



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Draeger Medical Systems, Inc.
Ms. Beth Zis
Regulatory Affairs Director
6 Tech Drive
Andover, Massachusetts 01810

Re: K152407
Trade/Device Name: Infinity Delta, Infinity Delta XL, Infinity Kappa
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: Class II
Product Code: MHX
Dated: August 20, 2015
Received: August 25, 2015

Dear Ms. Beth Zis,

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style and is positioned above the typed name.

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

Enclosure

Indications for Use

510(k) Number (if known)

K152407

Device Name

Infinity Delta, Infinity Delta XL, Infinity Kappa

Indications for Use (Describe)

The Infinity Delta Series Monitor (Delta/Delta XL/Kappa) 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
- etCO2
- Respiratory mechanics
- Anesthetic agents
- Neuromuscular transmission

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 Infinity Delta Series (Delta/Delta XL/Kappa) monitors 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 for the neonatal population, is to only be used when the patient is not under gas anesthesia.

For combination with Scio gas module:

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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary of Safety and Effectiveness

Submitter / Manufacturer Name and Address:

Draeger Medical System, Inc.
6 Tech Drive,
Andover, MA 01810
U.S.A.

Establishment Registration Number : 3005783425

Contact Person:

Beth Zis
Director Regulatory Affairs
Email: beth.zis@draeger.com
Tel. No.: +1 (978) 379 8265
Fax: +1 (978) 379-8335

Date submission was prepared: 08/20/2015

Device Name / Common Names / Classification Names:

Trade Name: Infinity Delta; Infinity Delta XL; Infinity Kappa

Common Name: monitor, physiological, patient(with arrhythmia detection or alarms)

Classification Name: monitor, physiological, patient(with arrhythmia detection or alarms)

Product Code: MHX

Class: II

Regulation Number: 870.1025

List of Product codes and classification regulations for clarification of multiple indications:

Special 510(k)
Of Infinity Delta and Kappa
Series Monitor



K152407
Page 2 of 5

Common Name	Product code	Class	Reg. Number 21 CFR
Proposed device			
monitor, physiological, patient(with arrhythmia detection or alarms)	MHX	II	870.1025
Subsequent Product Codes			
detector and alarm, arrhythmia	DSI	II	870.1025
monitor, st segment with alarm	MLD	II	870.1025
monitor, cardiac (incl. cardio tachometer & rate alarm)	DRT	II	870.2300
adaptor, lead switching, electrocardiograph	DRW	II	870.2350
electrocardiograph (partly)	DPS	II	870.2340
monitor, breathing frequency	BZQ	II	868.2375
monitor, apnea, facility use	FLS	II	868.2377
gas-machine, anesthesia	BSZ	II	868.5160
stimulator, Muscle, Powered (NMT)	IPF	II	890.5850
system, measurement, blood-pressure, non-invasive (NBP)	DXN	II	870.1130
computer, Blood-Pressure (iBP)	DSK	II	870.1110
amplifier And Signal Conditioner, Transducer Signal (iBP)	DRQ	II	870.2060
oximeter	DQA	II	870.2700
analyzer, gas, carbon-dioxide, gaseous-phase	CCK	II	868.1400
analyzer, gas, enflurane, gaseous-phase (anesthetic concentration)	CBQ	II	868.1500
analyzer, gas, halothane, gaseous-phase (anesthetic conc.)	CBS	II	868.1620
analyzer, gas, nitrous-oxide, gaseous phase (anesthetic conc.)	CBR	II	868.1700
analyzer, gas, oxygen, gaseous-phase	CCL	II	868.1720
thermometer, Electronic, Clinical	FLL	II	880.2910
monitor, carbon-dioxide, cutaneous (tpO2/CO2)	LKD	II	868.2480
monitor, oxygen, cutaneous, for infant not under gas anesthesia (tpO2/CO2)	KLK	II	868.2500
monitor, oxygen, cutaneous, for uses other than for infant not under gas anesthesia (tpO2/CO2)	LPP	II	868.2500
analyzer, spectrum, electroencephalogram signal	GWS	I	882.1420
system, network and communication, physiological monitors	MSX	II	870.2300
spirometer, monitoring (w/wo alarm)	BZK	II	868.1850
transmitters and receivers, physiological signal,	DRG	II	870.2910

Common Name	Product code	Class	Reg. Number 21 CFR
radiofrequency			
computer, diagnostic, pre-programmed, single-function	DXG	II	870.1435
stimulator, nerve, peripheral, electric	KOI	II	870.2775

Identification of Legally Marketed Devices to which the equivalence is claimed:

510(k) number	Trade name	
K070566	INFINITY DELTA/DELTA XL/ KAPPA/ GAMMA X XL/ VISTA XL/ SC7000/SC8000/ SC9000XL	Predicate Device

Device Description:

Infinity Delta and Kappa Series Monitors (Delta/Delta XL/ Kappa) are multi-parameter patient monitors intended for use at the patient bedside for the collection of physiological data. The intent of this 510(k) is to describe the proposed software and hardware modifications to the Infinity Delta and Kappa Series Monitors version VF9.1 which includes the integration of an alternative etCO₂ solution for the Delta and Delta XL patient monitors as well as software enhancements for the Delta, Delta XL and Kappa patient monitors.

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 recorder, either directly or via the Infinity Network.

Indications for Use:

The Infinity Delta Series Monitor (Delta/Delta XL/Kappa) 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
- etCO2
- Respiratory mechanics
- Anesthetic agents
- Neuromuscular transmission

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 Infinity Delta Series (Delta/Delta XL/Kappa) monitors 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 for the neonatal population, is to only be used when the patient is not under gas anesthesia.

For combination with Scio gas module:

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.

Summary of Technological Characteristics:

The major change to the Infinity Delta and Kappa Series Monitors (Delta/Delta XL/ Kappa) is the integration of the Draeger Infinity Mcable Mainstream CO2 sensor (K100941) which measures end-tidal CO2, inspired CO2 and Respiration Rate from the patient and displays it on the Infinity Delta and Delta XL patient monitors. Other software modifications were made for the enhancement of usability in field to all three monitors.

Summary of non-clinical data:

The substantial equivalence was assessed via internal verification tests, validation evaluations and external tests to FDA recognized consensus standards. Performance data related to each proposed modification has been tested and evaluated. High level summary reports are included in this special 510k demonstrate the changes to the monitors are substantially equivalent to the predicate devices.

Substantial Equivalence:

The modified Infinity Delta and Kappa Series Monitors have been tested in accordance with applicable standards and internal design control procedures and were determined to be as safe and effective as the predicate device for its intended use.

Biocompatibility

Not applicable for this change to Infinity Delta and Kappa Series Monitors. The integrated Infinity Mcable – Mainstream CO2 Sensor was already cleared under K100941 with the reusable/ disposable cuvettes.

Shelf Life

Not applicable. No components have been added that require shelf life data.

Sterilization

Not applicable for this change to Infinity Delta and Kappa Series Monitors. The integrated Infinity Mcable – Mainstream CO2 Sensor was already cleared under K100941 with the reusable/ disposable cuvettes, and monitors are provided non-sterile.

Conclusion:

The intended use and general construction of the patient monitors have not been changed. The comparison with predicate device and testing of the described VF9.1 modifications demonstrate the Infinity Delta and Kappa Series Monitors are as safe and effective as the previous cleared in K070566.