October 17, 2023

Draeger Medical Systems, Inc.
Deborah Herrington
Senior Principal Regulatory Affairs Specialist
6 Tech Drive
Andover, Massachusetts 01810

Re: K231477
Trade/Device Name: Infinity CentralStation Wide, Infinity M300, Infinity M300+
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
Dated: September 15, 2023
Received: September 18, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Shruti N. Mistry -S

Jennifer 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K231477

Device Name
Infinity CentralStation (ICS) Wide with Infinity M300/M300+

Indications for Use *(Describe)*

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.

The Infinity M300/M300+ is intended for use with the ICS to monitor ECG and pulse oximetry on ambulatory and non-ambulatory adult and pediatric patients using wireless communication over the Infinity patient monitoring network.

The Infinity M300/M300+ with TruST is intended for 12-Lead ECG monitoring with a reduced set of electrodes. Reconstructed leads are intended for real-time assessment of ST segment changes.

Contraindications:
The Infinity M300/M300+ is not compatible for use in an MRI magnetic field.

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.

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I. Submitter:

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

Tel: (978) 935-6561

Contact Person: Deborah Herrington
Senior Principal RA Specialist

E-mail: mailto:deborah.herrington@draeger.com
Date Prepared: May 22, 2023

II. Device

Names / Common Names / Classification Names:

Common Name:	Multi-parameter patient monitor
Trade Name:	Infinity CentralStation and Infinity M300/M300+
Classification Name:	Monitor, Physiological, Patient (with Arrhythmia detection or alarms)
Product Code:	MHX
Regulatory Class:	II
Regulation Number:	21 CFR §870.1025

III. Predicate Device:

Infinity CentralStation (VG2 MS26800) was cleared under K151860 on September 2, 2015 and Infinity M300 was cleared under K200859 on August 28, 2020.

Mindray BeneVision Central Monitoring System with TM80 was cleared under K193391 on May 21, 2020.

IV. Device Description:

Infinity CentralStation device description
The Infinity® CentralStation (ICS) Wide (or widescreen) is a Central monitoring station capable of real-time display and storage of multi-parameter physiological patient data and alarm annunciation for networked devices including but not limited to ambulatory and non-ambulatory wireless telemetry monitoring.

Infinity M300/M300+ device description
The Infinity M300/M300+ is a wireless telemetry, patient-worn device with rechargeable lithium-ion battery which monitors ECG and SpO2 physiological data and features a color display, local alarm alerts and keypad interface. ECG functions include heart rate, arrhythmia detection and ST segment analysis and SpO2 functions include pulse plethysmogram and pulse rate. Infinity M300/M300+ with TruST allows for 12-lead ECG monitoring with a reduced set of electrodes by deriving values for missing leads.

Infinity M300 components
The standard Infinity M300 includes the following:

- Infinity M300 patient-worn transceiver
- Infinity M300 Bedside Charger
- Infinity M300 CentralCharger
- Infinity M300 programming kit

Infinity M300+ components
The standard Infinity M300+ includes the following:

- Infinity M300+ patient-worn transceiver
- Infinity M300+ swappable battery (2)
- Infinity M300+ remote battery charging station (charging capacity of up to 10 swappable batteries)
- Infinity M300+ programming kit
- Infinity M300+ battery retainer (4)

Infinity M300/M300+ environment of use
The Infinity CentralStation with Infinity M300/M300+ 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.

Infinity M300/M300+ communications
Infinity M300/M300+ connects to the Infinity network via 802.11 wireless communication with hospital access points (AP). From the AP, data is routed over the Infinity network via wired Ethernet for real-time display and annunciation at the Infinity CentralStation Wide (Widescreen), the Dräger central monitoring workstation. The Infinity CentralStation (ICS) Wide allows for simultaneous central monitoring of up to thirty-two (32) Infinity M300/M300+ devices to support wireless telemetry monitoring.

Infinity M300/M300+ user interfaces and functions
The Infinity M300/M300+ communicates bilaterally with the Infinity CentralStation (ICS) central nursing workstation which serves as the primary display, user interface and alarm annunciator for acquired M300/M300+ physiological patient data. The Infinity M300/M300+ local keypad and display serves as a secondary user interface for clinicians to access local features and functions.

To facilitate patient mobility clinicians can place the Infinity M300/M300+ in a disposable or re-usable shower pouch worn by the patient. When a patient is sedentary (in bed or sitting) the clinician can place the Infinity M300 in the Bedside Charger to provide a slow charge for the device. When the Infinity M300 is not in clinical use, it may be stored and recharged at an accelerated rate in the CentralCharger. When an Infinity M300+ swappable battery is exchanged, it can be charged in the M300+ battery charger to be made ready for later use.

V. Indications for Use / Intended Use:

Infinity CentralStation
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.

