December 12, 2024

GE Medical Systems Information Technologies, Inc.
James Turner
Sr. Regulatory Affairs Manager
3114 N Grandview Blvd
Waukesha, Wisconsin 53188

Re: K243540
Trade/Device Name: Mac-Lab (AltiX AI.i); CardioLab (AltiX AI.i); ComboLab (AltiX AI.i); MLCL Client Software (AltiX AI.i)
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: November 15, 2024
Received: November 15, 2024

Dear James Turner:

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,

Stephen C. Browning -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243540

Device Name

Mac-Lab (AltiX AI.i);
CardioLab (AltiX AI.i);
ComboLab (AltiX AI.i);
MLCL Client Software (AltiX AI.i)

Indications for Use *(Describe)*

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 and/or transmitted.

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 and/or transmitted.

ComboLab:
The ComboLab system is indicated for use on patients of all ages when a physician determined 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 and/or transmitted.

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.

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 – K243540

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

Date:	15 November 2024
Submitter:	GE HealthCare GE Medical Systems Information Technologies, Inc. 3114 N Grandview Blvd Waukesha, WI 53188 USA
Primary Contact Person:	Mr. James T. Turner, MS Sr. Regulatory Affairs Manager GE HealthCare (GE Medical Systems Information Technologies, Inc.) Telephone: 414 491 9895 Email: james.t.turner@gehealthcare.com
Secondary Contact Person:	Ms. Michelle Huettner Regulatory Affairs Director GE HealthCare Telephone: 901 558 8035 Email: michelle.huettner@gehealthcare.com
Device Trade Name: (Brand)	Mac-Lab™ CardioLab™ ComboLab MLCL Client Software
Model/Version	AltiX AI.i
Common/Usual Name:	Hemodynamic and Electrophysiology (EP) Recording Systems
Classification Name: Product Code:	21 CFR 870.1425 – Computer, Diagnostic Programmable DQK
Predicate Device:	K213972 – Mac-Lab, CardioLab, ComboLab & MLCL Client Software AltiX
Reference Devices:	K202943 – OptoMonitor3 (Opsens, Inc., now part of Haemonetics) K173381 – Nexxis OR (Barco N.V.)

Marketed Devices:	Mac-Lab, CardioLab, ComboLab and MLCL Client Software AltiX AI.i are modifications of the cleared predicate devices (K213972). The primary changes are related to the introduction of a new version of the EP amplifier, updates to signal filtering and gain, inclusion of opSens/ HAEMONETICS Diastolic Pressure Ratio (dPR™), introduction of PruckaStream, and utilization of Barco Nexxis OR™ for video distribution.
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 <u>not</u> intended to be used as a patient monitor and are <u>not</u> intended to alert the licensed health care practitioner of a change in patient status.
Intended Use:	The intended use of the subject devices have not changed from that of the cleared predicate devices. *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 and/or transmitted.

	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 and/or transmitted. *ComboLab* The ComboLab system is indicated for use on patients of all ages when a physician determined 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 and/or transmitted. *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:	The indications for use of the subject devices have not changed from that of the cleared predicate devices. *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

<table>
<tr><td></td><td>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.</td></tr>
<tr><td>Technology:</td><td>The Mac-Lab, CardioLab and ComboLab Recording Systems AltiX AI.i employ the same fundamental scientific technology, basic design, construction, materials, energy source, control mechanism, and operating principles as the predicate devices, Mac-Lab, CardioLab, Combolab and MLCL Client Software AltiX, 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.

The table below summarizes the substantive feature/technological differences between the predicate and proposed devices:
<table>
<tr><th>Configuration</th><th>Predicate Device Features</th><th>Proposed Device Features</th></tr>
<tr><td>Mac-Lab</td><td>• Diastolic Pressure Ratio (dPR) not supported on the device</td><td>• Diastolic Pressure Ratio (dPR) incorporated in the Mac-Lab software</td></tr>
<tr><td>CardioLab</td><td>• Only a 128-channel option is available for the Prucka 3 EP amplifier
• Does not support digital waveform streaming to external, only analog output, binary or CSV data extraction
• Included high and low pass filters, powerline filters and gain settings</td><td>• Provides an option to use either a 128- or 64-channel Prucka 3 EP amplifier
• PruckaStream makes original digital signal data available from the EP amplifier and allows data return
• Expanded customizations, settings and capabilities to help minimize noise and provide better signal morphology</td></tr>
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<tr><td>Mac-Lab & CardioLab</td><td>• Utilizes video distribution via HDMI splitters and switches to replicate displays</td><td>• Allows an alternate video distribution system, Barco Nexxis OR, to route video signals and allows use of single command inputs (mouse, keyboard) for connected devices</td></tr>
</table>
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 (64-Channel Prucka 3 EP amplifier).
The device's technological characteristics do not create new questions of safety or effectiveness,
</td></tr>
<tr><td>Data Supporting Safety & Efficacy:</td><td>
<u>Summary of Non-Clinical Tests:</u>
The subject devices and applications have been independently tested and conform to the following voluntary standards:

IEC 60101-1 Ed 3.2 2020-08 CONSOLIDATED VERSON
IEC 60601-1-2 Ed 4.1 2020-09 CONSOLIDATED VERSION
IEC 60601-2-27 Ed 3.0 2011-03
IEC 60601-2-34 Ed 3.0 2011-05

In addition, the following standards were used to analyze the effectiveness of specific features and functionality of the subject devices even though the standards were not applicable in full:

IEC 80601-2-30 Ed 2.0 2018-03
IEC 80601-2-55 Second Edition 2018-02
IEC 80601-2-56 Second Edition 2017-03
IEC 80601-2-61 Second Edition 2017-12 (Corrected version)

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)

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	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 "Basic" 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. Summary of Clinical Tests: The subject of this premarket submission, Mac-Lab, CardioLab, ComboLab and MLCL Client Software AltiX AI.i, did not require clinical studies to support substantial equivalence.
Conclusion:	GE HealthCare considers Mac-Lab, CardioLab, ComboLab and MLCL Client Software AltiX AI.i to be as safe, as effective, and performance is comparable to the predicate device(s). The changes associated with the Mac-Lab, CardioLab, ComboLab and MLCL Client Software AltiX AI.i 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 HealthCare'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.