K022674

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

11/6/02

Manufacturing Site:	Bird Products Corporation 1100 Bird Center Drive Palm Springs, CA 92262
Contact:	Tom Gutierrez (760) 778-7255 (phone); (760) 778-7274 (fax)
Summary Date	July 24, 2002
Device Trade Name:	AVEA Ventilator
Device Common/Classification Name:	Classification name: 868.5895 Continuous Ventilator, 73 CBK
Establishment Registration Number	2021710
Device Class:	Class II
Classification Panel:	Anesthesiology
Predicate Device:	The predicate devices are:

BIRD AVEA Ventilator	Bird Products Corporation
DATEX-OHMEDA AESTIVA/5 with 7100 Ventilator Anesthesia System	DATEX-OHMEDA
OHMEDA EXCEL 3000 Anesthesia Gas System	OHMEDA
HOPE Nebulizer	B&B Medical Technologies

Device Description: The AVEA is a servo-controlled, software-driven ventilator. It has a dynamic range of breathing gas delivery that provides for neonatal through adult patients. Its user interface module provides maximum flexibility with simple operator interaction. It has a flat panel color LCD with real time charting and digital monitoring capabilities, a touch screen for interaction, membrane keys and a dial for changing settings and operating parameters. It also has an internal gas delivery system with servo controlled active inhalation and exhalation functions. The AVEA may be configured as a conventional ventilator or non-invasive positive pressure ventilator (NPPV). It has been designed to function using most commonly available accessories.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (Continued)

Intended Use:

The AVEA is intended to provide continuous respiratory support in an institutional health care environment. It may be used on adult, pediatric, and neonatal patients. Properly trained clinical personnel, under the direction of a physician should only operate it.

Substantial Equivalence

The modified AVEA Ventilator is the same device as the AVEA Ventilator, which was cleared for market under 510(k) K013642, except for the addition of a heliox connector and associated conforming labeling changes.

The modified AVEA Ventilator have the following similarities to those which previously received 510(k) concurrence:

- have the same indicated use,
- have similar indication as heliox predicate
- use the same operating principle,
- incorporate the same basic ventilator design with the exception of the modifications identified above.
- are manufactured and packaged utilizing the same basic processes.

In summary, the AVEA Ventilator described in this submission is, in our opinion, substantially equivalent to the predicate device(s).

Summary of Testing and Validation:

Performance testing of alarms, controls and monitors verified that the AVEA Ventilator meets it's performance requirements and that this device is substantially equivalent to medical devices currently legally marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 6 2002

Bird Products Corporation
C/O Mr. Jeffrey K. Shapiro
Hogan & Hartson
555 Thirteenth Street, NW
Washington, D.C. 20004-1109

Re: K022674
Trade/Device Name: AVEA Ventilator
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: August 12, 2002
Received: August 12, 2002

Dear Mr. Shapiro:

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.

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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 and additionally 21 CFR Part 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication For Use

510 (k) Number (if known): K022674 Page 1 of 1

Device Name: AVEA Ventilator

Indication For Use:

The AVEA is intended to provide continuous respiratory support in an institutional health care environment (e.g. hospitals). It may be used on adult, pediatric, and neonatal patients. It should only be operated by properly trained clinical personnel, under the direction of a physician. The AVEA is indicated for the delivery of air, oxygen or a helium-oxygen combination (Heliox).

(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 Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

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