DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 15, 2017

Datex-Ohmeda, Inc.
James Raskob
Regulatory Affairs Manager
3030 Ohmeda Drive
PO Box 7550
Madison, Wisconsin 53707-7550

Re: K170872
Trade/Device Name: Aisys $CS^2$
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine For Anesthesia Or Analgesia
Regulatory Class: Class II
Product Code: BSZ
Dated: July 13, 2017
Received: July 17, 2017

Dear James Raskob:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Tara A. Ryan -S

for
Lori Wiggins
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K170872

Device Name
Aisys CS2

Indications for Use *(Describe)*
The Aisys CS2 Anesthesia System is intended to provide general inhalation anesthesia and ventilatory support to a wide ride range of patients (neonatal, pediatric, adult). The device is intended for volume or pressure control ventilation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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**510(k) Summary**

In accordance with 21 CFR 807.92 the following summary of information is provided:

| | |
|---|---|
| Date: | July 13, 2017 |
| Submitter: | Datex-Ohmeda, Inc. (doing business as GE Healthcare)<br>Mailing Address:<br>Datex-Ohmeda, Inc.<br>3030 Ohmeda Drive<br>PO Box 7550<br>Madison, WI 53707-7550<br>USA<br>Physical Address:<br>Datex-Ohmeda, Inc.<br>3030 Ohmeda Drive<br>Madison, WI 53718<br>USA |
| Primary Contact Person: | James P. Raskob<br>Regulatory Affairs Manager<br>Telephone: (608) 709-3581<br>Fax: (608) 299-2132<br>Email: Jim.Raskob@med.ge.com |
| Secondary Contact Person: | Monica Morrison<br>Regulatory Affairs Director<br>Telephone: (608) 515-3077<br>Fax: (608) 646-7464<br>Email: Monica.Morrison@ge.com |
| Device Trade Name: | Aisys $CS^2$ |
| Common/Usual Name: | Gas Machine, Anesthesia |
| Classification Names:<br>Product Code:<br>Regulation Number: | Anesthesiology, 73<br>BSZ<br>21 CFR 868.5160 Gas Machine, Anesthesia |
| Predicate Device(s): | GE Datex-Ohmeda Aisys $CS^2$ Anesthesia System (K132530) |

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| Intended Use: | The Aisys $CS^2$ anesthesia system is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonatal, pediatric, adult). The device is intended for volume or pressure control ventilation. |

**Device Description:**

The GE Datex-Ohmeda Aisys $CS^2$ is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonatal, pediatric, adult). It represents one of the systems in a long line of products based on the Datex-Ohmeda Excel, Aestiva, Aespire, and Avance Anesthesia Systems. It is to be used only by trained and qualified medical professionals.

The Aisys $CS^2$ supplies set flows of medical gases to the breathing system using electronic gas mixing. Interfaces to control the system include the touch screen, keypad and rotary controller on the main display unit. Selected gas flows are displayed as electronic flow indicators on the system display unit. The Aisys $CS^2$ is equipped with a pneumatic back-up O2 delivery system and traditional flow tube, as well. A large selection of frames, gases, and vaporizer cassettes are available to give the user control of the system configuration. The Aisys $CS^2$ systems are also available in pendant models. The system shall support a maximum of two-cylinder supply connections mounted inboard on the machine and supported by cylinder yokes. All models have O2. The Aisys $CS^2$ comes with up to two optional gases (air, N2O). Safety features and devices within the Aisys $CS^2$ are designed to decrease the risk of hypoxic mixtures, agent mixtures and complete power or sudden gas supply failures. The Aisys $CS^2$ system is available with optional integrated respiratory gas monitoring. When supplied as an option, the integrated respiratory gas monitoring is provided via the CARESCAPE Modules cleared via K123195 (E-sCAiO, E-sCAiOV) and K150245 (E-sCAiOVX). The Aisys CS2 is also compatible with legacy M-Gas and E-Gas modules which are in the installed base but are no longer in forward production (M-CAiO and M-CAiOV cleared via K001814, and E-CAiOVX cleared via K051092).

