K031883 AUG 2 5 2003

Summary of Safety and Effectiveness

Date of Preparation
June 6, 2003

Applicant Name & Address
SensorMedics Corporation
a Subsidiary of VIASYS Healthcare
22705 Savi Ranch Parkway
Yorba Linda, CA 92887

Contact Person
Paul L. Kittinger
Manager, Regulatory Affairs
Phone: 714-283-2228
Fax: 714-283-8426

Trade Name of Device
Lyra™ Nasal Mask

Common Name of Device
Nasal Mask or Nasal Interface

Classification Name of Device
Non-continuous ventilator accessory

Classification & Classification Code
21 CFR 868.5905, 73 BZD, Class II

Device Description
The Lyra™Nasal Mask is intended for the delivery of air from either a CPAP or bi-level instrument (delivery device). The breathing circuit consists of the Lyra, which directly interfaces with the patient, and a pair of tubes, which connect the Lyra to the delivery device. The delivery device provides positive pressure air to the patient via the tubes and the Lyra™. Exhalation ports on the Lyra™ allows patient-exhaled gases to exhaust to the atmosphere.

The Lyra™ consists of the following:

1. two nasal prongs, which are easily removed or installed into a mask body for the interchange of different sizes, and for easy cleaning of the device;
2. adjustable head gear, which keeps the nasal mask in place during use;
3. a pair of tubings, with one end of the tubings attached to the mask body;
4. a standard 22-mm swivel which attached to the other end of the tubings.

The delivery device interfaces with the swivel via corrugated tubing, with a standard 22-mm fitting.

The Lyra™ nasal prongs, made from a soft, flexible silicone, form a seal with the patient's nares. The nasal prongs come in different sizes for better and more comfortable fit for patients with varying nares sizes.

The Lyra™ is packaged, along with instructions for use and recommended cleaning instructions, in a poly bag. The Lyra™ can be completely disassembled for cleaning. Mild soap and water may be used to clean the device.

Intended Use

The Lyra™ Nasal Mask is an accessory intended for use with devices that deliver Continuous Positive Airway Pressure (CPAP) and bi-level positive airway pressure in treating adult patients.

Predicate Device

Substantial equivalence is claimed to the Innomed Technologies' Nasal-Aire™ Nasal Mask having 510(k) No. K022465.

Summary of Performance Testing

There are no known mandatory or voluntary performance standards applicable to this device classification. The Lyra's performance is substantially equivalent to the performance of the Nasal Aire™ in comparative bench testing.

The Lyra's leak rates and dead space are comparable to Nasal Aire's data. Environmental and cleaning tests were also performed on Lyra™, the results of which are within the parameters as claimed in Nasal Aire's labeling.

Conclusion

Based on the above, we conclude that the Lyra™ Nasal Mask is substantially equivalent to the predicate device and, that, it is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 5 2003

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

Re: K031883
Trade/Device Name: Lyra Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Non-Continuous Ventilator, Accessory
Regulatory Class: II
Product Code: BZD
Dated: June 16, 2003
Received: June 19, 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,

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

510(k) Number (if known): K031883

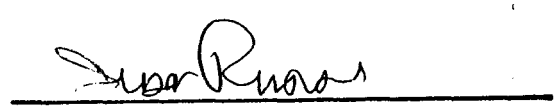
Device Name: **Lyra™ Nasal Mask**

Indications for Use:

The Lyra™ Nasal Mask is intended for use with devices that deliver Continuous Positive Airway Pressure (CPAP) and bi-level positive airway pressure in treating adult patients.

(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: K031883

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The Counter Use ____