May 21, 2026

Drägerwerk AG Co. KGaA
Laura Weaver
Regulatory Affairs Manager
Moislinger Allee 53 - 55
Lübeck, 23542
Germany

Re: K252746
Trade/Device Name: Atlan (A100); Atlan (A100 XL); Atlan(A350); Atlan (A350 XL)
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine For Anesthesia Or Analgesia
Regulatory Class: Class II
Product Code: BSZ
Dated: April 22, 2026
Received: April 22, 2026

Dear Laura Weaver:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic.

See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252746

Please provide the device trade name(s).

Atlan (A100)
Atlan (A100 XL)
Atlan (A350)
Atlan (A350 XL)

Please provide your Indications for Use below.

Intended Use:
This device is intended for use in anesthetizing adults, pediatric patients, and neonates. The device can be used for mechanical ventilation, manual ventilation, pressure-supported spontan-eous breathing, and spontaneous breathing.
The device is equipped with the following basic functions:
- Ventilation monitoring
- Inspiratory O2 measurement
- Device monitoring
- Anesthetic gas receiving system

The following options are additionally available:
- Patient-gas measurement module for O2, CO2, N2O, and anesthetic gases
- O2 insufflation

Anesthesia is achieved through a mixture of pure oxygen and Air (medical compressed air) or pure oxygen and nitrous oxide, with the addition of volatile anesthetic agents.
Ventilation is accomplished on the patient through a laryngeal mask, a breathing mask, or an endotracheal tube.
The integrated anesthetic breathing system can be used with partial rebreathing (low-flow or minimum-flow).

Indications for Use:
The device is specified for inhalational anesthesia and/or patient ventilation in accordance with the intended use during surgical or diagnostic interventions.

Please select the types of uses (select one or both, as applicable).

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

510(k) Premarket Notification Summary

Submitter:	Drägerwerk AG & Co. KGaA Moislinger Allee 53-55 23542 Lübeck, Germany Establishment's registration number: 9611500	
Official correspondent:	Laura Weaver Regulatory Affairs Manager Telephone: +49 451 882 3587 E-Mail: laura.weaver@draeger.com	
US agent:	John Ferros Head of Quality Assurance and Compliance Telephone: +1 978 379 6461 E-mail: john.ferros@draeger.com	
Date prepared:	May 19, 2026	
Device Name:	Trade name:	Atlan (A100); Atlan (A100 XL); Atlan (A350); Atlan (A350 XL)
	Common name:	Anesthesia machine
	Classification name:	Gas-machine, anesthesia
	Regulation number:	21 CFR §868.5160
	Product code:	BSZ
	Class:	II
Predicate Device:	Atlan, K230931	
Reference Devices:	AM-6000, K120075	

Drägerwerk AG & Co. KGaA is submitting this traditional 510(k) to request market clearance for the Atlan anesthesia workstation with a new gas mixer variant, the model A100/A100 XL, comprising a mechanically controlled gas mixer with flow tubes. This premarket notification will also include modifications to the device since clearance under K230931.

Device Description

The Atlan anesthesia workstation was developed and is manufactured by Dräger in Lübeck, Germany. The anesthesia workstation is specified for inhalational anesthesia using volatile anesthetic agents and/or patient ventilation, including the delivery of oxygen and the monitoring of device functions as well as the patient's and/or anesthetic parameters. Atlan is available in different device variants and can be upgraded by software and hardware options as well as attachable accessories.

The Atlan anesthesia workstation consists of four major subsystems, each of which operates on its own specific principle while interacting with the other subsystems to achieve the intended use. These major subsystems include:

- Gas reception and delivery, i.e., gas mixer
- Anesthetic breathing system
- Anesthetic ventilator
- Anesthetic gas scavenger

The Atlan anesthesia workstation receives medical gases from a cylinder or central gas supply, creates a gas mixture, or composition, and delivers this mixture at a determined flow rate to the anesthetic breathing system.

