K041622

JUL - 8 2004

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 – K030624 Fabius Tiro Anesthesia System – K031400 Narkomed 6400 Anesthesia System – K033498

Device Description:

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

Intended Use:

The Fabius GS 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 can monitor inspired oxygen concentration, breathing pressure, and respiratory volume.

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

Substantial Equivalence:

The compact breathing system (COSY) used with the Fabius GS (K030624) and Fabius Tiro (K031400) anesthesia systems is being modified to incorporate a heater plate. The addition of a heater plate is a hardware change only. The basic infrastructure, operating principle, alarm strategies, fault detection circuitry, and mechanical/pneumatic subassemblies within the Fabius GS/Tiro remain unchanged.

The heater consists of a heater foil, metal plate and insulator plate that are mounted between the absorber canister and COSY block. The heater subassembly is connected via a power cable to a separate power supply mounted externally to a Fabius GS/Tiro Anesthesia System.

Like the heater plate utilized in the NM6400's (K033498) Divan ventilator, the heater incorporated into the COSY is intended to warm the breathing system to minimize moisture accumulation in the breathing system components, especially during cases utilizing low flow anesthesia and/or during cases of low ambient environmental temperatures. It is not intended to control or maintain a set temperature of the patient breathing gas or to humidify the gas. Once activated, the heating plate in the COSY, like the NM6400, heats up to a constant temperature. This heat is then transferred, through conduction, to the components of the breathing system above it. In the NM6400, the heater plate is activated when the NM6400 System Power switch is turned to the "On" position and is de-activated when the NM6400 is switched to "Standby." With the COSY, heater activation is independent of the Fabius GS/Tiro. To activate the heater, the user is required to switch the heater power supply to the "On" position. To deactivate, the user is required to switch the power supply to the "Off" position.

Qualification of the modified compact breathing system included hazard analysis, system level qualification, and verification/validation tests.

Indications for Use

510(k) Number (if known): K041622

Device Name: Fabius GS Anesthesia System

Indications for Use:

The Fabius GS is indicated as a continuous flow anesthesia system. The Fabius GS 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 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 8 2004

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

Re: K041622
Trade/Device Name: 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: June 15, 2004
Received: June 16, 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.

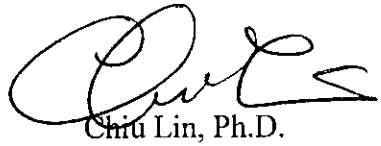
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K041622

Device Name: Fabius Tiro Anesthesia System

Indications for Use:

The Fabius Tiro is indicated as a continuous flow anesthesia system. The Fabius Tiro can be used for spontaneous, manually assisted or automatic 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 K041622