FEB 1 3 2004

K031745

510(k) SUMMARY

Date Summary Prepared

May 1st, 2002

COMPANY NAME AND ADDRESS

SensorMedics Corporation
22705 Savi Ranch Parkway
Yorba Linda, CA 92887
USA

CONTACT PERSON

Earl W. Draper
Director QS/RA
Telephone (714) 283-2228
Fax: (714) 283-8426

DEVICE TRADE NAME Infant Flow Plus™

COMMON NAME Bi-level Nasal CPAP

PREDICATE DEVICES

1. Device Name: Star Sync
Classification: Class II
Manufacturer: Infrasonics, Inc.
3911 Sorrento Valley Blvd.
San Diego
CA 92121-1402
510(k) #: K840865 & K884521

2. Device Name: Infant Flow System
Classification: Class II
Manufacturer: EME (Electro Medical Equipment) Ltd
60 Gladstone Place
Brighton
Sussex, BN2 3QD
United Kingdom
510(k) #: K011516

3. Device Name: Model IV-100B Infant Ventilator
Classification: Class II
Manufacturer: Sechrist
510(k)# K833982

4. Device Name: Infant Flow System
Classification: Class II
Manufacturer Manufactured for SensorMedics by
EME (Electro Medical Equipment) Ltd
60 Gladstone Place
Brighton
Sussex, BN2 3QD
United Kingdom
510(k)# K991972

When compared to the predicate devices, the Infant Flow Plus System does not incorporate any significant change in intended use, method of operation, material or design that could affect the safety or effectiveness of the subject device.

DEVICE DESCRIPTION

The Infant Flow Plus System is a factory-installed modification to the Infant Flow Plus System. It uses the existing manually operated air / oxygen mixer and CPAP flow control. An ancillary manual flow control with electronic control solenoid valve allows timed delivery of augmented flow and pressure. The modification is housed in a robust enclosure that is designed to "piggy back" on to the existing Infant Flow Driver Unit.

INTENDED USE

The Infant Flow Plus System consisting of a Driver and Generator plus NCPAP Prongs and Masks, is intended for the provision of a Bi-Level CPAP (SiPAP) to produce a sigh. The system is for use in hospitals, hospital-type facilities and intra-hospital transport environments and is indicated for the treatment of newborn and infant patients.

PERFORMANCE DATA

The Infant Flow Plus System has been verified to be compliant with the requirements of the following standards:

- IEC60601-1, Medical Electrical Equipment. Part 1; General requirements for safety, Second Edition, 1998; Amendment 1, 1991-11; Amendment 2, 1995-03
- IEC60601-1-2, Second Edition, 2001, Medical Electrical Equipment, Part 1; General Requirements for Safety; Electromagnetic Compatibility – Requirements for Tests.
- IEC60601-1-4: 1996. Medical Electrical Equipment - Part 1: General requirements for safety: 4. Collateral Standard: Programmable electrical medical systems.
- UL 2601-1: Medical Electrical Equipment: General Requirements for Safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2004

SensorMedics, Incorporated
c/o Mr. Tom Gutierrez P.E.
VIASYS Healthcare GmbH
1100 Bird Center Drive
Palm Springs, California 92262

Re: K031745
Trade/Device Name: Infant Flow Plus Infant CPAP System
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: December 11, 2003
Received: December 16, 2003

Dear Mr. Gutierrez:

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,

for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Applicant: SensorMedics Corporation

510(k) Number: K031745

Device Name: Infant Flow Plus System

Indications for Use: The Infant Flow Plus System consisting of a Driver and Generator plus NCPAP Prongs and Masks, is intended for the provision of Bi-Level CPAP (SiPAP) to produce a sigh. The system is for use in Hospitals, Hospital-type facilities and intra-Hospital transport environments and is indicated for the treatment of Newborn and Infant patients.

Prescription Use: Yes (Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

Prescription Use / or OTC Use _____

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K031745