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K042607

Summary of Safety and Effectiveness Data Relating to Substantial Equivalence

Proprietary Name: Primus US

Common Name: Gas Machine-Anesthesia

Classification Name: Gas Machine -Anesthesia

Product Codes: 73 BSZ

Device Class: Class II

Manufacturer: Draeger Medical AG & Co KGaA
53/55 Moislinger Allee
Luebeck, Germany

Establishment Registration Number: 9611500

Devices to which substantial equivalence is claimed:

Fabius GS Anesthesia Workstation (Fabius GS)	K041622
Julian Anesthesia Workstation (Julian)	K983635
Narkomed 6400 w/IPM Anesthesia Workstation (NM6400)	K033498
Divan Ventilator	K980208
Vamos w/ Return Sample Gas (Vamos w/ RGS)	K040847

Device Description:

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

Indications for Use:

The Primus Us is indicated as a continuous flow anesthesia system. The Primus US may be used for manually assisted, or automatic ventilation, and delivery of gases, anesthetic

vapor, and monitoring of; oxygen and CO2 concentration, breathing pressure, respiratory volume, and anesthetic agent identification and concentration. Federal law restricts this device to sale by or on the order of a physician.

Intended Use:

The Primus Us is an inhalation anesthesia machine for use in operating, induction and recovery rooms. It can be used with rebreathing systems, semi closed to virtually closed systems with low flow and minimal flow techniques, and non-rebreathing systems.

It may be used with O2, N2O, and AIR supplied by a medical gas pipeline system or by externally mounted gas cylinders. Anesthetic agent can be delivered via vaporizers mounted on the machine.

Substantial Equivalence:

Like the Fabius GS, the Primus US provides integrated electronic monitoring for inspired O2, breathing pressure, respiratory volume. The Primus US also provides integrated patient gas monitoring like the Julian. The Primus US uses the same Gas measurement technology as the Scio patient gas monitor (K031340).

Like the NM6400, Primus US has a color screen display with a combination of a rotary knob, hard keys, and soft keys for the user interface. Information presented on the screen includes machine status, numerics, alarms, graphics, and prompt fields, ventilation, gas measurement and monitoring parameters.

Like the Fabius GS the Primus US has a battery back up system which is automatically enabled in the event of an AC power failure.

Electronic flow sensor technology is used by the Fabius GS and the Primus US for the virtual and total flow meters. Control of the flow meters is via corresponding color coded mechanical flow control knobs. Both devices are available with an auxiliary O2 flow meter and O2 flush valve.

The oxygen ratio controller (ORC) of the Primus US and Fabius GS are identical in the way they control the percentage of O2 to N2O to prevent a hypoxic mixture, and cut off the flow of N2O in case of an O2 supply failure.

Like the Fabius GS, the ventilator of Primus US is an electronically controlled, electrically driven piston ventilator with fresh gas decoupling. The ventilators are volume or pressure controlled preset, time cycled, pressure limited, with electronic timing, pneumatic circuitry, and controls for frequency, inspiratory to expiratory ratio (inspiratory time), inspiratory flow rate, tidal volume and inspiratory pressure limit.

Both have an integrated breathing system consisting of inspiratory and expiratory valves with patient hose connectors, pneumatic connectors, rotary style APL valve, breathing bag, and a standard 1.5 liter absorber, or the Drägersorb CLIC disposable absorber.

Respiratory volume is derived via thermo anemometry flow sensors in both systems. A difference is that the Primus US uses flow sensors in the inspiratory and expiratory limbs, while the Fabius GS provides a flow sensor only in the expiratory limb. By adding the inspiratory flow sensor, leaks within the system can be measured, the functionality of the inspiratory valve can be monitored, and a better trigger performance for triggered patient ventilation modes is achieved.

Ventilation modes available in both the Primus US and the Fabius GS are: Manual/Spontaneous, Volume-Controlled, Pressure-Controlled, Pressure Support, and Pressure Support with Apnea ventilation. Like the Fabius GS the Primus US ventilator is piston driven.

Like the NM6400 the Primus US also offers synchronized intermittent mandatory ventilation (SIMV). Like the Evita 4, Primus US provides an optional synchronized volume controlled ventilation with pressure support mode, synchronized pressure controlled ventilation, and pressure support.

The ventilation parameters of the Fabius GS and Primus US are user adjustable via keys and an incremental encoder/confirmation knob.

The heated breathing circuit in Primus US and the Divan ventilator used in the NM6400, operate on the same principle to warm the gas in the patient breathing circuit.

Both the Fabius GS and Primus US can deliver up to three gases and one agent at a time, and use pipeline connections and back up gas cylinders for O2, N2O and Air.

The Primus Us is designed to interface with the same Anesthesia Gas Scavenger as the Fabius GS, or the passive scavenger system available for use Julian. An optional suction system is also provided.

Prior to use, the user is prompted to run a preuse checkout procedure. Like the NM6400, the checkout is run automatically by the machine, and prompts the user for interactions as necessary.

Electrical power is supplied to the ventilators via the anesthesia system's power supply.

Like the Fabius GS, Primus US can accommodate up to three vaporizers for use with either the Dräger Vapor® Selectatec™ interlock systems or the Dräger Auto Exclusion 3 Vaporizer Mount. The Dräger Auto Exclusion 2 Vaporizer Mount may also be used on Primus US.

Qualification of Primus US included a risk analysis, system level qualification, and verification/validation testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 26 2004

Mr. James J. Brennan
Director, Regulatory Affairs
Draeger Medical, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K042607
Trade/Device Name: Primus US Anesthesia Workstation
Regulation Number: 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: September 23, 2004
Received: September 24, 2004

Dear Mr. Brennan:

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.

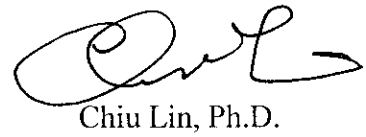
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Name: Primus US Anesthesia Workstation

Indications For Use:

The Primus US is indicated as a continuous flow anesthesia system. The Primus US may be used for manually assisted, or automatic ventilation, and delivery of gases, anesthetic vapor, and monitoring of; oxygen and CO2 concentration, breathing pressure, respiratory volume, and anesthetic agent identification and concentration. Federal law restricts this device to sale by or on the order of a physician.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K042667