Draeger Medical Systems, Inc.
Eileen Boyle
Manager, Regulatory Affairs
6 Tech Drive
Andover, Massachusetts 01810

May 17, 2024

Re: K203579
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

Dear Eileen Boyle:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 7, 2022. Specifically, FDA is updating this SE letter as an administrative correction. A second product code, LNX, was inadvertently included.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact LCDR Stephen Browning, OHT2: Office of Cardiovascular Devices, 240-402-5241, Stephen.Browning@fda.hhs.gov.

Sincerely,

Stephen C. Browning -S

LCDR Stephen Browning
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

June 7, 2022

Draeger Medical Systems, Inc.
Eileen Boyle
Manager, Regulatory Affairs
6 Tech Drive
Andover, Massachusetts 01810

Re: K203579
Trade/Device Name: Infinity Gateway Suite
Regulation Number: 21 CFR 870.2300
Regulation Name: System, Network and Communication, Physiological Monitors
Regulatory Class: Class II
Product Code: MSX, LNX
Dated: June 1, 2022
Received: June 2, 2022

Dear Eileen Boyle:

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,

Jennifer W. Shih -S

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

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)*
K203579

Device Name
Infinity Gateway Suite

Indications for Use *(Describe)*

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.

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.

Intended Operator
The Infinity Gateway software application is intended for use by Healthcare Providers, ie. Physicians, Nurses, and Technicians.

Intended Patient Population
The Infinity Gateway software application is not intended to be connected to patients.

Intended Use Environment
The infinity Gateway software application is intended for use in a healthcare environment.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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 USA

Contact Person: Eileen M. Boyle
Manager, Regulatory Affairs
Draeger Medical Systems, Inc.
Phone: 781-439-8120
E-mail:eileen.boyle@draeger.com
November 19, 2021 – Date Prepared

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:	§870.1025

III. Predicate Device

The Infinity® Gateway Suite, VF4 K043549 cleared on January 21, 2005.

510(k) No.	Trade Name	Manufacturer	Product Code/Common Name	Regulation Number
K043549 1/21/2005	Infinity Gateway Suite (VF4)	Draeger Medical Systems, Inc.	MSX – System, Network and Communication, Physiological Monitors LNX – Computers and Software, Medical	21CFR 870.1025

IV. Device Description

The Infinity Gateway Suite is a suite of 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.

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's Tools
- Remote View Applications
- Pager Interface
- Alarm history database
- Time master functions
- 12-lead electrocardiogram (ECG) export
- Service-Oriented Device Compatibility (SDC) interface with encryption

Infinity Gateway 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 Server facilitates the exchange of important clinical information between the Infinity/SDC protocol and existing hospital and patient care systems. The Infinity Gateway Server 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's Tools and Interface Options to create a seamless flow of information tailored to support clinical work flow.

Infinity Gateway Developer's Tools and Interface Options are licensed or "unlocked" by using option passwords that are associated with a USB license 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's 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 cost-effective software deployments and reduces the total cost of ownership.

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 Draeger Infinity Network and other hospital systems.

V. Indications for Use / 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.

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.

Intended Operator

The Infinity Gateway software application is intended for use by Healthcare Providers, ie. Physicians, Nurses, and Technicians.

Intended Patient Population

The Infinity Gate4way software application is not intended to be connected to patients.

Intended Use Environment

The infinity Gateway software application is intended for use in a healthcare environment.

VI. Comparison of Technological Characteristics with Predicate Device

The intended use, indications for use, performance and technological characteristics are substantially equivalent to the predicate device.

A summary of the main changes compared to the predicate device are listed in the comparison table below:

Comparison Table Between the Predicate Device K043549, VF4 and the Subject 510(k) K203579, VF9.0:

Attribute	Predicate Device Infinity Gateway Suite K043549 – VF4	Subject Device Infinity Gateway Suite 510(k)#K203579 – VF9.0	Explanation of Similarities and Differences
Manufacturer	Draeger Medical Systems, Inc.	Draeger Medical Systems, Inc.	Same
510(k) Number	K043549	K203579	-
Model Number	MS16076	MS40046	-
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 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.	Same, no change since VF4
Update the supported version Microsoft SQL to 2017	2008	2017	2008 will no longer be a supported version
Incorporate support for Microsoft SQL 2017 and Microsoft Server Operating System 2016	Windows NT 4.0, Windows 2000 or Windows XP	New feature in VF9.0 Support Microsoft SQL 2017 Express and Standard. Support Microsoft Server Operating System 2016 for the server application.	Windows NT 4.0, Windows 2000, Windows XP will no longer be supported versions.
Make the Service-Oriented Device Compatibility (SDC) a locked option with encryption	Not part of VF4 software.	SDC defines a communication architecture to establish distributed systems of medical devices in clinical environments.	This new feature is for use with Draeger SDC devices. This license option allows for interoperability and connectivity with the integrated Clinical Assistance Package which

