K133986

JUN 20 2014

Dräger

Premarket Notification 510(k) summary
As required per 807.92

General Company Information

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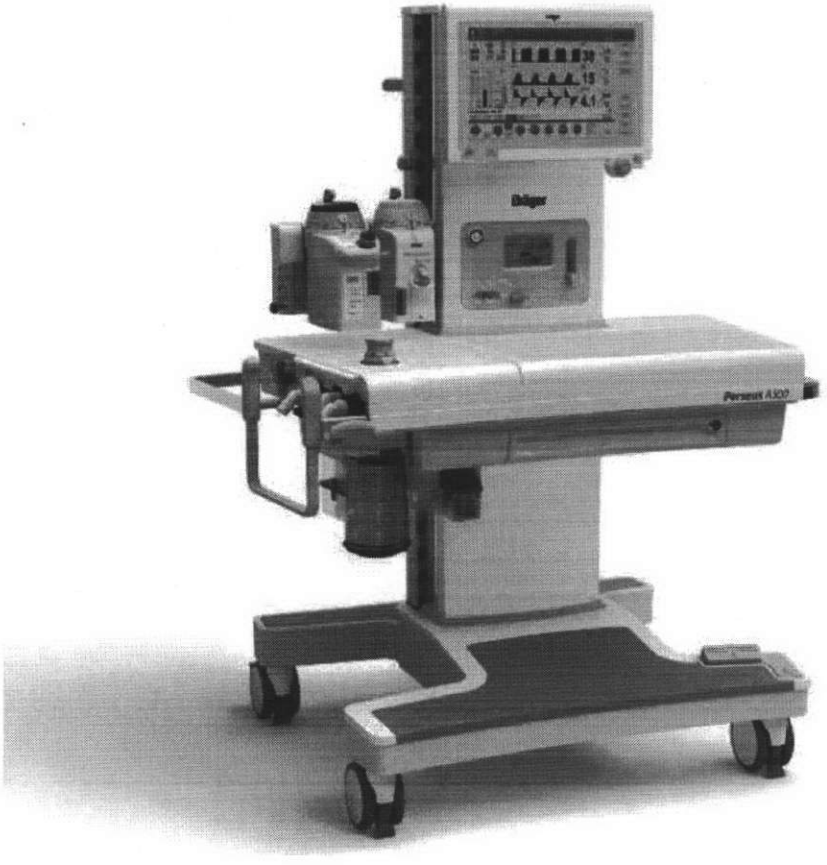
Dräger

Device Name

Common Name:	Gas-machine, anesthesia
Legally Marketed Device Identification:	Perseus A500
Regulation Number	868.5160
Regulation Description	Gas machine for anesthesia
Regulation Medical Specialty	Anesthesiology
Product Code	BSZ
Class	2

Device description:

The Perseus A500 is a continuous flow gas anesthesia system that delivers anesthetic vapour, provides for automatic and manual modes of ventilation, and is equipped with a monitoring system for ventilation, inspired and expired gas, and agent identification.

