K030943

APR 22 2003

6) SMDA Summary:

Hi-Ox^{80} - Summary of Safety and Effectiveness

Company: SensorMedics Corporation
Address: 22705 Savi Ranch Parkway
Yorba Linda, CA 92887
Telephone 714 283-1830
Fax 714 283-8493

Contact:
Earl Draper

Proprietary Name:
Hi-Ox^{80}

Common Name:
High FiO2 Mask

Intended Use:
The Hi-Ox^{80} High FiO2 Mask is intended to deliver high inspired oxygen concentrations to patients who require elevated inspired oxygen.

Description of the Device:
The Hi-Ox^{80} is an oxygen mask to enable patients to inhale high concentrations of oxygen at moderate flow rates of 8 –10 lpm. It is a simple device consisting of a central manifold section where the patient mask, oxygen tubing and an oxygen reservoir bag attach. The triple valving in the manifold directs the oxygen to the patient and acts as an anti-asphyxiation valve removing the need for ventilation holes in the mask itself, thus allowing for delivery of high FiO2's.

Oxygen from the supply is either delivered to the patient via a one-way valve (inhalation valve) or stored temporarily in the oxygen reservoir bag. During exhalation, expired gas is directed to the atmosphere via another one-way valve (exhalation valve). In the event the patient's minute ventilation exceeds the oxygen supply flow rate, a third sequential dilution valve allows ambient air to get drawn into the inspired limb of the manifold eliminating the potential for asphyxiation.

The inhalation and exhalation one way valves are designed to have very low flow resistance (less than 1.5 cmH_2O, typically ~ 1.07 cmH_2O at flow rates of 60 lpm) to minimize the work of breathing. The sequential dilution

valve's resistance is specified to be less than 3 cmH2O/l/sec. The oxygen mask is made of a soft material for conformance to the patient's facial contours. Positioning of the manifold connection on the mask minimizes the effective deadspace.

Clinical and Non-Clinical Tests of Equivalency:

Most oxygen masks dilute the inspired oxygen because of two reasons. One is the presence of two entrainment ports on the mask that patients exhaled through, and the other is gas leaking due to poor fit of the mask to the face.

On inspiration, these entrainment ports provided a large source of dilution, particularly when the flow path between the inspired reservoir and the mask is of higher resistance than the holes. The Hi-Ox^{80} mask has no holes in the mask, thereby eliminating this major source of oxygen dilution.

The Hi-Ox^{80} mask has dual straps (one above and one below the ear) to achieve better sealing between the mask and the face. Additionally, the lower durometer mask material allows the mask to conform better to the face. The use of foam on the inside of the nose bridge portion of the mask and a metal strip further improve the seal across the bridge.

By positioning a sampling port (probe) through a hole on the side of the mask and directly in front of a user's nose, the oxygen concentration of the inhaled gas can be monitored. In experiments conducted using a SensorMedics 229 metabolic measurement system, we observed FiO_2 values in excess of 90% and over 80% at all times. These tests are reported in Appendix 7a.

Flow resistance of all the one-way valves employed have been found to be well below the design target of 1.5 cmH_2O at flows of 60 lpm, i.e. 0.025 cmH_2O per lpm. Typical pressure drops are in the range of 1.07 cmH_2O at 60 lpm. Subjective testing also confirm little or no effort required for breathing through the Hi-Ox^{80} oxygen mask assembly.

The valve flow resistance performance after exposure to extreme storage temperatures has been found to be unchanged from room temperature. This validation was completed with the help of a nationally recognized test laboratory (NRTL) and following the established ASTM F920 test protocols.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 2 2003

Mr. Earl W. Draper
Director of Quality Systems & Regulatory Affairs
SensorMedics Corporation
22705 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K030943
Trade/Device Name: Hi-Ox^{80} High FiO2 Mask
Regulation Number: 868.5870
Regulation Name: Non-Rebreathing Valve
Regulatory Class: II
Product Code: CBP and KGB
Dated: March 24, 2003
Received: March 26, 2003

Dear Mr. Draper:

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 (301) 594-4646. 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,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5) Indications For Use Enclosure:

Indication for Use

510(k) Number (if known): K030943

Device Name: Hi-Ox^{80} High FiO2 Mask

Indications For Use:

The Hi-Ox^{80} High FiO2 Mask is intended to deliver high inspired oxygen concentrations to patients who require elevated inspired oxygen.

(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: K030943