July 16, 2025

GE Medical Systems Ultrasound and Primary Care Diagnostics
Lee Bush
Regulatory Affairs Director
3200 N Grandview Blvd
Waukesha, Wisconsin 53188

Re: K251342
Trade/Device Name: EchoPAC Software Only / EchoPAC Plug-in
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: April 30, 2025
Received: April 30, 2025

Dear Lee Bush:

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,

Jessica Lamb, Ph.D.
Assistant Director, Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
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.

510(k) Number *(if known)*
K251342

Device Name
EchoPAC Software Only / EchoPAC Plug-in

Indications for Use *(Describe)*
EchoPAC Software Only / EchoPAC Plug-in is intended for diagnostic review and analysis of ultrasound images, patient record management and reporting, for use by, or on the order of a licensed physician. EchoPAC Software Only / EchoPAC Plug-in allows post-processing of raw data images from GE ultrasound scanners and DICOM ultrasound images.
Ultrasound images are acquired via B (2D), M, Color M modes, Color, Power, Pulsed and CW Doppler modes, Coded Pulse, Harmonic, 3D, and Real time (RT) 3D Mode (4D).
Clinical applications include: Fetal/Obstetrics; Abdominal (including renal and GYN); Urology (including prostate); Pediatric; Small organs (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Transesophageal (TEE); Musculo-skeletal Conventional; Musculo-skeletal Superficial; Transrectal (TR); Transvaginal (TV); Intraoperative (vascular); Intra-Cardiac; Thoracic/Pleural and Intra-Luminal.

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

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

510(k) Number: K251342

Date: July 16, 2025

Submitter: GE Medical Systems Ultrasound and Primary care Diagnostics, LLC
3200 N Grandview Blvd
Waukesha, WI 53188
US

Manufacturer: GE Vingmed Ultrasound AS
Strandpromenaden 45
3193 Horte, Norway

Primary Contact Person: Lee Bush
Regulatory Affairs Director
GE Healthcare
T:(262)309-9429

Secondary Contact Person: Charlotte Jørgensen
Senior Regulatory Affairs Leader
GE Healthcare

Device Trade Name: EchoPAC Software Only / EchoPAC Plug-in

Common/Usual Name: Workstation Software for ultrasound image review, analysis and reporting

Classification Names: Class II
Product Code(s): QIH (primary), LLZ (secondary)
Automated Radiological Image Processing Software, 21 CFR 892.2050, QIH
Picture Archiving and Communications System, 21 CFR 892.2050, LLZ

Primary Predicate Device: EchoPAC Software Only / EchoPAC Plug-in (K220940),
Reference Device(s): EchoPAC Software Only / EchoPAC Plug-in (K200852),
EchoPAC Software Only / EchoPAC Plug-in (K170847),
Vivid E95, (K181685), Vivid iq (K2432260), Voluson Expert 22/20/18 (K231965), Logiq E10 (K173555)

Classification Names:	Class II
Product Code(s):	QIH (primary), LLZ, IYN, IYO, ITX (secondary) Automated Radiological Image Processing Software, 21 CFR 892.2050, QIH Picture Archiving and Communications System, 21 CFR 892.2050, LLZ Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550, 90-IYN; Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO; Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX

Device Description:

EchoPAC Software Only / EchoPAC Plug-in provides image processing, annotation, analysis, measurement, report generation, communication, storage and retrieval functionality to ultrasound images that are acquired via the GE Healthcare Vivid family of ultrasound systems, as well as DICOM images from other ultrasound systems. EchoPAC Software Only will be offered as SW only to be installed directly on customer PC hardware and EchoPAC Plug-in is intended to be hosted by a generalized PACS host workstation. EchoPAC Software Only / EchoPAC Plug-in is DICOM compliant, transferring images and data via LAN between systems, hard copy devices, file servers and other workstations.

Intended Use/Indication for Use:

EchoPAC Software Only / EchoPAC Plug-in is intended for diagnostic review and analysis of ultrasound images, patient record management and reporting, for use by, or on the order of a licensed physician. EchoPAC Software Only / EchoPAC Plug-in allows post-processing of raw data images from GE ultrasound scanners and DICOM ultrasound images.

Ultrasound images are acquired via B (2D), M, Color M modes, Color, Power, Pulsed and CW Doppler modes, Coded Pulse, Harmonic, 3D, and Real time (RT) 3D Mode (4D).

Clinical applications include: Fetal/Obstetrics; Abdominal (including renal and GYN); Urology (including prostate); Pediatric; Small organs (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Transesophageal (TEE); Musculo-skeletal Conventional; Musculo-skeletal Superficial; Transrectal (TR); Transvaginal (TV); Intraoperative (vascular); Intra-Cardiac; Thoracic/Pleural and Intra-Luminal.

Technology:

EchoPAC Software Only / EchoPAC Plug-in employs the same fundamental scientific technology as its predicate device.

