December 8, 2020

GE Medical Systems Information Technologies, Inc.
Camille Vidal
Director Regulatory Affairs Strategy
9900 W Innovation Dr.
Wauwatosa, Wisconsin 53226

Re: K202189
Trade/Device Name: Graffiti
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: November 6, 2020
Received: November 9, 2020

Dear Camille Vidal:

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
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202189

Device Name
Graffiti

Indications for Use *(Describe)*
Graffiti is a software solution that includes integrated team collaboration tools and a smart assistant for the retrieval and display of patient record information and data whenever needed by a Healthcare Provider (HCP). The smart assistant also includes analytical functions to enable user-defined notifications.

When the Parameter-Based Notification feature is enabled, the smart assistant is also intended to keep track of changes in patient information, data and status.

Graffiti may be used by members of the patient care team while on duty physically at the hospital or while on call, which could be remotely.

Graffiti is not intended to replace the Electronic Medical Record system or any patient monitoring or central station devices.

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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510(k) Summary

K202189

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

Date:	November 6, 2020
Submitter:	GE Medical Systems Information Technologies, LLC 9900 W Innovation Dr. Wauwatosa, WI 53226, USA
Primary Contact Person:	Camille Vidal Director of Regulatory Affairs Strategy GE Healthcare 240-280-5356 Camille.Vidal@ge.com
Device Trade Name:	Graffiti™
Common/Usual Name:	Programmable diagnostic computer
Classification Names: Product Code:	21 CFR 870.1425 Programmable diagnostic computer Class II DQK
Predicate Device(s):	Philips IntelliVue GuardianSoftware (K180534)
Device Description:	Graffiti is a software-only solution that interfaces with a healthcare facility's information system to retrieve, manage and display patient information on a handheld mobile device. It integrates care team collaboration tools and a smart virtual assistant to retrieve patient data and information from the hospital information systems through a conversational voice or text interface. The smart assistant also includes analytical functions to enable user-defined custom notifications including time-based, event-based and parameter-based notifications. When the condition for notification is met, Graffiti produces a notification on the user smartphone, thereby helping the user improve her situational awareness.

	Graffiti is intended to operate on customer supplied smartphones.
Indications for use	Graffiti is a software solution that includes integrated team collaboration tools and a smart assistant for the retrieval and display of patient record information and data whenever needed by a Healthcare Provider (HCP). The smart assistant also includes analytical functions to enable user-defined notifications. When the Parameter-Based Notification feature is enabled, the smart assistant is also intended to keep track of changes in patient information, data and status. Graffiti may be used by members of the patient care team while on duty physically at the hospital or while on call, which could be remotely. Graffiti is not intended to replace the Electronic Medical Record system or any patient monitoring or central station devices.
Comparison to Predicate Device:	Both Graffiti and its predicate device are clinical information software that display patient information and data including vitals and lab results on a mobile device, for access whenever it is needed by the care team. Both systems are intended to be used by healthcare providers caring for patients in a hospital or an acute care facility. Graffiti and its predicate have the same intended use. Both systems interface with the facility information system to retrieve and display patient information and data such as labs. Vitals presented in Graffiti come from validated values recorded in the EMR, while GuardianSoftware pulls data from patient monitoring systems at regular intervals. Both devices include a customizable rule engine that produces notifications to the user when the conditions for notification are fulfilled. The main technological difference between Graffiti and its predicate, is in how the user interacts with the device. Graffiti includes a digital personal assistant “Bot” which can retrieve data or set notifications at the user request. Graffiti’s conversational voice or text interface facilitate access to data stored in the hospital information system instead of the user having to go through the traditional menu selection interface.
Clinical and Non-Clinical Tests	<u>Summary of Non-Clinical Tests:</u> The following quality assurance measures were applied to the development of Graffiti: ▪ Risk Analysis

	▪ Requirements Reviews ▪ Design Reviews ▪ Software Verification ▪ Software Validation ▪ Usability Testing Design verification and validation testing was performed to confirm that software and user requirements have been met. In particular, bench testing was conducted to confirm that the conversational interface can accurately translate user conversational requests into executable data requests or notification requests. Usability testing demonstrate that intended users can successfully operate the system.
Conclusion:	Graffiti with Parameter Based Notifications has the same intended use as the predicate device. The main difference in technological characteristics is in the conversational voice or text interface of Graffiti. Human factor and usability evaluation shows that the intended users can safely use Graffiti through its conversational voice or text interface. Graffiti is substantially equivalent to IntelliVue GuardianSoftware.