K090892

Premarket Notification 510(k) Summary
As required by section 807.92
GE Datex-Ohmeda S/5 ADU Carestation

APR 30 2009

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

COMPANY NAME/ADDRESS/PHONE/FAX:

GE Healthcare Finland OY
C/O Datex-Ohmeda
PO Box 7550
Madison, WI 53707 USA
Tel: 608-221-1551
Fax: 608-223-2496

NAME OF CONTACT:

Ms. Adrienne Lenz, RAC
Ms. Tarja Sivonen (alternate)

DATE:

March 27, 2009

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

TRADE NAME:

GE Datex-Ohmeda S/5 ADU Carestation

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 GE Datex-Ohmeda S/5 ADU Carestation is substantially equivalent in safety and effectiveness to the legally marketed (predicate) GE Datex-Ohmeda Anesthesia Delivery Unit (ADU) (K050676, K973985) and GE Aisys anesthesia machine (K090233, K073707, K061609, K042154).

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

The S/5 ADU (Anesthesia Delivery Unit) Carestation is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients. It is to be used only by trained and qualified medical professionals.

The S/5 ADU Carestation (shortened as ADU) supplies set flows of medical gases to the breathing system using mechanical gas mixing. Gas flows are selected by the user using the rotary controller on the frame and then displayed as electronic flow indicators on the system display unit. The ADU is equipped with a traditional flow tube, as well. The ADU is also available in a pendant model. It is available with two or three gases, and up to three cylinder connections. All models have O2. The ADU comes with up to two optional gases (air, N2O). Safety features and devices within the ADU are designed to decrease the risk of hypoxic mixtures, agent mixtures and complete power or sudden gas supply failures.

The anesthetic agent delivery for the ADU is controlled via an anesthesia computer through user input from that computer. An Aladin cassette is inserted into the active cassette bay. The cassette holds the agent to be delivered - Halothane, Enflurane, Isoflurane, Desflurane or Sevoflurane. Agent is delivered as a percent volume/volume. The ADU is designed to allow only one active cassette at a time. Per the user input, valves within the active cassette bay will open and allow agent to be delivered. The agent is mixed with gas within the FGC unit. After mixing, the combination of gases and agent is delivered to the breathing system and then onto the patient.

The ADU Anesthesia Ventilator is a microprocessor based, electronically controlled, pneumatically driven ventilator that provides patient ventilation during surgical procedures. Sensors in the breathing circuit are used to control and monitor patient ventilation. 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. Ventilator modes for the device include Volume Mode, Pressure Control Mode, Pressure Support with Apnea Backup Mode (Optional) and Synchronized Intermittent Mandatory Ventilation (SIMV)Mode. Ventilator parameters and measurements are displayed on the system display unit.

The ADU must be used with additional monitoring that include at least inspired O2, expired volume, expired CO2 and Anesthetic Agent.

An RS-232 serial digital communications port connects to and communicates with external devices such a S/5 Anesthesia Monitor (most recently cleared via K051400). Several frame configurations are available, including one that allows for the physical integration of the S/5 Anesthesia Monitor. Additional configurations allow for the mounting of various patient monitors on the top shelf of the ADU.

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

The GE Datex-Ohmeda S/5 ADU Carestation is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients. The device is intended for volume or pressure control, pressure support and synchronized intermittent mandatory (SIMV) ventilation modes. The ADU is 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)

A new main electronic module, A-ELEC-02, was developed for ADU. The A-ELEC-02 includes hardware and software changes that allow for easier change of batteries and to accept a wider range of mains voltages without selecting the voltage. The hardware was modified by replacing the linear power with a switched power supply. The system uses new batteries and the battery access was changed to allow for easier replacement. The battery charger board was replaced with a new design supporting the switched power supply. A battery backup for GE AM patient monitor is also supplied.

The battery backup time and the mains voltage range are the same. The power supply, battery charger board and backup for AM monitor are similar to the ones used in the GE Aisys anesthesia machine (most recently cleared as K073707).

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

The ADU has been thoroughly tested through verification of specifications and validation, including software validation. Verification of compliance with the following standards has also been made to support safe use of the device in its intended environment.

1. UL 2601 - General requirements for Medical Electrical Equipment
2. EN 740 - Anesthetic Work Stations
3. EN/IEC 60601-1: 1988 with amendments A1:1991+A2:1995. General requirements for Medical Electrical Equipment
4. EN/IEC 60601-1-2: 2001 with Amendment 1:2004 - Medical Electrical Equipment - Electromagnetic Compatibility
5. EN 475 - Electrically Generated Alarm Signals
6. ASTM F1463-93 - Standard Specification for Alarm Signals
7. ASTM F1208-94 - Anesthesia Breathing Circuit Standard
8. ASTM F1101-90 - Standard Specification for Ventilators Intended for Use During Anesthesia
9. ISO 5358 - Anesthetic Gas Machines

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

The modifications to the ADU did not require clinical testing.

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the ADU as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2009

GE Healthcare Finland OY
C/o Ms. Adrienne Lenz
Datex-Ohmeda, Incorporated
3030 Ohmeda Drive
P.O. Box 7550
Madison, Wisconsin 53707-7550

Re: K090892
Trade/Device Name: GE Datex-Ohmeda S/5 ADU Carestation
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: March 27, 2009
Received: March 31, 2009

Dear Ms. Lenz:

This letter corrects our substantially equivalent letter of April 30, 2009.

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 (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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Susan Runner, D.D.S., MA
Acting 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 S/5 ADU Carestation

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)

L Schmitt

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

510(k) Number: K090892