K051691

DEC 9 2005

510(k) Summary

Precision Medical, Inc. Portable Liquid Oxygen System

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:	June 20, 2005

Device Name

Proprietary Name:	Minimate compressor
Common Name:	Portable Nebulizer Compressor
Classification Name:	Compressor, Air , Portable/73BTI
Device classification	Class II
Classification Number	868.6250

Predicate Device Equivalence

Precision Medical, Inc. is claiming substantial equivalence to Precision Medical Care Mist compressor/ K923324/A

Device Description

The compressor is made up of three basic sections

1. Electrical motor
2. Compressor
3. Housing

A 1/30 hp electrical motor drives the air compressor.
The compressor is a piston type, which is self lubricating, thus providing a oil free, air supply to the nebulizer.
The housing provides protection for the components, reduces noise, and dampens the vibration from the compressor. The housing also protects the end user from the components of the device.

Intended Use

To provide compressed air for a hand held medication small volume nebulizer.
Not for continuous use.
Use must be limited to maximum 30 minute intervals.

Comparison of Technological Characteristics

Precision Medical Inc is claiming equivalence to the Precision Medical, Inc. Care mist compressor

Summary of Performance Testing

The Precision Medical, Inc. Minimate compressor PM5 successfully passed tests in the following areas;
Mechanical / Climatic
Electrical
Device Performance

Conclusions

In Summary, Precision Medical, Inc. has demonstrated that the Precision Medical, Minimate compressor PM5 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 9 2005

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

Re: K051691
Trade/Device Name: Precision Medical, Inc. MiniMate Compressor
Regulation Number: 21 CFR 868.6250
Regulation Name: Portable Nebulizer Compressor
Regulatory Class: II
Product Code: BTI
Dated: November 3, 2005
Received: November 4, 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.

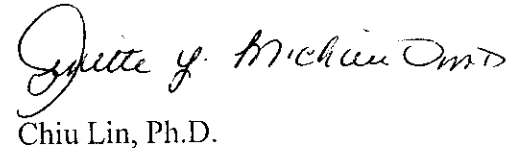
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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) K051691

Device Name: Precision Medical, Inc.MiniMate compressor

Indications for use:
The Precision Medical, Inc. Minimate compressor is intended to provide Compressed air to a small volume nebulizers. .The device is intended to be used at a 50% duty cycle. It is not intended as a life supporting device.

Prescription 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 if needed)

Concurrence of CDRH, office of device Evaluation (ODE)

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

510(k) Number K051691