Atlan's anesthetic breathing system is the interface between the anesthesia workstation and the patient. Its purpose is to deliver the gas composition to the patient. While doing so, the anesthetic breathing system converts the continuous gas flow to the patient's intermittent respiratory flow, supports controlled or assisted ventilation, and allows for gas sampling and pressure measurements. Furthermore, the anesthetic breathing system conditions the inspiratory gas by means of a heater and removes carbon dioxide from the patient's expired gas.

The anesthetic ventilator drives fresh gas from the anesthetic breathing system to the patient and expired gas to the anesthetic gas scavenger.

Atlan's integrated anesthetic gas scavenger collects all waste anesthetic gases received from the breathing circuit and passes it on to a hospital disposal system.

The anesthesia workstation is also comprised of several minor subsystems whose interactions with the main subsystems help to address considerations of patient safety and system integrity. The minor subsystems include:

- Gas monitoring
- Ventilation and airway monitoring
- Device monitoring, including system self-test
- Embedded control display
- RFID (wireless) capabilities

Indications for Use

Intended use

This device is intended for use in anesthetizing adults, pediatric patients, and neonates. The device can be used for mechanical ventilation, manual ventilation, pressure-supported spontaneous breathing, and spontaneous breathing.

The device is equipped with the following basic functions:

– Ventilation monitoring

– Inspiratory O2 measurement

– Device monitoring

– Anesthetic gas receiving system

The following options are additionally available:

– Patient-gas measurement module for O_2, CO_2, N_2O, and anesthetic gases

– O_2 insufflation

Anesthesia is achieved through a mixture of pure oxygen and Air (medical compressed air) or pure oxygen and nitrous oxide, with the addition of volatile anesthetic agents.

Ventilation is accomplished on the patient through a laryngeal mask, a breathing mask, or an endotracheal tube.

The integrated breathing system can be used with partial rebreathing (low-flow or minimum-flow).

Indications

The device is specified for inhalational anesthesia and/or patient ventilation in accordance with the intended use during surgical or diagnostic interventions.

List of Consensus Standards

Standard Number and Version	Title
IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
ISO 80601-2-13 Second edition 2022-04	Medical electrical equipment -- Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
ISO 80601-2-55:2018 [including AMD1:2023]	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
ISO 14971:2019-12	Medical devices - Application of risk management to medical devices
IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	Medical devices - Part 1: Application of usability engineering to medical devices
IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes
ISO 10993-1 Fifth edition 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 18562-1 Second edition 2024-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
ISO 18562-4 Second edition 2024-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate
ISO 17664-1 First edition 2021-07	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices
ISO 17664-2 First edition 2021-02	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices.
IEC/TR 60601-4-2 Edition 1.0 2016-05	Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
IEC TS 60601-4-2 Edition 1.0 2024-03	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

Comparison to Predicate and Reference Devices

Topic	*Proposed device Atlan (SW 2.11.00)*	*Predicate device Atlan (SW 2.00.01)*	*Predicate device, second AM-6000*
1. Intended Use			
Manufacturer	Drägerwerk AG & Co. KGaA	Drägerwerk AG & Co. KGaA	-
510(k) number	-	K230931	-
Regulation number / Classification name	21 CFR §868.5160 – Gas-machine – Anesthesia	21 CFR §868.5160 – Gas-machine – Anesthesia	-
Regulatory class	Class II	Class II	-
Product code	BSZ	BSZ	-
Patient population	• Adult • Pediatric • Neonate	• Adult • Pediatric • Neonate	-
Software Version	SW 2.11.00	SW 2.00.01 (K230931)	-
Chassis	Trolley-mounted or Ceiling-mounted (model A350)	Trolley-mounted	-

