December 20, 2022

GE Medical Systems Information Technologies, Inc.
Shlomi Deler
Regulatory Affairs Director
9900 Innovation Drive
Wauwatosa, Wisconsin 53226

Re: K221904
Trade/Device Name: EK12 V2 Algorithm
Regulation Number: 21 CFR 870.1025
Regulation Name: Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms)
Regulatory Class: Class II
Product Code: MHX
Dated: November 21, 2022
Received: November 22, 2022

Dear Shlomi Deler:

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,

for Shruti N. Mistry -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)*
K221904

Device Name
EK12 V2 Algorithm

Indications for Use *(Describe)*
EK12 V2 analyzes 10 or more seconds of a previously acquired electrocardiogram (ECG) from physiological ECG signal recording devices for rhythm and measurements.
EK12 is used to create reports intended for use by a Qualified Medical Professional, including a trained ECG Technician operating within Independent Diagnostic Testing Facility (IDTF) requirements and performance standards for the review and assessment of an ECG.

EK12 V2 is indicated for use on adults and pediatric patients older than 2 years. The device is intended for use in an IDTF or a professional medical facility, such as a hospital, clinic, or physician's office.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

Date:	20-June-2022
Submitter:	GE Medical Systems *Information Technologies,* Inc. 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Shlomi Deler Regulatory Affairs Director GE Medical Systems *Information Technologies,* Inc. Phone: +(972) 544301056
Secondary Contact Person:	Michael Petrini Regulatory Affairs Executive GE Medical Systems *Information Technologies,* Inc. Phone: +1(414)581-8987
Device Trade Name:	EK12 V2 Algorithm
Common/Usual Name:	Arrhythmia Detection Algorithm
Classification Names:	Monitor, Physiological, Patient (With Arrhythmia Detection or Alarms)
Product Code:	MHX , 21 CFR 870.1025
Predicate Device(s):	Ek12 Algorithm (K170155)
Reference Device:	12SL ECG Analysis Program (K141963)
Device Description:	EK12 V2 algorithm is a software only product that provides computerized measurements from the ECG parameter data acquired by the host device. EK12 V2 analyzes ECG recordings for rhythm and measurements that is deployed as part of a host system used to generate ECG reports

Intended Use:	EK12 v2 analyzes 10 or more seconds of a previously acquired electrocardiogram (ECG) from physiological ECG signal recording devices for rhythm and measurements. EK12 is used to create reports intended for use by a Qualified Medical Professional, including a trained ECG Technician operating within Independent Diagnostic Testing Facility (IDTF) requirements and performance standards for the review and assessment of an ECG. EK12 is indicated for use on adults and pediatric patients older than 2 years. The device is intended for use in an IDTF or a professional medical facility, such as a hospital, clinic, or physician's office.
Technology:	The EK12 V2 Algorithm employs the same fundamental scientific technology as its predicate and the reference devices.
Determination of Substantial Equivalence:	The EK12 V2 Algorithm is substantially equivalent to the predicate Ek12 Algorithm (K170155) and the reference device 12SL ECG Analysis Program (K141963) as described in the table below:

Feature / Function	**Proposed Device** EK12v2	**Predicate Device** EK12v1 (K170155)	Change Explanation / Notes
Intended Use	EK12 analyzes 10 or more seconds of a previously acquired electrocardiogram (ECG) from physiological ECG signal recording devices for rhythm and measurements. EK12 is used to create reports intended for use by a Qualified Medical Professional, including a trained ECG Technician operating within Independent Diagnostic Testing Facility (IDTF) requirements and performance standards for the review and assessment of an ECG. EK12 is indicated for use on adults and pediatric patients older than 2 years. The device is intended for use in an IDTF or a professional medical facility, such as a hospital, clinic, or physician's office.	EK12 analyzes ten or more seconds of a previously acquired electrocardiogram (ECG) from physiological ECG signal recording devices for rhythm and measurements. EK12 is used to create reports intended for use by a Qualified Medical Professional, including a trained ECG Technician operating within Independent Diagnostic Testing Facility (IDTF) requirements and performance standards for the review and assessment of an ECG. EK12 is indicated for use on adults and pediatric patients older than 2 years. The device is intended for use in an IDTF or a professional medical facility, such as a hospital, clinic, or doctor's office.	Identical
Indications for Use	EK12 is software algorithm that analyzes ECGs for rhythm and measurements that is deployed as part of a system used to generate ECG reports / findings.	EK12 is software algorithm that analyzes ECGs for rhythm and measurements that is deployed as part of a system used to generate ECG reports / findings.	Identical
Contraindications	EK12 cannot be used for active patient monitoring since it can only analyze prerecorded ECG signals that are at least 10 seconds long. It does not provide any time-sensitive information, continuous display of information, alarms, or alerts intended to alert a caregiver to take an immediate clinical action.	EK12 cannot be used for active patient monitoring since it can only analyze prerecorded ECG signals that are at least 10 seconds long. It does not provide any time-sensitive information, continuous display of information, alarms, or alerts intended to alert a caregiver to take an immediate clinical action.	Identical
Patient Population	EK12 is indicated for use on adults and pediatric patients older than 2 years.	EK12 is indicated for use on adults and pediatric patients older than 2 years.	Identical
Use Environment	The device is intended for use in an IDTF or a professional medical facility, such as a hospital, clinic, or physician's office.	The device is intended for use in an IDTF or a professional medical facility, such as a hospital, clinic, or doctor's office.	Identical
Result	An output text file containing the pass/fail status (result) of the analysis	An output text file containing the pass/fail result of the analysis	Identical
Final report	An output text file containing the final evaluation results for rhythms, measurements, and other information.	An output text file containing the final evaluation results for rhythms, measurements, and other information.	Identical
Event log detected arrhythmias, noise)	A column-oriented tab-delimited output text file annotating the beginning and end of all detected rhythm and noise events.	A column-oriented tab-delimited output text file annotating the beginning and end of all detected rhythm and noise events.	Identical
QRS detections	Two output files: 1. A column-oriented tab-delimited output text file listing annotations of QRS detection times and beat classification.	Two output files: 1. A column-oriented tab-delimited output text file listing annotations of QRS detection times and beat classification.	Identical

