K041775

OCT 2 6 2004

Date:	September 21, 2004
Subject:	510(k) Summary of Safety and Effectiveness Information for the GE Datex-Ohmeda Engstrom Carestation
Proprietary:	GE Datex-Ohmeda Engstrom Carestation
Common:	Ventilator, Continuous
Classification:	Anesthesiology, 73 CBK, 21 CFR 868.5895

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 1992.

The GE Datex-Ohmeda Engstrom Carestation is substantially equivalent to the following currently marketed device:

Drager Evita 4- Class II - 21CFR868.5895, which has been the subject of a cleared 510(k) with FDA log number K992608.

Drager Evita 2- Class II - 21CFR868.5895, which has been the subject of a cleared 510(k) with FDA log number K970165.

Datex-Ohmeda 7900 Ventilator –Class II - 21CFR868.5895, which has been the subject of several cleared 510(k)s, most recently with FDA log number K023366

The Engström Ventilator (EV) is a critical care ventilator that is flexible and physically adaptable to a variety of work environments and has an intuitive user interface that is common to many Datex-Ohmeda products. A wide selection of performance options gives the user full control of the system configuration. The Engström Carestation is a complete system featuring patient monitoring, patient ventilation, and the capability of interfacing with central information management systems.

The GE Datex-Ohmeda Engstrom Carestation is designed to provide mechanical ventilation for adults and pediatrics weighing 5kg and above having degrees of pulmonary impairment varying from minor to severe. The modes of ventilation are available include:

- Volume Controlled (VCV)
- Pressure Controlled (PCV)
- Pressure Controlled, Volume Guaranteed (PCV-VG)
- Synchronized Intermittent Mandatory Ventilation, Volume Controlled (SIMV-VC)
- Synchronized Intermittent Mandatory Ventilation, Pressure Controlled (SIMV-PC)
- Bi-level Airway Pressure Ventilation
- Constant Positive Airway Pressure/Pressure Support Ventilation (CPAP/PSV)
- Apnea backup (active in Bi-level and CPAP/PSV)

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The GE Datex-Ohmeda Engstrom Carestation is a microprocessor based, electronically controlled, pneumatically driven ventilator that includes integrated FiO2, airway pressure, spirometry and volume monitoring. Options include integrated respiratory gas monitoring capabilities via various Datex-Ohmeda patient monitoring modules.

The system is designed for facility use, including within-facility transport, and should only be used under the orders of a clinician.

The ventilator consists of three main components: a display, a ventilator unit, and an optional module bay. The display allows the user to interface with the system and control settings. The ventilator unit controls electrical power, nebulization, and pneumatic gas flow to and from the patient. The module bay allows the integration of various Datex-Ohmeda patient monitoring modules with the ventilator.
Optional accessories include a trolley/care, airway modules, module bay, support arm, humidifier and water trap mounting brackets, and auxiliary electrical outlets.

The GE Datex-Ohmeda Engstrom Carestation was designed to comply with the applicable portions of the following voluntary standards;

1. UL 2601 – General requirements for Medical Electrical Equipment
2. ASTM F1100 – Particular Requirements for Critical Care Ventilators
3. EN/IEC 60601-1: General requirements for Medical Electrical Equipment
4. EN/IEC 60601-1-2: 1998 - Medical Electrical Equipment - Electromagnetic Compatibility
5. EN 475 – Electrically Generated Alarm Signals
6. CGA V-1 ad ISO 5145 Medical Gas Cylinders – Threaded Cylinders
7. EN 980 Graphical Symbols
8. EN/IEC 60601-2-12, Medical Electrical Equipment – Critical Care Ventilators

The GE Datex-Ohmeda Engstrom Carestation and the currently marketed device are substantially equivalent in design concepts, technologies and materials. The GE Datex-Ohmeda Engstrom Carestation has been validated through rigorous testing that, in part, supports the compliance of GE Datex-Ohmeda Engstrom Carestation to the standards listed above.

Contact: Dan Kosednar, RAC
Manager, Regulatory Planning and Submissions

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 6 2004

Mr. Dan Kosednar
Manager, Regulatory Planning and Submissions
Datex-Ohmeda, Incorporated
CARE Business Area
P.O. Box 7550
Madison, Wisconsin 53707

Re: K041775
Trade/Device Name: GE Datex-Ohmeda Engstrom Carestation
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: September 27, 2004
Received: September 28, 2004

Dear Mr. Kosednar:

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.

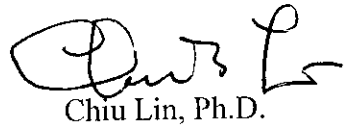
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Device Name: GE Datex-Ohmeda Engstrom Carestation

Indications For Use:

The GE Datex-Ohmeda Engstrom Carestation is designed to provide mechanical ventilation for adults and pediatrics weighing 5kg and above having degrees of pulmonary impairment varying from minor to severe. The modes of ventilation are available include:

- Volume Controlled (VCV)
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- Bi-level Airway Pressure Ventilation
- Constant Positive Airway Pressure/Pressure Support Ventilation (CPAP/PSV)
- Apnea backup (active in Bi-level and CPAP/PSV)

The Engstrom Carestation includes integrated Oxygen, FiO2, airway pressure, spirometry and volume monitoring and an integrated Aerogen Aeroneb Pro nebulizer. Options include integrated respiratory gas monitoring capabilities via various Datex-Ohmeda patient monitoring modules listed in the product labeling.

The system is designed for facility use, including within-facility transport, and should only be used under the orders of a clinician.

Prescription Use _XXX_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for AAG

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

510(k) Number: K040175