JUN 17 2004

K040847

Summary of Safety and Effectiveness Data Relating to Substantial Equivalence

Proprietary Name: Vamos Anesthetic Gas Monitor

Common Name: Analyzer, Gas

Classification Name: Analyzer Gas, Carbon-Dioxide, Gaseous Phase
Analyzer, Gas, Nitrous-Oxide, Gaseous Phase
Analyzer, Gas, Enflurane, Gaseous
Analyzer, Gas, Halothane, Gaseous
Oximeter

Product Codes: 73 CCK, CBR, CBQ, CBS, NHO, NHP, NHQ, and 74 DQA

Device Class:Class II

Manufacturer: Draeger Medical AG & Co KGaA
53/55 Moislinger Allee
Luebeck, Germany

Establishment Registration Number: 9611500

Devices to which substantial equivalence is claimed:
Vamos Anesthetic Gas Monitor K012139
As/3 Anesthesia Delivery Unit (As/3Adu) K973985
Capnomac Ultima Anesthesia Monitor K932098

Device Description:

The modified Vamos is an integrated monitoring system used for the multiple gas analysis (CO2), N2O), and anesthetic agent concentrations). Pulse Oximetry may also be included as an option.

Intended Use:

The Vamos, is intended to be used for measuring and monitoring the functional oxygen saturation (SPO2), pulse rate and the concentrations of CO2, N2O), Enflurane, Desflurane, Isoflurane, Halothane, and Sevoflurane.

Substantial Equivalence:

Like the AS/3 ADU with the integrated Capnomac Ultima Anesthesia Monitor, the Vamos (K012139) is being modified to include the ability to use return sample gas to the breathing circuit as an option during gas analysis. Testing was performed to assure that there would be no adverse effects to the patient as a result of the sample gas passing through the Vamos and back to the breathing circuit instead of being routed to the scavenger.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2004

Ms. Gale E. Winarsky, RAC
Regulatory Affairs Project Manager
Draeger Medical, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K040847
Trade/Device Name: Vamos Anesthesia Gas Monitor
Regulation Number: 868.1400, 868.1700, 868.1500, 868.1620, 870.2700
Regulation Name: Carbon Dioxide Gas Analyzer, Nitrous Oxide Gas Analyzer, Enflurane Gas Analyzer, Halothane Gas Analyzer, Oximeter
Regulatory Class: II
Product Code: 73 CCK, CBR, CBQ, CBS, NHO, NHP, NHQ, and DQA
Dated: May 28, 2004
Received: June 1, 2004

Dear Ms. Winarsky:

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.

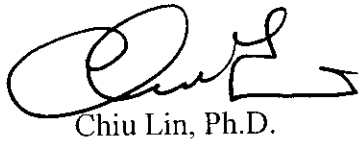
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Device Name: Vamos Anesthesia Gas Monitor

Indications for Use:

The Vamos Anesthetic Gas monitor is indicated for measuring and monitoring CO2 concentration, functional oxygen saturation (SPO2), pulse rate and the concentrations of N2O, 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 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: K040847