July 12, 2024

Draeger Medical Systems, Inc.
Megan Brewster
Regulatory Affairs Specialist
6 Tech Dr
Andover, Massachusetts 01810

Re: K233834
Trade/Device Name: Infinity Gateway Suite
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MSX
Dated: June 7, 2024
Received: June 10, 2024

Dear Megan Brewster:

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.

This clearance applies to the version of the device that is intended to be used with Infinity Central Station Wide version VG5.0.

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,

Kimberly N. Crowley -S

For:

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.

510(k) Number *(if known)*
K233834

Device Name
Infinity Gateway Suite

Indications for Use *(Describe)*
The Infinity Gateway software applications are intended to provide clinicians with the capability of viewing patient data remotely via the Infinity Network and for the data exchange of select clinical and administrative information between the Infinity Network and the hospital network.

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

510(k) SUMMARY

I. Submitter:

Draeger Medical Systems, Inc.
6 Tech Drive
Andover, MA 01810, U.S.A.

Contact Person: Megan Brewster
Senior Regulatory Affairs Specialist
Draeger Medical Systems, Inc.
Phone: 978-447-2410
E-mail: megan.brewster@draeger.com
July 10, 2024

II. Device

Names / Common Names / Classification Names:

Common Name:	Computers and Software, Medical
Trade Name:	Infinity® Gateway Suite
Classification Name:	System Network and Communication Physiological Monitors
Product Code:	MSX
Subsequent Code:	LNX
Regulatory Class:	II
Regulation Number:	§870.2300

III. Predicate Device

The Infinity® Gateway Suite, VF9.0, cleared via K203579 on June 7, 2022.

IV. Device Description

The Infinity Gateway Suite is a suite of software applications that are intended to provide clinicians with the capability of viewing patient data remotely via the Infinity Network and for the data exchange of select clinical and administrative information between the Infinity Network and the hospital network.

Infinity Gateway Suite is designed to support the unique needs of hospitals, and provide a complete range of options for information connectivity, including:

- Server Software Health Level seven (HL7) Interface Software Options
- American society for testing and materials (ASTM) Stat Lab interface
- Developer Tools
- Pager Interface
- Alarm history database
- Time master functions
- 12-lead electrocardiogram (ECG) export

Infinity Gateway Suite is designed as a client-server application that provides a way for users to view patient information on a hospital workstation that is connected via the hospital network. The server portion runs on a Windows server that is connected directly to the hospital Local Area Network (LAN) and to the Infinity Network. Data access methods are available as options that customers can purchase and enable independently once they install the basic Infinity Gateway application.

The Infinity Gateway Suite facilitates the exchange of important clinical information between the Infinity protocol and existing hospital and patient care systems. The Infinity Gateway Suite is designed to provide flexibility by using common healthcare protocols and data format standards for managing communications between multiple disparate systems. The user may select one or more Infinity Gateway Developer Tools and/or Interface Options to create a seamless flow of information tailored to support clinical workflow.

Infinity Gateway Developer Tools and Interface Options are licensed or unlocked by using option passwords associated with a dongle. An option password is the electronic proof of purchase for the Infinity Gateway software. During the at-hospital setup procedure, the user will be asked for an option or license password which is a unique number associated with the licensing dongle issued. The licenses are always associated with the physical dongle. The Infinity Gateway Developer Tools (such as WinAccess API) enable the development of custom applications to support customers' homegrown applications to support clinical research projects or downstream information systems. Finally, Infinity Gateway provides flexible deployment opportunities by leveraging the virtual machine technology, which facilitates software deployments.

Infinity Gateway also promotes patient safety with efficient workflows for timely decision-making by integrating patient data and providing continuity-of-care support. Furthermore, it makes comprehensive clinical data available at the point-of-care by facilitating the exchange of lab reports and admission information between the Infinity Network and other hospital systems.

The subject device is compatible with Infinity Central Station Wide version VG5.0

V. Intended Use

The Infinity Gateway software applications are intended to provide clinicians with the capability of viewing patient data remotely via the Infinity Network and for the data exchange of select clinical and administrative information between the Infinity Network and the hospital network.

The Infinity Gateway and its options are not intended to be used for primary patient monitoring or independent diagnosis.

VI. Indications for Use

The Infinity Gateway software applications are intended to provide clinicians with the capability of viewing patient data remotely via the Infinity Network and for the data exchange of select clinical and administrative information between the Infinity Network and the hospital network.

VII. Comparison of Technological Characteristics with Predicate Device

The Infinity Gateway Suite VF9.1.1 device, like its predicate, is a software only device; it has no physical form. The intended use, performance and technological characteristics of the subject device are substantially equivalent to the predicate device.

