November 3, 2017

Datex-Ohmeda, Inc.
Trishia Mercier
Regulatory Affairs Leader
3030 Ohmeda Drive, PO Box 7550
Madison, Wisconsin 53707-7550

Re: K172045
Trade/Device Name: Aestiva 7900, Aestiva MRI, Aestiva 7100, Aestiva 7100 Compact, Aespire 100, Aespire 7100, Aespire 7900, Aespire View, Avance, Avance CS2, Aisys, Aisys CS2
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: Class II
Product Code: BSZ
Dated: September 26, 2017
Received: September 27, 2017

Dear Trishia Mercier:

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 (DICE) 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 (DICE) 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,

Tina Kiang, Ph.D.
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)*
K172045

Device Name
Aespire 7100, Aespire 100

Indications for Use *(Describe)*
The Aespire Anesthesia Gas System with 7100 Ventilator is a gas machine that supplies set flows of medical gases to the breathing system. A large selection of frames, gases, and vaporizers give full control of the system configuration. It is available with up to three gases, two vaporizer positions and up to three cylinder connections. All models are available with O2/Air, O2/N2O, or O2/Air/N2O. All Aespire systems accept Tec series vaporizers. Safety features and devices within the Aespire with 7100 decrease the risk of hypoxic mixtures, agent mixtures and complete power or sudden gas supply failures.

The 7100 Ventilator is a microprocessor based, electronically controlled, pneumatically driven ventilator 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. 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.

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)

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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)*

K172045

Device Name
Aespire 7900

Indications for Use *(Describe)*

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.

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)

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510(k) Number *(if known)*

K172045

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*

K172045

Device Name
Aestiva 7100, Aestiva 7100 Compact

Indications for Use *(Describe)*

The Aestiva/5 Anesthesia Gas System with 7100 Ventilator is a gas machine that supplies set flows of medical gases to the breathing system. A large selection of frames, gases, and vaporizers give full control of the system configuration. The Aestiva/5 with 7100 is available in wide or narrow trolley and pendant models. The narrow trolley and pendant come with two or three gases, two vaporizer positions and up to four cylinder connections. The wide trolley comes with two, three or four gases, three vaporizer positions and up to five cylinder connections. All models have O2 and N2O. The Aestiva/5 with 7100 comes with up to two optional gases (air, CO2, heliox). All Aestiva systems accept Tec series vaporizers. Safety features and devices within the Aestiva/5 with 7100 decrease the risk of hypoxic mixtures, agent mixtures and complete power or sudden gas supply failures.

The 7100 Ventilator is a microprocessor based, electronically controlled, pneumatically driven ventilator 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. 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.

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)

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See PRA Statement below.

510(k) Number *(if known)*

K172045

Device Name
Aestiva 7900

Indications for Use *(Describe)*

This version of the Datex-Ohmeda 7900 Ventilator is used in Datex-Ohmeda Aestiva 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 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. 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. Ventilatory modes for the device, include Volume Mode, Pressure Control Mode, Synchronous Intermittent Mandatory Ventilation (optional), Pressure Support with Apnea Backup Ventilation. (optional).

This device is to be used only by trained and qualified medical professionals.

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)

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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*

K172045

Device Name
Aestiva MRI

Indications for Use *(Describe)*

The Aestiva/5 MRI Anesthesia System provides the functional feature set offered by the conventional Aestiva/5 to the clinician with the added ability to be used in the MR environment. Among those standard Aestiva/5 features is the Datex-Ohmeda user interface, all the ventilation parameters of the SmartVent along with the Aestiva breathing circuit. The Aestiva/5 MRI Anesthesia System performed to specifications when tested directly next to 1.5 and 3.0 Tesla shielded MRI devices in a field strength that did not exceed 300 gauss.

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)

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See PRA Statement below.

510(k) Number *(if known)*

K172045

Device Name
Aisys

Indications for Use *(Describe)*

The GE Datex-Ohmeda Aisys 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. The Aisys is not suitable for use in a MRI environment.

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)

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See PRA Statement below.

510(k) Number *(if known)*

K172045

Device Name
Aisys CS2

Indications for Use *(Describe)*

The GE Datex-Ohmeda Aisys CS2 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.

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)

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Indications for Use

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

510(k) Number *(if known)*

K172045

Device Name
Avance

Indications for Use *(Describe)*
The GE Datex-Ohmeda Avance 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.

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)

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Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172045

Device Name
Avance CS2

Indications for Use *(Describe)*

The GE Datex-Ohmeda Avance CS2 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.