Determination of Substantial Equivalence:

Comparison to Predicates:
The proposed EchoPAC Software Only / EchoPAC Plug-in is substantially equivalent to the predicated devices. The following is an overview of the differences between the proposed EchoPAC Software Only / EchoPAC Plug-in and the predicate EchoPAC Software Only / EchoPAC Plug-in (K220940).

Indications for Use
The proposed EchoPAC Software Only / EchoPAC Plug-in and predicate EchoPAC Software Only / EchoPAC Plug-in (K220940) have identical clinical indications for use.

Software Features/Functionality:

- **4D Auto LHQ,** combining two predicate tools, 4D Auto LAQ and 4D Auto LVQ, both previously available in predicate EchoPAC Software Only / EchoPAC Plug-in (K220940).

- **4D Auto MVQ,** available in predicate EchoPAC Software Only / EchoPAC Plug-in (K220940), is updated with 4D ColorFlow capabilities.

- **4D Auto TVQ,** available in predicate EchoPAC Software Only / EchoPAC Plug-in (K220940), is updated with 4D ColorFlow capabilities.

- **AI Cardiac Auto Doppler**: AI based algorithm for auto-tracing of additional doppler spectrums added to the predicate Cardiac Auto Doppler available in the predicate EchoPAC Software Only / EchoPAC Plug-in (K220940), introducing additional heart valve related measurements compared to the predicate Spectrum Recognition algorithm available in EchoPAC Software Only / EchoPAC Plug-in (K220940).

- **TSP Height:** Tool used to visualize and measure the distance between the mitral anulus and the tip of the catheter during guided transeptal puncture procedures. Substantially equivalent to caliper distance measurement available in predicate EchoPAC Software Only / EchoPAC Plug-in (K220940).

- **LAA Device compression**: A manual measurement and calculation tool that allows manual caliper measurements of the width and the length of the Left Atrial Appendage, calculating compression in percentage on a chosen LAA-closure device size. This helps with LAA device sizing. Measurements are based on the regular caliper tool available in predicate EchoPAC Software Only / EchoPAC Plug-in (K220940).

- **LAA Sizing Tool:** Used for tracing the Left Atrial Appendage lumen and for measuring basic parameters within the traced area. Based on ROI tracing and area measurement tool in predicate EchoPAC Software Only / EchoPAC Plug-in (K220940).

- **Clarity+ for 2D**: Multiple SRI filter settings, ranging from zero to strong filtering made available to the user in real time with a Clarity+ control. Available with reference Vivid iq (K243620).

- **Clarity+ for 4D:** A real-time processing/filtering technique that utilizes volumetric data vs traditional 2D-based filtering. Available as V-SRI filter in reference Voluson Expert 22/20/18 (K231965)

- **Soft Rendering**: a volume (4D) visualization mode offered as an alternative to the standard volume rendering of the predicate EchoPAC Software Only / EchoPAC Plug-in (K220940).

- **RadiantFlow:** Applying shading to regular 2D color flow imaging. Same as Radiant Flow in reference Voluson Expert (K231965).

- **Silhouette:** Visualization of the boundaries between cavities and cardiac tissue structures and devices. A modification based on Flexi-Light in predicate EchoPAC Software Only / EchoPAC Plug-in (K220940) and HD Live Silhouette in reference Voluson Expert 22/20/18 (K231965).

- **CT Fusion:** Added 4D ColorFlow visualization to the predicate CT Fusion in predicate EchoPAC Software Only / EchoPAC Plug-in (K220940).

- **2-Click Crop:** Modifications to the predicate Dual Crop workflow tool in predicate EchoPAC Software Only / EchoPAC Plug-in (K220940) now allowing up to 3 parallel crop planes.

- **2-Click Align:** Functionality added to the predicate Flexi-Slice in EchoPAC Software Only / EchoPAC Plug-in (K220940), for Improved 4D workflow.

- **Flexi-Slice:** Modifications to predicate Flexi-Slice in predicate EchoPAC Software Only / EchoPAC Plug-in (K220940) allowing independent crop plane movement, a new 3x1 image layout, Dual Crop for opposite direction views, and enhanced slice interaction.

- **PISA on DICOM images:** Enables manual PISA measurement tool on DICOM data typed including 3rd party acquisition system.

- **AFI LA on DICOM images:** Enables AFI LA analysis on DICOM images including data from 3rd party acquisition systems.

- **AFI RV on DICOM images:** Enables AFI RV analysis on DICOM images including data from 3rd party acquisition systems.

- **PDF Export to PACS server:** (aka DICOM Encapsulated PDF) To allow storing PDF reports to a DICOM/PACS server, available with reference Vivid iq (K2432260).

- **SW Based Licensing:** Cloud-based licensing system**,** allowing customers to use shared virtual licenses which removes the need for the physical USB license dongles.

- **Import from Local folder**: simplifies the process of importing DICOM images.