Topic	*Proposed device* *Atlan (SW 2.11.00)*	*Predicate device* *Atlan (SW 2.00.01)*	*Predicate device, second* *AM-6000*
Intended Use	This device is intended for use in anesthetizing adults, pediatric patients, and neonates. The device can be used for mechanical ventilation, manual ventilation, pressure-supported spontaneous breathing, and spontaneous breathing. The device is equipped with the following basic functions: – Ventilation monitoring – Inspiratory O_2 measurement – Device monitoring – Anesthetic gas receiving system The following options are additionally available: – Patient-gas measurement module for O_2, CO_2, N_2O, and anesthetic gases – O_2 insufflation Anesthesia is achieved through a mixture of pure oxygen and Air (medical compressed air) or pure oxygen and nitrous oxide, with the addition of volatile anesthetic agents. Ventilation is accomplished on the patient through a laryngeal mask, a breathing mask, or an endotracheal tube. The integrated breathing system can be used with partial rebreathing (low-flow or minimum-flow).	This device is intended for use in anesthetizing adults, pediatric patients, and neonates. The device can be used for mechanical ventilation, manual ventilation, pressure-supported spontaneous breathing, and spontaneous breathing. The device is equipped with the following basic functions: – Ventilation monitoring – Inspiratory O_2 measurement – Device monitoring – Anesthetic gas receiving system The following options are additionally available: – Patient-gas measurement module for O_2, CO_2, N_2O, and anesthetic gases – O_2 insufflation Anesthesia is achieved through a mixture of pure oxygen and Air (medical compressed air) or pure oxygen and nitrous oxide, with the addition of volatile anesthetic agents. Ventilation is accomplished on the patient through a laryngeal mask, a breathing mask, or an endotracheal tube. The integrated breathing system can be used with partial rebreathing (low-flow or minimum-flow).	-
Indications for Use	The device is specified for inhalational anesthesia and/or patient ventilation in accordance with the intended use during surgical or diagnostic interventions.	The device is specified for inhalational anesthesia and/or patient ventilation in accordance with the intended use during surgical or diagnostic interventions.	-

Topic	*Proposed device* *Atlan (SW 2.11.00)*	*Predicate device* *Atlan (SW 2.00.01)*	*Predicate device, second* *AM-6000*
2. Technological Characteristics			
Gas reception, supplies	Via: • Central gas supply • Reserve gas cylinder	Via: • Central gas supply • Reserve gas cylinder	-
Gas reception, reserve gas cylinder	• Basic cylinder support (cylinders closed if central supply available to prevent unintentional emptying if the central supply fails or falls below the specified level; the backup cylinders must be opened manually) or • Advanced cylinder support (cylinders open even if central supply available; if the central supply fails, cylinder supply automatically used) [model A350/A350 XL]	• Basic cylinder support (cylinders closed if central supply available to prevent unintentional emptying if the central supply fails or falls below the specified level; the backup cylinders must be opened manually) or • Advanced cylinder support (cylinders open even if central supply available; if the central supply fails, cylinder supply automatically used)	-
Gas delivery, gases/gas composition	Electronically controlled mixer • Air/O_2 • O_2/N_2O (optional) • O_2 flush (button on mixer front) Mechanically controlled mixer with electronic flow measurement • Air/O_2/N_2O (N_2O optional) • O_2 flush (button on mixer front) Mechanically controlled mixer with flow tubes • Air/O_2/N_2O (N_2O optional) • O_2 flush (button on device front)	Electronically controlled mixer • Air/O_2 • O_2/N_2O (optional) • O_2 flush (button on mixer front) Mechanically controlled mixer with electronic flow measurement • Air/O_2/N_2O (N_2O optional) • O_2 flush (button on mixer front)	For model A100's mechanically controlled gas mixer with flow tubes: Advanced Instrumentations, Inc. AM-6000 Anesthesia Machine (K120075) Fresh gas flowmeters • Air/O_2/N_2O