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)

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510(k) Summary

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

Date:	July 5, 2017
Submitter:	GE Healthcare Datex-Ohmeda, Inc. 3030 Ohmeda Drive PO Box 7550 Madison, WI 53707-7550
Primary Contact Person:	Trishia Mercier Regulatory Affairs Leader Datex-Ohmeda, Inc., a GE Healthcare company Telephone: +1 (608) 695-8319 Fax: +1 (608) 646-6488 Email: Trishia.Mercier@ge.com
Secondary Contact Person:	Monica Morrison Regulatory Affairs Director Datex-Ohmeda, Inc., a GE Healthcare company Telephone: +1 (608) 515-3077 Fax: +1 (608) 646-7464 Email: Monica.Morrison@ge.com
Device Trade Name:	Aestiva 7900 Aestiva MRI Aestiva 7100 Compact Aestiva 7100 Aespire 100 Aespire 7100 Aespire 7900 Aespire View Avance Avance CS2 Aisys Aisys CS2
Common/ Usual Name:	Gas Machine, Anesthesia
Classification Name:	Gas Machine, Anesthesia
Regulation Number:	21 CFR 868.5160

Product Code:	BSZ	
Predicate Devices:	Aestiva 7900	K023366
	Aestiva MRI	K050055
	Aestiva 7100 Compact	K000706
	Aestiva 7100	K000706
	Aespire 100	K000706
	Aespire 7100	K000706
	Aespire 7900	K122445
	Aespire View	K143530
	Avance	K112722
	Avance CS[2]	K131945
	Aisys	K110213
	Aisys CS[2]	K132530
Device Description:	The GE Healthcare anesthesia machines are intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonatal, pediatric, adult). The GE Healthcare anesthesia machines are to be used only by medical professionals trained and qualified in the administration of general anesthesia. The GE Healthcare anesthesia systems supply set flows of medical gases to the breathing system. Gas flows are selected by the user and displayed on the display unit or through pneumatic flow meters. A large selection of options may be available to configure the system, including frames, brake style, gases, and anesthetic agents. The GE anesthesia machines include a microprocessor based, electronically controlled, pneumatically driven ventilator that provides patient ventilation during surgical procedures. The ventilator is equipped with a built-in monitoring system for inspired oxygen, airway pressure, and inhaled and exhaled volume. Flow, gas, and pressure 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 settings and microprocessor calculations control breathing patterns. The user may change settings with a simple setting sequence. A bellows contains breathing gasses to be delivered to the patient. Positive End Expiratory Pressure (PEEP) is regulated electronically through control of the pneumatic valves. Positive pressure is maintained in the breathing system so that any leakage that occurs is outward. A digital communications port connects to and communicates with external devices. The ventilators include a wide range of ventilation modes, which are unchanged from the predicate version of the product. Ventilator parameters and measurements are displayed on the system display unit.	
Intended Use:	There is no change to the intended use or indications for use of the GE anesthesia machines as a result of the introduction of the proposed alternative flow sensors. Each anesthesia machine retains its intended use as previously cleared and legally marketed.	
Indications for	Aestiva 7900	This version of the Datex-Ohmeda 7900 Ventilator is used in Datex-Ohmeda Aestiva Anesthesia Systems. It is a

Use:		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 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. 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. Ventilatory modes for the device, include Volume Mode, Pressure Control Mode, Synchronous Intermittent Mandatory Ventilation (optional), Pressure Support with Apnea Backup Ventilation (optional). This device is to be used only by trained and qualified medical professionals.
	Aestiva MRI	The Aestiva/5 MRI Anesthesia System provides the functional feature set offered by the conventional Aestiva/5 to the clinician with the added ability to be used in the MR environment. Among those standard Aestiva/5 features is the Datex-Ohmeda user interface, all the ventilation parameters of the SmartVent along with the Aestiva breathing circuit. The Aestiva/5 MRI Anesthesia System performed to specifications when tested directly next to 1.5 and 3.0 Tesla shielded MRI devices in a field strength that did not exceed 300 gauss.
	Aestiva 7100 Compact Aestiva 7100	The Aestiva/5 Anesthesia Gas System with 7100 Ventilator is a gas machine that supplies set flows of medical gases to the breathing system. A large selection of frames, gases, and vaporizers give full control of the system configuration. The Aestiva/5 with 7100 is available in wide or narrow trolley and pendant models. The narrow trolley and pendant come with two or three gases, two vaporizer positions and up to four cylinder connections. The wide trolley comes with two, three or four gases, three vaporizer positions and up to five cylinder connections. All models have O2 and N2O. The Aestiva/5 with 7100 comes with up to two optional gases (air, CO2, heliox). All Aestiva systems accept Tec series vaporizers. Safety features and devices within the Aestiva/5 with 7100 decrease the risk of hypoxic mixtures, agent mixtures and complete power or sudden gas supply failures.

