February 17, 2022

GE Healthcare Information Technologies, Inc.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
Saint Paul, Minnesota 55114

Re: K213972
Trade/Device Name: Mac-Lab Recording Systems, CardioLab Recording Systems, ComboLab Recording Systems, MLCL Client Software
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: December 18, 2021
Received: December 20, 2021

Dear Prithul Bom:

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

LCDR Stephen Browning
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)*
K213972

Device Name

Mac-Lab™

Indications for Use *(Describe)*

The Mac-Lab system is indicated for use on patients of all ages when a physician determines that a patient would benefit from a hemodynamic procedure. Mac-Lab may be used in a variety of hospital and clinical settings to record hemodynamic data and measurements, which may then be displayed, filtered, digitized, amplified, measured, and calculated and/or transmitted for storage, analysis and viewing at distributed locations.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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510(k) Number *(if known)*
K213972

Device Name

CardioLab™

Indications for Use *(Describe)*

The CardioLab system is indicated for use on patients of all ages when a physician determines that a patient would benefit from an electrophysiology procedure. CardioLab may be used in a variety of hospital and clinical settings to record electrophysiology data and measurements, which may then be displayed filtered, digitized, amplified, measured, and calculated and/or transmitted for storage, analysis and viewing at distributed locations.

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)

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510(k) Number *(if known)*
K213972

Device Name

ComboLab

Indications for Use *(Describe)*

The ComboLab system is indicated for use on patients of all ages when a physician determines that a patient would benefit from either a hemodynamic or electrophysiology procedure. ComboLab may be used in a variety of hospital and clinical settings to record hemodynamic and electrophysiology data and measurements, which may then be displayed, filtered, digitized, amplified, measured, calculated and/or transmitted for storage, analysis and viewing at distributed locations.

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)

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Indications for Use

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213972

Device Name

MLCL Client Software

Indications for Use *(Describe)*

The MLCL Client Software is indicated for use on patients of all ages when a physician determines that a patient would benefit from either a hemodynamic or electrophysiology procedure. MLCL Client Software may be used in a variety of hospital and clinical settings to record, document and/or review hemodynamic and electrophysiology data and measurements, which may then be displayed, filtered, digitized, amplified, measured, calculated and/or transmitted for storage, analysis and viewing at distributed locations.

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)

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510(k) Summary

This 510(k) Summary of Safety and Effectiveness information is submitted in accordance with 21 CFR 807.87(h).

Date:	06 October 2021
Submitter:	GE Healthcare GE Medical Systems Information Technologies, Inc 9900 West Innovation Drive Wauwatosa, WI 53226 USA
Primary Contact Person:	Mr. James T. Turner, MS, RAC Sr. Regulatory Affairs Manager GE Healthcare (GE Medical Systems Information Technologies, Inc.) Telephone: 414 491 9895 Email: james.t.turner@ge.com
Secondary Contact Person:	Mr. Philip Malca Regulatory Affairs Director GE Healthcare Telephone: 33(0) 1 3070 4207 Email: philip.malca@ge.com
Device Trade Name: (Brand)	Mac-Lab™ CardioLab™ ComboLab MLCL Client Software
Common/Usual Name:	Hemodynamic and Electrophysiology (EP) Recording Systems
Device Classification	Class II
Regulation Number: Product Code:	21 CFR 870.1425 – Computer, Diagnostic Programmable DQK
Predicate Device:	K130626 – GE's Mac-Lab, CardioLab, ComboLab, SpecialsLab Recording Systems v6.9.5
Reference Device:	K191008 – Boston Scientific's iLab Polaris Multi-Modality Guidance System
Marketed Device(s):	Mac-Lab, CardioLab and ComboLab AltiX, and MLCL Client Software AltiX are modifications of the predicate device. The primary changes are related to the introduction of a new EP amplifier and the inclusion of Boston Scientific's Diastolic Hyperemia-Free Ratio (DFR) technology.