Topic	*Proposed device* *Atlan (SW 2.11.00)*	*Predicate device* *Atlan (SW 2.00.01)*	*Predicate device, second* *AM-6000*
Gas delivery, Safety Oxygen Ratio Controller (SORC)	Yes Electronically controlled gas mixer: O_2 ≥ 25% if N_2O open Mechanically controlled gas mixer with electronic flow measurement: O_2 ≥ 21% if N_2O open Mechanically controlled gas mixer with flow tubes: O_2 ≥ 21% if N_2O open	Yes Electronically controlled gas mixer: O_2 ≥ 25% if N_2O open Mechanically controlled gas mixer with electronic flow measurement: O_2 ≥ 21% if N_2O open	For model A100's mechanically controlled gas mixer with flow tubes: Advanced Instrumentations, Inc. AM-6000 Anesthesia Machine (K120075) Hypoxic Guard
Gas delivery, control	Electronically or manually	Electronically or manually	-
Gas delivery, auxiliary oxygen (for O2 insufflation)	Optionally in one of three ways: • integrated in the gas mixer front for both electronically controlled gas mixer and mechanically controlled gas mixer with electronic flow measurement (model A350/A350 XL) • externally mounted as a flowmeter for the mechanically controlled gas mixer variants only • not included at all, but only if one of the mechanically controlled gas mixer variants is configured	Optionally in one of three ways: • integrated in the gas mixer front for both electronically and mechanically controlled gas mixer with electronic flow measurement • externally mounted as a flowmeter for the mechanically controlled gas mixer variant only • not included at all, but only if the mechanically controlled gas mixer is configured	-
Anesthetic breathing system	Integrated, supports partial rebreathing • low-flow anesthesia • minimum-flow anesthesia	Integrated, supports partial rebreathing • low-flow anesthesia • minimum-flow anesthesia	-

Topic	*Proposed device* *Atlan (SW 2.11.00)*	*Predicate device* *Atlan (SW 2.00.01)*	*Predicate device, second* *AM-6000*
Anesthetic breathing system, components	• fresh-gas and anesthetic gas inlet • CO_2 absorber (accessory) • anesthetic gas scavenger outlet / valve • airway pressure limitation/limiting (APL) valve • breathing bag (accessory) • PEEP / maximum pressure Pmax valve • expiratory valve • pressure gauge, optional • patient connection / interface • inspiratory valve • piston interface • fresh-gas decoupling valve • pneumatic connection nozzles (reusable) • breathing system heater	• fresh-gas and anesthetic gas inlet • CO_2 absorber (accessory) • anesthetic gas scavenger outlet / valve • airway pressure limitation/limiting (APL) valve • breathing bag (accessory) • PEEP / maximum pressure Pmax valve • expiratory valve • pressure gauge, optional • patient connection / interface • inspiratory valve • piston interface • fresh-gas decoupling valve • pneumatic connection nozzles (disposable) • breathing system heater	-
Anesthetic breathing system, gas flow	• from gas inlet • through mixer chamber/flow tubes • passing through vaporizer mount • channeled into anesthetic breathing system	• from gas inlet • through mixer chamber • passing through vaporizer mount • channeled into anesthetic breathing system	-
Anesthetic ventilator, drive type	Piston	Piston	-

Anesthetic ventilator, basic ventilation types	• Spontaneous breathing
	• Manual ventilation
	• Automatic (or controlled) ventilation
	  ○ Pressure-controlled
	  ○ Volume/flow-controlled
		• Spontaneous breathing
		• Manual ventilation
		• Automatic (or controlled) ventilation
		  ○ Pressure-controlled
		  ○ Volume/flow-controlled
			-

Anesthetic ventilator, features	• Compliance compensation • Fresh-gas decoupling	• Compliance compensation • Fresh-gas decoupling	-

