October 18, 2022

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

Re: K221321
Trade/Device Name: MAC 5 A4/ MAC 5 A5/ MAC 5 Lite Resting ECG Analysis System
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, DQK, DXH
Dated: September 16, 2022
Received: September 20, 2022

Dear Honghong 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. 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

Jennifer Shih
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)*

K221321

Device Name
MAC 5 A4/MAC 5 A5/MAC 5 Lite Resting ECG Analysis System

Indications for Use *(Describe)*

The MAC 5 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.

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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

I. SUBMITTER

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Date 510(k) Summary was Prepared:
April 29, 2022

II. DEVICE

Device Trade Name:	MAC 5 A4/MAC 5 A5/MAC 5 Lite 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:	DPS, DQK and DXH

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

Reference Device: ELI 380 12 lead Resting ECG (K142105)

Device Description:

The MAC 5 A4/MAC 5 A5/MAC 5 Lite 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, 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 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.

Indications for Use:

The MAC 5 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

Technology:

The MAC 5 A4/ MAC 5 A5/ MAC 5 Lite 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 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, such as communication options which is similar to the predicate device.

The MAC 5 A4/ MAC 5 A5/ MAC 5 Lite Resting ECG Analysis System is similar to the 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 5 A4/MAC 5 A5/MAC 5 Lite Resting ECG Analysis System is substantially equivalent to the predicate MAC 7 Resting ECG Analysis System (K203786) and the reference device ELI 380 – 12 Lead Resting ECG(K142105) as described in the following table:

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Specification	Predicate Product: MAC 7 Resting ECG Analysis System (K203786)	Proposed Product: MAC 5 A4/ MAC 5 A5/ MAC 5 Lite 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 5 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 5 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.	**Identical**
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. • The device is indicated for use on adult and pediatric (birth through 21 years of age) populations.	The MAC 5 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.	**Identical**

Specification	Predicate Product: MAC 7 Resting ECG Analysis System (K203786)	Proposed Product: MAC 5 A4/ MAC 5 A5/ MAC 5 Lite Resting ECG Analysis System	Discussion of Differences
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	This MAC 5 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	Adult and pediatric (birth through 21 years of age) populations	**Identical**
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	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. 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.	**Substantially Equivalent** The pacemaker pulses channel can be turned off by the user, according to preference. GE Healthcare considers the MAC 5 to be substantially equivalent to the predicate device

Specification	Predicate Product: MAC 7 Resting ECG Analysis System (K203786)	Proposed Product: MAC 5 A4/ MAC 5 A5/ MAC 5 Lite Resting ECG Analysis System	Discussion of Differences
Display type, size, resolution, and information	10 inch diagonal LCD, 1280 x 800 text and waveforms.	8.9 inch diagonal LCD, 892 x 558 text and waveforms.	**Substantially Equivalent** A more compact display is offered; there is no change to displayed information. GE Healthcare considers the MAC 5 to be substantially equivalent to the predicate device
Battery Operation	Yes. Battery is rechargeable and user replaceable.	Yes. Battery is rechargeable and user replaceable, a more compact battery is provided for the proposed compact design.	**Substantially Equivalent.** A compact battery for the proposed device. GE Healthcare considers the MAC 5 to be substantially equivalent to the predicate device
Recorder Method	Thermal dot array	- Thermal dot array - MAC 5 Lite: Offered without an integrated printer	- Identical for MAC 5 A4 and MAC 5 A5 which support thermal printing. MAC 5 Lite offered without an integrated printer. GE Healthcare considers the MAC 5 to be substantially equivalent to the predicate device
Thermal Paper size	A4 or Letter format, thermal paper Z-fold	- models with printers, A4, A5, Letter format, or thermal paper Z-fold	**Substantially Equivalent** Only different thermal paper from predicate device. GE Healthcare considers the MAC 5 to be substantially equivalent to the predicate device