The above modules can be physically integrated into the Anesthesia device, receive electronic power from the said device and communicate measured values to the said device for display on the system display unit.

The anesthetic agent delivery for the Aisys $CS^2$ is controlled via an anesthesia computer through user input from the central display. The vaporization technology is based upon the electronic vaporizer cleared as part of the Datex-Ohmeda Anesthesia Delivery Unit (ADU) cleared via K973985. An Aladin 2 is inserted into the active cassette bay. The cassette holds the agent to be delivered - Isoflurane, Desflurane or Sevoflurane. Agent is delivered as a percent volume/volume. The Aisys $CS^2$ is designed to allow only one active cassette at a time. Per the user input into the main display, valves within the active cassette bay will open and allow agent to be delivered. The agent is mixed with gas from the FGC unit. After mixing, the combination of gases and agent is delivered to the breathing system and then onto the patient.

The Datex-Ohmeda 7900 Anesthesia Ventilator is used in the Aisys $CS^2$. 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 Control Ventilation -Volume Guaranteed (SIMV/PCV-VG) Mode, 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), Pressure Control Ventilation- Volume Guaranteed (PCV-VG) mode (Optional), and Continuous Positive Airway Pressure/ Pressure Support Ventilation (CPAP-PSV).

Ventilator parameters and measurements are displayed on the system display unit.

The system display unit is mounted to an arm on the top shelf of the Aisys $CS^2$. The arm is counter balanced and capable of moving vertically and/or horizontally, and tilting the display, enabling the user to position the display to the most advantageous viewing position. The arm length is limited such that the display position is always within the footprint of the Aisys $CS^2$ frame. The arm also supports the mounting of additional display units for a variety of patient monitors.

Several frame configurations are available, including one that allows for the physical integration of the GE Monitors (cleared Carescape B850 via K092027 and B650 cleared on K102239). This configuration also provides cable management solutions such that the necessary connections from the monitor display unit to the monitor are hidden within the Aisys $CS^2$ frame. An additional option allows the monitor to be linked to the power supply of the Aisys $CS^2$ such that when the Aisys $CS^2$ is turned on, the monitor is also turned on. Additional configurations allow for the mounting of various patient monitors on the top shelf of the Aisys $CS^2$.

**Summary of the Technological Characteristics of the Device:**

The modified Aisys $CS^2$ (version 11) is an updated version of the cleared predicate Aisys $CS^2$ (version 10) from K132530. Changes include software updates and enhancements incorporated into version 11, the addition of the sample gas return feature, network connectivity, and compliance for IEC 60601-1:2005 +A1:2012 (Edn 3.1), IEC 60601-1-2:2014 (Edn 4), and ISO 80601-2-13. There are no changes to the intended use or fundamental scientific technology of the anesthesia system.

The following list identifies the modifications to the Aisys $CS^2$ from version 10 to version 11:

- Software updates: The modified device introduces Software Version 11 which includes enhancements and updates for standards compliance. These are listed below in the list.

- Standards compliance: Compliance to IEC 60601-1:2005 +A1:2012 (Edn 3.1), IEC 60601-1-2:2014 (Edn 4), and ISO 80601-2-13:2011 (Edn 1).
- Service Log export: Export the service log files from the anesthesia machine over FTP (file transfer protocol). The graphic user interface allows the field engineer or biomed to configure network information of the FTP server, user name and password.
- Monitor Only mode: Implemented a 'respiratory gas monitoring only' mode on the anesthesia machine for cases where only monitoring functionality is required, and no gas flow is needed. This is applicable for patient cases which are less invasive when the patient is breathing spontaneously and is consciously sedated (for example: sedated with IV drugs).
- Enhanced Lung procedures: Included improvements to lung mechanics functionality and display including updates to the user interface to show lung compliance and progress of the procedures.
- EcoFlow improvements: Revised the existing cleared EcoFlow feature to include usability improvements on the graphic user interface, addition of more currencies, and improved logging of the data.
- ACGO notification: Included a clear notification to the user that the machine is in ACGO Mode (auxiliary common gas outlet).
- Daylight Time Savings option: Included an option for the user to automatically set the time during Daylight Savings time changes.