Feature / Function	Proposed Device EK12v2	Predicate Device EK12v1 (K170155)	Change Explanation / Notes
	2. A binary file in the WFDB annotation file format containing QRS detection times and beat classification.	2. A binary file in the WFDB-format annotation file format containing QRS detection times and beat classification.	

Substantial Equivalence to the reference device, 12SL ECG Analysis Program (K141963):

Feature / Function	Proposed: EK12v2	Reference device: 12SL ECG Analysis Program (K141963)	Discussion of Differences
Patient age and gender	Optional inputs. If present, they are contained within the WFDB input record. When present, they are validated and passed directly to the 12SL analysis. If not present, the value for unknown age and/or gender are provided to the 12SL analysis	Required inputs which are used in the ECG interpretation. Age is provided to the program in years, an encoded value for age less than one year, or an encoded value for age unknown. Gender is provided to the program as one of male, female, or unknown.	Substantial equivalent The proposed EK12 V2 adds support for the optional input of patient age and/or gender.
Identification of ECG leads	Lead names are an optional component of the input WFDB input record and are an optional input of EK12 V2. Any input signals containing a lead name from the set {I, II, V1, V2, V3, V4, V5, V6} will be treated as that lead in the internal 12SL analysis	Assumes the first 8 channels are ECG leads I, II, V1, V2, V3, V4, V5, V6. Measurements are provided for leads after the first 8 channels but are otherwise not used in any interpretation statements with the exception of lead V4r, which if present, will be examined for right ventricular involvement (ST elevation) if an acute inferior infarct is detected	Substantial equivalent The proposed EK12 V2 adds support for the optional identification of ECG leads.
12SL rhythm statement trends	A column-oriented tab-delimited text file that provides the 12SL interpretation statement codes for rhythm statements from each 10-second 12SL analysis at intervals of every 5 seconds. That is, each consecutive analysis has 5 seconds of overlapping waveform. The 12SL interpretation statement codes are censored to remove all statement codes not related to rhythm interpretation.	All output is contained in an in-memory data structure; the host product is responsible for creation of the output record and/or report. There is no concept of “trends” in a single execution of the 12SL analysis. The method of creating the 12SL statements are identical to the reference device for the “12SL interpretation statement codes” as described above	Substantial equivalent Interpretation statement codes forming the overall ECG interpretation is identical to the reference 12SL ECG Analysis Program (K141963). The proposed EK12 v2 adds the export of the rhythm statement codes to an output file.
Median complex waveform trends	A column-oriented tab-delimited text file that provides the median complexes for each supplied lead from each 10-second 12SL analysis at intervals of every 5 seconds. That is, each consecutive analysis has 5 seconds of overlapping waveform	All output is contained in an in-memory data structure; the host product is responsible for creation of the output record and/or report. There is no concept of “trends” in a single execution of the 12SL analysis. The method of creating the 12SL median complexes are identical to the reference device for the “12SL median complexes” as described above	Substantial equivalent Median complexes were formed as part of the internal 12SL analysis and were the basis for the per-lead measurements provided in the predicate EK12 v1 (K170155). The method for median waveform formation is identical to the reference device 12SL ECG Analysis Program (K141963). The proposed EK12 v2 adds the export of the median complexes to an output file.

Performance standards:	The EK12 V2 Algorithm complies with the voluntary consensus standard AAMI/ANSI EC57: 2012 – Testing And Reporting Performance Results Of Cardiac Rhythm and St-Segment Measurement Algorithms.
Determination of Substantial Equivalence: tested	<u>Summary of Non-Clinical Tests</u> The EK12 V2 Algorithm program was designed and for compliance with applicable clauses of the following voluntary standard: AAMI/ANSI EC57: 2012 – Testing And Reporting Performance Results Of Cardiac Rhythm and St-Segment Measurement Algorithms. (Cardiovascular) The following quality assurance measures were applied to the development of the system: - Risk Analysis - Requirements Reviews - Code Inspections - Software Verification Testing - Performance testing
Summary of Clinical Tests:	The subject of this premarket submission, EK12 V2 Algorithm, did not require clinical studies to support substantial equivalence.
Conclusion:	GE Healthcare considers the EK12 V2 Algorithm to be as safe, as effective, and performance is substantially equivalent to the predicate device.