July 23, 2023

Drägerwerk AG Co. KGaA
Marianne Selent
Regulatory Affairs Manager
Moislinger Allee 53-55
Lübeck, Schleswig-Holstein 23542
Germany

Re: K230931
Trade/Device Name: Atlan
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine For Anesthesia Or Analgesia
Regulatory Class: Class II
Product Code: BSZ
Dated: June 23, 2023
Received: June 23, 2023

Dear Marianne Selent:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

James J. Lee -S

James J. Lee, Ph.D.
Division Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230931

Device Name
Atlan

Indications for Use *(Describe)*

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 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 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.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Premarket Notification Summary

Submitter:
Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck, Germany
Establishment's registration number: 9611500

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Date prepared: July 18, 2023

Device Name:

Trade name:	Atlan
Common name:	Anesthesia machine
Classification name:	Gas-machine, anesthesia
Regulation number:	21 CFR §868.5160
Product code:	BSZ
Class:	II

Predicate Device: Perseus A500, K133886

Reference Devices:
Dräger Primus US Apollo, K042607
Maquet Flow-I, K191027
GE Aisys CS2, K170872
Dräger Fabius GS/Fabius Tiro, K042419

Drägerwerk AG & Co. KGaA is submitting a traditional 510(k) premarket notification for a new device, the Atlan anesthesia workstation.

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 dioxides 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 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 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 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
AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
ANSI AAMI IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
AIM 7351731 Rev. 2.00 2017-02-23	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers - An AIM Standard
IEC 60601-1-6 Edition 3.1 2013-10	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ANSI AAMI IEC 60601-1-8:2012	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 80601-2-13:2011 AMD 1 2015 AMD 2 2018	Medical electrical equipment -- Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
ISO 80601-2-55:2018	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 1.0 2015-02 Including Corrigendum 1 (2016)]	Medical devices - Part 1: Application of usability engineering to medical devices
ANSI AAMI IEC 62304 Edition 1.1 2015-06	Medical device software - Software life cycle processes
ANSI AAMI ISO 10993-1: 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 18562-1:2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
ANSI AAMI ISO 17664:2017	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of 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

Comparison to Predicate and Reference Devices

Specification	Subject Device Atlan	Predicate Device Perseus A500	Reference Device(s)
Manufacturer	Drägerwerk AG & Co. KGaA	Drägerwerk AG & Co. KGaA	-
510(k) Number	-	K133886	-
Regulation Number	868.5160	868.5160	-
Product Code	BSZ	BSZ	-
Classification name	Gas-machine - Anesthesia	Gas-machine - Anesthesia	-
Regulatory Class	2	2	-
Indications for Use	The device is specified for inhalational anesthesia and/or patient ventilation in accordance with the intended use during surgical or diagnostic inter-ventions.	Perseus is specified for inhalational anesthesia and/or patient ventilation in accordance with the intended use during surgical or diagnostic interventions.	-
Target Population / Patient Population	This device is intended for use in anesthetizing adults, pediatric patients, and neonates.	The Perseus anesthesia workstation is intended for use in anesthetizing adults, children, and neonates.	-
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)	• 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)	-

Specification	Subject Device Atlan	Predicate Device Perseus A500	Reference Device(s)
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 • Air/O_2/N_2O (N_2O optional) • O_2 flush (button on mixer front)	Electronically controlled mixer • Air/O_2 • O_2/N_2O (optional) • O_2 flush (button on mixer front) Mechanically controlled mixer • Air/O_2/N_2O (N_2O optional) • O_2 flush (button on mixer front)	-
Gas delivery, Safety Oxygen Ratio Controller (SORC)	Yes Electronically controlled gas mixer: O_2 to N_2O ≥25% Mechanically controlled gas mixer: O_2 to N_2O ≥21%	Yes Electronically controlled gas mixer: O_2 to N_2O ≥25% Mechanically controlled gas mixer: O_2 to N_2O ≥21%	-
Gas delivery, control	Electronically or manually	Electronically or manually	-
Gas delivery, auxiliary oxygen	Optionally in one of three ways: • integrated in the gas mixer front for both electronically and mechanically controlled gas mixer variants • 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	• integrated in the gas mixer front for both electronically and mechanically controlled gas mixer variants	-
Anesthetic breathing system	Integrated, supports partial rebreathing • low-flow anesthesia • minimum-flow anesthesia	Integrated, supports partial rebreathing • low-flow anesthesia • minimum-flow anesthesia	-
Anesthetic ventilator, drive type	Piston	Blower	Primus US Apollo (K042607): Piston

Specification	Subject Device Atlan	Predicate Device Perseus A500	Reference Device(s)

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	-
Anesthetic ventilator, ventilation modes, applicable to all patient populations	Manual / Spontaneous Man/Spon	Manual / Spontaneous Man/Spon	-
	-	Manual / Spontaneous with CPAP, optional when PS option enabled	-
	Continuous positive airway pressure / Pressure-controlled ventilation, CPAP / PSV	CPAP / Pressure Support	-
	Pressure-controlled ventilation – Controlled mandatory ventilation, PC – CMV	Pressure Control - CMV	-
	Pressure-controlled ventilation – Synchronized intermitted mandatory ventilation, PC – SIMV	Pressure Control - SIMV+	-
	Pressure-controlled ventilation – Synchronized intermitted mandatory ventilation – Pressure support, PC – SIMV/PS	Pressure Control - SIMV+ / PS	-
	Volume-controlled ventilation – Controlled mandatory ventilation / AutoFlow, VC – CMV/AutoFlow	Volume Control - CMV / AF	-
	Volume-controlled ventilation – Synchronized intermittent mandatory ventilation/AutoFlow, VC – SIMV/AutoFlow	Volume Control - SIMV / AF	-

