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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:	Karen Iorio, Director QA/RA Ph: (978) 564-8364 Fax: (978) 750-6879
Date submission was prepared:	January 25, 2006
Device Name:	
Common Name:	Detector and Alarm, Arrhythmia
Classification Name:	MHX
Regulation Number:	21 CFR 870.1025
Class:	2
Legally Marketed Device Identification:	Infinity MultiView Workstation and Telemetry

Device Description:

Infinity Telemetry Pacer Fusion
Infinity MultiView Telemetry with VF6 software supports the new pacer detection mode, Fusion. The Pacer Fusion mode has increased sensitivity to psuedo-fusion paced beats, sometimes known as fused beats.

Infinity Symphony
The MultiView WorkStation with VF6 supports the new web-based browser application, Infinity Symphony, for enhanced full disclosure review. Infinity Symphony provides users with retrospective reviews of stored continuous and episodic patient information -- continuous physiologic waveforms and other stored data over an extended period of time -- to provide review, analysis, and documentation of the patient's condition.

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Intended Use:
The Infinity MultiView WorkStation, Infinity Network and Remote Display are indicated for use as a central monitoring device, communications network, and remote display for Draeger Patient Monitoring Systems and recorders.

The Infinity MultiView WorkStation (MVWS) Telemetry System is intended to measure and produce visual and audible alarms for one or more physiological parameters

This device is intended for use in an environment where patient care is provided by Healthcare Professionals, i.e. Physicians, Nurses, and Technicians, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

Substantial Equivalence:

Assessment of non-clinical performance data for equivalence:
Verification and validation testing performed indicates that the modifications implemented are as safe and effective as previous versions and have not altered the fundamental technology of the device(s).

Assessment of clinical performance data for equivalence: Not applicable

Biocompatability:
Not applicable

Sterilization:
Not applicable

Standards and Guidance: IEC 60601-1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 2 2006

Draeger Medical Systems, Inc.
c/o Mr. Thomas M. McIntosh
Regulatory Submission Manager
16 Electronics Avenue
Danvers, MA 01923

Re: K060223
Trade Name: Infinity MultiView WorkStation and Telemetry
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: March 21, 2006
Received: March 22, 2006

Dear Mr. McIntosh:

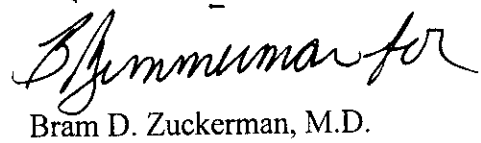
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May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

K060223

510(k) Number (if known):_____

Device Name: Infinity MultiView WorkStation and Telemetry

Indications for Use

The Infinity MultiView WorkStation, Infinity Network and Remote Display are indicated for use as a central monitoring device, communications network, and remote display for Draeger Patient Monitoring Systems and recorders.

Use of the Infinity MultiView WorkStation Telemetry System is indicated for adult and pediatric patient populations in an environment where patient care is provided by Healthcare Professionals (Physicians, Nurses, Technicians) when the professional determines that a device is required to measure and produce visual and audible alarms for any one or more of the following parameters:

- Heart rate
- ECG Arrhythmia Analysis
- Arterial oxygen saturation
- Pulse rate
- ST segment analysis

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 K060223