JUN 1 1 2002

K014211

Non-Confidential Summary of Safety and Effectiveness

June 5, 2002

Southmedic, Inc.
50 Alliance Blvd.
Barrie, Ontario, L4M 5K3
Canada

Tel - (705) 726-9383
Fax - (705) 728-9537

Official Contact: Lee McDonald - President

Proprietary or Trade Name: OxyArm CO_2

Common/Usual Name: Oxygen / Carbon Dioxide Sampling Mask

Classification Name: Accessory to Analyzer, gas, carbon dioxide, gaseous phase

Device: Oxygen / Carbon Dioxide Sampling Mask

Predicate Devices: Medsys / Southmedic - Capnoxygen mask - K971229
Southmedic – OxyArm oxygen - K001865
Respan Oxygen mask – K942907

Device Description:

The Southmedic OxyArm CO_2 is an oxygen delivery device with a headset and oxygen delivery port, which is placed in front of the patient vs. nasal cannula or over their mouth and nose. It also contains a port for taking a sample of expired gases, to measure exhaled end-tidal carbon dioxide. It is connected to a standard oxygen source and the sampling tubing to a standard end-tidal carbon dioxide monitor.

Intended Use:

Indicated Use -- To deliver oxygen to patients in low to medium concentrations and provide a means to sample expired gases.

Environment of Use -- Hospital, Sub-acute Institutions, Emergency services, Physician offices

Comparison to Predicate Devices:

Attribute	Proposed device – OxyArm CO_2	Southmedic OxyArm O_2 - K001865	Medsys / Southmedic Capnoxygen mask K971229
Intended use	To deliver oxygen to patients and provide a means to sample expired gases	To deliver oxygen to patients	To deliver oxygen to patients and provide a means to sample expired gases

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Attribute	Proposed device OxyArm CO_2	Southmedic OxyArm – O_2 - K001865	Medsys / Southmedic Capnoxygen mask K971229
Intended for single patient, multi-use	Yes	Yes	Yes
Prescription	Yes	Yes	Yes
Intended population	Any patient requiring oxygen delivery and expired gas sampling	Any patient requiring oxygen delivery	Any patient requiring oxygen delivery and expired gas sampling
Intended Environment of Use	Hospital, Physician Office, sub-acute, Emergency services	Same plus Home	Hospital, Physician Office, sub-acute, Emergency services
Design Features			
Various sizes	One size fits all	One size fits all	Multiple sizes
Delivers oxygen to patient nose and mouth	Yes	Yes	Yes
Covers patient nose and mouth	No	No	Yes
Can measure expired gases	Yes	No	Yes
Held on patient by	Head set	Head set	Elastic band
Comes into contact with patient's face	No	No	Yes
Materials			
Polyethylene, polypropylene, PVC	Yes	Yes	PVC and elastic rubber band for head strap
Contains latex	No	No	Yes
Performance			
Yields comparable CO_2 waveforms and values at various flow rates of oxygen	Yes	Note applicable	Yes
Capable O_2 % concentration at various flows	Yes	Yes	Yes

Differences between Other Legally Marketed Predicate Devices

There are no significant differences between the intended device and the predicates – Medsys Southmedic - Capnoxygen mask - K971229, Southmedic – OxyArm Oxygen - K001865, and Respan Oxygen mask – K942907.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2002

Southmedic, Inc.
Mr. Paul E. Dryden
c/o ProMedic Inc.
6329 W. Waterview Court
McCordsville, IN 46051-9501

Re: K014211
OxyArm CO_2
Regulation Number: 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II (two)
Product Code: 73 CCK
Dated: March 14, 2002
Received: March 15, 2002

Dear Mr.Dryden:

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.

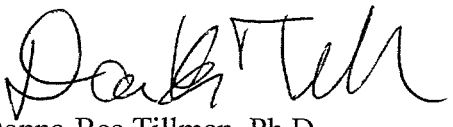
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.3 Indications for Use

510(k) Number: K014211 (To be assigned)

Device Name: OxyArm CO_2

Intended Use: To deliver oxygen to patients in low to medium concentrations and provides a means to sample expired gases

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K014211

Prescription Use ✓ **or** **Over-the-counter use** __
(Per CFR 801.109)