Specification	Subject Device Atlan	Predicate Device Perseus A500	Reference Device(s)
	Volume-controlled ventilation – Synchronized intermittent mandatory ventilation/Pressure support/AutoFlow, VC – SIMV/PS/AutoFlow	Volume Control - SIMV / AF / PS	-
	Volume-controlled ventilation – Controlled mandatory ventilation, VC – CMV	Volume Control - CMV	-
	Volume-controlled ventilation – Synchronized intermittent mandatory ventilation, VC – SIMV	-	Primus US Apollo (K042607): Volume-controlled ventilation with Synchronization Volume Mode Sync.
	Volume-controlled ventilation – Synchronized intermittent mandatory ventilation/Pressure support, VC – SIMV/PS	-	Primus US Apollo (K042607): Volume-controlled ventilation with Pressure Support Volume Mode Press. Support
	-	Pressure Control - APRV	-
Anesthetic ventilator, ventilation modes, applicable to all patient populations, maneuvers	Inspiration hold, or “inspiratory pause” or “manual inspiration” Insp. Hold	-	Maquet Flow-i (K191027): Inspiratory Hold
	Expiration hold, or “expiratory pause” Exp. Hold	-	Maquet Flow-i (K191027): Exspiratory Hold
	One-step recruitment, or “sustained inflation”	-	GE Aisys CS2 (K170872): Procedure “Vital capacity”
	Multi-step recruitment, or “incremental PEEP”	-	GE Aisys CS2 (K170872): Procedure “Cycling”

Specification	Subject Device Atlan	Predicate Device Perseus A500	Reference Device(s)
Anesthetic ventilator, additional operation modes	-	External fresh-gas outlet (optional)	-
	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	-	Primus US Apollo (K042607): Monitoring mode - for use during standby (not available during automatic ventilation) - no fresh-gas delivery - general time function displayed on screen for timing events
	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	Pause mode - ventilation is stopped - if equipped with an electronically controlled gas mixer, gas delivery also stopped - gas concentration measurement active, waiting for respiratory phases - remains in current operation mode until deliberately switched to a specific ventilation mode - equipped with an adjustable Timer depending on the patient category; when set time elapses, alarm posted as a reminder that ventilation should be resumed - total elapsed time displayed	-

Specification	Subject Device Atlan	Predicate Device Perseus A500	Reference Device(s)
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	Fresh-gas delivery failure: - current ventilation mode remains active - gas delivery via emergency O_2 [Add. O_2] delivery or ambient air - with acoustic and optical alarm signals of high priority - downgrade to low priority via rotary confirmation knob	-
Anesthetic gas scavenger	active, integrated	active, integrated	-
	passive	-	GE Aisys CS2 (K170872): passive
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	-	GE Aisys CS2 (K170872): - positive and negative release valves - negative pressure relief 0.3 cmH2O - for use with a non-recirculating ventilation system

Specification	Subject Device **Atlan**	Predicate Device **Perseus A500**	Reference Device(s)
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 history • 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	-
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 absorption (consumption-free) • side-stream	-
Gas monitoring, integrated patient-gas measurement module for N_2O and anesthetic gases	• infrared spectrometry (consumption-free) • side-stream	• infrared absorption (consumption-free) • side-stream	-

Specification	Subject Device Atlan	Predicate Device Perseus A500	Reference Device(s)
Gas monitoring, integrated inspiratory O_2	• electrochemical • mainstream, inspiratory limb	-	Fabius (K011404): - electrochemical - mainstream, inspiratory valve
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	• 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) • degree of filling of the breathing bag	-
Device monitoring, supply pressure monitoring	• electronically monitored and status displayed on the mixer front	• electronically monitored and status displayed on the mixer front	-
Device monitoring, system self test	• covering all system-relevant functions • fully automatic • can be cancelled in case of emergency • can be set for automated start-up	• covering all system-relevant functions • fully automatic • can be cancelled in case of emergency • can be set for automated start-up	-

Specification	Subject Device Atlan	Predicate Device Perseus A500	Reference Device(s)
User interface, hardware	• 15” TFT LCD touchscreen display • rotary knob for selecting, adjusting, and confirming therapy parameters • alarm silence key • LED lighting key • power ON/OFF key	• 15” 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	• waveforms • graphical trends • numeric trends • loops • alarm history • logbook • numeric parameters • low-flow wizard	-
RFID capabilities	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 new device and has undergone extensive testing to qualify it 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 to the predicate device and were carried out under well-established methods, their results summarized in Test Summary tables and the evidence included in this submission.

- Sterilization
- Biocompatibility
- Software, including cybersecurity
- Electrical safety
- Electromagnetic compatibility (EMC)
- 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
- Waveforms, including comparisons to the predicate device and performance as per ASTM-F1101
- Technical System Requirements, covering:
    - Risk control measures
    - Technical data
    - Essential safety and performance
- Accessories compatibility
- Human factors engineering
- IEC 60601-1-6 for Usability
- 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 new product Atlan is as safe, as effective and performs as well as or better than the legally marketed device Perseus K133886 as identified in this section of the submission.

- END -