February 1, 2022

Draeger Medical Systems, Inc.
Deborah Herrington
Senior Manager, Regulatory Affairs
6 Tech Dr.
Andover, Massachusetts 01810

Re: K203088
Trade/Device Name: Infinity Acute Care System (IACS) Monitoring System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MHX, MSX, DRT, DQA, DSK, MLD, DXN, DSF, DSA, DSB, DQE, DXG, BZQ, FLS, CCK, FLL, DSI, DPS
Dated: January 26, 2022
Received: January 27, 2022

Dear Deborah Herrington:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Jennifer Shih Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203088

Device Name
Infinity® Acute Care System™ (IACS)

Indications for Use *(Describe)*

Intended Use

Infinity® Acute Care System™ (IACS)

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 health care professionals.

The IACS obtains the physiologic, multi-parameter data from the connection to the M540 monitor and optional medical devices and displays. The real-time physiologic and multi-parameter data collected from the IACS is made available on the Infinity network.

The IACS and optional connected hardware are not intended for use in the following hospital environments:
– Hyperbaric chambers
– Environments containing MRI equipment

Indications for use

The IACS, in connection with the M540 Patient Monitor, monitors the following parameters:
– Heart rate
– Arrhythmia (adult and pediatric patients only)
– 12-lead Rest ECG analysis (adult and pediatric patients only)
– ST segment analysis including TruST (adult and pediatric patients only)
– Apnea
– Impedance respiratory rate – RRi
– Invasive blood pressure – IBP
– Non-invasive blood pressure – NIBP
– Temperature
– Cardiac output (adult and pediatric patients only)
– Carbon dioxide – etCO2, inCO2, RRc
– Arterial oxygen saturation – SpO2
– Pulse rate
– Perfusion index – PI
– Total hemoglobin – SpHb, (adult and pediatric patients only)
– Total oxygen content – SpOC, (adult and pediatric patients only)
– Carboxyhemoglobin saturation – SpCO (adult and pediatric patients only)
– Methemoglobin saturation – SpMet
– Pleth variability index – PVI

The IACS can connect to third-party devices to display physiologic, multi-parameter data and stored trends. It can also send information across the Infinity network.

Intended Use

The Infinity Medical Cockpits, consisting of the C500, and the C700 are monitoring and control displays for the Infinity Acute Care System (IACS).

Medical Cockpits are intended to be used to monitor waveforms, parameter information, and alarms as well as to control

settings.

The Infinity Series Medical Cockpits are intended to be used in environments where patient care is provided by trained healthcare professionals.

Indications for Use
As the Infinity Medical Cockpits are used in conjunction with the Infinity Acute Care System and the M540 Patient Monitors they do not have their own indication for use.

Intended Use
The Infinity M540 (M540) is intended for the monitoring of multi-parameter, physiologic patient monitoring of adult, pediatric, and neonatal patient information in environments where patient care is provided by trained health care professionals.

The M540 obtains physiological data from connection to optional accessory devices. The real-time physiologic and multi-parameter data collected from the M540 is made available on the Infinity network.
The M540 is intended to monitor one patient at a time.

The M540 and any connected hardware are not intended for use in the following hospital environments:
– Hyperbaric chambers
– Environments containing MRI equipment

Indications for use
The M540 monitors the following parameters:
– Heart rate
– Arrhythmia (adult and pediatric patients only)
– 12-lead Rest ECG analysis (adult and pediatric patients only)
– ST segment analysis including TruST (adult and pediatric patients only)
– Apnea
– Impedance respiratory rate – RRi
– Invasive blood pressure – IBP
– Non-invasive blood pressure – NIBP
– Temperature
– Cardiac output – only available when the M540 is docked in an IACS configuration (adult and pediatric patients only)
– Carbon dioxide – etCO2, inCO2, RRc
– Arterial oxygen saturation – SpO2
– Pulse rate
– Perfusion index – PI
– Total hemoglobin – SpHb, (adult and pediatric patients only)
– Total oxygen content – SpOC, (adult and pediatric patients only)
– Carboxyhemoglobin saturation – SpCO (adult and pediatric patients only)
– Methemoglobin saturation – SpMet
– Pleth variability index – PVI

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.