Topic	*Proposed device* *Atlan (SW 2.11.00)*	*Predicate device* *Atlan (SW 2.00.01)*	*Predicate device, second* *AM-6000*
Anesthetic ventilator, ventilation modes, applicable to all patient populations	Manual / Spontaneous Man/Spon	Manual / Spontaneous Man/Spon	-
	Continuous positive airway pressure / Pressure-controlled ventilation, CPAP / PSV	Continuous positive airway pressure / Pressure-controlled ventilation, CPAP / PSV	-
	Pressure-controlled ventilation – Controlled mandatory ventilation, PC – CMV	Pressure-controlled ventilation – Controlled mandatory ventilation, PC – CMV	-
	Pressure-controlled ventilation – Synchronized intermitted mandatory ventilation, PC – SIMV	Pressure-controlled ventilation – Synchronized intermitted mandatory ventilation, PC – SIMV	-
	Pressure-controlled ventilation – Synchronized intermitted mandatory ventilation – Pressure support, PC – SIMV/PS	Pressure-controlled ventilation – Synchronized intermitted mandatory ventilation – Pressure support, PC – SIMV/PS	-
	Volume-controlled ventilation – Controlled mandatory ventilation / AutoFlow, VC – CMV/AutoFlow	Volume-controlled ventilation – Controlled mandatory ventilation / AutoFlow, VC – CMV/AutoFlow	-
	Volume-controlled ventilation – Synchronized intermittent mandatory ventilation/AutoFlow, VC – SIMV/AutoFlow	Volume-controlled ventilation – Synchronized intermittent mandatory ventilation/AutoFlow, VC – SIMV/AutoFlow	-
	Volume-controlled ventilation – Synchronized intermittent mandatory ventilation/Pressure support/AutoFlow, VC – SIMV/PS/AutoFlow	Volume-controlled ventilation – Synchronized intermittent mandatory ventilation/Pressure support/AutoFlow, VC – SIMV/PS/AutoFlow	-
	Volume-controlled ventilation – Controlled mandatory ventilation, VC – CMV	Volume-controlled ventilation – Controlled mandatory ventilation, VC – CMV	-
	Volume-controlled ventilation – Synchronized intermittent mandatory ventilation, VC – SIMV	Volume-controlled ventilation – Synchronized intermittent mandatory ventilation, VC – SIMV	-

Topic	*Proposed device* *Atlan (SW 2.11.00)*	*Predicate device* *Atlan (SW 2.00.01)*	*Predicate device, second* *AM-6000*
	Volume-controlled ventilation – Synchronized intermittent mandatory ventilation/Pressure support, VC – SIMV/PS	Volume-controlled ventilation – Synchronized intermittent mandatory ventilation/Pressure support, VC – SIMV/PS	-
Anesthetic ventilator, ventilation modes, applicable to all patient populations, maneuvers (model A350/A350 XL)	Inspiration hold, or “inspiratory pause” or “manual inspiration” Insp. Hold	Inspiration hold, or “inspiratory pause” or “manual inspiration” Insp. Hold	-
	Expiration hold, or “expiratory pause” Exp. Hold	Expiration hold, or “expiratory pause” Exp. Hold	-
	One-step recruitment, or “sustained inflation”	One-step recruitment, or “sustained inflation”	-
	Multi-step recruitment, or “incremental PEEP”	Multi-step recruitment, or “incremental PEEP”	-
Anesthetic ventilator, additional operation modes	Cardiac Bypass Mode (CBM)	Cardiac Bypass Mode (CBM)	-
	Monitoring mode - the anesthesia machine must be equipped with an integrated respiratory gas measurement module - for patient gas monitoring - no fresh-gas delivery	Monitoring mode - the anesthesia machine must be equipped with an integrated respiratory gas measurement module - for patient gas monitoring - no fresh-gas delivery	-
	Pause mode (model A350/350 XL) - ventilation stopped - if equipped with an electronically controlled gas mixer, gas delivery also stopped - gas concentration measurement active, waiting for respiratory phases - remains in this operation mode until deliberately switched to a specific ventilation mode - configurable Timer [for all patient categories] allows defined period after which an alarm is posted to remind user to initiate ventilation manually - total elapsed time displayed	Pause mode - ventilation stopped - if equipped with an electronically controlled gas mixer, gas delivery also stopped - gas concentration measurement active, waiting for respiratory phases - remains in this operation mode until deliberately switched to a specific ventilation mode - configurable Timer [for all patient categories] allows defined period after which an alarm is posted to remind user to initiate ventilation manually - total elapsed time displayed	-