Summary of Non-Clinical Tests:

The EchoPAC Software Only / EchoPAC Plug-in complies with voluntary standards:

- ISO 14971, Application of risk management to medical devices, 2019
- NEMA PS 3.1 - 3.20, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology), 2024e
- IEC 62304 Edition 1.1 2015 - Medical device software - Software life cycle process
- IEC 62366-1: 2015 + A1:2020 – Medical Device-Part 1: Application of Usability.

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

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)

AI Auto Doppler Summary of Testing:

Summary test statistics and other results including acceptance criteria and information supporting the appropriateness of the characterized performance are provided below. The AI Auto Doppler feature utilizes 2 AI algorithms, Tissue Doppler and Doppler Trace, which are referenced below.

Testing dataset:

- Testing dataset representative of standard clinical practices used to collect typical cardiac images in clinical environments were assessed by experts for accuracy.
- Tissue Doppler testing dataset included 4106 recordings from 805 individuals.
- Doppler Trace testing dataset included 3390 recordings from 1369 individuals.

Distribution of testing dataset (Demographics and Ultrasound System):

- Gender: Male and Female
- Age: Adult and Pediatric
- Ethnicity/Country: USA (several locations), Australia, France, Spain, Norway, Italy, Germany, Thailand, Philippines
- Ultrasound Console(s): Vivid E80, Vivid E95, Vivid E9, Vivid IQ, Vivid S70, Vivid T9, Vivid Q, Vivid Pioneer
- Probe(s): 6Sc, 6Vc, 3Sc, 4Vc, 4V, M5S, 6S, M4S, M5Sc, M5S, 12S, 9VT, 6VT, 10T

Information about clinical subgroups and confounders present in the testing dataset:

- The algorithm performance was verified across a range of confounders: Ethnicity/Country (USA - several locations, Australia, France, Spain, Norway, Italy, Germany, Thailand, Philippines), wide range of Vivid consoles, wide range of probes.

Performance demonstrated on the verification (testing) dataset:

- The verification requirement included a step to check for a feasibility score of more than 95%, as well as an expected accuracy threshold calculated as the mean absolute difference in percentage for each measured parameter.
- The verification requirement included a step to check mean percent absolute error across all cardiac cycles against a threshold. All clinical parameters, as performed by AI Cardiac Auto Doppler without user edits passed this check These results indicate that observed accuracy of each of the individual clinical parameters met the acceptance criteria.
- The performance of AI Cardiac Doppler algorithm was evaluated across two BMI groups (<25 and ≥25) using a subset of the Vivid Pioneer dataset containing BMI data (41 patients, 433 Doppler measurements). Manual Doppler measurements, reviewed by clinical experts, served as reference values for assessing the AI results.

  Performance was evaluated separately for tissue and flow Doppler parameters using a predefined metric quantifying agreement between manual and AI-derived peak velocities. For tissue Doppler, the mean performance metric was -0.002 (SD = 0.077) for BMI < 25 and -

0.006 (SD = 0.081) for BMI ≥ 25. For flow Doppler, the means were 0.021 (SD = 0.073) and 0.003 (SD = 0.057), respectively.

The number of total samples, if different from above, and the relationship between the two:

- Tissue Doppler development dataset included 1482 recordings from 4 unique clinical sites (not used for testing dataset).
- Doppler Trace development dataset included 2070 recordings from 4 unique clinical sites (not used for testing dataset).

Information about equipment and protocols used to collect images:

- Development dataset included images obtained with the M5Sc, M5S, 4Vc, 4V, M4S, 6S, 12S, 6Vc, 6VT probes on a variety of Vivid cardiovascular ultrasound systems (Vivid E80, Vivid E95, Vivid E9, Vivid 7, Vivid S70N)

Information about how the reference standard was derived from the dataset (i.e. the "truthing" process): Ground truth annotations of the development and verification datasets were obtained as follows:

- In all Training, Validation, and Testing datasets, annotators performed manual measurements after assessing Doppler signal quality and ECG signal quality of curated images.
- Two cardiologists performed the annotations following US ASE based annotation guidelines.
- A review panel of five clinical experts provided feedback on the annotations which were corrected (as needed) until a consensus agreement was achieved between the annotators and reviewers.

Description of how independence of test data from training data was ensured:

- The testing dataset is selected from independent clinical research institutions that have never been used for training and validation (tuning), ensuring the elimination of potential data leakage.

Summary of Clinical Tests:

The subject of this premarket submission, EchoPAC Software Only / EchoPAC Plug-in, did not require clinical studies to support substantial equivalence.

Conclusion:

Based on the design similarities, conformance to recognized performance standards, and performance testing, GE HealthCare considers the proposed EchoPAC Software Only / EchoPAC Plug-in to be as safe, effective, and performs in a substantially equivalent manner as the predicate EchoPAC Software Only / EchoPAC Plug-in (K220940).