K053484

Special 510(k)
Infinity Gamma Series
VF6 Modifications

Dräger medical
A Dräger and Siemens Company

FEB 2 2 2006

510(k) SUMMARY
as required per 807.92(c)

Submitter's Name and Address: Draeger Medical Systems, Inc.
16 Electronics Avenue
Danvers, MA 01923

Contact Person: Karen A. Iorio
Director QA/RA
Tel: (978) 907-7500
Fax: (978) 750-6879

Date submission was prepared: December 2, 2005

Device Name:

Common Name: Monitor, Physiological, Patient (with arrhythmia detection or alarms)
Classification Name: MHX
Regulation Number: 21 CFR 870.1025 Class: 2

Legally Marketed Device Identification: Infinity Gamma Series Monitors

Device Description:
The intent of this 510(k) is to describe modifications for the Infinity Gamma/GammaXL and Vista monitors, including Pacer Fusion mode, three new versions of the Scio gas module, and Draeger's Masimo SET pod.

Intended Use:
The intended use of this device is to monitor heart rate, respiration rate, invasive pressure, non-invasive pressure, arrhythmia, temperature, arterial oxygen saturation and pulse rate, central apnea, end-tidal carbon dioxide*, and ST Segment Analysis. This device will produce visual and audible alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings. This device will connect to R50 recorders either directly or via the Infinity network.
* not available with the Infinity Vista monitor

Predicate Devices:

Infinity Gamma Series & Vista with VF5	K042656
Infinity GammaXL & SC 6802XL with Scio	K033600, K040188
Infinity Gamma	K041087

Substantial Equivalence:
Verification and validation testing performed indicates that the modifications implemented in the VF6 release of the Gamma series monitors are as safe and effective as previous versions and have not altered the fundamental technology of the device(s).

Draeger Medical Systems, Inc.
16 Electronics Avenue
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2006

Draeger Medical Systems, Inc.
c/o Ms. Karen A. Iorio
Director, QA/RA
16 Electronics Ave.
Danvers, MA 01923

Re: K053484
Trade Name: Infinity Gamma / GammaXL, Infinity Vista
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: January 25, 2006
Received: January 26, 2006

Dear Ms. Iorio:

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,

B Zimmerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K053484

Device Name: INFINITY Gamma/GammaXL and Vista

Indications for Use:

This devices are capable of monitoring:

- Heart Rate
- Respiration Rate
- Invasive Pressure
- Non-Invasive Pressure
- Arrhythmia
- Temperature
- Arterial oxygen saturation
- Pulse rate
- central apnea
- end-tidal CO2*
- ST Segment Analysis

This device will produce visual and audible alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings. The devices will connect to R50 recorders either directly or via the Infinity network.

When a GammaXL is connected to a SCIO* module sampled breathing gases from adults and pediatrics can be displayed. The gas module continuously measures the content of CO2, N2O, O2 and one of the anesthetic agents, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane in any mixture and communicates real time and derived gas information to the GammaXL.

The device is intended to be used in an environment where patient care is provided by Healthcare Professionals, i.e. physicians, nurses, and technicians, trained on the use of the device, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

The devices are intended for use in the Adult, Pediatric and Neonatal populations, *with the exception of Arrhythmia and ST Segment Analysis which are not intended for the neonatal population.*

* not available with Infinity Vista

MRI Compatibility Statement:
The devices are not compatible for use in an MRI magnetic field.

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

(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 Cardiovascular Devices
510(k) Number K053484