K 051658

NOV 16 2005

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

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

Contact Person: Penelope H. Greco
Regulatory Affairs Manager
Tel: (978) 907-7503
Fax: (978) 750-6879

Date submission was prepared: June 17, 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 Alpha

Device Description:

The Infinity Alpha is a light-weight, handheld portable patient monitor that displays real-time vital signs and provides continuous trending. The Infinity Alpha is capable of measuring heart rate, respiration rate, invasive blood pressure, non-invasive blood pressure, arrhythmia, temperature, cardiac output, arterial oxygen saturation, pulse rate, apnea, ST segment analysis, and 12-lead ST segment analysis. The device produces visual and audible alarms if any of the physiological parameters monitored vary beyond preset limits and timed or alarm recordings will be produced.

Intended Use:

The Infinity Alpha is intended for multi-parameter patient monitoring. The device produces visual and audible alarms if any of the physiological parameters monitored vary beyond preset limits and timed or alarm recordings will be produced.

Predicate Devices:

Infinity Modular Monitors K043439

Substantial Equivalence:

Assessment of non-clinical performance data for equivalence:

The Infinity Alpha Patient Monitor was tested in accordance with applicable standards and internal design control procedures and was determined to be as safe and effective for its intended use as the predicate device.

Assessment of clinical performance data for equivalence:

Clinical performance evaluations indicate that the Infinity Alpha Patient Monitor is substantially equivalent to the Infinity Delta series monitors.

Biocompatability:

Not applicable

Sterilization:

Not applicable

Standards and Guidance:

IEC 60601-1 and applicable and collateral standards
IEC 60601-1-2 Electromagnetic Compatibility
CISPR11, Class B
UL60601-1, CSA 22.2 No 60601-1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2005

Draeger Medical Systems, Inc.
c/o Ms. Penelope H. Greco
Regulatory Affairs Manager
16 Electronics Avenue
Danvers, MA 01923

Re: K051658
Trade Name: Infiniti Alpha
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarm)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: October 14, 2005
Received: October 17, 2005

Dear Ms. Greco:

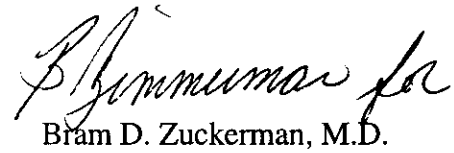
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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,



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):_____

Device Name: InfinityAlpha

Indications for Use:

This device is capable of monitoring heart rate, respiration rate, invasive blood pressure, non-invasive blood pressure, arrhythmia, cardiac output, temperature, arterial oxygen saturation, pulse rate, apnea, ST segment analysis.

Infinity Alpha will produce visual and audible alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings.

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.*

MRI Compatibility Statement:
The Infinity Alpha is not compatible for use in a 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 K051458