DEC 20 1999

K993449

510(k) Summary

BIRD V.I.P. GOLD/STERLING INFANT /PEDIATRIC VENTILATOR

Bird Products Corporation.
1100 Bird Center Drive
Palm Springs, California 92262
Contact:
Neil Battiste
Phone Number (760) 778-7341
FAX (760) 778-7274

1.	CLASSIFICATION NAME:	Ventilator, Continuous
	COMMON/USUAL NAME:	Neonatal/Infant/Pediatric Ventilator
	TRADE/PROPRIETARY NAME:	BIRD V.I.P. GOLD/STERLING Infant/Pediatric Ventilator
2.	ESTABLISHMENT REGISTRATION NUMBER:	2021710
3	PRODUCT CLASSIFICATION	Class II
4.	ANESTHESIOLOGY DEVICE CLASSIFICATION PANEL	(73 CBK)

Bird 8400Sti Bird Products Corporation	(K930474)
Siemens Servo 300 A Ventilator Siemens	(K970839)
Bird Partner Volume Monitor Bird Products Corporation	(K901885) (K915488)

The additions to the ventilator will be:

The addition of Pressure Control mode of ventilation with Variable Rise Time, Volume Assured Pressure Support, Flow Triggering in Volume modes, a decelerating waveform, Inspiratory Pause and Inspiratory/ Expiratory Hold.

The V.I.P Bird ventilator is a self-contained unit, combining an advanced pneumatic system with microprocessor -based technology. The result is a state-of-the-art ventilator system capable of providing excellent patient monitoring. Packaged in a compact lightweight unit, the V.I.P. Bird Gold/Sterling will incorporate all previous function of the V.I.P. Bird and the addition of Pressure Control mode of ventilation with Variable Rise Time, Volume Assured Pressure Support, Flow Triggering in Volume modes and a decelerating waveform. Other enhancements include expanded control setting range for Tidal Volume, improved resolution for the Inspiratory Time and Peak Flow controls. These specifications also include the volume monitoring functions of the Partner IIi.

Statement of Intended use:

"The VIP Bird Gold and VIP Sterling are ventilators intended to treat respiratory failure or respiratory insufficiency, in neonatal, infant and pediatric patients. The ventilators are intended for institutional use only, and not for emergency medical transport or home use."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 20 1999

Mr. Darryl L. Shelby
Bird Products Corp.
1100 Bird Center Drive
Palm Springs, CA 92262

Re: K993449
Bird V.I.P. Gold/Sterling
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: November 22, 1999
Received: November 23 1999

Dear Mr. Shelby:

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,

Joanne Whitehead for,

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

Statement of Intended use:

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(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991449

✓ For Prescription Use