January 26, 2026

GE Medical Systems Information Technologies, Inc.
Yang Honghong
Regulatory Affair Specialisr
9900 Innovation Drive
Wauwatosa, Wisconsin 53226

Re: K251670
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, DSA
Dated: December 29, 2025
Received: December 29, 2025

Dear Yang Honghong:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 W. SHIH -S

Jennifer Kozen
Assistant Director
Division of Cardiac Electrophysiology,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251670

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 over-read 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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 information is provided:

I. SUBMITTER

GE Medical Systems Information Technologies, Inc.
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Date 510(k) Summary was Prepared:
Feb 28, 2025

II. DEVICE

Device Trade Name:	MAC 7 Resting ECG Analysis System
Common / Usual Name:	Electrocardiograph
Classification Names	21 CFR 870.2340 – Electrocardiograph 21 CFR 870.1425 – Programmable Diagnostic Computer 21 CFR 870.2920 – Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class:	II
Product Code:	Primary Product Code: DPS Subsequent Product Codes: DQK, DXH, DSA

Predicate Device(s): MAC 7 Resting ECG Analysis System (K203786)

Reference Device: MAC VU360 Resting ECG Analysis System (K173830) and Page Writer TC30 Cardiograph (K210560)

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 device can capture 3, 6, 12 or 15 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 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 simultaneously acquires data from each lead. Once the data is acquired, it can be analyzed, reviewed, stored, printed or transmitted. 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.

Technology:

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

The basic system prints 3, 6 12 or 15 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, such as communication options which is similar to the predicate device.

The subject MAC 7 Resting ECG Analysis System is similar to the predicate MAC 7 Resting ECG Analysis System (K203786), 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.

Determination of Substantial Equivalence:

The MAC 7 Lite Resting ECG Analysis System is substantially equivalent to the primary predicate MAC 7 Resting ECG Analysis System (K203786) and reference MAC VU360(K173830)/TC30(K210560) as described in the following table:

Specification	Predicate Product: MAC 7 Resting ECG Analysis System (K203786)	Proposed Product: MAC 7 Resting ECG Analysis System	Discussion of Differences
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 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.	The MAC 7 Resting ECG Analysis System is intended to acquire, analyze, display, and record electrocardiographic information from adult or pediatric populations. Basic system simultaneously acquires data from each lead. Once the data is acquired, it can be analyzed, reviewed, stored, printed or transmitted. Transmission and reception of ECG data and other clinical data to and from a central clinical information system is optional. The MAC 7 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.	Equivalent The change in the intended use statement reflects the flexibility of the system without impacting the core functionality or safety profile. The change in the intended use statement doesn't alter the substantial equivalence of the device.
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 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 healthcare practitioner. It is not intended as a sole means of diagnosis. • The interpretations of ECG offered by the device are only	Equivalent The updated language to include healthcare practitioner broadens the description to reflect current clinical practices without altering the device's safety or performance.

Specification	Predicate Product: MAC 7 Resting ECG Analysis System (K203786)	Proposed Product: MAC 7 Resting ECG Analysis System	Discussion of Differences
	• 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. • The device is indicated for use on adult and pediatric (birth through 21 years of age) populations.	significant when used in conjunction with a physician over-read 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.	
Contraindications	This MAC 7 Resting ECG Analysis System is not intended in the following manner: • During patient transport • With high-frequency surgical units • As an intra-cardiac application • As a sole means of diagnosis • As a vital signs physiological monitor	The MAC 7 Resting ECG Analysis System is not intended in the following manner: • During patient transport • With high-frequency surgical units • As an intra-cardiac application • As a sole means of diagnosis • As a vital signs physiological monitor	Identical
Patient Population	Adult and pediatric (birth through 21 years of age) populations Exception: The ACS (Acute Coronary Syndrome) interpretation is not executed when patient is younger than 16 years of age.	Adult and pediatric (birth through 21 years of age) populations Exception: The Lead reversal detection is not performed when patient age is ≤ 15 years. The ACS (Acute Coronary Syndrome) interpretation is not executed when patient is younger than 16 years of age.	Substantial Equivalent The subject device maintains full alignment with the adult and pediatric patient population indications of the predicate and reference devices. Age-related limitations for Lead Reversal Detection and ACS interpretation are consistent with those of the predicate/reference devices and do not alter the overall patient population equivalence