- Network Connectivity: The modified device allows the anesthesia machine to be connected to a hospital network. The HL7 connectivity allows connection to EMR systems. The Aisys $CS^2$ supports the existing Datex-Ohmeda Comm port, as well as the Sapphire Binary Exchange port. Cybersecurity concerns have been addressed as per the associated FDA Guidance.
- Hardware updates: The modified device contains Ethernet cables to enable new network connectivity functionality. A bacterial filter is now included to address cross-contamination mitigations for the sample gas return configuration.
- Sample Gas Return: The modified device adds the Sample Gas Return feature to the Aisys $CS^2$. The proposed change returns the sample gas back to the breathing system where it is mixed with the other gases in the anesthesia breathing circuit, rather than exhausted to scavenging and wasted.

**Summary of Non-Clinical Testing for the Device:**

The modified Aisys $CS^2$ (version 11) has been thoroughly tested through verification of specifications and validation, including software validation, and materials testing including volatile organic compounds, to ensure safe use of the device in its intended use environment. Verification of compliance with applicable standards has also been completed. The following quality assurance measures were applied during the development of the Aisys CS2 anesthesia system (version 11):

- Risk Analysis

- Requirements/Specification Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing results for the verification of new features and functionality of the version 11 software within the Aisys $CS^2$ including the following.

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| Privacy and Security verifies that Privacy and Security functionality including an option to disable viewing the patient identifiable information on the display unit. |
| Duplicate Interface Detection test verifies the Duplicate Interface Detection functionality including that the system continues communication with its clients even if a duplicate IP condition is detected during the communication. |
| Ethernet Interface test verifies Ethernet functionality including that the system supports 100Mbps speed and full duplex settings within the Ethernet Interface. |
| Network Hazard Mitigation verifies Hazard Mitigations related to the Network functionality including that the system has no open ports except for specific clients. |
| Network Requirements test verifies Network functionality including that the system supports clock synchronization with a network device. |
| Sapphire and HL7 verifies Sapphire and HL7 communication protocols including that the system will support communication with a network device using Sapphire or HL7 protocol. |
| Address Resolution Protocol Requirements testing verifies the Address Resolution Protocol including correct system subnet mask functionality. |
| Respiratory Gas Monitors testing verifies all requirements related to the Respiratory Gas Monitors including functionality of the Sample Gas Return option. |
| Monitoring Only Mode testing verifies Monitoring Only Mode functionality including O2 being administered through the auxiliary O2 port when the mode is enabled. |
| System Hazard Mitigations testing verifies functionality including that the system performs as intended during a recovery state. |

- Materials Testing including the following tests:
    - Volatile Organic Compounds
    - Particulate Matter Testing
    - Bacterial Filter Efficiency Testing
    - Viral Filter Efficiency Testing

- Simulated use/user testing (Validation)

- Reprocessing Instructions Validation Testing

- Verification testing including electrical safety and electromagnetic compatibility testing with compliance to the following standards:

    1. AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (FDA Recognized)
    2. IEC 60601-1-2: 2014 (FDA Recognized)
    3. ISO 80601-2-13: 2011 (FDA Recognized)

**Summary of Clinical Testing for the Device:**

The Aisys $CS^2$ (version 11) incorporates modifications to the predicate Aisys $CS^2$ (version 10). These modifications did not require clinical testing. The changes made were completely evaluated by non-clinical tests to verify and validate the performance of the anesthesia system.

**Conclusion- Determination of Substantial Equivalence:**

Datex-Ohmeda, Inc., doing business as GE Healthcare, considers the modified Aisys $CS^2$ to be as safe and as effective, and the performance is substantially equivalent to the predicate device, the previous version of the Aisys $CS^2$ anesthesia system. The summary above demonstrates that there are no different questions of safety or effectiveness for the Aisys $CS^2$ (version 11).