SEP - 9 2011

GE Healthcare

K111116

Datex-Ohmeda Inc.
P.O. Box 7550
Madison, WI 53707-7550 USA

Premarket Notification 510(k) Summary
As required by section 807.92
Engstrom Ventilator

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda, Inc.
PO Box 7550
Madison, WI 53707-7550 USA
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NAME OF CONTACT:

Ms. Monica Morrison
Mr. Jim Raskob (alternate)

DATE:

April 19, 2011

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Engström Carestation
Engström Pro

COMMON NAME:

Ventilator, Continuous

CLASSIFICATION NAME:

ventilator, continuous, facility use

CDRH PRODUCT CODE:

CBK

REGULATION NUMBER:

21 CFR 868.5895

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Engstrom Ventilator is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Engstrom Ventilator (K093886), and the Hamilton G5 Ventilator (K070513).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The GE Datex-Ohmeda Engström family of ventilators (Engström Carestation and Engström Pro) are flexible, adaptable, and intuitive critical care ventilators. 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 Engström Pro is a defeatured variant of the Engström Carestation.

Both the GE Datex-Ohmeda Engström Carestation and Engström Pro are designed to provide mechanical ventilation for adults and pediatrics weighing 5kg and above having degrees of pulmonary impairment varying from minor to severe. Optional Neonatal capabilities expand its patient range to 0.25 kg.

The modes of ventilation currently available include:

1. Volume Controlled (VCV)
2. Pressure Controlled (PCV)
3. Pressure Controlled, Volume Guaranteed (PCV-VG)
4. Synchronized Intermittent Mandatory Ventilation, Volume Controlled (SIMV-VC)
5. Synchronized Intermittent Mandatory Ventilation, Pressure Controlled (SIMV-PC)
6. Synchronized Intermittent Mandatory Ventilation, Pressure Controlled Volume Guarantee (SIMV-PCVG)
7. Bi-level Airway Pressure Ventilation
8. Constant Positive Airway Pressure/Pressure Support Ventilation (CPAP/PSV)
9. Apnea backup (available in SIMV-VC, SIMV-PC, SIMV-PCVG/BiLevel-VG, BiLevel, CPAP/PSV, and VG-PS)
10. Non-invasive ventilation (NIV), not available in neonatal mode
11. Infant Nasal CPAP (nCPAP), only available in neonatal mode
12. Volume Guarantee, Pressure Support (VG-PS), only available in neonatal mode

The GE Datex-Ohmeda Engström Carestation and Engström Pro are microprocessor based, electronically controlled, pneumatically driven ventilators that include integrated FiO2, airway pressure, spirometry and volume monitoring and an Aerogen Aeroneb Pro nebulizer control board.

The ventilator consists of two main components: a display and a ventilator unit. The display allows the user to interface with the system and control settings through use of soft keys on the display, a com wheel, and a resistive touch screen. The ventilator unit controls electrical power, nebulization, and pneumatic gas flow to and from the patient. The Engstrom Carestation also includes a module bay that allows the integration of various Datex-Ohmeda patient monitoring modules with the ventilator.

The user interface for control of nebulization is provided via the ventilator display unit. The Aerogen Aeroneb Pro Nebulizer board (K021175) is provided standard with the unit. Nebulizers are options for both the Engström Carestation and Engström Pro. Users have the option to configure the system to use an external pneumatic nebulizer in place of the Aerogen.

Optional accessories common to both Engström Carestation and Engström Pro include a trolley/cart, integrated air compressor, support arm, humidifier and water trap mounting brackets, and a data capture accessory. The GE Datex-Ohmeda EV Air Compressor is intended for use as an accessory to provide a dry, filtered, breathable compressed air supply. The compressor has no alarm functions. The Engström Carestation or Engström Pro provides all alarm functions and reactions to a failure of the compressed gas supply. The compressor is installed in the base of the ventilator cart. The compressor is powered from AC mains only. A source of compressed oxygen is required to be connected to Engström Carestation/Engström Pro equipped with the optional compressor. The compressor was cleared in K041775.

