510(k) Summary (Section 10)

Summary of Safety and Effectiveness

Applicants Name and Address

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

Applicants Contact Person

Mr. Ulrich Schröder
Manager Regulatory Affairs

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Applicants US Contact Person

Mr James J. Brennan
Director Regulatory Affairs

Tel. No.: (215) 721-5400
Fax No.: (215) 721-5412

Date the Summary was prepared

July 15, 2004

Device Name

Trade Name:	Essential Gas Module (EGM)
Common Name:	Anesthetic Multi Gas Monitor

Classification

Regulation No.	Device	Product Code
868.1400	Analyzer, Gas, Carbon Dioxide, Gaseous Phase	(73CCK)
868.1700	Analyzer, Gas, Nitrous Oxide, Gaseous Phase	(73CBR)
868.1500	Analyzer, Gas, Enflurane, Gaseous Phase	(73CBQ)
868.1620	Analyzer, Gas, Halothane, Gaseous Phase	(73CBS)
868.1500	Analyzer, Gas, Desflurane, Gaseous Phase	(73NHO)
868.1500	Analyzer, Gas, Sevoflurane, Gaseous Phase	(73NHP)
868.1500	Analyzer, Gas, Isoflurane, Gaseous Phase	(73NHQ)
868.1720	Analyzer, Gas, Oxygen, Gaseous-Phase	(73CCL)

Legally marketed device to which Substantial Equivalence is claimed

VAMOS (K012139, K040847)
Manufactured by Dräger Medical AG & Co. KGaA; Germany
Distributed in the United States by Draeger Medical Inc.

SCIO (with Infinity Patient Monitors) (K031340)
Manufactured by Dräger Medical AG & Co. KGaA; Germany
Distributed in the United States by Draeger Medical Inc.

Philips M1026B Anesthetic Gas Monitor (with IntelliVue Patient Monitors) (K040917)
Distributed in the United States by Philips Medical Systems

Description of the Device

The M1013A Essential Gas Module provides a nondispersive infrared measurement of respiratory and anesthetic gases and a paramagnetic measurement of oxygen (Fast O2).

It is designed to work with the Philips IntelliVue MP20/30/40/50/60/70/90 Anesthesia option #H30 through a digital interface (RS232). It is intended for measuring the airway gases of ventilated patients during the induction of, maintenance of, and emergence from anesthesia.

The module produces display waves for O2, CO2, N2O, and anesthetic agents, together with numerics for inspired and end-tidal values for O2, CO2, N2O, anesthetic agents, and airway respiration rate. An anesthetic agent must be selected manually for measurement.

An automatic zero calibration is performed by the Essential Gas Module as required to maintain measurement accuracy.

Intended Use

The EGM gas monitor is indicated for measuring and monitoring CO2 concentration and the concentrations of N2O, O2, Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane.

Federal Law restricts this device to sale by or on the order of a physician.

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Substantial Equivalence

The intended use of Savina SW 3.n with LPO Option is comparable by the referenced predicate devices

- Dräger Medical VAMOS Variable Anesthetic Gas Monitor
- Dräger Medical SCIO Multi Gas Monitor
- Philips M1026B Anesthetic Gas Monitor

The technical characteristics of the Essential Gas Module do not raise new questions regarding safety or effectiveness. Furthermore the labeling of the Essential Gas Module provides similar information as the predicate devices except for the subject of this submission.

Information provided in the 510(k) Premarket Notification supports the determination of substantial equivalence. Design, development, verification and validation of the device was performed in accordance with FDA regulations and guidances and company internal standards. The testing and analysis of results provide assurance that the device meets its specifications and is safe and effective for its intended use.

In summary Dräger Medical AG & Co. KGaA has demonstrated that the Essential Gas Module is safe and effective. The Essential Gas Module is considered to be substantial equivalent to currently marketed predicate devices which have been previously cleared by the FDA.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 9 2004

Dräger Medical AG & Company KGaA
C/O Mr. James J. Brennan
Director, Regulatory Affairs
Draeger Medical, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K041956
Trade/Device Name: EGM – Essential Gas Module
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: July 15, 2004
Received: July 21, 2004

Dear Mr. Brennan:

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.

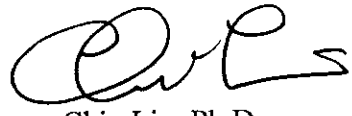
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Device Name: EGM - Essential Gas Module

Indications For Use: The EGM gas monitor is indicated for measuring and monitoring CO2 concentration and the concentrations of N2O, O2, Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane.
Federal Law restricts this device to sale by or on the order of a physician.

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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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ann Symon

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

510(k) Number K041956