K081837

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Manufacturer:	Cardinal Health 207 22745 Savi Ranch Parkway Yorba Linda, CA 92887-4668
Contact:	Andre von Muller 714-283-8472 (Phone/Fax)
Summary date:	June 20, 2008
Device Trade Name:	AVEA Ventilator
Device Common/ Classification Name:	Continuous Ventilator
Regulation Number:	868.5895
Product Code:	CBK
Device Class:	II
Classification Panel:	Anesthesiology
Predicate Device:	The predicate devices used on this optional disposable Filter are: • Existing reusable filter assembly (Which is part of the AVEA Ventilator, cleared under K013642) • Intersurgical: Clear Guard II – K990949
Device Description:	The AVEA Ventilator is a fourth generation servo-controlled, software-driven ventilator. It has a dynamic range of breathing gas delivery that provides for neonatal through adult patients. Its revolutionary user interface module (UIM) provides maximum flexibility wit6h simple operator interaction. It has a flat panel color LCD with real time graphic displays and digital monitoring capabilities, a touch screen for easy interaction, membrane keys and a dial for changing settings and operating parameters. A precision gas delivery engine with servo controlled active inhalation and exhalation improves performance over previous generations. The only design change is an optional Disposable Expiratory Filter / Water Trap to be used exclusively with the AVEA Ventilator.

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Intended Use:	The AVEA Ventilator 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 be operated by properly trained clinical personnel, under the direction of a physician. This is the same intended use as previously cleared for AVEA under K013642, K022674, and K062093. There is no change to the AVEA intended use.
Substantial Equivalence:	The AVEA Ventilator remains the same in terms of intended use and fundamental scientific technology. The optional AVEA Disposable Expiratory Filter / Water Trap has the following similarities to the existing reusable filter, currently used on the AVEA Ventilator, which previously received 510(k) concurrence: • Is substantially equivalent in terms of BFE / VFE and resistance performance to predicate device (Clear-Guard II) previously cleared under K990949 • Has the same indicated use as the reusable existing filter / water trap which is integral to the AVEA Ventilator approved under K013642 In summary, the AVEA Disposable Expiratory Filter / Water Trap described in this submission is, in our opinion, substantially equivalent, in terms of safety, effectiveness, and performance, to the predicate device(s) currently in the market.
Summary of Testing Verification and Validation: (PERFORMANCE)	Verification and Validation Testing demonstrated that the AVEA Disposable Expiratory Filter / Water Trap meets its performance requirements at both: Component Level and System Level, 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

Mr. Andre von Muller
Regulatory Affairs Engineer
Cardinal Health 207, Incorporated
22745 Savi Ranch Parkway
Yorba Linda, California 92887-4668

AUG 13 2008

Re: K081837
Trade/Device Name: AVEA Disposable Expiratory Filter / Water Trap
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: August 7, 2008
Received: August 8, 2008

Dear Mr. Muller:

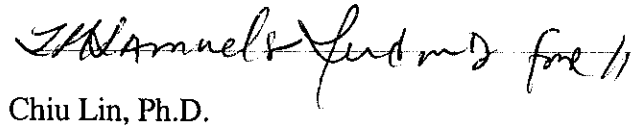
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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

Indications for Use

510(k) Number (if known): K081837

Device Name: AVEA Disposable Expiratory Filter / Water Trap

Indications for Use: The AVEA Ventilator 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 be operated by properly trained clinical personnel, under the direction of a physician.

This is the same intended use as previously cleared for AVEA under K013642, K022674, and K062093. There is no change to the AVEA intended use.

Prescription Use ✔ AND/OR Over the Counter Use _____
(21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE IN ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

W. Maly for M. Hasbad

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

510(k) Number: K081837

Posted November 13, 2003)