OCT 8 - 2004

K042418

SUMMARY OF SAFETY AND EFFECTIVENESS DATA RELATING TO SUBSTANTIAL EQUIVALENCE

Proprietary Name: Fabius GS/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/Fabius Tiro Anesthesia System – K042086
Evita 4 Continuous Ventilator – K961687
7900 Ventilator – K023366

Device Description:

The Fabius GS/Fabius Tiro is a continuous flow gas anesthesia system.

Intended Use:

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

Substantial Equivalence:

The current software used in the Fabius GS/Fabius Tiro Anesthesia System (K042086) is being modified to include Synchronized Intermittent Mandatory Ventilation with Pressure Support (SIMV/PS) as an optional ventilation mode. The addition of SIMV/PS is essentially a software change and is incorporated in Fabius GS/Fabius Tiro software version 3.00. The only hardware change was the addition of a SIMV/PS hard key on the operator control panel. The basic infrastructure, operating principle, alarm strategies, fault detection circuitry, and mechanical/pneumatic subassemblies within the Fabius GS/ Fabius Tiro remain unchanged.

SIMV/PS mode is a mechanical ventilation mode influenced by spontaneous breathing. In SIMV/PS mode, when the patient breathes spontaneously, the ventilator will synchronize mechanical ventilation to the patient efforts. Between these intervals, mandatory (automatically delivered) un-synchronized ventilation is delivered to ensure a minimum degree of ventilation. SIMV ventilation strokes are the same as those for Volume Controlled ventilation. The synchroneous trigger mechanism for SIMV/PS is the

same as that used in pure pressure support mode. Adjustable parameters are Tidal Volume (Vt), Ventilator Frequency (Freq), Inspiratory Time (Tinsp), Inspiratory Pause (TIP: TI), and Positive End Expiratory Pressure (PEEP).

Pressure Support ventilation can be added to augment the patient's spontaneous breathing efforts by adjusting the Inspiratory Pressure Setting (ΔPPS) level to a value other than "Off." When turned "On", the Pressure Support aspect of SIMV functions the same as the Pressure Support ventilation mode cleared for commercial distribution on the Fabius GS/Fabius Tiro under 510(k)s K030624 and K042086.

Adjustable ventilation settings available in SIMV/PS are:

- Maximum Ventilation Pressure (Pmax)
- Tidal Volume (Vt)
- Ventilator Frequency (Freq)
- SIMV Inspiratory Time (TInsp)
- Inspiratory Pause (TIP:TI)
- Positive End Expiratory Pressure (PEEP)
- Inspiratory Pressure Setting (ΔPPS)*
- Inspiratory Flow*
- Trigger Level*

* For Pressure Support aspect of SIMV if Inspiratory Pressure Setting (ΔPPS) is set to a value other than "Off."

The SIMV/PS ventilation mode for the Fabius GS/Fabius Tiro is substantially equivalent to the SIMV with Pressure Support ventilation mode in the Evita 4 Ventilator (K961687) and 7900 Ventilator (K023366). Similarities are:

- All provide a user settable number of volume controlled ventilator delivered breaths per minute.
- All synchronize to spontaneous breaths.
- All incorporate the option of adding pressure support to assist the patient's spontaneous breaths between ventilator breaths.
- All provide user selectable ventilation parameters during SIMV/PS for; Maximum Ventilation Pressure (Pmax), Tidal Volume (Vt), Ventilator Frequency (Freq), Inspiratory Time (TInsp), and Positive End Expiratory Pressure (PEEP). Additionally, when SIMV is augmented with Pressure Support, all provide user selectable ventilation parameters for; Inspiratory Pressure Setting (ΔPPS), Inspiratory Flow, and Trigger Level.

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

OCT 8 - 2004

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

Re: K042419
Trade/Device Name: Fabius GS/Fabius Tiro Anesthesia System
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: September 3, 2004
Received: September 7, 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.

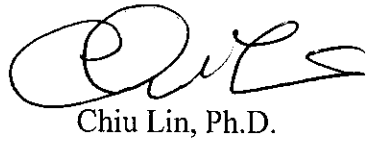
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (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): K042419

Device Name: Fabius GS/Fabius Tiro Anesthesia System

Indications for Use:

The Fabius GS/Fabius Tiro is indicated as a continuous flow anesthesia system. The Fabius GS/Fabius Tiro can be used for spontaneous, manually assisted, automatic, pressure support, or synchronized mandatory intermittent ventilation, delivery of gases and anesthetic vapor, and monitoring oxygen concentration, breathing pressure and respiratory volume of patients during anesthesia. Federal law restricts this device 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 K042419