		The 7100 Ventilator is a microprocessor based, electronically controlled, pneumatically driven ventilator 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. 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.
	Aespire 100 Aespire 7100	The Aespire Anesthesia Gas System with 7100 Ventilator is a gas machine that supplies set flows of medical gases to the breathing system. A large selection of frames, gases, and vaporizers give full control of the system configuration. It is available with up to three gases, two vaporizer positions and up to three cylinder connections. All models are available with O2/Air, O2/N2O, or O2/Air/N2O. All Aespire systems accept Tec series vaporizers. Safety features and devices within the Aespire with 7100 decrease the risk of hypoxic mixtures, agent mixtures and complete power or sudden gas supply failures. The 7100 Ventilator is a microprocessor based, electronically controlled, pneumatically driven ventilator 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. 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.
	Aespire 7900	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.
	Aespire View	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.
	Avance	The GE Datex-Ohmeda Avance 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.
	Avance CS^2	The GE Datex-Ohmeda Avance CS2 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.
	Aisys	The GE Datex-Ohmeda Aisys 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. The Aisys is not suitable for use in a MRI environment.
	Aisys CS^2	The GE Datex-Ohmeda Aisys CS2 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.
Technology:	The GE Healthcare anesthesia machines employ the same fundamental scientific technology as their predicate devices. This 510(k) does not introduce new technology to the anesthesia machine or the two alternate flow sensors. The GE Healthcare anesthesia machines are identical to the predicate GE Healthcare anesthesia machines, except for the introduction of two alternate flow sensors The changed components can be used with all of the Aestiva, Aespire, Avance and Aisys models of anesthesia machine offered from GE Healthcare, and they differ from the predicate version in the following ways: • Material composition: There are some new materials which are introduced to the patient gas path. Biocompatibility testing has been completed to demonstrate that the proposed materials do not introduce any new biomaterials risk, and are substantially equivalent to the predicate. • Performance: The performance requirements of the anesthesia machine and the changed components are identical. Minor changes were made to the proposed alternative flow sensors to deliver equivalent performance. There is no change to the performance of the anesthesia machine or the alternate flow sensors. As described below, the performance of the GE Healthcare anesthesia machines has been fully verified and validated with the changes described in this 510(k).	

	• Reprocessing instructions: the proposed components are reprocessed differently from the predicate version, and the updated reprocessing instructions are included with the device and the spare parts. The updated reprocessing instructions have been verified and validated. There are no other changes to the GE Healthcare anesthesia machines being introduced in this 510(k). Testing has demonstrated that the proposed GE Healthcare anesthesia machines perform in a substantially equivalent manner to the predicate devices.
Determination of Substantial Equivalence:	<u>Summary of Non-Clinical Tests:</u> The GE anesthesia machines comply with voluntary standards. The changes described in this 510(k) have been fully verified and validated to demonstrate that the GE anesthesia machines are substantially equivalent to the predicate anesthesia machines currently on the market. The following is a summary of the testing performed to demonstrate substantial equivalence: ▪ Component-level testing verifying specifications related to: ▪ Mating parts and interface ▪ Accuracy, sensitivity and pressure drop ▪ Leak ▪ Over range flow ▪ Breath cycle life ▪ Shipping ▪ Agent exposure ▪ Connector performance ▪ MRI compatibility and MR safety ▪ Power, communications and data ▪ Biocompatibility – Cytotoxicity testing per ISO 10993-5, Sensitization testing per ISO 10993-10, Extractable testing ▪ System-level testing verifying specifications related to ▪ Internal pressure ▪ System pressure drop ▪ System electrical safety, EMC and EMI ▪ Operational temperature and humidity ▪ Storage environment ▪ System interface ▪ Material regulation ▪ System ventilation accuracy

	▪ System water management ▪ Shipping ▪ System communication ▪ Agent compatibility ▪ Validation of design inputs, including the following: ▪ Reprocessing ▪ User needs The changes to the GE anesthesia machines described in this 510(k) did not require clinical studies to support substantial equivalence. All testing passed, demonstrating that all design outputs meet the intended design inputs, and all product specifications continue to be met and the GE anesthesia machines perform in a manner which is substantially equivalent to the predicate products.
Conclusion:	GE Healthcare considers the GE anesthesia machines described in this 510(k) with the alternate flow sensors to be substantially equivalent to the predicate devices.