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510(k) SUMMARY of SAFETY AND EFFECTIVENESS

MAR 2 2 2012

Submitter : Draeger Medical Systems, Inc.
6 Tech Drive
Andover, MA 01810
Tel : (978) 379-8265
Fax: (978) 379-8335
Contact : Beth A. Zis, RAC
Director of Regulatory Affairs

Date Prepared : February 29, 2012

Device Names/Common Names/Classification Names:

Trade Name: Infinity® Acute Care System™ (IACS) Monitoring Solution
Common Name : Physiological Patient Monitor
Classification Name : Monitor, Physiological, Patient (with arrhythmia detection or Alarms)
Product Code : MHX

Trade Name : Infinity MCable - Masimo Rainbow SET ®
Common Name : Pulse CO-Oximeter
Classification Name : Oximeter
Product Code : DQA

Class : II

Regulation Numbers : 21 CFR 870.1025, 21 CFR 870.2700

Identification of Predicate or Legally Marketed Devices :

The modified devices are substanitally equivalent to the previously cleared :

Infinity® Acute Care System™ (IACS) Monitoring Solution and the
Infinity® MCable - Masimo SET® MCable (smart pod) manufactured by Draeger Medical Systems, Inc. cleared under 510(k) #K093788 and #K061329.

Masimo Radical 7 Pulse CO-Oximeter and Accessories manufactured by Masimo Corporation cleared under 510(k) #K110028.

Device Description :

The Infinity Acute Care System (IACS) Monitoring Solution is a multi-parameter physiological patient monitoring system that acquires and displays patient data at the bedside. The IACS Monitoring Solution is a combination of two devices ; Infinity M540 patient monitor with Infinity M500 docking station integrated with the Infinity C500 Medical Cockpit or optional C700 (larger screen size) Medical Cockpit and respective software.

The physiological patient data acquired from the interconnected components is displayed on the Infinity M540 patient, and is transmitted via network to the patient bedside Infinity Medical

Dräger
K113798

Cockpit. The Infinity M540 patient monitor is a light weight hand held portable patient monitor that displays real-time vital signs, provides continuous trending and produces visual and audible alarms if any of the physiological parameters monitored vary beyond present limits and transmits the data over the network. The Infinity M540 patient monitor can be used as a stand alone medical device without any integration with the Infinity Medical Cockpits similar to other Draeger Medical Pick-And-Go patient monitors.

The Infinity Mcable Masimo Rainbow SET is a new Pulse CO-Oximeter model for use with the IACS Infinity M540 Patient Monitor to provide continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), perfusion index (PI), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin (SpMet), total hemoglobin (SpHb), pleth variability index (PVI) and total oxygen content (SpOC).

Intended Use: Infinity® Acute Care System™ (IACS) Monitoring Solution:
The IACS is intended for multi-parameter, physiologic patient monitoring of adult, pediatric and neonatal patients in environments where patient care is provided by trained healthcare profess sionals. The IACS obtains the physiologic, multi-parameter data from the connection to the M540 monitor and optional medical devices and displays. The transfer of this data is accomplished by the Infinity network.

Intended Use: Infinity M540 Patient Monitor:
The Infinity M540 is intended for the monitoring of multi-parameter, physiological patient information obtained from connected hardware in environments where patient care is provided by trained healthcare professional. The M540 is intended to monitor one patient at a time.

Indications for Use: The M540 monitors the following parameters:
- Heart rate
- Arrhythmia (adult and pediatric only)
- 12-lead analysis
- ST segment analysis including TruST® (adult and pediatric only)
- 12-lead ST segment analysis (adult and pediatric only)
- Apnea
- Respiration rate
- Invasive pressure
- Non-invasive pressure
- Temperature
- Cardiac output (only available when the M540 is docked in an IACS configuration)
- Arterial oxygen saturation (SpO2)
- Pulse rate
- Perfusion Index (PI)
- Total hemoglobin (SpHb) - adult and pediatric only
- Total oxygen content (SpCO) - adult and pediatric only
- Methemoglobin saturation (SpMet)
- Pleth variability index (PVI)
- Mainstream etCO2

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K113798

MRI Compatibility Statement:

The IACS, Infinity M540 and any connected optional hardware are not intended for use in hyperbaric chambers and environments containing MRI equipment.

Substantial Equivalence:

The modified Infinity Acute Care System (IACS) Monitoring Solution VG2 software and Infinity MCable – Masimo Rainbow SET have been tested in accordance with applicable standards and internal design con trol procedures and were determined to be as safe and effective for its intended use as the predicate devices.

Biocompatibility:

Not applicable – The Infinity Acute Care System Monitoring Solution and its components are not intended to contact the patient. If patient contact is made, it is transient with intact skin.

Sterilization:

Not applicable – The Infinity Acute Care System (IACS) Monitoring Solution and its components are not supplied sterile.

Standards:

Electrical Safety: IEC60601-1: Medical electrical equipment general requirements for safety and essential performance; and applicable collateral standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

MAR 2 2 2012

Draeger Medical Systems, Inc.
c/o Ms. Beth A. Zis
Director of Regulatory Affairs
6 Tech Drive
Andover, MA 01810

Re: K113798
Trade/Device Name: Infinity acute care system, Infinity Mcable-Masimo rainbow SET
Regulation Number: 21 CFR 878.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II
Product Code: MHX, MSX, DRT, DQA, BZQ, FLL, DSK, FLS, MLD, DXN, CCK
Dated: March 7, 2012
Received: March 8, 2012

Dear Ms. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

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

Enclosure

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K113798

Indications for Use

510(k) Number (if known): K113798

Device Name: **Infinity® Acute Care System™ (IACS) Monitoring Solution**

Intended Use: Infinity® Acute Care System™ (IACS) Monitoring Solution:

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113798