June 23, 2022

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

Re: K220732
Trade/Device Name: Mural Perinatal Surveillance
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal Monitoring System and Accessories
Regulatory Class: II
Product Code: HGM
Dated: March 11, 2022
Received: March 14, 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,

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K220732

Device Name
Mural Perinatal Surveillance

Indications for Use *(Describe)*
Mural Perinatal Surveillance is a perinatal monitoring system intended for electronic collection, display, and documentation of clinical data with optional features to store, export, annotate, calculate, and retrieve clinical data. Data is acquired from medical devices, electronic health records, or other data sources on a hospital's network. This device is intended for use by healthcare professionals in clinical support settings for obstetric patients during and after pregnancy.

This product is not intended to control or alter any of the medical devices providing data across the hospital network. All information or indications provided are intended to support the judgment of medical professionals and are not intended to be the sole source of information for decision making.

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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510(k) Summary
K220732

Submitter Information	
Date Summary Prepared:	23 June 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
Device Information	
Device Trade Name:	Mural Perinatal Surveillance
Common/Usual Name:	Perinatal monitoring system and accessories
Regulation Name:	Perinatal monitoring system and accessories
Regulation Number:	21 CFR 884.2740
Regulation Class:	Class II
Product Code:	HGM (System, Monitoring, Perinatal)
Review Panel:	Obstetrics/Gynecology
Predicate Device	
510(k) Number:	K173941
Manufacturer	Philips Medizin Systeme Boeblingen GmbH
Device Name	IntelliSpace Perinatal Revision K.00
	The predicate device has not been subject to a design-related recall.

Device Description

Device Design
Mural Perinatal Surveillance is a software only, information management system designed for the obstetrical (OB) care environment. Its use covers patients during pregnancy, labor, birth and covers newborn documentation. The software interfaces with a healthcare facility's Electronic Medical Records (EMR) and patient monitoring network to collect, display and document relevant patient data.

The software combines patient surveillance and alarm capabilities with patient documentation and record keeping into a single application to support patient care for their complete obstetrical care journey.

Environment of Use
Mural Perinatal Surveillance is intended to be used in a healthcare facility environment within or supporting the Obstetrical/Gynecological (OB/GYN) department.

Principle of Operation and Deployment
Mural Perinatal Surveillance software is installed on a server architecture and accessed via web browser through a credential-based log-in within a hospital supplied network. The application provides a means for obstetrical patient surveillance, alarming, investigation and patient documentation management.

The software comes with modular features to store, export, annotate, calculate and retrieve clinical data to support patient documentation and record keeping.

The product is not intended to control or alter any of the medical devices providing data across the hospital network. All information or indications provided are intended to support the judgment of medical professionals and are not intended to be the sole source of information for decision making.

Indications for Use

Mural Perinatal Surveillance is a perinatal monitoring system intended for electronic collection, display, and documentation of clinical data with optional features to store, export, annotate, calculate, and retrieve clinical data. Data is acquired from medical devices, electronic health records, or other data sources on a hospital's network. This device is intended for use by healthcare professionals in clinical support settings for obstetric patients during and after pregnancy.

This product is not intended to control or alter any of the medical devices providing data across the hospital network. All information or indications provided are intended to support the judgement of medical professionals and are not intended to be the sole source of information for decision making.

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** **Philips IntelliSpace Perinatal Revision K.00** **K173941**	**Subject Device** **Mural Perinatal Surveillance** **K220732**
Patient Population	Hospital Based Obstetric Patients	Hospital Based Obstetric Patients
Environment of Use	Healthcare facility environment within the Obstetrical/Gynecological (OB/GYN) department	Healthcare facility environment within the Obstetrical/Gynecological (OB/GYN) department
Intended User	Bedside care team (nurses, physicians)	Bedside care team (nurses, physicians)
Software Level of Concern	Major	Major
User Interface	Standard PC/Laptop Web client available on mobile device screens.	Standard PC/Laptop Web client available on mobile device screens (excluding mobile phones).
SW and HW Components	Software only product; client server architecture installed on off-the-shelf IT devices.	Software only product; client server architecture installed on off-the-shelf IT devices.

Software Capabilities – Clinical Annotations & Record Archive	Ability for users to generate annotations on fetal strips and save a report to the patients records for long term storage.	Ability for users to generate annotations on fetal strips and save a report to the patients records for long term storage.
Software Capabilities – Computed Items & Assessment Tools	None	Mural Perinatal Surveillance utilizes a combination of standard general computes widely accepted and generally available along with more complex computes derived directly from well-established industry standards or evidence-based studies and peer-reviewed research journals. The basis for complex computes are fully disclosed to the user. The complex computes include Shoulder Dystocia Risk, Postpartum Hemorrhage Risk Score, and Bishop Score. The software provides a Fetal Waveform Assessment Tool (FWAT) which acts as a digital line on the screen to allow clinicians to view waveforms against the manually set reference line.
Software Capabilities –Alarms	Capable generating alarm conditions within the software based on information coming from fetal monitors.	Capable generating alarm conditions within the software based on information coming from fetal monitors.
Connectivity	HL7 link for Admission Discharge Transfer (ADT) messages and ORU. Acquire physiological data from compatible measuring devices. WAN/LAN hospital connectivity	HL7 link for Admission Discharge Transfer (ADT) messages and ORU. Acquire physiological data from compatible measuring devices. WAN/LAN hospital connectivity
Operating System(s)	Operating System: • Servers – Windows Server 2012 R2 • Clients – Windows 10 LTSB 2016	Operating System: • Servers – Linux distribution with container orchestration • Clients – WebKit based browser with support for HTML5 & JavaScript The Mural Perinatal Surveillance 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) HL7, Fetal monitors (on a network), Connectivity & Output IntelliSpace Perinatal provides an interface to launch the Philips IntelliVue XDS Remote Display for remote viewing and operating of compatible patient monitors. Additionally, the system can output reports/records.	Data Sources (inputs) HL7, Fetal monitors (on a network) Connectivity & Output Mural Perinatal Surveillance does not control other medical devices. The software generates reports that can be stored in a patients record.

Mural Perinatal Surveillance and Philips IntelliSpace Perinatal Revision K.00 (K173941) are software-only clinical information systems that have the same intended use - for the monitoring, analysis and documentation of fetal waveforms for obstetric patients during and after pregnancy.

The Mural Perinatal Surveillance software employs the same fundamental scientific technology as its predicate device. Both Mural Perinatal Surveillance and Philips IntelliSpace Perinatal Revision K.00 both operate off a client server architecture installed on off-the-shelf client servers utilizing standard communication languages such as HL7 and ORU. The Mural Perinatal Surveillance and Philips IntelliSpace Perinatal Revision K.00 software both include clinical decision support, annotation and alarm functionality. The subject device has different technological features, including different user interfaces, software capabilities (computed items and assessment tools), and operating systems. However, the different technological characteristics do not raise different questions of safety and effectiveness.

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 Perinatal Surveillance software was developed following the GE Healthcare Quality Management System (QMS). The following activities were successfully completed: ▪ Risk Analysis / Management ▪ Requirements Reviews ▪ Design Reviews ▪ Software Verification ▪ Software Validation ▪ Usability Testing Mural Perinatal Surveillance 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 Successful completion of design verification and validation testing was performed to confirms 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."
Conclusion	
The performance data described above demonstrate that the Mural Perinatal Surveillance is as safe and effective as the IntelliSpace Perinatal Revision K.00 and supports a determination of substantial equivalence.	