DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 24, 2015

Datex-Ohmeda, Inc.
Ms. Michelle Huettner, RAC
Regulatory Affairs Leader
3030 Ohmeda Drive
P.O. Box 7550
Madison, WI 53707

Re: K143530
Trade/Device Name: Aespire View
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: Class II
Product Code: BSZ
Dated: March 25, 2015
Received: March 26, 2015

Dear Ms. Huettner:

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 yours,

Tina Kiang -S

for Erin I. Keith, M.S.
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)*
K143530

Device Name
Aespire View

Indications for Use *(Describe)*
The Aespire View anesthesia system 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 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.

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Section 5: 510(k) Summary

Aespire View

510(k) Summary

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

Date:	April 24, 2015
Submitter:	Datex-Ohmeda, Inc.(doing business as GE Healthcare) Mailing Address: Datex-Ohmeda, Inc. 3030 Ohmeda Drive PO Box 7550 Madison, WI 53707-7550 USA Physical Address: Datex-Ohmeda, Inc. 3030 Ohmeda Drive Madison, WI 53718 USA
Primary Contact Person:	Michelle Huettner Regulatory Affairs Leader Telephone: (608) 709-3384 Fax: (262) 546-0902 Email: Michelle.Huettner@ge.com
Secondary Contact Person:	Monica Morrison Regulatory Affairs Manager Telephone: (608) 709-3439 Fax: (608) 646-7464 Email: Monica.Morrison@ge.com
Device Trade Name:	Aespire View
Common/Usual Name:	Gas Machine, Anesthesia

Classification Names:	Anesthesiology, 73
Product Code:	BSZ
Regulation Number:	21 CFR 868.5160 Gas Machine, Anesthesia
Predicate Device(s):	GE Datex-Ohmeda Aespire Anesthesia System (K122445)
Intended Use:	The Aespire View anesthesia system 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 ventilation.

Device Description:

The Aespire View (version 7) anesthesia system with 7900 ventilator is intended to provide general inhalation anesthesia and ventilator support to a wide range of patients. The system is to be used only by trained and qualified medical professionals.

The Aespire View (version 7) supplies set flows of medical gases to the breathing system (predicate device cleared via 510k submissions K092864 and K122445). A large selection of frames, gases, and vaporizers are available to give the user control of the system configuration. It is 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 and N2O). The Aespire View system accepts 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 provides optional electronic Total Fresh Gas Flow (TFS) monitoring. The Aespire View also features a color display.

The Datex-Ohmeda 7900 Anesthesia Ventilator is used in the Aespire View anesthesia machine. 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, bellow 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 using the ComWheel. 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).

Summary of the Technological Characteristics of the Device:

The modified Aespire View (version 7) is an updated version of the cleared predicate Aespire View (version 6.x) from K122445 and K092864. Changes include software updates to version 7, hardware modifications including the addition of a central brake, and IEC 60601-1:2005 (3rd Edn) compliance including the associated labeling updates. There are no changes to the intended use or fundamental scientific technology of the anesthesia system.

The following list identifies the modifications to the Aespire View from version 6.x to version 7:

- Software Version: The modified device introduces Software Version 7 which includes enhancements and updates for standards compliance.
- IEC 60601-1 Compliance: The modified device is dual compliant to 2nd Edition and 3rd Edition of IEC 60601-1.
- Alarm System Compliance: The modified device is in compliance with 60601-1-8 and 80601-2-13 3rd Edition, including updates to the audio pause and alarm inhibit symbols.
- Body Temperature and Pressure Saturated units: The modified device includes the option for a service authorized user to change the ventilator flow measurements between Standard Temperature and Pressure Dry (STPD) and Body Temperature and Pressure Saturated (BTPS) units.
- Real Time Clock: The modified device includes a real time clock for ease of use and practicality to the user, rather than showing an arbitrary time from boot-up or elapsed time.
- Auxiliary Common Gas Outlet (ACGO): The modified device includes a more visible ACGO message, as well as a graphical illustration to show it has been activated.

- Positive and Expiratory Pressure (PEEP) Values: The modified device includes the display of the measured PEEP numeric value.
- Spontaneous Breaths Waveform: The modified device includes colored spontaneous breaths in the waveform to differentiate it from the mechanical breath.
- Flow Waveforms: The modified device has two waveforms, rather than one (Paw airway pressure and flow).
- Spirometry Loops: The modified device added the option to display spirometry loops.
- Central Brake: The modified device added a single brake lever for the front two wheels, rather than having to lock the brake on each caster individually.
- Large cylinder kit update: The modified device updates the large cylinder kit option for compliance with 60601-1 3rd Edition tip testing and sliding clauses.
- Lubricant material change on pneumatic connectors: In response to an end-of-life component supplier change request, the lubricant used on the Aespire View pneumatic fittings was changed to a similar lubricant for the same condition of use. The modified device with this lubricant material change was tested for volatile organic compounds (VOCs). The results demonstrated that the material change did not present an increased biocompatibility risk to the patient.

Summary of Non-Clinical Testing for the Device:

The modified Aespire View (version 7) 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 Aespire View anesthesia system (version 7):

- Risk Analysis
- Requirements/Specification Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)

- Performance Testing (Verification)
- Materials Testing including Volatile Organic Compounds (VOC)
- Verification Testing including electrical safety testing and electromagnetic compatibility testing
- Simulated Use/User Requirements Testing (Validation)

The Aespire View with software version 7 was designed and tested for 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 Edition 3: 2007 (FDA Recognized)
3. IEC 60601-2-13 Edition 3.1: 2009 (FDA Recognized)
4. ISO 80601-2-13 Edition 1: 2011 (Not FDA Recognized)

Summary of Clinical Testing for the Device:

The Aespire View with software version 7 incorporates modifications to the predicate Aespire View with software version 6.x. 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 Aespire View to be as safe and as effective, and the performance is substantially equivalent to the predicate device, the Aespire View anesthesia system. The summary above demonstrates that there are no new questions of safety or effectiveness for the Aespire View (version 7).