AUG 3 1 2004

K042086

SUMMARY OF SAFETY AND EFFECTIVENESS DATA RELATING TO SUBSTANTIAL EQUIVALENCE

Proprietary Name:	Fabius GS Anesthesia System Fabius Tiro Anesthesia System
Classification Name:	Gas Machine, Anesthesia – 73 BSZ
Device Class:	Class II
Initial Distributor:	Draeger Medical, Inc. 3135 Quarry Road Telford, Pennsylvania 18969 USA
Establishment Registration No.:	2517967
Devices to which substantial equivalence is claimed:	Fabius GS Anesthesia System – K041622 Fabius Tiro Anesthesia System – K041622 Evita 4 Continuous Ventilator – K961687 7900 Ventilator – K023366

Device Description:

The Fabius GS and Fabius Tiro are continuous flow gas anesthesia systems.

Intended Use:

The Fabius GS and Fabius Tiro may be used for spontaneous, manually assisted, automatic, or pressure support ventilation of patients during anesthesia, and delivery of gases and anesthetic vapor. The Fabius GS and Fabius Tiro can monitor inspired oxygen concentration, breathing pressure, and respiratory volume.

Substantial Equivalence:

The current Fabius GS/Tiro Anesthesia Systems (K041622) are being modified to incorporate an Apnea Ventilation feature into the Pressure Support ventilation mode. The addition of Apnea Ventilation is a software change only. The basic infrastructure, operating principle, alarm strategies, fault detection circuitry, and mechanical/pneumatic subassemblies within the Fabius GS/Tiro remain unchanged.

The Apnea Ventilation feature is intended as a short term backup to prevent an apnea condition should a patient's spontaneous effort fail to trigger Pressure Support ventilation or cease entirely. It is not intended as a long term substitute for patient triggered pressure support ventilation. When Apnea Ventilation is enabled, if the patient spontaneous breathing rate falls below the minimum ventilation frequency (Freq Min) setting, the ventilator automatically delivers a Pressure Support breath at the pre-set Pressure Support settings.

The Apnea Ventilation feature in the Fabius GS/Tiro is substantially equivalent to the Apnea Ventilation feature in the Evita 4 (K961687) and the Apnea Backup Mode feature in the 7900 Ventilator (K023366). All three are triggered if a user selected time elapses without a spontaneous breath during pressure support ventilation and all three can be disabled by the user. As stated earlier, when Apnea Ventilation is triggered in the Fabius GS, a pressure support breath is delivered at the pre-set Pressure Support settings. The Fabius GS/Tiro stays in Pressure Support mode. In the Evita 4, when Apnea Ventilation is triggered, the ventilator switches to Volume Controlled ventilation at a pre-set tidal volume and breath rate. The Evita 4 then stays in Volume Controlled mode unless the user switches back to Pressure Support mode. In the 7900 Ventilator, when Apnea Backup Mode is triggered, the ventilator switches to Synchronized Intermittent Mandatory Ventilation – Pressure Controlled (SIMV - PC) mode at a pre-set inspired pressure, breath rate and inspiratory time. The 7900 Ventilator stays in SIMV-PC mode unless the user switches back to Pressure Support mode. From a safety and efficacy standpoint, all three devices prevent an apnea condition and alert the user to the condition.

Qualification included hazard analysis, system level qualification, and verification/ validation tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2004

Mr. Michael A. Kelhart
Regulatory Affairs Project Manager
Draeger Medical, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K042086
Trade/Device Name: Fabius GS and Fabius Tiro Anesthesia Systems
Regulation Number: 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: August 2, 2004
Received: August 3, 2004

Dear Mr. Kelhart:

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 (301) 594-4646. 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): K042086

Device Name: Fabius GS and Fabius Tiro Anesthesia Systems

Indications for Use:

The Fabius GS and Fabius Tiro are indicated as a continuous flow anesthesia systems. The Fabius GS and Fabius Tiro can be used for spontaneous, manually assisted, automatic or pressure support ventilation, delivery of gases and anesthetic vapor, and monitoring oxygen concentration, breathing pressure and respiratory volume of patients during anesthesia. Federal law restricts these devices to sale by or on the order of a physician.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K042086