NOV 1 0 1999

K993167

510(K) SUMMARY
9-21-99

Device Name:

Classification Name:	Continuous ventilator
Common Name:	Infant ventilator
Proprietary Name:	Millennium

Devices to which Equivalence is Claimed: Model IV-100B K833982A
V.I.P. Bird Infant Ventilator K895541/K901885

Contact: Greg Godfrey, Vice President
Quality Assurance & Regulatory Affairs
4225 E. La Palma Avenue
Anaheim, CA 92807
Phone: (714) 579-8400 Fax: (714) 579-0814

Indication for Use

The intended use of the device is to provide ventilation to neonatal, infant, and pediatric patients.

Device Description

The Sechrist Millennium Infant Ventilator is an electro-pneumatic, continuous flow, time cycled, pressure limited infant ventilator. It is designed to ventilate neonatal to pediatric patients in Assist/Control, Synchronous Intermittent Mandatory Ventilation (SIMV), Continuous Positive Airway Pressure (CPAP), and Standby modes. In addition, pressure triggered ventilation and spontaneous breathing is also provided.

The ventilator has an electronically controlled pneumatic system. The pneumatic subsystem consist of an air/oxygen mixer, continuous flow control, pressure controls, and waveform control.

The electronically controlled subsystem uses the respiratory rate and inspiratory time control inputs to activate or deactivate the exhalation valve. The electronic subsystem also includes the pressure trigger sensing and manual breath functions.

Comprehensive alarm, display, and measurement subsystems are designed to provide patient safety and ease of user interface.

Performance Standards

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for infant ventilators.

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Summary of Substantial Equivalence

There are no significant changes in the intended use, performance specifications, or principal of operation of the Millennium Infant Ventilator. Existing technology, consistent with that used in comparative ventilators, has been incorporated into the design of this device. Cosmetic enhancements were made to the displays and packaging of the device. The addition of a trigger mechanism provides the ability to synchronize ventilation and includes SIMV and trigger sensitivity. Additional enhancements, not available on the cleared device, include CPAP+ backup, standby, breath type display , high rate alarm, and an hour meter.

Conclusion

Modifications made to the device do not affect the intended use or alter the fundamental scientific technology of the device. Therefore, the modified device is substantially equivalent to the cleared devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 1999

Mr. Greg Godfrey
Sechrist Industries, Inc.
4225 E. La Palma Avenue
Anaheim, CA 92807

Re: K993167
Millennium™ Infant/Pediatric Ventilator
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: October 12, 1999
Received: October 14, 1999

Dear Mr. Godfrey:

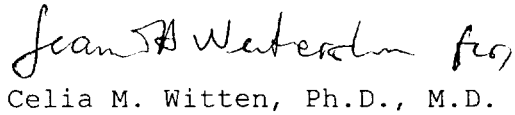
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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,



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): ~~K833982A~~ K993167

Device Name: Sechrist Millennium Infant Ventilator

Indications for Use:

The intended use of the device is to provide ventilation to neonatal, infant, and pediatric patients.

(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** _____
(Per 21 CFR 801.109)

(Optional Format 1-1-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K993167