Device Description:	Mac-Lab and CardioLab are hemodynamic and electrophysiology (EP) recording systems, respectively. A third configuration, ComboLab, allows the user to access both CardioLab and Mac-Lab functions, though only one application may be accessed at a time. These devices are used during interventional and related procedures to process, display and record hemodynamic and electrophysiology (EP) data depending on the type of procedure performed. The data is acquired and displayed real-time for multiple physiological parameters to allow the user to view the data. The data may be entered manually through the use of a dedicated keyboard/mouse/barcode scanner or acquired via procedural information devices, imaging devices and interfaced data devices, and may then be displayed, filtered, digitized, amplified, measured, and calculated. A fourth configuration, called the MLCL Client Software, is the core Mac-Lab and CardioLab application software which is available for installation on a stand-alone workstation (i.e. outside of the Mac-Lab/CardioLab/ComboLab acquisition systems described above). The MLCL Review Software may be used to record, document, analyze, store and transmit data, including data from supported patient monitors. Mac-Lab, CardioLab, ComboLab and the MLCL Client Software provide the ability to transmit patient data for storage, analysis and viewing at distributed locations within a clinical facility via network connectivity but may also be used stand-alone (not connected to a network). Mac-Lab, CardioLab, ComboLab and the MLCL Client Software are not intended to be used as a patient monitor and are not intended to alert the licensed health care practitioner of a change in patient status.
Intended Use:	*Mac-Lab™* The Mac-Lab system is intended for recording hemodynamic clinical data, and may then be displayed, filtered, digitized, amplified, measured, calculated and/or transmitted for storage, analysis and viewing at distributed locations. *CardioLab™* The CardioLab system is intended for recording electrophysiology clinical data, and may then be displayed, filtered, digitized, amplified, measured, calculated and/or transmitted for storage, analysis and viewing at distributed locations. *ComboLab* The ComboLab system is the combination of both the Mac-Lab and CardioLab systems intended for recording hemodynamic and electrophysiology clinical data, respectively and may then be displayed, filtered, digitized, amplified, measured, calculated and/or transmitted for storage, analysis and viewing at distributed locations.

	MLCL Client Software The MLCL Client Software is intended for recording, documenting and/or reviewing clinical data for hemodynamic and electrophysiology procedures and may then be displayed, filtered, digitized, amplified, measured, calculated and/or transmitted for storage, analysis and viewing at distributed locations.
Indications for Use:	*Mac-Lab™* The Mac-Lab system is indicated for use on patients of all ages when a physician determines that a patient would benefit from a hemodynamic procedure. Mac-Lab may be used in a variety of hospital and clinical settings to record hemodynamic data and measurements, which may then be displayed, filtered, digitized, amplified, measured, and calculated and/or transmitted for storage, analysis and viewing at distributed locations. *CardioLab™* The CardioLab system is indicated for use on patients of all ages when a physician determines that a patient would benefit from an electrophysiology procedure. CardioLab may be used in a variety of hospital and clinical settings to record electrophysiology data and measurements, which may then be displayed filtered, digitized, amplified, measured, and calculated and/or transmitted for storage, analysis and viewing at distributed locations. *ComboLab* The ComboLab system is indicated for use on patients of all ages when a physician determines that a patient would benefit from either a hemodynamic or electrophysiology procedure. ComboLab may be used in a variety of hospital and clinical settings to record hemodynamic and electrophysiology data and measurements, which may then be displayed, filtered, digitized, amplified, measured, calculated and/or transmitted for storage, analysis and viewing at distributed locations. *MLCL Client Software* The MLCL Client Software is indicated for use on patients of all ages when a physician determines that a patient would benefit from either a hemodynamic or electrophysiology procedure. MLCL Client Software may be used in a variety of hospital and clinical settings to record, document and/or review hemodynamic and electrophysiology data and measurements, which may then be displayed, filtered, digitized, amplified, measured, calculated and/or transmitted for storage, analysis and viewing at distributed locations.
Technology:	Mac-Lab, CardioLab and ComboLab AltiX employ the same fundamental scientific technology, basic design, construction, materials, energy source, control mechanism, and operating principles as the predicate

devices, Mac-Lab, CardioLab and Combolab v6.9.5, in recording and displaying hemodynamic and electrophysiology data.