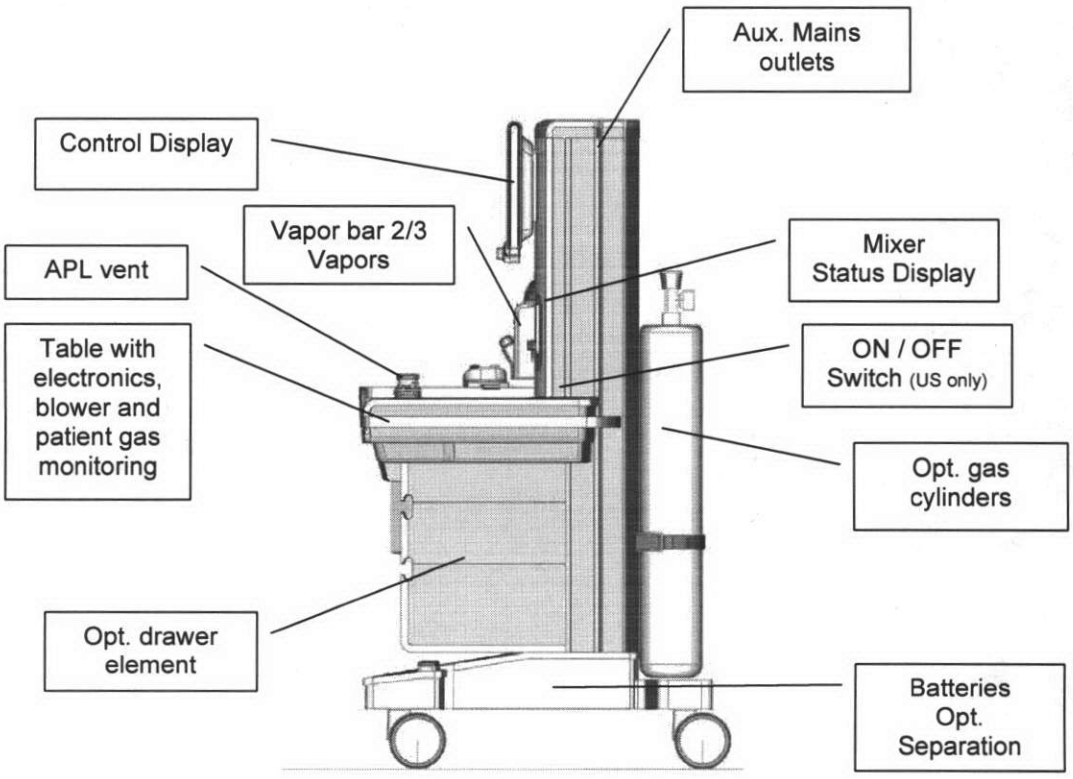


The main functionality of the anesthesia system comprises

- gas delivery for mixing oxygen and carrier gases,
- anesthetic agent delivery (via vaporizers such as Dräger Vapor 3000),
- anesthesia ventilator (blower based),
- anesthesia breathing system ABS,
- airway monitoring (flow, pressure, gas concentrations)

The Perseus A500 consists of the following main components:

- M3 Blower based Anesthesia Ventilator, electrical driven, supporting the Ventilation modes
  - Man/Spont
  - Volume Controlled
  - Pressure Controlled
- Embedded control display with touch screen technology and rotary/confirm knob for selecting and confirming parameters.
- Gas Mixer
- Heated integrated Anaesthesia Breathing System ABS
- Patient Gas Monitoring with agent mixture detection and Oxygen monitoring
- Integrated Anesthesia Gas Scavenging System
- Auxiliary Oxygen Therapy w/ flow indicator
- Oxygen cylinder support (reserve gas inlet)



Indications / Intended Use:

The anesthesia workstation Perseus is intended for use in anesthetizing adults, children, and neonates and can be used for automatic and manual ventilation, pressure-supported spontaneous breathing, and spontaneous breathing.

Perseus is equipped with airway monitoring, gas measurement and device monitoring, O_2 insufflation, and an anesthetic gas receiving system.

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 mask, or an endotracheal tube.

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

A non-rebreathing system such as the Kuhn or Medec Water System may be used at the external fresh-gas outlet (optional).

Perseus A500 is specified for inhalational anesthesia and/or patient ventilation in accordance with the intended use during surgical or diagnostic interventions.

Substantial Equivalence:

The Perseus A500 is substantial equivalent to the following predicate devices:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
K042607	Primus US	Draeger Medical GmbH
K983635	JULIAN ANESTHESIA WORKSTATION, MODEL # JULIAN	Draeger Medical GmbH
K093633	Infinity Acute Care System Workstation Critical Care	Draeger Medical GmbH

The devices are substantial equivalent the following characteristics:

General performance including operation concept

The Perseus is equivalent to the predicate devices by a uniform use concept, user interface and integrated display. The general performance is equivalent to the predicate devices and typical for anesthesia devices available on the market. The gas mixing concept is equivalent to the Primus US (K042607) for the product variant with the mechanically controlled mixer and equivalent to the Julian (K983635) for the product variant with the electronically controlled mixer.

