JUL 2 4 2001 K012034

Infant Flow System - Summary of Safety and Effectiveness

Company:

SensorMedics Corporation
22705 Savi Ranch Parkway
Yorba Linda, CA 92887
714 283-1830

Contact:

Paul Kittinger

Proprietary Name:

SiPAP Infant Nasal CPAP Circuit

Common Name:

Nasal CPAP Circuit

Intended Use:

The SensorMedics SiPAP Infant Nasal CPAP Circuit, consisting of a pressure generator, Nasal CPAP Prongs and Masks, is intended to provide CPAP for use in hospitals to treat newborns and infants with RDS or who are recovering from RDS.

Description of the Device:

Detailed description of the device circuit is contained in the SiPAP Infant Nasal CPAP Operator's Instructions.

Clinical and Non-Clinical Tests of Equivalency:

The SiPAP Infant Nasal CPAP Circuit is the equivalent device circuit as the Infant Flow distributed by Hamilton Medical under the "Aladdin" name (510(k) #"s K960359 and K945740) and the Infant Flow distributed by SensorMedics under 510(k)'s K974303, K984254 and K991972.

Because there are no performance differences between the SensorMedics SiPAP Infant Nasal CPAP Circuit, the SensorMedics Infant Flow Circuit and the Hamilton Medical Aladdin Circuit, no additional clinical or non-clinical tests were performed or submitted in the premarket notification. Refer to 510(k) numbers s K960359 and K945740 for this data.

Appendix 7

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 4 2001

Mr. Earl Draper
SensorMedics Corporation
22705 Savi Ranch Parkway
Yorba Linda, CA 92887-4645

Re: K012034
SiPAP Infant Nasal CPAP Circuit
Regulation Number: 868.5905
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: June 27, 2001
Received: June 29, 2001

Dear Mr. Draper:

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.

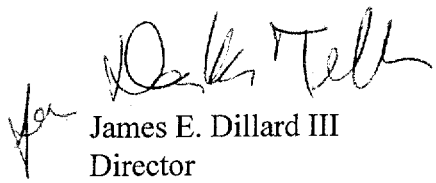
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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) 594-4646. 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 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,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K012034

DEVICE NAME: SiPAP Infant Nasal CPAP Circuit

INDICATIONS FOR USE:

The SensorMedics SiPAP Infant Nasal CPAP Circuit, consisting of a pressure generator, Nasal CPAP Prongs and Masks, is intended to provide CPAP for use in hospitals to treat newborns and infants with RDS or who are recovering from RDS.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format (1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012034

Appendix 6