MAY 12 2011

K103211

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Manufacturing Site:	CareFusion 22745 Savi Ranch Parkway Yorba Linda, CA 92887 Tel. (714)922-7615
Contact:	Farokh Etemadieh (714) 922-7615 (phone); (714) 922-7615 (fax)
Summary Date	May 12, 2011
Device Trade Name:	AVEA Ventilator
Device Common/Classification Name:	Classification name: 868.5895 Continuous Ventilator, 73 CBK
Establishment Registration Number	2050001
Device Class:	Class II
Classification Panel:	Anesthesiology
Predicate Device:	The predicate devices are: 1. K083693: 840 Ventilator (Covidien) 2. K974176: Baby log 8000 (Drager Inc.)
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.

AVEA Volume Guarantee / Nasal intermittent positive pressure ventilation

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 neonatal through adult 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, K022674, k062093, K073069, and K081837.

Modifications to the AVEA Ventilator associated with this submittal:

The purpose of this traditional 510K submission is to request authorization for enhancement to the AVEA Ventilator applicable only to changes that are necessary to software implement Volume Guarantee which is the automated regulation of inspiratory pressure to achieve a Clinician specified target tidal volume, and is applicable to TCPL and PRESSURE modes of Ventilation and Nasal Intermittent Mandatory Ventilation which is a time-triggered time-cycled mode of pressure control Ventilation provided via nasal prongs on cannula.

All other AVEA requirements shall remain unchanged.

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 (Volume Guarantee and Nasal intermittent positive pressure ventilation) to the predicate devices.

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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Farokh Etemadieh
Senior Regulatory Affairs Associate
CareFusion
22745 Savi Ranch Parkway
Yorba Linda, California 92887

MAY 12 2011

Re: K103211
Trade/Device Name: AVEA Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: May 6, 2011
Received: May 11, 2011

Dear Mr. Etemadieh:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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): K103211

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 neonatal through adult patients. It should only be operated by properly trained clinical personnel, under the direction of a physician.

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

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

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

510(k) Number: K103211