GE Healthcare

1C09286 4

Datex-Ohmeda Inc.
P.O. Box 7550
Madison, WI 53703
USA

JAN 12 2010

Premarket Notification 510(k) Summary

As required by section 807.92
GE Datex-Ohmeda Aespire Anesthesia System

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)
COMPANY NAME/ADDRESS/PHONE/FAX:

GE Healthcare
Datex-Ohmeda, Inc.
PO Box 7550
Madison, WI 53707 USA
Tel: 608-221-1551
Fax: 608-223-2476

NAME OF CONTACT:

Ms. Adrienne Lenz, RAC
Ms. Karla Krause (alternate)

DATE:

September 16, 2009

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

GE Datex-Ohmeda Aespire Anesthesia System

COMMON NAME:

Gas Machine, Anesthesia

CLASSIFICATION NAME:

Anesthesiology, 73 BSZ, 21 CFR 868.5160 Gas Machine, Anesthesia

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

The original GE Datex-Ohmeda Aespire 7900 Anesthesia Systems received 510(k) clearance under the submittal number K050626.

Both the GE Datex-Ohmeda Aespire 7900 Anesthesia System and the GE Datex-Ohmeda Aisys (most recent clearance K090233) are used as predicates.

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

The family of GE Datex-Ohmeda Aespire anesthesia systems with 7900 ventilator (Aespire 7900 and Aespire View) is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients. The systems are to be used only by trained and qualified medical professionals.

The Aespire 7900 and Aespire View supply set flows of medical gases to the breathing system. A large selection of frames, gases, and vaporizers are available to give the user control of the system configuration. They are available in trolley and pendant models, with two or three gases, two vaporizer positions and up to three cylinder connections. All models connect to oxygen and can additionally connect with up to two optional gases (air, N2O). The Aespire systems accept Tec 4, Tec 5, Tec 6, Tec 6+ and Tec 7 vaporizers on a Selectatec manifold. Safety features are designed to decrease the risk of hypoxic mixtures, agent mixtures and complete power or sudden gas supply failures. The Aespire View family member provides optional electronic Total Fresh Gas Flow (TFS) monitoring. The Aespire View also features a color display, while the Aespire 7900 uses a monochromatic display.

The Datex-Ohmeda 7900 Anesthesia Ventilator is used in this family of Anesthesia Systems. It is a microprocessor based, electronically controlled, pneumatically driven ventilator that provides patient ventilation during surgical procedures. The 7900 ventilator is equipped with a built-in monitoring system for inspired oxygen, airway pressure and exhaled volume. Sensors in the breathing circuit are used to control and monitor patient ventilation as well as measure inspired oxygen concentration. This allows for the compensation of compression losses, fresh gas contribution and small leakage in the breathing absorber, bellows and system. User setting and microprocessor calculations control breathing patterns. The user interface keeps settings in memory. The user may change settings with a simple and secure setting sequence. A bellows contains breathing gasses to be delivered to the patient. Positive End Expiratory Pressure (PEEP) is regulated electronically. Positive pressure is maintained in the breathing system so that any leakage that occurs is outward. An RS-232 serial digital communications port connects to and communicates with external devices. Ventilator modes for the device include Volume Control (VCV) Mode, Pressure Control (PCV) Mode (Optional), Synchronized Intermittent Mandatory Ventilation with Pressure Support Ventilation (SIMV/PSV) Mode, Pressure Support with Apnea Backup (PSVPro) Mode (Optional), Synchronized Intermittent Mandatory Ventilation with Pressure Control (SIMV-PC) Mode (Optional), and Pressure Control Ventilation – Volume Guaranteed (PCV-VG) mode (Optional on Aespire View variant only).

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

The family of GE Datex-Ohmeda Aespire anesthesia systems with 7900 ventilator (Aespire 7900 and Aespire View) is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients. The devices are intended for volume or pressure control ventilation. The devices are not suitable for use in a MRI environment.

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

This submission introduces the Aespire View variant to the family of GE Datex-Ohmeda Aespire anesthesia systems with 7900 ventilator. The Aespire 7900 variant remains available. The GE Datex-Ohmeda Aespire View Anesthesia System includes the following significant changes compared to the Aespire 7900:

- Software version (6.X) which includes pressure control ventilation- volume guarantee (PCV-VG) ventilation mode and Total Flow Sensing monitoring (optional)
- Total Flow Sensor Module (optional)
- New display unit including a color display, high performance CPU and increased system memory

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

The GE Datex-Ohmeda Aespire View Anesthesia System has been thoroughly tested through verification of specifications and validation, including software validation. Biocompatibility testing was conducted for the total flow sensor module. Electrical safety and electromagnetic compatibility testing were also completed.

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

The modifications to the family of GE Datex-Ohmeda Aespire anesthesia systems with 7900 ventilator did not require clinical testing.

CONCLUSION:

The summary above shows that, as compared to the predicate device, there are no new questions of safety and effectiveness for the introduction of the Aespire View to the family of GE Datex-Ohmeda Aespire anesthesia systems with 7900 ventilator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN 12 2010

Ms. Adrienne Lenz
Regulatory Affairs Director
GE Healthcare
Datex-Ohmeda, Incorporated
P.O. Box 7550
3030 Ohmeda Drive
Madison, Wisconsin 53707-7550

Re: K092864
Trade/Device Name: GE Datex-Ohmeda Aespire Anesthesia System
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: December 18, 2009
Received: December 22, 2009

Dear Ms. Lenz:

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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): K092864

Device Name: GE Datex-Ohmeda Aespire Anesthesia System

Indications For Use:

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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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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L Schultheis

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

510(k) Number: K092864