K031400

JUL 15 2003

SUMMARY OF SAFETY AND EFFECTIVENESS DATA RELATING TO SUBSTANTIAL EQUIVALENCE

Proprietary Name:	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 – K011404 OBA-1 Anesthesia Unit – K000859

Device Description:

The modified Fabius GS (Fabius Tiro) is a continuous flow gas anesthesia system.

Intended Use:

The Fabius Tiro may be used for spontaneous, manually assisted, or automatic 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 Fabius Tiro is a modification to the current Fabius GS Anesthesia System (K011404). The Fabius Tiro incorporates the same control module, gas flow control module, ventilator and breathing system subassemblies of the Fabius GS into a basic core module. Two versions of the Fabius Tiro are available; one that is designed to be mounted on a trolley and one that is designed to interface with other manufacturers' wall mounting solutions. The differences between the Fabius Tiro and Fabius GS are:

- Vaporizer mounting system: The Fabius GS can accommodate the mounting of up to two vaporizers and incorporates a mechanical exclusion system to ensure that only one vaporizer can be activated at one time. The Fabius Tiro can accommodate the mounting of only one vaporizer.

- Medical Gas Pipeline connections: On the Fabius GS, the medical gas pipeline connections are located on the back. On the Fabius Tiro, the medical gas pipeline connections are located on the right side (when viewed from the front).

- Pin-index hanger yokes: The Fabius GS has three pin-index hanger yokes mounted on the back of the machine to accommodate the mounting of two Oxygen and either a Nitrous Oxide or Air cylinder as secondary gas sources. Cylinder regulators are mounted internally and cylinder contents gauges are on the front of the machine. The Fabius Tiro wall mount version has one external tethered pin-index yoke, regulator and cylinder contents gauge assembly, which can be mounted to an Oxygen cylinder as a secondary gas source. The tethered yoke assembly is similar to the oxygen manifold for one e-cylinder and pipeline supply offered by OBAMED Inc. for the OBA-1 Anesthesia Unit (K000859) in that both contain a yoke assembly, regulator, cylinder contents gauge, and a connecting hose. The manifold and check valve are internally mounted on the Fabius Tiro while the manifold and check valve are external (part of the yoke assembly) on the OBA-1. The yoke assembly is standard equipment on the Fabius Tiro and is permanently connected to the right side of the machine while the assembly is optional for the OBA-1 and is connected to the machine via a DISS connector. The Fabius Tiro trolley mount version has one pin index hanger yoke mounted on the back of the machine to accommodate the mounting of an Oxygen cylinder as a secondary gas source and an optional second pin-index hanger yoke is available to accommodate a Nitrous Oxide cylinder. As with the Fabius GS, cylinder regulators are mounted internally and cylinder contents gauges are on the front of the machine.

- Software: There are no functional or operational changes to the software version from previously qualified software. The only software change was to change "Fabius GS" to "Fabius Tiro" as the name shown on the graphics display.

Qualification of the Fabius Tiro included a hazard analysis, system level qualification, and verification tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2003

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

Re: K031400
Trade/Device Name: Fabius Tiro Anesthesia System
Regulation Number: 868.5160
Regulation Name: Gas machine, Anesthesia
Regulatory Class: II
Product Code: 73 BSZ
Dated: June 13, 2003
Received: June 16, 2003

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,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K031400

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109)

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

510(k) Number: K031400

(Optional Format 1-2-96)