The basic systems can acquire data from a variety of inputs which may then be displayed, filtered, digitized, amplified, measured and calculated. These systems also provide the ability to transmit patient data for storage, analysis and viewing, or may be used in a stand-alone (non-networked) mode.

The table below summarizes the substantive feature/technological differences between the predicate device and the proposed device:

Configuration	Predicate Device Features	Proposed Device Features
Mac-Lab	▪ Diastolic Hyperemia-Free Ratio (DFR) technology not supported	▪ Includes Diastolic Hyperemia-Free Ratio (DFR) technology
CardioLab	▪ CLAB II Plus EP Amplifier ▪ Utilizes only 3rd party ECG trunk cables ▪ Cycle Length supported on channels 1 & 2 only ▪ 1 real-time window available ▪ 2 review windows available ▪ ClearMatch/Signal Overlay not supported	▪ CLAB II Plus EP Amplifier or Prucka 3 EP Amplifier, ECG ▪ Includes GE ECG trunk cables ▪ Cycle Length supported on up to 10 channels ▪ 2 real-time windows available ▪ 5 review windows available ▪ Includes ClearMatch/Signal Overlay feature

ComboLab utilizes the combined hardware and software features noted in the table above for both CardioLab and Mac-Lab on a single platform. The MLCL Client Software utilizes the combined software features from the table above but does not include the hardware features (Prucka 3 EP amplifier and ECG trunk cables).

The device's technological characteristics do not create new questions of safety or effectiveness, and did not introduce any new risks/hazards, warnings or limitations.

Data Supporting Safety & Efficacy:

Summary of Non-Clinical Tests:

The subject device and its applications have been independently tested and conforms to voluntary standards:

- IEC 60601-1 Ed. 3.1 applicable Collateral and Particular Standards,
- IEC 62366:2015
- IEC 62304:2006/A1:2015
- IEC 82304-1:2016-10
- ISO 15223-1:2016
- IEC 60601-2-27:2011
- IEC 60601-2-34:2011

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Technical Design Reviews
- Formal Design Reviews

	▪ Testing on unit level (Module verification) ▪ Integration testing (System verification) ▪ Performance testing (Verification) ▪ System Testing: - Safety testing (Verification) - System performance testing (Verification) - Simulated use testing (Validation) The testing and results did not raise new or different questions of safety and effectiveness than those associated with the predicate device. Software documentation for a "Moderate" level of concern was also considered as a point of comparison to the predicate device. The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective and performs as well as the legally marketed predicate device. <u>Summary of Clinical Tests:</u> The subject of this premarket submission, Mac-Lab, CardioLab and ComboLab AltiX, did not require clinical studies to support comparability to the predicate device.
Conclusion:	GE Healthcare considers the Mac-Lab, CardioLab and ComboLab AltiX to be as safe, as effective, and performance is comparable to the predicate device(s). The changes associated with the Mac-Lab, CardioLab and ComboLab AltiX and the MLCL Client Software do not create a new Intended Use and represent similar technological characteristics, with no impact on the control mechanisms, operating principle, and energy type. GE's quality system's design verification, and risk management processes did not identify any new questions of safety or effectiveness, hazards, unexpected results, or adverse effects stemming from the changes to the predicate. Based on development under GE Healthcare's quality system, the successful system and software verification and validation testing, conformance to standards, and additional engineering bench testing demonstrates that the subject device is comparable to, and hence as safe and as effective for its Intended Use, as the legally marketed predicate and reference devices.