K070566

Special 510(k)
Infinity Delta and Kappa Series Monitors
Modifications

Dräger medical
A Dräger and Siemens Company

JUN - 4 2007

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

Submitter's Name and Address: Draeger Medical Systems, Inc.
6 Tech Drive
Andover, MA 01810

Contact Person: Mark Kieras
Sr. Regulatory Affairs Manager
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Date submission was prepared: February 16, 2007

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 Delta and Kappa Series Monitors

Device Description:
The intent of this 510(k) is to describe software modifications for the Infinity Delta and Kappa series modular monitors (Delta, Delta XL, Kappa, Vista XL, Gamma X XL, SC7000, SC8000, SC9000XL), including MIB modifications.

Intended Use:
The Infinity Delta and Kappa series modular monitors are intended for multi-parameter patient monitoring. The devices will produce visual and audible alarms if any of the physiological parameters monitored vary beyond preset limits and timed or alarm recordings will be produced. These devices will connect to an R50 Bedside re-corder, either directly or via the Infinity Network.

Predicate Devices:

Infinity Delta and Kappa Series Monitors with VF6 Modifications	K060039
Infinity Modular Monitors with SCIO Modifications	K051628
Infinity Delta and Kappa Series Monitors with VF5 Modifications	K043439

Substantial Equivalence:
Verification and validation testing performed indicates that the software modifications described in this submission are as safe and effective as previous versions and have not altered the fundamental technology of the device(s).

DRAEGER MEDICAL SYSTEMS, INC.
6 Tech Drive
Andover, MA 01810
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2007

Draeger Medical Systems, Inc.
c/o Mr. Mark Kieras
Sr. Regulatory Affairs Manager
6 Tech Drive
Andover, MA 01810

Re: K070566
Trade/Device Name: Infinity Delta and Kappa Series Modular Monitors (Infinity Delta/Delta XL/Kappa/Vista XL/Gamma X XL, SC7000, SC8000, SC9000XL)
Regulation Number: 21 CFR 870.1025
Regulation Name: Physiological Patient Monitor (with arrhythmia detection or alarms)
Regulatory Class: Class II
Product Code: MHX
Dated: May 1, 2007
Received: May 7, 2007

Dear Mr. Kieras:

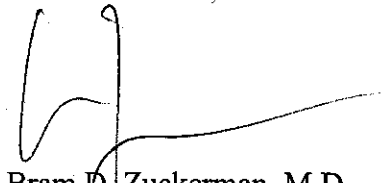
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-3150 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): K070566

Device Name: Infinity Delta / Delta XL / Kappa / Gamma X XL / Vista XL / SC7000 / SC8000 / SC9000XL

Indications for Use:

The INFINITY Modular monitors are capable of monitoring:

- Heart rate
- Respiration rate
- Invasive pressure
- Non-invasive pressure
- Arrhythmia
- Temperature
- Cardiac output
- Arterial oxygen saturation
- Pulse rate
- Apnea
- ST Segment Analysis
- 12-Lead ST Segment Analysis
- tcpO2/tcpCO2
- EEG signals
- FiO2

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Indications for Use

SCIO gas module samples breathing gases from adults and pediatrics. The gas module continuously measure 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 Infinity monitors.

With etCO2 the monitors can measure end tidal carbon dioxide, inspired carbon dioxide, and respiration rate in either mainstream or side-stream measurement mode; and with etCO2+Respiratory Mechanics, spirometry and carbon dioxide can be monitored.

The monitors can interface with specific third party devices via an MIB protocol converter.

The devices are intended to be used in the 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.

The devices are intended to be used on Adult, Pediatric and Neonatal populations, *with the exception of the parameter Cardiac Output, ST Segment Analysis, and arrhythmia which are intended for use in the adult and pediatric populations only; and tcpO2 which is to be used in the neonatal population only when the patient is not under gas anesthesia.*

MRI Compatibility Statement:
The INFINITY Modular Monitors are not compatible for use in a MRI magnetic field.

Concurrence of CDRH, Office of Device Evaluation (ODE)