Specification	Predicate Product: MAC 7 Resting ECG Analysis System (K203786)	Proposed Product: MAC 7 Resting ECG Analysis System	Discussion of Differences
Environment of Use	Intended to be used under the direct supervision of a licensed healthcare practitioner in a hospital or medical professional's facility by trained operators	Intended to be used under the direct supervision of a licensed healthcare practitioner in a hospital or medical professional's facility by trained operators	Identical
Patient Acquisition Circuitry	Acquisition module integrated in the device and digitalizing functions provided by the device itself.	Acquisition module integrated in the device and digitalizing functions provided by the device itself.	Identical
Interpretive ECG Analysis	Yes	Yes	Identical
Critical Values	Critical Test Values identified and indicated: - Dialog Box - Printed Report User acknowledgement required to clear notification	Critical Test Values identified and indicated: - Dialog Box - Printed Report User acknowledgement required to clear notification	Identical
ECG Pacemaker Detection and HD Pace	Pacemaker pulses are detected digitally and maintained in a separate printable and viewable channel from the ECG waveform. All recorded leads are examined for pace pulse presence. For the acquisition module integrated in the device, software instructs 12SL to disable digital detection/reconstruction and accept all pace detections from acquisition module.	Pacemaker pulses are detected digitally and maintained in a separate printable and viewable channel from the ECG waveform. All recorded leads are examined for pace pulse presence. The separate pacemaker pulses channel is configurable for enable and disable (This on/off control is referred to as the HD Pace function). It is enabled by default. For the acquisition module integrated in the device, software instructs 12SL to disable digital detection/reconstruction and accept all pace detections from acquisition module.	Substantial Equivalent The change involves adding the ability to configure the separate pacemaker pulses channel to enable or disable detection, with the default setting being enabled. This modification provides additional flexibility without affecting the device's core functionality or safety.
Frequency Response	Limited by acquisition module. 0.04 to 150Hz	Limited by acquisition module. 0.04 to 300Hz. Default is 0.04 to 150Hz. It is software option controlled to support 0.04 to 300Hz.	Equivalent The proposed product expands bandwidth support from 150 to 300Hz as included in the K221321. There

Specification	Predicate Product: MAC 7 Resting ECG Analysis System (K203786)	Proposed Product: MAC 7 Resting ECG Analysis System	Discussion of Differences
			was no change in measurements or accuracy. The difference does not significantly affect substantial equivalence.
Prior ECG	Not supported	Prior ECG: Download to device, review on the screen and, print from the thermal printer the most recent previous ECG from the same patient.	The proposed MAC 7 can download the most recent previous ECG from the ECG management server for the same patient. This change has been verified to not significantly impact substantial equivalence.
Display type, size, resolution, and information	10 inch diagonal LCD, 1280 x 800 text and waveforms. Displays patient name, lead label, patient I.D., heart rate and date/time.	10 inch diagonal LCD, 1280 x 800 text and waveforms. Displays patient name, lead label, patient I.D., heart rate and date/time.	Identical
Battery Operation	Yes. Battery is rechargeable and user replaceable.	Yes. Battery is rechargeable and user replaceable,	Identical
Recorder Method	Thermal dot array	Thermal dot array	Identical
Number of Channels	Selectable 3, 6, or 12 channels with the addition of a pace annotation channel when detected	Selectable 3, 6, 12 or 15 channels with the addition of a pace annotation channel when detected	Equivalent The proposed device supports up to 15 channels due to the addition of three more electrodes and their corresponding signal acquisition.
Thermal Paper size	A4 or Letter format, thermal paper Z-fold	A4 or Letter format, thermal paper Z-fold	Identical
Network Printer Option	Not supported.	Support to print the report via the network printer.	The contents of the network printer reports are the same as thermal printer reports.

