DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 6, 2017

GE Medical Systems Information Technologies, Inc.
Amy Yang
Regulatory Affairs Program Manager
9900 West Innovation Drive
Wauwatosa, Wisconsin 53226

Re: K170155
Trade/Device Name: EK12 Algorithm
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: April 25, 2017
Received: April 27, 2017

Dear Amy Yang:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170155

Device Name
EK12 Algorithm

Indications for Use *(Describe)*
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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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:	January 16, 2017
Submitter:	GE Medical Systems *Information Technologies,* Inc. 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Amy Yang Regulatory Affairs Program Manager GE Medical Systems *Information Technologies,* Inc. Phone: (414)721-3807 Fax: (414) 721-3863
Secondary Contact Person:	Doug Kentz Regulatory Affairs Director GE Medical Systems *Information Technologies,* Inc. Phone: (414)581-8987 Fax: (414)362-2585
Device Trade Name:	EK12 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):	EK-Pro Arrhythmia Detection Algorithm – K031320 12SL ECG Analysis Program – K141963
Device Description:	The EK12 algorithm is a software only algorithm
Intended Use:	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.
Technology:	The EK12 Algorithm employs the same fundamental scientific technology as its predicate device.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The EK12 Algorithm program was designed and tested 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 Algorithm, did not require clinical studies to support substantial equivalence.
Conclusion:	GE Healthcare considers the EK12 Algorithm to be as safe, as effective, and performance is substantially equivalent to the predicate device.