2-24-99

K984254

Appendix 3: 510(k) Summary

Preparation Date:
November 23, 1998

Company:
SensorMedics Corporation
22705 Save Ranch Parkway
Yorba Linda, CA 92887
Telephone: (714) 283-2228
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Contact:
Paul L. Kittinger
Director, Regulatory Affairs

Proprietary Name:
Infant Flow Nasal CPAP Masks

Common Name:
Nasal CPAP Masks

Intended Use:
The SensorMedics Infant Flow Nasal CPAP Mask is intended for use with the SensorMedics Infant Flow System, consisting of a Driver and NCPAP Generator. It is intended to provide CPAP with a nasal mask for use in hospitals to treat newborns and infants with RDS or who are recovering from RDS.

Description:
The SensorMedics Infant Flow Nasal CPAP Mask is a silicone mask that fits into the generator of the Infant Flow System in place of the standard nasal prongs.

Clinical and Non-Clinical Tests of Equivalency:
The Infant Flow Mask is similar in purpose to the Hans Rudolph CPAP Mask (K962848) and provides the same function as the nasal CPAP prongs of the SensorMedics Infant Flow System (K974303) and Hamilton Aladdin CPAP System (K960359 and K945740).

Because there are no differences other than facial mounting and labeling between the SensorMedics Infant Flow System prongs and the SensorMedics Infant Flow Mask, no additional clinical tests were performed or submitted in the premarket notification. Refer to 510(k) numbers K960359 and K945740 for these data.

Non-clinical testing of the Infant Flow System using the mask as compared to the prongs demonstrated no differences in safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 1999

Mr. Paul L. Kittinger
SensorMedics Corporation
22705 Savi Ranch Parkway
Yorba Linda, CA 92887

Re: K984254
Infant Flow NCPAP Masks
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: November 23, 1998
Received: November 27, 1998

Dear Mr. Kittinger:

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 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). 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/dsma/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: K984254

DEVICE NAME: Infant Flow NCPAP Masks

INDICATIONS FOR USE:

The SensorMedics Infant Flow NCPAP Masks are intended for use with the SensorMedics Infant Flow System, consisting of a Driver and NCPAP Generator. It is intended to provide CPAP with a nasal mask for use in hospitals to treat newborns and infants with RDS or who are recovering from RDS.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K984254

Prescription Use ✓
(Per 21 CFR 801.109)

Over-The-Counter-Use ____
[Optional Format (1-2-96)]