April 30, 2021

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

Re: K203786
Trade/Device Name: MAC 7 - Resting ECG Analysis System
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, DQK, DXH
Dated: April 2, 2021
Received: April 7, 2021

Dear Lee Bush:

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,

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)*

K203786

Device Name

MAC 7 Resting ECG Analysis System

Indications for Use *(Describe)*

The MAC 7 Resting ECG Analysis System is a non-invasive prescription device.

- The device is indicated for use to acquire, analyze, display and print electrocardiograms.
- The device is indicated for use to provide interpretation of the data for consideration by a physician.
- The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician.
- It is not intended as a sole means of diagnosis. The interpretations of ECG offered by the device are only significant when used in conjunction with a physician overread as well as consideration of all other relevant patient data.
- The device is indicated for use on adult and pediatric (birth through 21 years of age) populations

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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510k Summary

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h):

DATE: December 22, 2020

SUBMITTER

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PRODUCT IDENTIFICATION

Device Trade Name:	MAC 7 Resting ECG Analysis System
Common / Usual Name:	Electrocardiograph
Regulation Number - Classification Name(s)	21 CFR 870.2340 – Electrocardiograph 21 CFR 870.1425 – Programmable Diagnostic Computer 21 CFR 870.2920 – Telephone electrocardiograph Transmitter and Receiver
Device Classification:	Class II

Product Code(s): DPS, DQK, DXH

Predicate Device(s): MAC VU360 Resting ECG Analysis System (K173830)

Device Description:

The MAC 7 Resting ECG Analysis System is a mobile electrocardiograph designed to acquire, analyze, display, and record ECG signals from surface ECG electrodes.

The MAC 7 can capture 3, 6 or 12 lead electrocardiograms, provide interpretive analysis, and print reports.

The device can connect to a network, either through a wired LAN connection or via wireless WiFi access points. Once on the network, the device can optionally interface with the cardiology information systems such as the GEHC MUSE® system to participate in a complete electrocardiology workflow.

The device provides state-of-the-art information technology security features and a contemporary user interface. Mobility is provided via an optional trolley.

Intended Use:

The MAC 7 Resting ECG Analysis System is intended to acquire, analyze, display, and record electrocardiographic information from adult or pediatric populations. Basic system delivers 3, 6, or 12 lead ECG's and interpretive analysis. Transmission and reception of ECG data and other clinical data to and from a central clinical information system is optional.

The MAC 7 Resting ECG Analysis System is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital, medical professional's facility or wherever ECG testing is performed.

Indications for Use

The MAC 7 Resting ECG Analysis System is a non-invasive prescription device.

- The device is indicated for use to acquire, analyze, display and print electrocardiograms.
- The device is indicated for use to provide interpretation of the data for consideration by a physician.
- The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis.

- The interpretations of ECG offered by the device are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data.

Technology:

The MAC 7 employs the same fundamental scientific technology, basic design, construction, materials, energy source, control mechanism, operating principles as the predicate device MAC VU360 in acquiring, analyzing, recording, displaying and printing ECG data for both adult and pediatric populations.

The basic system prints 3, 6 or 12 leads of ECG and provides optional transmission and reception of ECG data to and from a central ECG cardiovascular information system. The system can be upgraded with software options, similar to the predicate device.

The MAC 7 is similar to the MAC VU360 Resting ECG Analysis System, K173830, in the technology of downloading orders and patient demographics from a central ECG cardiovascular information system (e.g. MUSE) as well as supporting ECG reports in PDF. Both are able to use WiFi communication.

Performance Standards:

The MAC 7 Resting ECG Analysis System has completed testing and demonstrated compliance with IEC 60601-1 Ed. 3.1 and it associated collateral and particular standards.

Sterilization:

The MAC 7 Resting ECG Analysis System does not require sterilization.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The MAC 7 Resting ECG Analysis System and its applications comply with applicable voluntary standards. It was designed and manufactured under the Quality System Regulations of 21CFR820 and ISO 13485. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Required Reviews
- Design Reviews
- Software Development Lifecycle
- Testing on unit level
- Usability Testing
- Connectivity Bench Testing

- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)

Summary of Clinical Tests: The subject of this premarket submission, MAC 7 Resting ECG Analysis System, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the MAC 7 Resting ECG Analysis System to be as safe, and as effective, and performance is substantially equivalent to the predicate device, MAC VU360 Resting ECG Analysis System.