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

February 5, 2015

GE Medical Systems Information Technologies, Inc.
Kristin Pabst
Regulatory Affairs Manager
9900 West Innovation Drive
Wauwatosa, Wisconsin 53226

Re: K141963
Trade/Device Name: 12SL ECG Analysis Program
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: January 29, 2015
Received: February 2, 2015

Dear Kristin Pabst,

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 yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

GE Healthcare

510(k) Premarket Notification Submission

510(k) Number:

Device Name: 12SL ECG Analysis Program

Indications for Use:

The 12SL ECG Analysis Program assists the physician in measuring and interpreting resting 12-lead ECGs for rhythm and contour information by providing an initial automated interpretation. The interpretation by the analysis program may then be confirmed, edited, or deleted by the physician. The analysis program is intended for use in the general population ranging from healthy subjects to patients with cardiac and/or non-cardiac abnormalities. The analysis program is intended for use in hospitals, outpatient clinics, emergency departments, and out-of hospital sites such as ambulances and patients' homes.

The ACS Tool option is intended for adult patient populations who are suspected clinically to have acute coronary syndrome.

Prescription Use__X___ AND/OR Over-The-Counter Use_ _
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

GE Healthcare

510(k) Premarket Notification Submission

510(k) Summary

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

Date:	July 17, 2014
Submitter:	GE Medical Systems *Information Technologies* 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Kristin Pabst Regulatory Affairs Manager GE Medical Systems *Information Technologies* Phone: (414) 721-3104 Fax: (414) 721-3863
Secondary Contact Person:	Doug Kentz Regulatory Affairs GE Medical Systems *Information Technologies* Phone (414) 362-2038 FAX: (414) 362-2585
Device: Trade Name:	12SL ECG Analysis Program
Common/Usual Name:	ECG Analysis Program
Classification Names:	Monitor, Physiological, Patient (With Arrhythmia Detection Or Alarms)
Product Code:	MHX 21CFR 870.1025
Predicate Device(s):	12SL ECG Analysis Program K#092369
Device Description:	The 12SL ECG Analysis Program is a software only algorithm
Intended Use:	The 12SL ECG Analysis Program assists the physician in measuring and interpreting resting 12-lead ECGs for rhythm and contour information by providing an initial automated interpretation. The interpretation by the analysis program may then be confirmed, edited, or deleted by the physician. The analysis program is intended for use in the general population ranging from healthy subjects to patients with cardiac and/or non-cardiac abnormalities. The analysis program is intended for use in hospitals, outpatient clinics, emergency departments, and out-of hospital sites such as ambulances and patients' homes. The ACS Tool option is intended for adult patient populations who are suspected clinically to have acute coronary syndrome.
Technology:	The 12SL ECG Analysis Program employs the same functional scientific technology as its predicate device.12SL ECG Analysis Program (K092369).
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The 12SL ECG Analysis program was designed and tested for compliance with applicable clauses of the following voluntary standard:

- IEC 60601-2-25:2011Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs - Edition 2.0

The 12SL ECG Analysis Program and its applications comply with the Guidances and/or Special Controls as detailed in Section 9 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Requirements Reviews
- Risk Analysis
- Software Verification and Validation
- Performance testing

Summary of Clinical Tests:

The subject of this premarket submission, 12SL ECG Analysis Program, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the 12SL ECG Analysis Program to be as safe, as effective, and performance is substantially equivalent to the predicate device.