Topic	*Proposed device* *Atlan (SW 2.11.00)*	*Predicate device* *Atlan (SW 2.00.01)*	*Predicate device, second* *AM-6000*
Anesthetic ventilator, manual override operation	Emergency oxygen delivery Add. O_2	Emergency oxygen delivery Add. O_2	-
	Backup manual mode: - enables direct change to manual ventilation [via Add. O_2] - with acoustic and optical alarm signals of high priority - automatic downgrade to low priority after 20 s	Backup manual mode: - enables direct change to manual ventilation [via Add. O_2] - with acoustic and optical alarm signals of high priority - automatic downgrade to low priority after 20 s	-
Anesthetic gas scavenger	active, integrated	active, integrated	-
	passive, integrated	passive, integrated	-
Anesthetic gas scavenger, active, type	open reservoir system	open reservoir system	-
Anesthetic gas scavenger, passive	• for gas disposal without an active disposal system • anesthetic gas transported by overpressure within the breathing system • positive and negative release valves	• for gas disposal without an active disposal system • anesthetic gas transported by overpressure within the breathing system • positive and negative release valves	-
General monitoring, alarm principles	• optical and acoustical alarm signaling • adjustable alarm volume • high, medium, and low alarm priorities • alarm silence key available • downgrading for some alarms • alarm logbook • user-adjustable alarm limits • automatic alarm settings adaptation when changing ventilation modes	• optical and acoustical alarm signaling • adjustable alarm volume • high, medium, and low alarm priorities • alarm silence key available • downgrading for some alarms • alarm logbook • user-adjustable alarm limits • automatic alarm settings adaptation when changing ventilation modes	-
Gas monitoring, types	integrated patient-gas measurement module for O_2, CO_2, N_2O, and anesthetic gases **or** integrated inspiratory O_2 sensor	integrated patient-gas measurement module for O_2, CO_2, N_2O, and anesthetic gases **or** integrated inspiratory O_2 sensor	-

Topic	*Proposed device* *Atlan (SW 2.11.00)*	*Predicate device* *Atlan (SW 2.00.01)*	*Predicate device, second* *AM-6000*
Gas monitoring, integrated patient-gas measurement module for O_2	• paramagnetic (consumption-free) • side-stream	• paramagnetic (consumption-free) • side-stream	-
Gas monitoring, integrated patient-gas measurement module for CO_2	• infrared spectrometry (consumption-free) • side-stream	• infrared spectrometry (consumption-free) • side-stream	-
Gas monitoring, integrated patient-gas measurement module for N_2O and anesthetic gases	• infrared spectrometry (consumption-free) • side-stream	• infrared spectrometry (consumption-free) • side-stream	-
Gas monitoring, integrated inspiratory O_2 sensor	• electrochemical • mainstream, inspiratory limb	• electrochemical • mainstream, inspiratory limb	-
Gas monitoring, parameter O_2	• inspiratory O_2 concentration	• inspiratory O_2 concentration	-
Gas monitoring, other parameters	with the integrated patient-gas measurement module for O_2, CO_2, N_2O, and anesthetic gases • expiratory O_2 concentration • inspiratory and expiratory CO_2 concentrations • inspiratory and expiratory N_2O concentrations • inspiratory and expiratory anesthetic gas concentrations • occurrence of anesthetic gas mixtures	with the integrated patient-gas measurement module for O_2, CO_2, N_2O, and anesthetic gases • expiratory O_2 concentration • inspiratory and expiratory CO_2 concentrations • inspiratory and expiratory N_2O concentrations • inspiratory and expiratory anesthetic gas concentrations • occurrence of anesthetic gas mixtures	-
Ventilation / airway monitoring, parameters	• airway pressure • minute volume / tidal volume • respiratory rate, apnea (derived from pressure, flow, and CO_2) • apnea (pressure, flow, and CO_2) • lack of fresh gas in the breathing system and the breathing circuit	• airway pressure • minute volume / tidal volume • respiratory rate, apnea (derived from pressure, flow, and CO_2) • apnea (pressure, flow, and CO_2) • lack of fresh gas in the breathing system and the breathing circuit	-

