September 18, 2018

GE Medical Systems Information Technologies, Inc.
Marcella Entwisle
Regulatory Affairs Leader
9900 West Innovation Drive
Wauwatosa, Wisconsin 53226

Re: K173830
Trade/Device Name: MAC VU360 Resting ECG Analysis System
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, DQK, DXH
Dated: August 17, 2018
Received: August 20, 2018

Dear Marcella Entwisle:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica E. Paulsen -S

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)*
K173830

Device Name
MAC VU360 Resting ECG Analysis System

Indications for Use *(Describe)*

The MAC VU360 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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510(k) Summary

Section 5: 510(k) Summary

In accordance with 21 CFR Part 807.92(a)(1) the following summary of information is provided:

Date: September 17, 2018

Submitter:
GE Medical Systems *Information Technologies*, Inc.
9900 Innovation Drive
Wauwatosa, WI 53226

Primary Contact:
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PRODUCT IDENTIFICATION

Device Trade Name: MAC VU360 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

Product Codes: DPS, DQK, and DXH

Predicate Device(s): ELI™ 380 Resting Electrocardiograph (K142105)

Reference Device(s):
MAC™ 5500 HD Resting ECG Analysis System (K073625)
12SL™ (v23) ECG Analysis Program (K141963)

Device Description:

The MAC VU360 Resting ECG Analysis System is a mobile electrocardiograph designed to acquire, analyze, display, and record ECG signals from surface ECG electrodes.

The MAC VU360 can capture 3, 6, 12, or 15 lead electrocardiograms, provide interpretive analysis, and print reports. The MAC VU360 is indicated for use on adult and pediatric (birth through 21 years of age) populations.

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 can also optionally display data from external systems which provide web or Citrix content.

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

Intended Use /

The MAC VU360 is intended to be a high-performance, multichannel resting electrocardiograph. As a resting electrocardiograph, the MAC VU360 simultaneously acquires data from each lead. Once the data is acquired, it can be analyzed, reviewed, stored, printed or transmitted. It is a device primarily intended for use in hospitals, but may be used in medical clinics and offices of any size. The MAC VU360 is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or medical professional's facility.

Indications for Use /

The MAC VU360 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.

Contraindications:

The MAC VU360 Resting ECG Analysis System is not intended for use 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

Technology:

The MAC VU360 employs the same fundamental scientific technology, basic design, construction, materials, energy source, control mechanism, operating principles as the predicate device ELI 380 and the MAC 550 HD in acquiring, analyzing, recording, displaying and printing ECG data for both adult and pediatric populations. The MAC VU360 utilizes the 12SL Algorithm as does the MAC 5500 HD.

The basic system prints 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 MAC VU360 is similar to the ELI 380 Resting ECG Analysis System, K142105, 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.

For more on the predicate device comparison refer to Section 12 of this submission.

Performance Standards:

The MAC VU360 Resting ECG Analysis System complies with the voluntary standards as detailed in Section 9 of this submission.

Sterilization:

The MAC VU360 Resting ECG Analysis System does not require sterilization.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The MAC VU360 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 (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)

Summary of Clinical Tests:

The subject of this premarket submission, MAC VU360 Resting ECG Analysis System, did not require clinical studies to support substantial equivalence.

Conclusion:

GE Healthcare considers the MAC VU360 Resting ECG Analysis System to be as safe, and as effective, and performance is substantially equivalent to the predicate device, ELI 380 Resting Electrocardiograph.