Infinity M300/M300+
The Infinity M300/M300+ is intended for use with the ICS to monitor ECG and pulse oximetry on ambulatory and non-ambulatory adult and pediatric patients using wireless communication over the Infinity patient monitoring network.

The Infinity M300/M300+ with TruST is intended for 12-Lead ECG monitoring with a reduced set of electrodes. Reconstructed leads are intended for real-time assessment of ST segment changes.

Contraindications:
The Infinity M300/M300+ is not compatible for use in an MRI magnetic field.

VI. Comparison of Technological Characteristics with the Predicate Device:
The intended use, performance and technological characteristics are substantially equivalent to the referenced predicate devices. In comparison to the predicate devices, the modified ICS Wide VG4.0 with M300/M300+ VG3.0 has the same intended use, indications for use, packaging materials and shelf life. Proposed modifications do not change the fundamental scientific technology of the cleared devices. The ICS Wide VG4.0 with M300/M300+ VG3.0 differs from the predicate device in regards to proposed significant change modifications and non-significant historical modifications listed below:

Significant Change Modifications introduced in this submission:

Infinity CentralStation VG4 with M300/M300+ VG3

- TLSv1.2 secure communications for ICS-M300(+) data-in-transit (Authentication/Authorization, Encryption and Integrity)
- Configurable service and engineering passwords

Infinity M300/M300+ VG3

- Denial of Service protections (i.e. packet storm, input validation)
- KRACK fix with wireless module firmware update
- Update FTP to SFTP
- Added SSH for service access
- Infinity M300+ swappable battery and battery retainer

VII. Performance Data

Verification Testing:
Dräger evaluated the substantial equivalence of the devices with proposed modifications through system performance and verification testing. Dräger performed a risk assessment for the devices with proposed modifications and identified the need for risk mitigations to support cybersecurity protections. The risk control measures were designed, developed and tested in accordance with 21 CFR 820.30 design controls. The results of Verification testing confirm that the modified device continues to meet equivalent criteria demonstrating substantial equivalence to the predicate device. The devices with proposed modifications meet the criteria for substantial equivalence to the predicate devices and do not raise new issues of safety and effectiveness.

Validation Testing:
Dräger design controls in compliance with 21 CFR 820.30 (g) govern validation and risk analysis of device modifications. Dräger identified hazardous situations following recommendations in FDA guidance documents “General Principles of Software Validation” issued January 2002 and “Applying Human Factors and Usability Engineering to Medical Devices” issued February 2016. Validation tests were conducted to confirm the implementation of software design input requirements, established risk mitigations and user adoption of the proposed modifications. Validation test results support the claim of substantial equivalence to the predicate devices and do not raise new issues of safety and effectiveness.

Biocompatibility:
Dräger design controls in compliance with 21 CFR 820.30 govern the assessment of materials used in the Infinity M300/M300+. Dräger selected materials appropriate for the use-case of the device per FDA’s guidance document “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.’” Considering the intended use of the device and the transient nature of skin contact, an assessment was made for compliance to ISO 10993-1 and appropriate methods of testing were conducted on the materials. The results of testing and assessment demonstrate materials are biocompatible for their intended use and support the claim of substantial equivalence with the predicate device.

Sterilization:
ICS Wide and Infinity M300/M300+ do not require sterilization to accomplish their intended use. Reprocessing of the Infinity M300/M300+ follows the criteria for low level cleaning and disinfecting.

Standards / Compliance testing:
ICS Wide with Infinity M300/M300+ has been tested and complies with the following standards in support of Electrical Safety, EMC and particular standards requirements:

Infinity CentralStation with Infinity M300/M300+:

AAMI/ANSI ES60601-1 **FR Recognition # 19-4**	2005/(R)2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
IEC60601-1-2 **(M300/M300+) and ICS FR Recognition # 19-8**	M300/M300+ Edition 4.0 2014-02 ICS Edition 4.1 2014	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
IEC60601-1-8 **FR Recognition # 5-76**	Edition 2.1 2012-11	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-2-27 **FR Recognition # 3-126**	Edition 3.0 2011-03	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment [Including: Corrigendum 1 (2012)]
ANSI/AAMI EC57 **FR Recognition # 3-118**	Edition 2012	Testing and Reporting Performance Results of Cardiac Rhythm and ST-Segment Measurement Algorithms
ISO 80601-2-61	Edition 2017	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

VIII. Conclusion

Substantial Equivalence:

Infinity CentralStation VG4.0 with Infinity M300/M300+ VG3.0 significant change modifications are substantially equivalent to the predicate devices cleared under K151860 on September 2, 2015 and K200859 on August 28, 2020. The intended use of the Infinity CentralStation VG4.0 and Infinity M300/M300+ VG3.0 as described in the product labeling has not changed as a result of the proposed modifications. The results of verification and validation for the proposed modifications support substantial equivalence to the predicate devices.