SEP - 6 2005

K051192

SUMMARY OF SAFETY AND EFFECTIVENESS

PRAXAIR, INC.
Proprietary and Confidential Information

COMPANY INFORMATION

Praxair, Inc.
175 East Park Drive
Tonawanda, NY 14150
Contact: Tamara Brown, Associate Project Manager, Healthcare R&D
Phone; 716-879-7465
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PREPARATION DATE

April 19, 2005

DEVICE NAME

PROGENAIRE™ Compressor-free Medical Air system

COMMON NAME

Mixer, Breathing Gases, Anesthesia Inhalation

PRODUCT CLASSIFICATION

Class II, 21 C.F.R. § 868.5330 Product Code: BZR

PREDICATE DEVICE

K031860 M202 Monitoring Mixer

DESCRIPTION

The PROGENAIRE™ Compressor-free Medical Air system is a device which mixes medical grade oxygen and nitrogen from hospital bulk supply systems to provide a product Medical Air USP.

INTENDED USE

The Praxair Medical Air system is designed to provide Medical Air on demand up to a peak flow rate of 4000 scfh. It is to be used to supply Medical Air only to the central supply system of a hospital/ healthcare facility for delivery to patients for purposes under the direction of a physician. Typical uses of the Medical Air produced by the mixer are respiration and calibration of medical devices for respiratory applications.

Both the Praxair Medical Air system and the predicate device are intended to blend two different gases. While the predicate device blends independent streams of oxygen and Medical Air, the Praxair Medical Air mixer blends independent streams of oxygen and nitrogen. Additionally, the Praxair Medical Air system is intended to provide Medical Air to the central supply system of a hospital/health care facility for delivery to multiple patients through wall outlets, whereas the predicate device provides mixed gas to a single

patient. These differences between the Praxair mixer and the predicate device do not raise new issues of safety or effectiveness.

TECHNOLOGY CHARACTERISTICS

Both the Praxair Medical Air system and the predicate device provide continuous monitoring of oxygen concentration and pressure levels and alarms to signal when these and other critical operating parameters are outside specified ranges. The Praxair blender provides Medical Air USP at a pressure sufficient to provide Medical Air at a pressure of 50-55 psig to hospital outlets. Pneumatic pressure regulators and flow control are used to control oxygen concentration in the product mixture. Unlike the predicate device, the oxygen concentration of the product air is not selectable by the user.

A visual alarm system and shutdown is provided with the Praxair system to alert the user should oxygen concentration fall out of range. Alarms are also activated when critical operating parameters are non-conforming. In addition, backup system(s) activate during mixer shutdown; audible and visual alarms are provided in case of back-up system activation.

TESTING

In order to verify that the Praxair system does not raise new issues of safety or effectiveness and, thus, is substantially equivalent to the predicate device, bench and environmental testing were performed. These tests confirmed that the mixer produces Medical Air within USP limits for oxygen concentration, 19.5 % - 23.5%. The relationship of critical processing and use-related parameters to the mixer performance was also evaluated. Alarm verification was also performed. The device complies with applicable sections of multiple standards, including ASTM 1462-93, the FDA guidance on electrical and mechanical safety and EMI/EMC, and FDA software guidelines. The results demonstrate that the Praxair Medical Air Mixer is as safe and effective as the predicate device and performs as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2005

Praxair, Incorporated
C/O Ms. Tamara Brown
Associate Project Manager
Healthcare Applications R&D
175 East Park Drive, 2/144
Tonawanda, New York 14150

Re: K051192
Trade/Device Name: PRAXAIR MEDICAL AIR MIXER
Regulation Number: 21 CFR 868.5330
Regulation Name: Medical Air Mixer/Breathing Gas Mixer
Regulatory Class: II
Product Code: BZR
Dated: August 22, 2005
Received: August 24, 2005

Dear Ms. Brown:

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 Device and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051192

Device Name: Praxair PROGENAIRE™ Compressor-free Medical Air System

Indications For Use:

The Praxair Medical Air mixer blends oxygen USP and nitrogen NF in order to provide Medical Air, USP having an oxygen concentration ranging between 19.5% and 23.5%. The device is to be used to supply Medical Air at a specific delivery pressure to the central supply system of a hospital/ healthcare facility for delivery through the hospital wall outlets to patients for purposes under the direction of a physician.

The mixer will be located outside of the patient care area of the hospital, in a location such as the hospital mechanical room.

Prescription Use ___X___ 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)

Sylvette Y. Richmond

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

510(k) Number: K051192