Topic	*Proposed device* *Atlan (SW 2.11.00)*	*Predicate device* *Atlan (SW 2.00.01)*	*Predicate device, second* *AM-6000*
Device monitoring, supply pressure monitoring	• electronically monitored and status displayed on the mixer front (model A350/A350 XL) • manometer on the mixer front (model A100)	• electronically monitored and status displayed on the mixer front	-
Device monitoring, system self-test	• covering all system-relevant functions • manual checklist • fully automatic • can be cancelled in case of emergency • can be set for automated start-up (model A350/A350 XL)	• covering all system-relevant functions • manual checklist • fully automatic • can be cancelled in case of emergency • can be set for automated start-up	-
User interface, hardware	• 15.3” TFT LCD touchscreen display • rotary knob for selecting, adjusting, and confirming therapy parameters • alarm silence key • LED lighting key • power ON/OFF key	• 15.3” TFT LCD touchscreen display • rotary knob for selecting, adjusting, and confirming therapy parameters • alarm silence key • LED lighting key • power ON/OFF key	-
User interface, displaying information	• waveforms • graphical trends • numeric trends • loops • alarm logbook • logbook • numeric parameters • low-flow wizard (A350/A350 XL)	• waveforms • graphical trends • numeric trends • loops • alarm logbook • logbook • numeric parameters • low-flow wizard	-

Topic	*Proposed device* *Atlan (SW 2.11.00)*	*Predicate device* *Atlan (SW 2.00.01)*	*Predicate device, second* *AM-6000*
RFID capabilities (model A350/A350 XL)	utilization of radio-frequency identification (RFID) wireless technology • Infinity ID water trap for compatibility and exchange control, i.e., replacement interval (maximum period of use) • Infinity ID flow sensors for compatibility and exchange control, i.e., replacement interval • Infinity ID CLIC absorber for compatibility, exchange control, and detection for “absorber locked in position” • Infinity ID breathing circuits for compatibility, exchange control, and identifying and reporting possible breathing hose or breathing bag mismatches	utilization of radio-frequency identification (RFID) wireless technology • Infinity ID water trap for compatibility and exchange control, i.e., replacement interval (maximum period of use) • Infinity ID flow sensors for compatibility and exchange control, i.e., replacement interval • Infinity ID CLIC absorber for compatibility, exchange control, and detection for “absorber locked in position” • Infinity ID breathing circuits for compatibility, exchange control, and identifying and reporting possible breathing hose or breathing bag mismatches	-

Discussion of Non-clinical Testing

The Atlan anesthesia workstation is a modified device and has undergone extensive testing to qualify all changes with e.g., national and international consensus standards, technical system requirements and other requirements. The following verification and validation activities were deemed necessary to establish substantial equivalence between the modified device and its previous version (predicate device, cleared under K230931) and were carried out under well-established methods, their results summarized in Test Summary tables and the evidence included in this submission.

- Reprocessing, including, e.g., ISO 17664-1 and ISO 17664-2
- Biocompatibility, including, e.g., ISO 10993-1 and the ISO 18562 series
- Software/Firmware, including, e.g., IEC 62304
- Cybersecurity/Interoperability, including e.g., IEC 60601-4-5
- Electromagnetic compatibility (EMC) and Wireless as per e.g., IEC 60601-1-2
- Electrical, Mechanical and Thermal Safety as per e.g., IEC 60601-1
- IEC 60601-1-8 for alarm systems in medical electrical equipment
- ISO 80601-2-13 for anesthetic workstations
- ISO 80601-2-55 for respiratory gas monitors
- Waveform comparison to the predicate device
- Performance testing, covering:
    - Risk control measures
    - Technical data
    - Essential safety and performance
- Accessories compatibility
- Human factors engineering, including e.g., IEC 60601-1-6 for Usability and IEC 62366-1 for the application of usability engineering to medical devices

Conclusion

The conclusions drawn from non-clinical tests and the comparison of intended use and technological characteristics with its predicate demonstrate that the modified product Atlan is as safe, as effective and performs as well as its legally marketed previous version cleared under K230931.

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