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Draeger Medical Systems, Inc.
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510(k) SUMMARY

1. Submitter:

Draeger Medical Systems, Inc.
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Date Prepared: 01-Dec-21

2. Device Names / Common Names / Classification Names

Device Trade Name: Infinity® Acute Care System™ Monitoring Solution
Classification Name: Monitor, Physiological, Patient (with Arrhythmia detection or alarms)
Common Name: Multi-Parameter Patient Monitor
Classifications: See **Table 5.1** below

Table 5.1: Device Classification / Pro Code / Common Name

Classification	Pro Code	Common Name
Primary Product Classification		
§870.1025	MHX	Monitor, physiological, Patient (with Arrhythmia Detection or Alarms)
Subsequent Product Codes		
§870.2300	MSX	System, Network and Communication, Physiological Monitors
§870.2300	DRT	Monitor, Cardiac (incl. Cardio-tachometer & Rate Alarm)
§870.2700	DQA	Oximeter
§870.1110	DSK	Computer, Blood Pressure
§870.1025	MLD	Monitor, ST Segment with Alarm
§870.1130	DXN	System, Measurement, Blood-Pressure, Non-Invasive

Table 5.1: Device Classification / Pro Code / Common Name		
Classification	**Pro Code**	**Common Name**
§870.2810	DSF	Recorder, Paper Chart
§870.2900	DSA	Cable, Transducer and Electrode, Patient
§820.2770	DSB	Plethysmograph, Impedance
§870.1230	DQE	Catheter, Oximeter, Fiber-Optic
§870.1435	DXG	Computer, Diagnostic, Pre-Programmed, Single-Function
§868.2375	BZQ	Monitor, Breathing Frequency
§868.2377	FLS	Monitor, Apnea, Facility Use
§868.1400	CCK	Analyzer Gas, Carbon-Dioxide, Gaseous-Phase
§880.2910	FLL	Thermometer, electronic, clinical
§870.1025	DSI	detector and alarm, arrhythmia
§870.2340	DPS	Electrocardiograph

3. Predicate Device:

Primary: K201764 - Infinity® Acute Care System™ Monitoring Solution Version

Secondary: K113798 - Infinity® Acute Care System™ Monitoring Solution Version VG2.0

The predicate devices have not been the subject of a design-related recall.

4. 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 is a combination of the following devices: Infinity M540 Patient Monitor (Model #MS20401) with the Infinity M500 Docking Station (Model #MS20407) integrated with the Infinity Medical Cockpit (Model #MK31501 – 17" screen or Model MK31701 – 21" screen) and respective software, powered by the Infinity P2500 power supply (Model #MS22277).

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

Medical Cockpit. The Infinity M540 Patient Monitor is a lightweight 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 preset limits and transmits the data over the network. The Infinity M540 Patient Monitor can be used as a stand-alone medical device without integration with the Infinity Medical Cockpits.

Associated accessories may include:

- Infinity MCable – Masimo SET – Model #MS20667
- Infinity MCable – Masimo SET Rainbow – Model #MS27900 / MS27003
- Infinity MCable – Nellcor OxiMax – Model #MS20668
- Infinity MPod – Quad Hemo – Model #MS20725
- Infinity MCable – Dual Hemo – Model #MS20783
- Infinity MCable – Mainstream CO2 – Model #6871950
- Infinity MCable – Analog/Sync – Model #MS20662
- Infinity MCable – Nurse Call – Model #8417370
- PS120 Desktop Power Supply – Model #2606270
- Y-Adapter (for PS120) – Model #MS29702

The IACS, Monitoring Solution is a software driven device that is supplied and used non-sterile in a hospital environment by trained personnel. The IACS, Monitoring Solution is capital equipment.

5. Intended Use/Indications for Use:

Infinity® Acute Care System™ (IACS)
Intended Use
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 health care professionals.

The IACS obtains the physiologic, multi-parameter data from the connection to the M540 monitor and optional medical devices and displays. The real-time physiologic and multi-parameter data collected from the IACS is made available on the Infinity network.

