K072884

Dräger medical
A Dräger and Siemens Company

510(k) Summary

21 CFR part 807.92

JUL 30 2008

Applicants Name and Address:

Dräger Medical AG & Co. KG
Moislinger Allee 53-55
23542 Lübeck
Germany

Manufacturer Name and Address:

Dräger Medical AG & Co. KG
Moislinger Allee 53-55
23542 Lübeck
Germany

Establishment Regulation Number:

9611500

Contact Person:

Dr. Karin Luebbers
Senior Manager Regulatory Affairs

Phone: + 49 (451) 882-5367
Fax: + 49 (451) 882-4351

Applicants US Contact Person:

Joyce Kilroy
Vice President, PQR
(Processes, Quality & Regulatory)

Phone: +1 (215) 660-2626
Fax: +1 (215) 721-5424

Date submission was prepared:

2007-10-05

Device Name:

Common Name:	Fabius MRI
Classification Name:	Gas-machine, anesthesia (73 BSZ)
Regulation Number:	21 CRF 868.5160
Class:	II

Predicate Device Identification:

Fabius GS K042419

GE Datex Ohmeda Aestiva /5 MRI Anesthesia System K050055

Dräger medical
A Dräger and Siemens Company

Device Description:

The Fabius MRI is a continuous flow anesthesia system usable in an MRI environment.

Intended Use:

Fabius MRI is an inhalation anesthesia machine for use in MRI environments and standard ORs, induction and recovery rooms. It can be used in MRI environments with 1.5 and 3 tesla magnets at a location of < 40 millitesla (400 gauss).

It may be used with O2, N2O, and AIR supplied by a medical gas pipeline system or by externally mounted gas cylinders.

Fabius MRI is equipped with a compact breathing system, providing fresh gas decoupling, PEEP, and pressure limitation.

The following ventilation options are available:

- Volume Controlled Ventilation
- Pressure Controlled Ventilation
- Pressure Support (Optional)
- SIMV/PS (Optional)
- Manual Ventilation
- Spontaneous Breathing

Fabius MRI is equipped with an electrically driven and electronically controlled ventilator and monitors for airway pressure (P), volume (V), and inspiratory oxygen concentration (FiO2).

As per IEC 60601-2-13 (Anesthetic Workstations and their Modules – Particular Requirements), additional monitoring of the concentrations of CO2 and anesthetic agent is required when the machine is in use.

Predicate Devices:

510(k) Number	Device Name	Manufacturer
K042419	Fabius GS	Draeger Medical AG & Co. KG
K050055	GE Datex Ohmeda Aestiva /5 MRI	GE Healthcare

Substantial Equivalence:

The Fabius MRI is substantially equivalent to the Fabius GS (K042419) and the GE Datex Ohmeda Aestiva /5 MRI (K050055).

The Fabius GS was modified into the Fabius MRI. The two devices are identical with exception of modifications for the MRI environment (e.g. tesla sensor, alarm indicators, MRI specific labeling reduction of ferromagnetic materials) and a few other minor differences, (e.g. auxiliary outlet standard, 2 vapors instead of 3).

The Fabius MRI is similar to the Aestiva/5MRI in that both devices can be used in MRI environments with shielded magnets of 1.5 and 3.0 Tesla. Both devices have limitations to the location of use. The Fabius MRI may be used at a location of <400 gauss, while the Aestiva/5MRI may be used at locations of 300 gauss. Both devices have integral gauss alarms that notify the user when the device in excess of their operating parameters (> 400 gauss, 300 gauss).

Qualification of the Fabius MRI includes a risk management report, system level qualification and verification testing according to applicable standards and testing in an MRI environment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2008

Draeger Medical AG & CO. KG
Ms. Joyce Kilroy
Vice President of Processes, Quality, and Regulatory
Draeger Medical System, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K072884
Trade/Device Name: Fabius MRI
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: July 22, 2008
Received: July 25, 2008

Dear Ms. Kilroy:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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): K_____

Device Name: Fabius MRI

Indications For Use:
The Fabius MRI is indicated as a continuous flow anaesthesia system. The Fabius MRI may be used for spontaneous, manually assisted or automatic ventilation, delivery of gases and anaesthetic vapor, and monitoring of oxygen concentration, breathing pressure and respiratory volume.

The Fabius MRI is indicated for use in MRI scanner rooms with 1.5 and 3.0 tesla magnets at a location of 40 m tesla (400 gauss) or less.

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: K072884