K032516

MAR - 4 2004

6) SMDA Summary:

Hi-Ox^{80} High FiO2 Oxygen Mask with the Aerosol Adapter - Summary of Safety and Effectiveness

Company:	SensorMedics Corporation
Address:	22705 Savi Ranch Parkway
	Yorba Linda, CA 92887
Telephone	714 283-2228
Fax	714 283-8426

Contact:

Yvette Lloyd

Proprietary Name:

Hi-Ox^{80} High FiO2 Oxygen Mask with the Aerosol Adapter

Common Name:

Oxygen Mask with Nebulizer Adapter

Intended Use:

The Hi-Ox^{80} High FiO2 Mask with the Aerosol Adapter is intended as an accessory for compatible nebulizers. The mask with adaptor is intended to enable the delivery of nebulized drugs to patients who also require elevated inspired oxygen concentrations.

Description of the Device:

The Aerosol Adapter for the Hi-Ox^{80} is an adapter that enables standard small-volume nebulizers (use only cup type, gas driven nebulizers without tee-fittings or air entrainment ports) with either 18 mm OD or 22 mm ID outlet ports to be adapted to the Hi-Ox^{80}. This will enable patients to be treated with nebulized products while receiving high concentrations of oxygen at moderate flow rates of 8 – 10 lpm. The valves in the Hi-Ox^{80} have been tested and found to function normally after nebulization of some commonly nebulized drugs in aqueous formulations. However, the valves could malfunction if the prescribed drug creates a sticky residue on the valves. The practitioner should observe the patient's respiration and the function of the Hi-Ox^{80} valves during and after nebulization of drugs via the Hi-Ox^{80}.

The Aerosol Adapter is a simple right angle fitting made of Santoprene, a medical grade thermoplastic elastomer material. The adapter can be snapped into a normally plugged port on the Hi-Ox^{80} just below the mask and between the inhalation-exhalation valves. This location for

the adapter places nothing between the nebulizer and the patient's airway so as to not impact any of the particles produced by the nebulizer.

The gas driving the nebulizer can supplement the normal oxygen supply for the Hi-Ox^{80}, and any flow in excess of what is required by the patient can exit the mask via the normal exhalation pathway. There is no risk of pressure buildup beyond that of the cracking pressure and flow resistance of the exhalation valve (~ 1 cmH2O/L/sec). This enables the patient to receive their nebulizer treatments while maintaining an elevated FiO2.

Clinical and Non-Clinical Tests of Equivalency:

Most aerosol adapters, which are considered as Class I devices, connect a nebulizer either directly to a disposable aerosol mask or via a right-angle adapter to a mouthpiece. The Aerosol Adapter for the Hi-Ox^{80} is equivalent to a right-angle adapter that connects a nebulizer to a mask. The Aerosol Adapter for the Hi-Ox^{80} would have the same effects on nebulizer performance as any other tee-fitting for nebulizer connections.

Flow resistance of all the one-way valves in the Hi-Ox^{80} 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. Testing of up to 2.5 hours of continuous nebulization of commonly nebulized aqueous solutions (i.e., Albuterol Sulfate, Ipratropium Bromide and Cromolyn Sodium) indicates that nebulization of these drugs have no material impact on the performance of the valves within the Hi-Ox^{80} and therefore imposes no increase in risk to the patient.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 4 2004

Mr. Paul Kittinger
Manager, Regulatory Affairs
SensorMedics Corporation
22705 Savi Ranch Parkway
Yorba Linda, California 92887-4645

Re: K032516
Trade/Device Name: Hi-OX 80 Aerosol Adapter
Regulation Number: 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: December 9, 2003
Received: December 11, 2003

Dear Mr. Kittinger:

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.

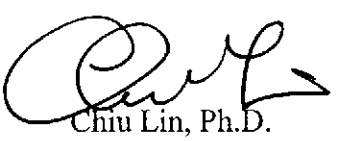
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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): K032516

Device Name: Hi-Ox^{80} High FiO2 Mask with the Aerosol Adapter

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 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: K032516