K053204

FEB 2 2006

510(k) Summary (Section 10)

Summary of Safety and Effectiveness

Applicants Name and Address

Draeger Medical AG & Co. KGaA
Moislinger Allee 53-55
D-23542 Luebeck
Germany

Applicants Contact Person

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Senior Manager Regulatory Affairs

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Applicants US Contact Person

Ms Monica Ferrante
Director of Regulatory Affairs

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Date the Summary was prepared

October 31, 2005

Device Name

Trade Name: IntelliVue G5 M1019A / IntelliVue G1 M1013A
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 Draeger Medical AG & Co. KGaA; Germany
Distributed in the United States by Draeger Medical Inc.

SCIO (with Infinity Patient Monitors) (K031340, K051628)
Manufactured by Draeger 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

EGM – Essential Gas Monitor (K041956)
Manufactured by Draeger Medical AG & Co. KGaA; Germany
Distributed in the United States by Draeger Medical Inc.

Description of the Device

The IntelliVue G5 M1019A / G1 M1013A gas modules provide a nondispersive infrared measurement of respiratory and anesthetic gases and a paramagnetic measurement of oxygen (Fast O_2).

They are designed to work with Philips IntelliVue through a digital interface (RS232). They are intended for measuring the airway gases of ventilated patients during the induction of, maintenance of, and emergence from anesthesia.

The modules produce display waves for O_2, CO_2, N_2O, and anesthetic agents, together with numerics for inspired and end-tidal values for O_2, CO_2, N_2O, anesthetic agents, and airway respiration rate. Automatic identification of up to two anesthetic agents and measurement of mixtures of up to two anesthetic agents are available as options. Return of the sample gas into the breathing circuit is available optional.

An automatic zero calibration is performed by the IntelliVue gas module as required to maintain measurement accuracy.

Intended Use

The IntelliVue gas modules are indicated for measuring and monitoring CO_2 concentration and the concentrations of N_2O, O_2, Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane.

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

Substantial Equivalence

The intended use of IntelliVue gas modules is comparable by the referenced predicate devices

- Draeger Medical VAMOS Anesthetic Gas Monitor
- Draeger INFINITY Monitors with SCIO
- Philips M1026B Anesthetic Gas Monitor
- EGM – Essential Gas Monitor

The technical characteristics of the IntelliVue gas modules do not raise new questions regarding safety or effectiveness. Furthermore the labeling of the IntelliVue 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 guidance and company internal standards. The testing and analysis of results provide assurance that the devices meet their specifications and are safe and effective for their intended use.

In summary Draeger Medical AG & Co. KGaA has demonstrated that the IntelliVue gas modules are safe and effective. They are considered to be substantial equivalent to currently marketed predicate devices which have been previously cleared by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 2006

Ms. Monica Ferrante
Director, of Regulatory Affairs
Draeger Medical AG & Company KG
3155 Quarry Road
Telford, Pennsylvania 18969

Re: K053204
Trade/Device Name: IntelliVue G5 M1019A / IntelliVue G1 M1013A
Regulation Number: 868.1440
Regulation Name: Carbon Dioxide gas analyzer
Regulatory Class: II
Product Code: CCK
Dated: January 24, 2006
Received: January 27, 2006

Dear Mr. Ferrante:

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/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 053204

Device Name: IntelliVue G5 M1019A / IntelliVue G1 M1013A

Indications for Use: The IntelliVue gas modules are indicated for measuring and monitoring CO_2 concentration and the concentrations of N_2O, O_2, Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane.

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 801 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: K 053204