	Portable Liquid Oxygen Unit (73 BYJ) as per CFR 868.5655

Class II Device

Predicate Device Equivalence

Precision Medical, Inc. is claiming substantial equivalence to the Puritan-Bennett Helios Liquid Oxygen System K 993220.

Device Description

The Precision Medical, Inc. Liquid Oxygen system consists of a vacuum insulated cryogenic container that includes a pressure relief valve
and a pneumatic conserver.
The vacuum insulated container allows oxygen to be stored in a liquid state under pressure. When the control valve is positioned to deliver, liquid oxygen inside the container is warmed and changes to gaseous state.
The gas is than allowed to be released to the patient at the set rate.
The device is intended to be used with a larger stationary liquid
oxygen reservoir,where it is filled by a connection that allows the portable
device to be filled by the larger reservoir.
The Precision Medical Inc System is a mechanical device containing no electrical components.

Intended Use

The Precision Medical, Inc. Liquid Oxygen System is intended to provide supplemental oxygen to patients who may have difficulty extracting oxygen from the air that they breathe. The patients would normally receive the oxygen via a nasal cannula. The system delivers 100% oxygen at 4 different flow settings. It is intended to be used as ambulatory source of oxygen both inside and out side of the patient's home. It is not intended as a life-supporting device. The device has no contraindications.

Comparison of Technological Characteristics

The Helios and the Precision Medical, Inc. Liquid Oxygen System include a vacuum insulated cryogenic container, heat exchange system, and a pneumatic conserver. Both devices are intended only as sources of supplemental oxygen and are not intended to be life-supporting devices.

Summary of Performance Testing

The Precision Medical, Inc. Liquid Oxygen System successfully passed tests in the following areas;
Mechanical / Climatic
Device Performance

Conclusions

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

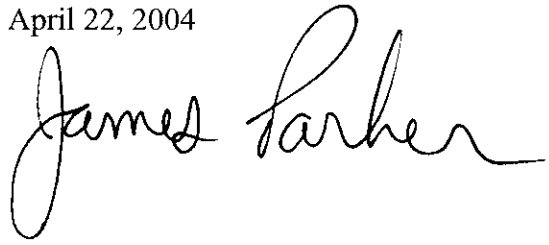
Risk Analysis:

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.

James Parker
Quality Assurance Manager
April 22, 2004



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 4 - 2004

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

Re: K041122
Trade/Device Name: Precision Medical, Inc. Liquid Oxygen System
Regulation Number: 868.5655
Regulation Name: Portable Liquid Oxygen Unit
Regulatory Class: II
Product Code: BYJ
Dated: September 9, 2004
Received: September 10, 2004

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) 276-0115. 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/dsma/dsmamain.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):

Device Name: Precision Medical, Inc. Liquid Oxygen System

Indications For Use:

The Precision Medical, Inc. Liquid Oxygen System is intended to provide supplemental oxygen to oxygen patients who may have difficulty extracting oxygen from the air that they breathe. The patients would normally receive the oxygen via a nasal cannula. The system delivers 100% oxygen at 4 different flow settings. It is intended to be used as ambulatory source of oxygen both inside and out side of the patient's home. It is not intended as a life supporting device. The device has no contraindications.

Prescription Use ✔ 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

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