Specification	Predicate Product: MAC 7 Resting ECG Analysis System (K203786)	Proposed Product: MAC 7 Resting ECG Analysis System	Discussion of Differences
			The difference does not significantly affect substantial equivalence.
eDelivery	Not supported	Support to self register device and activate device by customer, after registration, customer will receive notification when new software version is available.	This is a service feature which make it easier to deliver new software version to customer, it does not affect substantial equivalence.
RSvP	Not supported	Support to upload service snapshot to remote server for service to do trouble shooting.	This is a service feature which make it easier to get device data for trouble shooting, it does not affect substantial equivalence.
Interpretation Statements	Provides interpretive statements from the 12SLTM analysis algorithm (v23.1) for 10 seconds ECG.	Provides interpretive statements from the 12SLTM analysis algorithm (v24) for 10 seconds ECG.	Equivalent Interpretive Statements are provided by 12SL (v24) ECG Analysis Program which was previously cleared under K221321.

Specification	Predicate Product: MAC 7 Resting ECG Analysis System (K203786)	Proposed Product: MAC 7 Resting ECG Analysis System	Discussion of Differences
Lead Reversal Detection	Limb lead reversal detection	Limb lead and chest lead reversal detection.	Equivalent The predicate device supports limb lead reversal detection using the 12SL (v23.1) algorithm. The proposed device extends this functionality to include both limb and chest lead reversal detection, utilizing the updated 12SL (v24) ECG Analysis Program, which was previously cleared under K221321. The primary change involves an algorithm update from 12SL (v23.1) to 12SL (v24), which allows the detection of additional lead reversals without altering the core substantial equivalence of the device. The MAC 7 interface presents the new detection capability, without compromising the device's safety and performance.
Acute Coronary Syndrome (ACS)	ACS provides interpretation statement for Acute Coronary Syndrome which is an abnormality detectable on the 12-lead ECG.	ACS provides interpretation statement for Acute Coronary Syndrome which is an abnormality detectable on the 12-lead ECG.	Identical

Specification	Predicate Product: MAC 7 Resting ECG Analysis System (K203786)	Proposed Product: MAC 7 Resting ECG Analysis System	Discussion of Differences
Dimensions and Weight	40 x 32 x 21 cm, 5.2 Kg	40 x 32 x 21 cm, 5.2 Kg	Identical

Substantial Equivalence to the Secondary reference device, MAC VU360 (K173830)

Feature / Function	Predicate Product: MAC VU360 Resting ECG Analysis System (K173830)	Proposed Product: MAC 7 Resting ECG Analysis System(V2)	Discussion of Differences
General			
ECG			
Patient Acquisition Circuitry	External acquisition module CAM CONNECT 14(CC14) connected through USB interface.	External acquisition module CAM CONNECT 14(CC14) connected through USB interface.	Equivalent The proposed device uses the same acquisition module as the reference device. The only difference is that the proposed product uses a standard USB port. These differences do not affect the substantial equivalence of the device.
ECG Channel	15	15	Identical

Substantial Equivalence to the Secondary reference device, TC30(K210560, PHILIPS)

Feature / Function	Predicate Product: PHILIPS PageWriter TC30 Cardiograph (K210560)	Proposed Product: MAC 7 Resting ECG Analysis System (V2)	Change Explanation / Notes
Prior ECG	**Last ECG:** Download to device, review on the screen and print from the cardiograph the most recent previous ECG from the same patient.	**Prior ECG:** Download to device, review on the screen and print from the thermal printer the most recent previous ECG from same patient.	**Equivalent** The proposed MAC 7 V2 system includes a "Prior ECG" feature, which allows the user to download, review, and print the most recent previous ECG from the same patient using the device's screen and thermal printer. This functionality is equivalent to the "Last ECG" feature in the reference device, PHILIPS, TC30 (K173830). The design of the Prior ECG feature uses current patient identification to query historical ECG data from the management system, enabling the retrieval and comparison of the most recent previous ECG with the current one from the same patient. The output of this process is consistent between the proposed and reference device. The only notable difference is in the labelling of the printed report, where MAC 7 V2 displays "Prior ECG" while TC30 uses "Previous ECG". The labelling difference does not alter the functionality, or performance of the feature. Therefore, the addition of this feature does not impact the substantial equivalence of the proposed device.

Performance Standards:	The MAC 7 Resting ECG Analysis System complies with the voluntary consensus standard ANSI/AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]and its relevant collateral and particular standards.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The MAC 7 Resting ECG Analysis System and its applications comply with voluntary standards. 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 - 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 subject MAC 7 Resting ECG Analysis System to be as safe, as effective, and perform as well as the legally marketed predicate device, MAC 7 Resting ECG Analysis System(K203786).