Additional optional accessories specific to the Engström Carestation include airway modules, intratracheal pressure sensor, auxiliary electrical outlets, and module bay. Optional functionality specific to the Engström Carestation includes integrated respiratory gas monitoring, capabilities to measure SpiroDynamics via a GE supplied intratracheal pressure sensor in patients using sized 6.5 tracheal tubes and larger, and calculation of functional residual capacity of mechanically ventilated patients using Nitrogen Wash In/Wash Out method. The integrated respiratory gas monitoring is provided via the Datex-Ohmeda Gas Modules, M-C, M-CO, M-COV, M-COVX, M-CaiO, M-CAiOV, M-CAiOVX, rev 3.2 software and higher (K001814), E-CO, E-COV, E-COVX, E-CAiO, E-CAiOV, E-CAiOVX (K051092), or M-Mini-CO2 Module (K023454) or E-MiniC module (K052582) which are physically integrated into the Engström Carestation, receive electronic power from the Engström Carestation and communicate measured values to the Engström Carestation for display on the system display unit.

INTENDED USE as required by 807.92(a)(5)

The GE Datex-Ohmeda Engström family of ventilators (Engström Carestation and Engström Pro) are designed to provide mechanical ventilation for adults and pediatrics weighing 5kg and above having degrees of pulmonary impairment varying from minor to severe. Optional Neonatal capabilities on Engström family expand the patient range to 0.25 kg.

The GE Datex-Ohmeda Engström family of ventilators are microprocessor based, electronically controlled, pneumatically driven ventilators that include integrated FiO2, airway pressure, spirometry and volume monitoring. Options include an Aerogen Aeroneb nebulizer, data capture accessory and an integrated air compressor. Options available on Engström Carestation only include integrated respiratory gas monitoring capabilities via various Datex-Ohmeda patient monitoring modules listed in the product labeling, capabilities to measure SpiroDynamics via an intratracheal pressure sensor in patients using sized 6.5 tracheal tubes and larger, and calculation of functional residual capacity of mechanically ventilated patients using Nitrogen Wash In/Wash Out method.

Not all features are available with all patient populations.

The Engström Carestation is not a pulmonary function calculation device.

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

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The GE Datex-Ohmeda Engstrom ventilator has been updated from the predicate version (K093886). There have been no changes to the intended use or fundamental scientific technology.

The software for the Engstrom ventilator has been updated to include touch screen functionality for navigation to existing Engstrom ventilator functions and menus. Additional minor software updates have been included that are primarily based on customer feedback (such as nuisance alarm conditions) and minor changes to bring the product in line with current specifications.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The GE Datex-Ohmeda Engstrom Carestation and Engstrom Pro ventilators have been thoroughly tested through verification of specifications and validation, including software validation. Verification of compliance with applicable standards has also been completed to ensure safe use of the device in its intended use environment, including electrical safety and electromagnetic compatibility testing. The following quality assurance measures were applied during the development of the Engstrom ventilator system:

- Risk Analysis
- Requirements/Specification Reviews
- Design Reviews
- Testing on unit level
- Integration testing
- Performance Testing (Verification)
- Safety Testing (Verification)
- Simulated Use/User Requirements Testing (Validation)

SUMMARY OF CLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(2)

The modifications made to the Engstrom ventilator did not require clinical testing. The software changes made to introduce touch screen functionality, as described in this submission, were completely evaluated by non-clinical tests to verify and validate the safety and functionality of the ventilator.

CONCLUSION:

The summary above demonstrates that there are no new questions of safety and effectiveness for the Engstrom Carestation and Engstrom Pro ventilators as compared to the predicate devices. Based on the performance data, GE Healthcare considers the Engstrom Carestation and Engstrom Pro ventilators with 7.X software to be as safe and effective, and perform in a substantially equivalent manner to the predicate devices.

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

Datex-Ohmeda, Incorporated
C/O Ms. Monica Morrison
Regulatory Affairs Leader
Life Support Solution
P.O. Box 7550
3030 Ohmeda Drive
Madison, Wisconsin 53707

SEP - 9 2011

Re: K111116
Trade/Device Name: Engstrom Carestation Engstrom Pro
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: July 8, 2011
Received: July 11, 2011

Dear Ms. Morrison:

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): K

Device Name: GE Datex-Ohmeda Engström Ventilator

Indications For Use:

The GE Datex-Ohmeda Engström family of ventilators (Engström Carestation and Engström Pro) are designed to provide mechanical ventilation for adults and pediatrics weighing 5kg and above having degrees of pulmonary impairment varying from minor to severe. Optional Neonatal capabilities on Engström family expand the patient range to 0.25 kg.

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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 IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K 111116