August 1, 2024

Draeger Medical Systems, Inc.
Patrice Cocco
Regulatory Affairs Specialist
6 Tech Drive
Andover, Massachusetts 01810

Re: K240312
Trade/Device Name: Infinity CentralStation Wide
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: June 25, 2024
Received: June 26, 2024

Dear Patrice Cocco:

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,

Jennifer W. Shih -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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240312

Device Name

Infinity CentralStation Wide

Indications for Use *(Describe)*

The Infinity CentralStation (ICS) is intended for use by trained health care 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.

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.

I. Submitter:

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Andover, MA 01810-2434

Tel: (215)622-6239

Contact Person: Patrice Cocco
Regulatory Affairs Specialist

E-mail: mailto: patrice.cocco@draeger.com
Date Prepared: February 02, 2024

II. Device

Names / Common Names / Classification Names:

Common Name:	Multi-parameter patient monitor
Trade Name:	Infinity CentralStation Wide
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 VG4 cleared via K231477 on October 17, 2023

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.

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.

VI. Comparison of Technological Characteristics with the Predicate Device:

The intended use, performance and technological characteristics are substantially equivalent to the referenced predicate device. In comparison to the predicate device, the modified ICS Wide VG5.0 has the same intended use, indications for use, packaging materials and shelf life. The proposed modifications do not change the fundamental scientific technology of the cleared device. The ICS Wide VG5.0 differs from the predicate device in regard to enhanced cybersecurity modifications and defect fixes. The proposed significant change modifications are listed below:

Significant Change Modifications introduced in this submission:

Infinity CentralStation VG5

- Enhanced encryption
- Addition of Biomed and Clinical accounts
- Elimination of hard coded passwords

VII. Performance Data

Verification Testing:

Dräger evaluated the substantial equivalence of the device 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 device with proposed modifications meets the criteria for substantial equivalence to the predicate device and does 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 device and do not raise new issues of safety and effectiveness.

VIII. Biocompatibility:

Like the predicate device ICS VG4, the ICS VG5 subject device has no patient contact and therefore biocompatibility is not applicable.

IX. Reprocessing:

The reprocessing information for the ICS is listed in the "Instructions for Use Infinity CentralStation Wide Software VG5.0" document (document number 3728297). There have been no changes to the exterior components of the ICS device since the ICS VG4 was cleared in submission K231477 on October 17th, 2023. Therefore, reprocessing information provided in the IFU remains unchanged.

X. Sterility and Shelf-Life:

ICS Wide VG 5, like its predicate ICS VG4, does not require sterilization to accomplish its intended use and is supplied and used non-sterile. Therefore, sterilization data and shelf-life data are not applicable.

XI. Standards / Compliance testing:

Although, there have been no hardware changes between the ICS Wide VG4 and the ICS Wide VG5 device 60601 testing was conducted in order to comply with updated standards. Therefore, the ICS Wide VG5 has been tested and complies with the following standards and particular standards requirements:

Infinity CentralStation VG5

AAMI ES60601-1	2005/(R)2012/A2: 2021	Medical electrical equipment - Part 1: General Requirements for basic safety and essential performance
IEC 60601-1-2	ICS Edition 4.1 2014	Medical electrical equipment - Part 1-2: General Requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-8	2006/A2:2020	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 60601-1-6	2010/A2:2020	Medical electrical equipment – Part 1-6: General Requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-2-25	2011	Medical electrical equipment – Part 2: Particular Requirements for the basic safety and essential performance of electrocardiographs
IEC 60601-2-27	2011	Medical electrical equipment – Part 2: Particular Requirements for the Safety, Including Essential Performance of Electrocardiographic Monitoring Equipment
ISO 80601-2-49	2018	Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors
ISO 80601-2-61	Edition 2017	Medical electrical equipment – Part 2-61: Particular Requirements for basic safety and essential performance of pulse oximeter equipment

XII. Conclusion

Substantial Equivalence:

The significant change modifications to the Infinity CentralStation Wide VG5 have been demonstrated to be substantially equivalent to the predicate device Infinity CentralStation Wide VG4 cleared under K231477 on October 17,2023. The intended use of the Infinity CentralStation Wide VG5.0 device 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 a claim of substantial equivalence to the predicate device. The ICS Wide VG5 is substantially equivalent to the ICS VG4.