K103324

APR 2 1 2011

510(k) Summary
Precision Medical, Inc. Easymate 6+6

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 6, 2011

Device Name

Easy Mate 6+6

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 Precision Medical 2200 liquid oxygen system K041122

Intended Use

The Precision Medical, Inc. Easy Mate 6+6 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 Easy Mate 6+6 deliver 100% oxygen at 5 Conserved settings or 6 continuous flow settings. The device is intended to be used as ambulatory source of oxygen both inside and outside of the patient's home.

Device Description

The Precision Medical, Inc. Easy Mate 6+6 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 Easy Mate 6+6
Is a mechanical device containing no electrical components.

Comparison of Technological Characteristics

The Easy Mate and the Easy Mate 6+6 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. Easy Mate 6+6 has successfully passed tests in the following areas;
Mechanical / Climatic
Device Performance

Conclusions

In Summary, Precision Medical, Inc. has demonstrated that the Precision Medical, Inc. Easy Mate 6+6 is safe and effective. The combined testing and analysis of results provides assurance that the device meet the specifications and is safe and effective for the intended use.

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

APR 2 1 2011

Re: K103324
Trade/Device Name: Precision Medical, Inc. Easy Mate 6+6
Regulation Number: 21 CFR 868.5655
Regulation Name: Portable Liquid Oxygen Unit
Regulatory Class: II
Product Code: BYJ
Dated: April 7, 2011
Received: April 8, 2011

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. 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

510 (k) number 103324

Device Name: Precision Medical, Inc. Easy Mate 6+6

Indications for use:

The Precision Medical, Inc. Easy Mate 6 + 6 are intended to provide supplemental oxygen to patients who may have difficulty extracting oxygen from the air that they breathe. These patients would normally receive the oxygen via a nasal cannula. The systems delivers 100% oxygen at different flow settings. It is intended to be used as ambulatory source of oxygen both inside and out side of the patient's home.

(Please do not write below this line- continue on another page if needed)

Concurrence of CDRH, office of device Evaluation (ODE)

Prescription Use: X (Per 21 CFR 801.109) Or Over the counter use_____ (Optional Format 1-2-9)

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

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