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.
Mr. Thomas Ostrowski
Regulatory Affairs Specialist
6 Tech Drive
Andover, Massachusetts 01810

Re: K151860
Trade/Device Name: Infinity CentralStation Wide
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: Class II
Product Code: MHX
Dated: July 6, 2015
Received: July 8, 2015

Dear Mr. Thomas Ostrowski,

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.

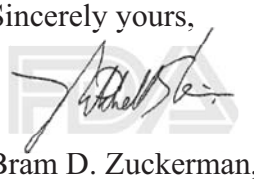
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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

Enclosure

K151860

510(k) Number (if known): _____

Device Name: Infinity CentralStation Wide

Indications for Use:

The Infinity CentralStation (ICS) is intended for use by trained healthcare professionals for the purpose of centralized monitoring of adult, pediatric and neonatal patient data within the hospital or clinical environment. Centralized monitoring involves the display and management of data from networked patient monitors including the annunciation of visual and audible physiologic parameter alarms at a central monitoring workstation. Infinity CentralStation with Rest ECG is intended for the production and interpretation of diagnostic electrocardiograms for adult and pediatric patients when connected to a monitor with diagnostic 12-Lead ECG monitoring enabled.

Contraindications:

There are no known contraindications.

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)

K151860

510(k) SUMMARY

I. Submitter:

Draeger Medical Systems, Inc.
6 Tech Drive
Andover, MA 01810-2434

Tel: (978) 379-8002
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Contact Person: Thomas Ostrowski
Regulatory Affairs Specialist
E-mail: tom.ostrowski@draeger.com
Date Prepared: July 6, 2015

II. Device

Names / Common Names / Classification Names:

Name of Device:	Infinity CentralStation Wide
Common Name:	Central Monitoring Station
Classification Name:	Patient Physiological Monitor (with Arrhythmia detection or alarms)
Product Code:	74 MHX
Regulatory Class:	II
Regulation Number:	21 CFR §870.1025

III. Predicate Device:

Infinity CentralStation VG1 MS26800 and components / accessories were cleared under K130711 on April 11, 2013.

IV. Device Description:

Device Identification:

Infinity CentralStation (ICS) Wide (MS26800) consists of medical grade software installed and configured on an information technology platform available in one model with configurable software options and optional touch and/or non-touch widescreen displays.

Device Description:

The Infinity CentralStation (ICS) Wide with proposed VG2 modifications is a Central monitoring station capable of real-time display and storage of multi-parameter physiological patient data and alarm annunciation for patient monitors including but not limited to ambulatory and non-ambulatory wireless telemetry monitoring.

The key device hardware components for ICS Wide consist of the following:

- Commercial grade computer with a central processing unit (CPU) (MS25707)
- 22" Widescreen (MS26806) and/or optional Touch-screen (MS26807) displays
- Keyboard
- Mouse
- External speakers
- Optional hardware components include:
    - Uninterruptible Power Supply (UPS) (MS23562)
    - Laser printer
    - CPU Mount (MS18840)
    - R50-N strip recorder (5740068)

Software for ICS Wide VG2 consists of a base system package which includes the following functionality:

- Configurable Main Screen
- Support for Wireless Telemetry monitoring
- Central Patient Admission (Wireless Telemetry)
- Remote bed view
- Alarm annunciation
- Continuous 2 hour storage of up to 4 waveforms
- 2-hour storage of up to 1000 events per patient
- 72 hour trend storage (graphical and tabular)
- Support of 2-channel strip recordings (requires R50-N recorder)
- Support of printed reports (requires network laser printer)
- Support for up to 64 patient monitors (up to 32 main screen plus 32 surveillance)
- Infinity® Network connectivity

Optional features and functionality available separately for use with ICS Wide VG2 include:

- Second screen
- RAID 1 Database hard drive

- RAID 1 Operating System hard drive
- Expanded 28, 48, 72, 96 or 120 hour Full/Event Disclosure and Trends
- Wireless Telemetry options (ST Analysis, Full arrhythmia, TruST derived 12-lead, SpO2)
- Diagnostic 12-L REST ECG Report (requires compatible 12-lead Draeger bedside)
- Web-based review of stored data (requires Infinity® Symphony)
- Import of patient demographics from HIS (requires Infinity® Gateway)
- Export of Full/Event disclosure data to Innovian (requires Innovian Critical or Perioperative Care)
- VentCentral® application for displaying ventilator data received via patient monitors
- Uninterruptable Power Supply (UPS)

Environment of Use:

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. ICS Wide is not intended to be used in the patient environment.

V. Indications for Use / Intended Use:

The Infinity CentralStation (ICS) is intended for use by trained healthcare professionals for the purpose of centralized monitoring of adult, pediatric and neonatal patient data within the hospital or clinical environment. Centralized monitoring involves the display and management of data from networked patient monitors including the annunciation of visual and audible physiologic parameter alarms at a central monitoring workstation. Infinity CentralStation with Rest ECG is intended for the production and interpretation of diagnostic electrocardiograms for adult and pediatric patients when connected to a monitor with diagnostic 12-Lead ECG monitoring enabled.

Contraindications:

There are no known contraindications for ICS Wide.

VI. Comparison of Technological Characteristics with the Predicate Device:

The primary modification of the Infinity CentralStation Wide VG2 release is a change in the operating system of the device to support enhanced cybersecurity protection. Additional proposed modifications do not significantly alter technological characteristics and do not impact the safety or effectiveness of the device.

VII. Performance Data

Verification Testing:

ICS Wide VG2 has been verified through performance / functional testing to confirm that the proposed modifications have been effectively implemented and design outputs satisfy design inputs. The results of verification have been documented and included in the design history file of the device. Verification testing of the proposed modifications supports the claim of substantial equivalence with the predicate device and do not raise any new issues of safety and effectiveness.

Validation Testing:

Validation testing was performed in a hospital environment for the purpose of determining user acceptance, satisfaction and observations. User acceptance criteria was established and assessed based on user feedback obtained in the form of surveys with pre-determined assessment questions and user ratings for the various functionality tested. Results of Validation testing have been documented and support the claim of substantial equivalence and do not raise any new issues of safety and effectiveness.

Biocompatibility:

Not applicable – Infinity CentralStation Wide VG2 is not intended for use in the patient vicinity and does not come into contact with the patient.

Sterilization:

Not applicable – Infinity CentralStation Wide VG2 is not intended for use in the patient vicinity and does not require sterilization for use.

Standards / Compliance testing:

Infinity CentralStation Wide VG2 has been tested and complies with the following standards in support of EMC and electrical safety requirements:

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IEC60601-1-2	Edition 3: 2007-03	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
IEC60950-1	Edition 2: 2005 + Am 1:2009 + Am 2:2013	Information technology equipment – Safety – Part 1: General requirements

VIII. Conclusions

Substantial Equivalence:

The Infinity CentralStation Wide VG2 modifications have been tested in accordance with applicable standards and internal design control procedures. The results of verification and validation testing have demonstrated that the Infinity CentralStation Wide VG2 when compared to the predicate device Infinity CentralStation VG1 is as safe and effective as the predicate for its intended use.