The IACS and optional connected hardware are not intended for use in the following hospital environments:

- Hyperbaric chambers
- Environments containing MRI equipment

Indications for Use
The IACS, in connection with the M540 Patient Monitor, monitors the following parameters:

– Heart rate
– Arrhythmia (adult and pediatric patients only)
– 12-lead Rest ECG analysis (adult and pediatric patients only)
– ST segment analysis including TruST (adult and pediatric patients only)
– Apnea
– Impedance respiratory rate – RRi
– Invasive blood pressure – IBP
– Non-invasive blood pressure – NIBP
– Temperature
– Cardiac output (adult and pediatric patients only)
– Carbon dioxide – etCO2, inCO2, RRc
– Arterial oxygen saturation – SpO2
– Pulse rate
– Perfusion index – PI
– Total hemoglobin – SpHb, (adult and pediatric patients only)
– Total oxygen content – SpOC, (adult and pediatric patients only)
– Carboxyhemoglobin saturation – SpCO (adult and pediatric patients only)
– Methemoglobin saturation – SpMet
– Pleth variability index – PVI

The IACS can connect to third-party devices to display physiologic, multi-parameter data and stored trends. It can also send information across the Infinity network.

Infinity Medical Cockpits
Intended Use
The Infinity Medical Cockpits, consisting of the C500, and the C700 are monitoring and control displays for the Infinity Acute Care System (IACS).

Medical Cockpits are intended to be used to monitor waveforms, parameter information, and alarms as well as to control settings.

The Infinity Series Medical Cockpits are intended to be used in environments where patient care is provided by trained healthcare professionals.

Indications for Use
As the Infinity Medical Cockpits are used in conjunction with the Infinity Acute Care System and the M540 Patient Monitors they do not have their own indication for use.

Infinity M540 Patient Monitor
Intended Use
The Infinity M540 (M540) is intended for the monitoring of multi-parameter, physiologic patient monitoring of adult, pediatric, and neonatal patient information in environments where patient care is provided by trained health care professionals.

The M540 obtains physiological data from connection to optional accessory devices. The real-time

physiologic and multi-parameter data collected from the M540 is made available on the Infinity network.
The M540 is intended to monitor one patient at a time.

The M540 and any connected hardware are not intended for use in the following hospital environments:
– Hyperbaric chambers
– Environments containing MRI equipment

Indications for Use
The M540 monitors the following parameters:
– Heart rate
– Arrhythmia (adult and pediatric patients only)
– 12-lead Rest ECG analysis (adult and pediatric patients only)
– ST segment analysis including TruST (adult and pediatric patients only)
– Apnea
– Impedance respiratory rate – RRi
– Invasive blood pressure – IBP
– Non-invasive blood pressure – NIBP
– Temperature
– Cardiac output – only available when the M540 is docked in an IACS configuration (adult and pediatric patients only)
– Carbon dioxide – etCO2, inCO2, RRc
– Arterial oxygen saturation – SpO2
– Pulse rate
– Perfusion index – PI
– Total hemoglobin – SpHb, (adult and pediatric patients only)
– Total oxygen content – SpOC, (adult and pediatric patients only)
– Carboxyhemoglobin saturation – SpCO (adult and pediatric patients only)
– Methemoglobin saturation – SpMet
– Pleth variability index – PVI

6. Comparison of technological characteristics with the predicate device:

Both the subject and predicate devices use the same basic fundamental scientific technology and are comprised of the same components which include the:

- Infinity C500 or C700 Medical Cockpit,
- Infinity Communications Hub (power supply),
- Infinity M500 Docking Station,
- Infinity M540 Patient Monitor, and
- various accessories.

The subject and predicate devices have the same technological characteristics pertaining to:

- Intended use:
  - Patient categories
  - Intended hospital environments
  - Physiologic patient information obtained from connected hardware
  - Device connection to an R50N recorder, either directly or via the Infinity Network.
- Indications for use:
  - Measured parameters:
    - Heart Rate, Arrhythmia,
    - ST Segment Analysis,
    - 12-Lead ST Segment Analysis,
    - Apnea,
    - Respiration Rate,
    - Invasive Blood Pressure,
    - Non-Invasive Blood Pressure,
    - Temperature,
    - Cardiac Output,
    - Arterial Oxygen Saturation,
    - Pulse Rate,
    - Perfusion Index,
    - Mainstream End Tidal CO2,
    - Total Hemoglobin,
    - Total Oxygen Content,
    - Carboxyhemoglobin Saturation,
    - Methemoglobin saturation,
    - Pleth Varibility Index

- Physical characteristics:
  - Cockpit & M540 display, weight, dimensions, cooling, power, alarm indicator light
  - Battery indicator, AC Power LED, Navigation

