Capnoxygen LLC
522 Powell Grove Road
Lebanon, Tennessee 37090
Telephone 615-444-9536

K971229

SEP 2 3 1997

510(k) Summary

CAPNOXYGEN MASK

Submitter Information

Name:
Capnoxygen LLC

Address:
Capnoxygen LLC
522 Powell Grove Road
Lebanon, Tennessee 37090

Telephone number:
615-444-9536

Contact Person:
Dr. George Myers, 201-727-1703
Mr. R. Alan Davenport, 615-444-9536

Date of preparation:
March 20, 1997

Device Data

Trade Name: Capnoxygen Mask

Common Name: Oxygen mask with CO_2 sampling tube

Classification Name: None

Legally-marketed predicate device: Jemsdal A-221 Capnographic Mask

Description

The Capnoxygen mask provides a means to sample exhaled carbon dioxide via a sample tube inside an oxygen mask, during mouth and/or nose breathing. The gas sample line is

connected to the Capnograph monitor by a standard female Luer connector.

Intended Use

The CAPNOXYGEN mask is a medium concentration single-use mask intended to be used for the delivery of supplemental oxygen and monitoring breathing by sampling exhaled carbon dioxide. Standard connectors for the oxygen tubing and a standard female Luer connector for the gas sample line are provided. The mask is intended to be used for monitoring non-intubated patients who are breathing spontaneously.

Technological characteristics

The device has the same technological characteristics as the predicate device. Both are molded from plastic, provided with a sampling tube, and used in the same way.

Non-clinical tests

The submission presents data on the biocompatibility of the plastic materials used in the mask.

Clinical Tests

A clinical test was performed comparing the accuracy in measuring CO_2 with the Capnoxygen mask and with the predicate device in a group of volunteers. The test showed that the two had the same accuracy ± 10% with 95% confidence. Neither mask had any adverse effects.

Conclusion

The tests show that the two masks are equivalent in safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 1997

Mr. George H. Myers
Medsys Inc.
377 Route 17 South
Hasbrouck Heights, New Jersey 07601

Re: K971229
Capnoxygen Mask
Regulatory Class: II (two)
Product Code: 73 CCK
Dated: July 9, 1997
Received: July 11, 1997

Dear Mr. Myers:

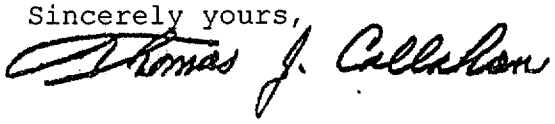
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: Capnoxygen Mask

Indications for Use:

The CAPNOXYGEN mask is a medium concentration single-use mask intended to be used for the delivery of supplemental oxygen and monitoring breathing by sampling exhaled carbon dioxide. Standard connectors for the oxygen tubing and a standard female Luer connector for the gas sample line are provided. The mask is intended to be used for monitoring non-intubated patients who are breathing spontaneously.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Charles C. Ho for NSC

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K971229

Prescription Use ✓ **OR** **Over-the-Counter Use**_____
(Per 21 CFR 810.109)

(Optional Format 1-2-96)