Ventilation parameters, gas delivery, ventilation monitoring

The ventilation parameters Pressure Support, Pressure Control, Press. Ctrl. APRV (Airway Pressure Release Ventilation), Volume Control and Vol. Ctrl. AutoFlow are equivalent to the predicate devices Primus US (K042607) and the Infinity Acute Care System Workstation Critical Care (K093633) for Airway Pressure Release Ventilation.

The monitoring principals and parameters like Pressure waveform display, Volume measurement, Anesthetic gas measurement CO2 and O2 measurement are equivalent to the predicate devices.

Indications:

The side by side comparison of the indications between the Perseus A500 and the predicate devices showed that labelling and indications are substantial equivalent.

Performance and testing:

Dräger installed and maintains an internal Quality Management (QM) System. The QM System describes the procedures for development related to medical devices and requires a particular development process with all related activities including risk management, verification, validation and documentation. This procedure is in accordance with the design controls as defined in the current "Good Manufacturing Practice" published by FDA.

Design controls procedures are implemented and maintained at Dräger. All product developments and changes to Dräger products follow this internal procedure laid down in internal standard operating procedures DMS IN4000 "Develop Product" and DMTN LM2310 "Execute Product Design Changes" respectively. The software has been verified and validated according to the specification and test requirements, and documented as described in the FDA Guidance for the Content of Premarket Submissions for Software.

The development of Perseus A500 was in accordance with these procedures and passed all verification activities. The risk management file identifies potential hazards and documents the result of the risk analysis including mitigation of hazards. Usability features have been evaluated by end-users and found that the Perseus A500 is safe and effective for use by the intended users, intended use, and use environment.

Utilized Standards:

The Perseus A500 has been tested and found to be in compliance with recognized safety, performance and electromagnetic compatibility standards:

IEC 60601-1 Medical electrical equipment - Part 1:
General requirements for basic safety and essential performance
Including: National Deviations as per UL 60601.1

IEC 60601-1-4 Medical electrical equipment - Part 1-4: General requirements for safety; Collateral standard: Programmable electrical medical systems

IEC 60601-1-8 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

IEC 60601-2-13 Medical electrical equipment - Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems (Recognition Number 1-61)

IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for safety
- Collateral standard: Electromagnetic compatibility - Requirements and tests

ISO 8835-2 Inhalational anaesthesia systems - Part 2: Anaesthetic breathing systems

ISO 8835-3 Inhalational anaesthesia systems - Part 3: Transfer and receiving systems

of active anaesthetic gas scavenging systems

ISO 8835-5 Inhalational anaesthesia systems - Part 5: Anaesthesia ventilators

ISO 21647 Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors (Recognition Number 1-65)

Biocompatibility was verified according to the requirements Memorandum - #G95-1 (and tested based on the requirements of IEC 60601-1 (Clause 48) and the applicable ISO 10993 standards)

Hygienic evaluation as defined in ISO 17664.

ISO 15001 Oxygen Compatibility

Conclusion:

Based on similarities in the indications and technological characteristics the Perseus A500 is considered substantially equivalent to the predicate devices. The results of performance and validation/verification testing show, that the use of the device is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 20, 2014

Dräger Medical GmbH
Mr. Ulrich Schroeder
Moislinger Allee 53-55
D-23542 Luebeck, Germany

Re: K133886
Trade/Device Name: Gas-machine, anesthesia
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas-machine for anesthesia
Regulatory Class: II
Product Code: BSZ
Dated: May 12, 2014
Received: May 12, 2014

Dear Mr. Schroeder:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

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The anesthesia workstation Perseus A500 is intended for use in anesthetizing adults, children, and neonates and can be used for automatic and manual ventilation, pressure-supported spontaneous breathing, and spontaneous breathing.

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neha Gujarati -S
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