Attribute	Predicate Device Infinity Gateway Suite K043549 – VF4	Subject Device Infinity Gateway Suite 510(k)#K203579 – VF9.0	Explanation of Similarities and Differences
			consists of an anesthesia workstation, a patient monitoring system and the Hospital Information System: Infinity Gateway software VF9.0 Infinity Acute Care System (IACS) patient monitor with software version VG7.1 Connectivity Converter CC300 with software version 1.1 Perseus A500 Anesthesia Machine Babylog VN500 Evita Infinity V500 Ventilator
Redundant Server Option	Not part of VF4 software.	An administrator performs the switchover manually by powering up or enabling the Gateway service on the redundant server.	Gateway supports the use of an optional redundant server. This is a licensed option. It allows a separate server to be configured in advance which can temporarily replace a failed Gateway server.
IHE/HL7 Alarm Interface Locked Option (For SDC Only)	Not part of VF4 software.	New feature in VF9.0 The IHE/HL7 Alarm Communication interface exports Alarm data from devices on the SDC network to a CIS for long term storage and record keeping. The interface support IEEE 11073 output and can be configured to be IHE PCD ACM Compliant.	The IHE/HL7 alarm communication management interface is only available for use with SDC devices.

Attribute	Predicate Device Infinity Gateway Suite K043549 – VF4	Subject Device Infinity Gateway Suite 510(k)#K203579 – VF9.0	Explanation of Similarities and Differences
Intended Population	The communication network and central monitoring device are not connected to patients.	The communication network and central monitoring device are not connected to patients.	Same
Intended Environment	A healthcare facility where healthcare professionals provide patient care.	A healthcare facility where healthcare professionals provide patient care.	Same
Gateway Pager Access application	Yes	Yes	Same
Global Session Manager	Yes	No	Global Session Manager is no longer supported. No change to intended use.
Display either the patient name or the patient identifier on WinView/Webviewer Gateway	Yes	Yes, WinView/WebViewer is renamed to PatientWatch	Same. WinView/WebViewer is renamed to PatientWatch
Network Technology	• TCP/IP • Health Level 7 (HL7 2.3) • ASTM • HTML, Active X • Windows Dynamic Link • Library (DLL) • TAP	• TCP/IP • Health Level 7 (HL7 2.x) • ASTM • HTML, Active X • Windows Dynamic Link • Library (DLL) • TAP	VF9.0 added additional support for protocol interfaces and supports different versions of the HL7 2.x protocols for various interfaces
Alarm (audible)	Yes	Yes	Audible alarm information is available only if a paging service provides the capability. No change since VF4, no impact to the intended use.
Alarm Display String	Advisory (ADV) Serious (SER) Life Threatening (LT)	Advisory (ADV) Serious (SER) Life Threatening (LT)	Available for informational purposes only. The primary alarm notification is at the patient bedside or the Infinity Central Station. No change since VF4, no impact to the intended use.
Alarm (Visual)	Yes	Yes	Same

Attribute	Predicate Device Infinity Gateway Suite K043549 – VF4	Subject Device Infinity Gateway Suite 510(k)#K203579 – VF9.0	Explanation of Similarities and Differences
Alarm Grade	Life-Threatening Serious Advisory via WinView/WebViewer	Yes, WinView/WebViewer is renamed to PatientWatch	PatientWatch alarms are available for informational purposes and are not available for SDC The alarm grades have not changed between VF4 and VF9.
Alarm State	Active Silenced None	Yes, via PatientWatch	PatientWatch alarms are available for informational purposes and are not available for SDC The alarm states have not changed between VF4 and VF9.

VII. Performance Data

Verification and Validation Testing:

The verification and validation that was conducted confirmed the Infinity Gateway product performs according to 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 functioned with the new code, with all test cases passing without exception.

Additionally, all possibly known use related hazards, inclusive those beyond the primary operating functions, that are related to usability have been reviewed. 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 the modified software is substantially equivalent to the predicate device.

Biocompatibility: The proposed enhancement to the Infinity Gateway Suite involves software only. No modifications affecting biocompatibility of the device is being proposed at this time and does not apply.

Sterilization: Sterilization and shelf-life do not apply as the Infinity Gateway Suite is software only.

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
- IEEE Std 11073 -10101-2019 Health informatics – Point-of-care medical device communication. Part 10101: Nomenclature
- IEEE Std 11073-10201-2018 Health informatics – Point-of-care medical device communication Part 10201: Domain Information Model
- ANSI AAMI IEC 62304:2006/a1:2016
- Medical device software – Software life cycle processes [Including Amendment 1 (2016)]
- ANSI AAMI IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices

VIII. Conclusion

The Infinity Gateway Suite significant change modifications are substantially equivalent to the predicate device cleared under K043549 on January 21, 2005. The intended use of the Infinity Gateway Suite as described in the product labeling has not changed as a result of the proposed modifications. Verification and Validation results for the proposed modifications support substantial equivalence to the predicate device.