December 21, 2022

GE Medical Systems Information Technologies, Inc.
Brandon O'shea
Sr. Regulatory Affairs Manager
9900 Innovation Drive
Wauwatosa, Wisconsin 53226

Re: K222586
Trade/Device Name: Mural Clinical Viewer
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: November 22, 2022
Received: November 22, 2022

Dear Brandon O'Shea:

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,

Shruti N. Mistry -S

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

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)*
K222586

Device Name
Mural Clinical Viewer

Indications for Use *(Describe)*
Mural Clinical Viewer is a patient monitoring software application intended for the electronic collection, display, trending, annotation, measurement and export of clinical data. Data is acquired from medical devices, Electronic Health Records (EHRs) and other data sources on a hospital's network. The application is designed to accept a patient selection from a host Electronic Health Record (EHR) program and then display that particular patient's data and waveforms within the EHR. The device is intended to be used by healthcare professionals in general hospital (including ICU) or remote clinical support settings while operating within a single patient's EHR.

This product does not control or alter any of the medical devices providing data across the hospital network. All information, alerts or visual indications provided are intended to support the judgement of medical professionals. The product is not a bedside patient monitor and can only receive processed signal data from a 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.

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

807.92(a)(1) – Submitter Information	
Date	26 August 2022
Submitter	GE Medical Systems Information Technologies, Inc. 9900 Innovation Drive Wauwatosa, WI 53226, USA
Primary Contact Person	Brandon O'Shea Sr. Regulatory Affairs Manager GE Medical Systems Information Technologies, Inc. Email: brandon.oshea@ge.com Ph: (414) 323-3147
Secondary Contact Person	Michael Petrini Regulatory Affairs Executive GE Medical Systems Information Technologies, Inc. Ph: (360) 294-9283
807.92(a)(2) – Device Information	
Device Trade Name	Mural Clinical Viewer
Common/Usual Name	Monitor, Physiological, Patient (with arrhythmia detection or alarms)
Regulation Name	Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulation Number	21 CFR 870.1025
Regulation Class	Class II
Product Code	MHX
Review Panel	Cardiovascular
807.92(a)(3) – Predicate Device	
510(k) Number	K141811
Manufacturer	Mortara Instruments, Inc.
Predicate Device(s)	Mortara Monitoring Waveform Viewer
The predicate device has not been subject to a design-related recall	
807.92(a)(4) – Device Description	

Device Design

Mural Clinical Viewer is a software only, information management system designed to enable viewing of patient's monitoring data. The system is accessible from the Electronic Health Record (EHR) application. Its use covers near real time and retrospective display of patient vitals, waveforms and events. The system also covers documentation of patient vitals including discrete values and waveform strips.

The software is integrated with a healthcare facility's Electronic Health Records (EHR) and Medical Gateway Interface (MGI) for electronic collection, display, trending, annotation, measurement and export of clinical data. The software accessed as an integral part of the host EHR application, provides a single place to view patient monitoring data and to record documentation in EHR system without having to switch between multiple different applications and devices.

Environment of Use
Mural Clinical Viewer is intended to be used in a healthcare facility environment within a host EHR application.

Principle of Operation and Deployment
Mural Clinical Viewer software is a cloud-based application with client-server architecture, accessed on web browser embedded within a host EHR system. Mural Clinical Viewer application is accessed via the EHR application within a hospital network. EHR application manages user authentication with credential-based log-in within a hospital supplied network. The application provides a means for viewing and documenting patient monitoring data including vitals, waveforms and alarms/events as supplied by a Medical Gateway Interface (MGI), supporting clinicians in investigation and patient documentation management.

The software comes with features to view, annotate, measure, save and retrieve clinical data to support patient documentation and record keeping.

This product does not control or alter any of the medical devices providing data across the hospital network. All information, alerts or visual indications provided are intended to support the judgement of medical professionals. The product is not a bedside patient monitor and can only receive processed signal data from a hospital network.

807.92(a)(5) – Indications for Use

Mural Clinical Viewer is a patient monitoring software application intended for the electronic collection, display, trending, annotation, measurement and export of clinical data. Data is acquired from medical devices, Electronic Health Records (EHRs) and other data sources on a hospital's network. The application is designed to accept a patient selection from a host Electronic Health Record (EHR) program and then display that particular patient's data and waveforms within the EHR. The device is intended to be used by healthcare professionals in general hospital (including ICU) or remote clinical support settings while operating within a single patient's EHR.

This product does not control or alter any of the medical devices providing data across the hospital network. All information, alerts or visual indications provided are intended to support the judgement of medical professionals. The product is not a bedside patient monitor and can only receive processed signal data from a hospital network.

807.92(a)(6) – Comparison of Intended Use and Technological Characteristics

The table below compares the intended use and technological characteristics of the subject and predicate device.