- User Interface:
  - Waveform area, parameter boxes, displays of physiological parameters
  - ECG heartrate leads & measuring range
  - Respiration leads, measuring method and measuring range, detection threshold
  - Arrhythmia types
  - Invasive blood pressure measuring method and range, display, frequency
  - Non-invasive blood pressure measuring method, display
  - Temperature measuring range
  - QRS detection

The following characteristics were added to the subject device in VG4.1.1:

Software changes:

- Improvements:
  - Added header bar touch functionality, graphical volume indicator and reset tone to the Medical Cockpit
  - Configurable QRS detection threshold
  - Connectivity to certain 3rd party ventilators and anesthesia machines
  - ST algorithm improvements
  - ST algorithm modified decimation filter – M540
  - New System Settings & Patient Profile Settings - Medical Cockpit
  - Target bed automatic discharge before network transfer complete - Medical Cockpit
  - Configurable buttons & increased options - Medical Cockpit
  - Alarm for units of measure mismatch when M540 is undocked from the Medical Cockpit
  - Battery alarms recorded in alarm history - Medical Cockpit
  - Multicast configurable option - Medical Cockpit
  - Configurable clinical password – M540
  - M540 alarm volume escalation in stand-alone configuration, docked & not connected to a Central Station
  - Storage of arrhythmia events
- IEC 60601-1-8 Third edition related changes:
  - Audible alarms speaker volume increase on Cockpit & M540
  - Audio alarms set during audio pause
  - Configurable Alarms
  - Updated banner colors & alarms
  - New IEC tones
  - Transducer failure detection
  - Quiet mode on/off
  - Data storage - Alarm Volume and Store Events configured for both the Masimo & Nellcor Sensor messages
  - Configurable low battery alarm - M540
  - Alarm volume controls - M540
- Defect corrections:
  - Non-invasive blood pressure intervals adjusted to actual time and setting of 5 minutes or more
  - Real-time clock error handling - Medical Cockpit
  - Display of ECG Artifact Message w/ESU Artifacts
- Y-Adapter Cable for M540 in stand-alone configuration

The following technological differences exist between the subject and predicate devices:

Software changes:

- Defect corrections
  - Wrong data output scale for the ECG network is sent to the Infinity Network
  - Waveform template for the ECG algorithm
  - New instructions for correct ECG pacer sensing
  - Change of the etCO2 adapter during sensor warm up
  - Duplicate IP function and alarms in different network use cases
  - M540 not joining the network while roaming
  - Production of unusual amount of Infinity protocol traffic
  - Network data package handling on big loads
  - Incorrect detection of internal hardware failure
  - Synchronization between system components in specific workflows
  - Device handling of malformed Infinity network messages
  - Export protocol disconnections
  - Device resiliency for internal error reading and transmitting files in the memory of the device
- Improvements:
  - M540 Distributed Denial of Service packet storm resiliency
  - Added security for the FTP connection between components of the system
  - Closing unused ports and services on network connection

7. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility:

The Infinity® Acute Care System™ Monitoring Solution and its components are not intended to directly contact the patient during use. If patient contact is made it is transient with intact skin.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on devices equivalent to the IACS VG4.0.3 and M540 VG4.1.1 devices. The system complies with:

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-1-8
- IEC 606001-2-25
- IEC 60601-2-27
- ISO 80601-2-55

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDAs Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Major Level of Concern", since the device provides diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death. Additionally, the device provides vital signs monitoring and alarms for potentially life-threatening situations in which medical intervention is necessary.

Performance Bench Testing

Verification testing was conducted to confirm the new requirements that were added to the IACS system, Medical Cockpit or M540 Patient Monitor based on the differences between the subject and predicate devices as listed above. EC57 testing was conducted for performance of cardiac rhythm and ST segment measurement algorithms.

Human Factors/Usability Engineering Validation testing was conducted regarding the changes made to the Instructions for Use relevant to the device modifications since the IACS VG2 devices were cleared.

Animal Studies

Animal performance testing was not performed or required for the device modifications subject of this 510(k).

Clinical Studies

Clinical studies were not performed or required for the device modifications subject of this 510(k).

8. Conclusion

The predicate devices were cleared based on results which did not include clinical studies. The non-clinical data supports the substantial equivalence of the device and the hardware and software verification and validation demonstrate that the subject device, IACS VG4.2, should perform as intended in the specified use conditions.