Specification	Predicate Product: MAC 7 Resting ECG Analysis System (K203786)	Proposed Product: MAC 5 A4/ MAC 5 A5/ MAC 5 Lite Resting ECG Analysis System	Discussion of Differences
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. GE Healthcare considers the MAC 5 to be substantially equivalent to the predicate device
Pharmacy Option	Not supported.	New data entry feature convenience to enter clinical trial data along with the patient data which could be included in the report.	The new data entry feature is for convenience of additional data appended to the record; it is available on similar devices as a user preference. GE Healthcare considers the MAC 5 to be substantially equivalent to the predicate device
Interpretation Statements	Provides interpretive statements from the 12SL™ analysis algorithm (v23.1) for 10 seconds ECG.	Provides interpretive statements from the 12SL™ analysis algorithm (v24) for 10 seconds ECG.	**Substantially Equivalent** No changes to the interpretive statements of the 12SL™ analysis algorithm (v24) under K141963 and compared to the predicate device. The changes introduced with the 12SLTM (v24) do not impact the ECG analysis (measurement or accuracy) of the algorithm. GE Healthcare considers the MAC 5 to be substantially equivalent to the predicate device

Specification	Predicate Product: MAC 7 Resting ECG Analysis System (K203786)	Proposed Product: MAC 5 A4/ MAC 5 A5/ MAC 5 Lite Resting ECG Analysis System	Discussion of Differences
Dimensions and Weight	40 x 32 x 21 cm, 5.2 Kg	- MAC 5 A4: 31.5 x 36.0 x 11.4 cm, 3.6 Kg - MAC 5 A5: 31.5 x 26.0 x 10.8 cm, 3.0 Kg - MAC 5 Lite: 30.9 x 26.0 x 8.4 cm, 2.0 Kg	**Substantially Equivalent** The proposed product has a more compact design from predicate device. GE Healthcare considers the MAC 5 to be substantially equivalent to the predicate device

Substantial Equivalence to the reference device, ELI 380 (K142105)

Specification	Reference device: ELI 380 K142105	Proposed MAC 5 A4/ MAC 5 A5/ MAC 5 Lite Resting ECG Analysis System	Discussion of Differences
Frequency Response	0.05-300Hz	0.04-300Hz	Substantially equivalent The 300Hz filter is being added to the MAC 5 A4/ MAC 5 A5/ MAC 5 Lite Resting ECG. The 300Hz frequency response feature is substantially equivalent to the reference device, ELI 380. The technology for the delivery of 300Hz low pass filter, is not novel or new to the Resting ECG. The 300Hz filter feature is available for pediatric patients. The addition of 300Hz low-pass filter will present waveforms with high frequency elements. Verification evidence demonstrates that the performance and specifications of the 300Hz filter feature on the MAC 5 A4/ MAC 5 A5/ MAC 5 Lite Resting ECG Analysis System are equivalent to those on the ELI 380. The 300 Hz filter feature on the MAC 5 A4/ MAC 5 A5/ MAC 5 Lite Resting ECG Analysis System does not differ in its technological characteristics, function, or performance and therefore, it is substantially equivalent. The lower limit of 0.04Hz frequency bandwidth is identical to the predicate device, MAC 7 therefore, it is substantial equivalent The 300Hz bandwidth feature for MAC 5 shall include the MAC 7 (K203786) and MAC VU 360 (K173830) as a bundle as they all developed on the same software platform. Verification evidence demonstrates that the performance and specifications of the 300Hz filter feature on the MAC 7 and MAC VU 360 are equivalent to the MAC 5.

Performance Standards:	The MAC 5 A4/ MAC 5 A5/ MAC 5 Lite Resting ECG Analysis System complies with the voluntary consensus standard ANSI/AAMI ES60601-1:2005/(R)2012 and its relevant collateral and particular standards.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The MAC 5 A4/ MAC 5 A5/ MAC 5 Lite 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 5 Resting ECG Analysis System, did not require clinical studies to support substantial equivalence.
Conclusion:	GE Healthcare considers the MAC 5 A4/ MAC 5 A5/ MAC 5 Lite 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.