Specification	Predicate Device Mortara Monitoring Waveform Viewer K141811	Subject Device Mural Clinical Viewer K[TBD]
Patient Population	Hospital Based Patients of any age connected to a hospital monitor, network and host application	Hospital Based Patients of any age connected to a hospital monitor, network and host application
Environment of Use	Hospital Environment and securely networked clinics or offices	Hospital Environment and securely networked clinics or offices

	This product is not for home monitoring use	This product is not for home monitoring use
Intended User	Licensed Healthcare Providers	Licensed Healthcare Providers (nurses, physicians, tele-technicians)
Software Level of Concern	Unknown (assumed to be Major)	Major
User Interface	Standard PC/Laptop Client application embedded in a host application	Standard PC/Laptop Web client application embedded in a host application **NOTE**: This application is not intended for use on tablets or mobile phones
SW and HW Components	Software only product; utilizing off-the-shelf IT devices.	Software only product; utilizing off-the-shelf IT devices.
Software Capabilities – Patient Data and Information	Clinical Data Display (Detailed Bedside View + Vital Signs) + Alerts/Alarms	Clinical Data Display (Detailed Bedside View + Vital Signs) + Alerts/Alarms
Software Capabilities – Caliper Tool	The application can perform measurements with the support of a caliper tool (providing horizontal/time measurements and vertical/signal amplitude measurements). The caliper tool can be activated when the Monitoring Waveform Viewer displays still waveforms	The application allows user to perform caliper measurements (horizontal measurements only) using the electronic Caliper tool on ECG waveforms to assess the patient's cardiac rhythm. The Caliper tool can be activated from the Create Strip report panel window when user documents a selected strip
Software Capabilities – Annotations	(Unknown) Not available from the 510K Summary Document	The application allows the clinician to capture and save their annotation for a selected strip on the Full disclosure. These saved strips on the worklist can be viewed on the Mural Clinical Viewer and in the EHR as a PDF file.
Software Capabilities – Alarms	Capable of receiving data from external systems for the display of alarm states. Not capable of generating unique alarms or influencing external systems.	Capable of receiving data from external systems for the display of alarm states. Not capable of generating unique alarms or influencing external systems.
Connectivity	Acquire physiological data provided by the connected application provider WAN/LAN hospital connectivity	Acquire physiological data from MDI/MGI provided by EHR application provider WAN/LAN hospital connectivity
Operating System(s)	**Operating System:** • Windows 10 (64-bit)	**Operating System:** • Servers – Linux distribution with container orchestration • Clients – WebKit based browser with support for HTML5 & JavaScript The Mural Clinical Viewer system is designed as a cloud-native application utilizing virtualization technology on a Linux operating system with containerized services. The application runs on premises (on prem) within a hospital network.
Data Sources / Connectivity / Outputs	**Data Sources (inputs)** Patient monitoring systems	**Data Sources (inputs)** MDI/MGI interface provided by EHR application provider

	Connectivity & Output Send data to host EHR application for documentation purposes with no ability to influence the original monitoring system	**Connectivity & Output** Send data to the host application for documentation purposes with no ability to influence the original monitoring system

Mural Clinical Viewer and the Mortara Monitoring Waveform Viewer (K141811) are software-only clinical information systems for monitoring analysis and documentation of patient waveforms within a hospital environment or clinical support setting.

The Mural Clinical Viewer software employs the same fundamental scientific technology as its predicate device. Both Mural Clinical Viewer and the Mortara Monitoring Waveform Viewer both operate off a client server architecture installed on off-the-shelf client servers utilizing standard communication languages. The Mural Clinical Viewer and Mortara Monitoring Waveform Viewer both include waveform review, caliper and transmitted alarm display functionality. The subject device has different technological features including different user interfaces and operating systems. However, the different technological characteristics do not raise different questions of safety and effectiveness.

807.92(b)(1) – Performance Testing	
Summary of Non-Clinical Tests	Software was evaluated as recommended in the 2005 FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The Mural Clinical Viewer software was developed following the GE Healthcare Quality Management System. The following activities were successfully completed: ▪ Risk Analysis / Management ▪ Requirements Reviews ▪ Design Reviews ▪ Software Verification ▪ Software Validation ▪ Usability Testing Mural Clinical Viewer has also been subject to the following non-clinical V&V activities: ▪ Safety classification and Performance testing in accordance with IEC 62304 Edition 1.1 2015 ▪ Testing in accordance with IEC 60601-1-8 Edition 2.2 2020-07 for alarm functionality ▪ Testing in accordance with IEC 60601-2-25 Edition 2.0 for basic safety and essential performance of electrocardiographs Successful completion of design verification and validation testing was performed to confirm that software and user requirements have been met.

	Cybersecurity was evaluated as recommended in the 2014 FDA guidance document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices." Interoperability was evaluated as recommended in the 2017 FDA guidance document "Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices."
807.92(b)(2) – Summary of Clinical Tests	
Summary of Clinical Tests	The similarities and differences between the subject device and the predicate device, were determined not to have a significant impact on the device's performance, the clinical performance, and the actual use scenarios. Therefore, the subject of this premarket submission, Mural Clinical Viewer, did not require clinical studies to support substantial equivalence.
807.92(b)(3) - Conclusion	
The performance data described above demonstrate that the Mural Clinical Viewer is as safe and effective as the Mortara Monitoring Waveform Viewer and supports a determination of substantial equivalence.	