K062093

SEP 20 2006

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Manufacturing Site:	VIASYS Respiratory Care Inc 1100 Bird Center Drive Palm Springs, CA 92262
Contact:	Tom Gutierrez (760) 778-7255 (phone); (760) 883-7181 (fax)
Summary Date	August 28, 2006
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:

510K	Product	Manufacturer
1 K031745	Infant Flow Plus Infant CPAP System (Trade Name: SIPAP System)	VIASYS Respiratory Care Inc
2 K970460	840 Ventilator with Neo Mode Option	Tyco Puritan Bennett

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 graphical user interface module (UIM) 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. Using internal batteries this provides inter-hospital transport as well as back up capability due to loss of AC power. The AVEA may be configured as a conventional ventilator or non-invasive positive pressure ventilator (NPPV). It has been designed to function using commonly available accessories.

Intended 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.

Substantial Equivalence

The AVEA Ventilator is the same device as the AVEA Ventilator, which was cleared for market under 510(k) K013642 and K022674.

Modifications to the AVEA Ventilator are associated with this submittal

- Software update encompasses a modification to the current Non-Invasive ventilation previously cleared under K013642 of which allows for a particular mode on the Infant Flow Plus, Nasal CPAP.
- This Nasal CPAP mode that is emulated is accomplished by a software modification only, utilizing existing AVEA hardware.
- This Nasal CPAP mode is only for single level continuous positive airway pressure to nasal prongs.

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

- have the same indicated use,
- use the same ventilation operating principle,
- incorporate the same basic ventilator design with the exception of modifications described in this submittal.
- incorporate the same basic electronic control system
- are manufactured and packaged utilizing the same basic processes.

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

Summary of Testing and Validation:

Performance testing 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

SEP 20 2006

Mr. Tom Gutierrez
Regulatory Affairs Manager
Viasys Respiratory Care, Incorporated
1100 Bird Center Drive
Palm Springs, California 92262

Re: K062093
Trade/Device Name: AVEA Ventilator
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: August 31, 2006
Received: September 1, 2006

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.

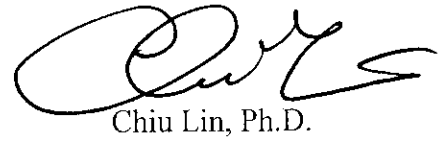
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,



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

Indication For Use

510(k) Number (if known): K062093

Device Name: AVEA VENTILATOR

Indications 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.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

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

(510(k) Number: K062093

(Posted November 13, 2003)