Some device modifications were made to mitigate vulnerabilities by eliminating device features as outlined in the "Significant Modifications Introduced in this Submission" section below. These modifications have no negative impact on the safety and effectiveness of the Gateway VF9.1.1 device. See the Table below for the comparison between the predicate device, Infinity Gateway VF9.0, and the subject device, Infinity Gateway VF9.1.1.

Infinity® Gateway Suite VF9.0 and VF9.1.1 Comparison			
Device Attributes	**Infinity® Gateway Suite VF9.0 Predicate Device (K203579)**	**Infinity® Gateway Suite VF9.1.1 Subject Device**	**Explanation of Changes**
Microsoft SQL Compatible	2017	2022	Migrate to latest Microsoft SQL to stay current.
Microsoft Server	2016	2022	Migrate to latest Microsoft Server to stay current.
Service-Oriented Device Connectivity (SDC) – OUS only	Includes SDC functionality	SDC functionality removed	This was a non-standard implementation of SDC.
Infinity Unicast/Multicast encryption	N/A	Includes unicast and multicast encryption	Increases cybersecurity of the Gateway device.
Passwords	No password complexity requirements	Password NIST SP800-63B compliant	Increases cybersecurity of the Gateway device.
Network allow listing	N/A	Communication between authenticated devices only	Increases cybersecurity of the Gateway device.
PatientWatch	PatientWatch support	PatientWatch functionality removed	PatientWatch used ActiveX, which is no longer supported by

Infinity® Gateway Suite VF9.0 and VF9.1.1 Comparison			
Device Attributes	**Infinity® Gateway Suite VF9.0 Predicate Device (K203579)**	**Infinity® Gateway Suite VF9.1.1 Subject Device**	**Explanation of Changes**
			Microsoft and the removal increases cybersecurity of the Gateway device.. Alarm (Visual) removed as part of PatientWatch removal.
Alarm Grade / State	PatientWatch, Pager, WinAccess API, FileAccess, and HL7 ACM allow for accessing alarm grade and state.	Pager, WinAccess API, and FileAccess allow for accessing alarm grade and state.	PatientWatch and HL7 ACM removed from VF9.1.1. Alarm Grade/State still available through Pager, WinAccess API, and FileAccess

VIII. Significant Modifications Introduced in this Submission

Cybersecurity updates and other software improvements in Infinity Gateway VF9.1.1. See the Table above for detailed information on the modifications introduced in Infinity Gateway VF9.1.1.

IX. Performance Data

Verification and Validation Testing:

The verification and validation testing conducted, confirms that the Infinity Gateway Suite VF9.1.1 product performs and functions according to its intended use with no adverse effects upon other medical devices in the Infinity system to which it is connected. Testing confirmed that identified product risk mitigations functions with the new code. All test cases were determined to meet their respective requirements.

Also, all known use-related hazards pertaining to usability have been reviewed, including those beyond the primary operating functions. As a result of this review, all risk control measures identified in the risk management process are deemed adequate to further mitigate and control the risks at an acceptable level under consideration of the intended use. The results of the Verification and Validation testing confirm that the modified software is substantially equivalent to that of the predicate device.

Biocompatibility: The proposed Infinity Gateway Suite VF9.1.1 is a software only device and has no physical form. Therefore, biocompatibility requirements are not applicable.

Sterilization: Sterilization and Shelf-Life: The proposed Infinity Gateway Suite VF9.1.1 is a software only device and has no physical form. Therefore, sterilization and shelf-life requirements are not applicable.

Standards/Compliance Testing:

The Infinity Gateway Suite software modifications have been tested and developed in compliance with the following standards:

- ANSI AAMI ISO 14971: 2019 Medical devices - Applications of risk management to medical devices
- ANSI AAMI IEC 62304:2015
- Medical device software – Software life cycle processes [Including Amendment 1 (2016)]
- ANSI AAMI IEC 62366-1:2020 Medical devices - Part 1: Application of usability engineering to medical devices

X. Conclusion

The Infinity Gateway Suite VF9.1.1 modifications have been demonstrated to be substantially equivalent to the predicate device, Infinity Gateway Suite VF9.0, which was cleared under K203579 on June 7, 2022. The intended use of the Infinity Gateway Suite as described in the product labeling, although slightly modified, does not change the actual intended use of the device. The intended use statement has been modified for clarification purposes only, not as a result of the proposed device modifications. Verification and Validation results for the proposed modifications support substantial equivalence to the predicate device.