GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC
℅ Lee Bush
Regulatory Affairs Director
9900 W. Innovation Drive
WAUWATOSA WI 53226

July 22, 2022

Re: K220940
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: June 30, 2022
Received: July 1, 2022

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 (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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220940

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:

Date:	July 21, 2022
Submitter:	GE Medical Systems Ultrasound and Primary Care Diagnostics 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Lee Bush Regulatory Affairs Director GE Healthcare T:(262)309-9429
Secondary Contact Person:	Charlotte Jørgensen Sr. 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): (Primary)	Automated Radiological Image Processing Software, 21 CFR 892.2050, QIH
Product Code(s): (Secondary)	Picture Archiving and Communications System, 21 CFR 892.2050, LLZ
Predicate Device:	EchoPAC Software Only / EchoPAC Plug-in (K200852), Workstation Software for ultrasound image review, analysis and reporting
Classification Names:	Class II
Product Code(s):	Picture Archiving and Communications System, 21 CFR 892.2050, LLZ
Reference Device:	LOGIQ E10 (K211488), Diagnostic Ultrasound System
Classification Names:	Class II
Product Code(s):	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

Reference Device:	Vivid E95 (K202658), Diagnostic Ultrasound System
Classification Names:	Class II
Product Code(s):	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
Reference Device:	Venue (K202132), Diagnostic Ultrasound System
Classification Names:	Class II
Product Code(s):	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:
The EchoPAC Software Only / EchoPAC Plug-in employs the same fundamental scientific technology as its predicate device.

Determination of Substantial Equivalence:
The proposed EchoPAC Software Only / EchoPAC Plug-in is substantially equivalent to the predicate EchoPAC Software Only / EchoPAC Plug-in and reference devices with regards to intended use, indications for use, imaging capabilities, technological characteristics and safety effectiveness.

The following is an overview of the differences between the proposed EchoPAC Software Only / EchoPAC Plug-in and its predicate device.

Indications for use:

- Added Thoracic/Pleural application, cleared in reference Venue (K202132)

Software:

- Added CT Fusion, cleared in reference Vivid E95 (K202658)
- Added workflow enhancements tools: Dual Crop, Pre-Post Compare and SR Interpreter
- Updates made to: Flexi-Slice, Launchpad, DICOM Spooler, 4D Auto LVQ and 4D Auto TVQ
- Added Easy AutoEF -based on AutoEF 3.0 (includes AI Auto ROI algorithm)
- Added Easy AFI LV -based on AFI 3.0 (includes AI Auto ROI algorithm)
- Added Spline Tool -area measurement method
- Added Strain Elastography feature, cleared in LOGIQ E10 (K211488)

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), 2016
- IEC 62304:2006 A1 2015 - Medical device software - Software life cycle process
- IEC 62366-1: 2015 – Medical Device-Part 1: Application of Usability

The following quality assurance measures are 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 Summary of Testing: Easy Auto EF and Easy AFI LV

Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance

- The accuracy of the AI algorithm (average dice score) as tested on datasets from different countries, is 92% or higher; as tested on datasets from different scanning views, is 91% or higher; as tested on dataset from different left ventricle volumes, is 92% or higher.
- The number of individual patients' images were collected from:
  45 exams from assumed 45 patients (exact number of patients unknown due to anonymization of dataset).
- The number of samples, if different from above, and the relationship between the two:
  135 images extracted from the 45 exams

Demographic distribution including:

- Gender: Unknown, due to data anonymization during data collection
- Age: Adult, specific age unknown
- Ethnicity/Country: Europe, Asia, US

Information about clinical subgroups and confounders present in the dataset:

- During testing of the AI algorithm, we have included images from different countries, from different scanning views, and a range of different LV Volumes

Information about equipment and protocols used to collect images:

- Mix of data from across 5 different probes and 4 different Console variants.
  The data collection protocol was standardized across all data collection sites.

Information about how the reference standard was derived from the dataset (i.e., the "truthing" process)

- For all datasets, two certified cardiologists performed manual delineation, then reviewed the annotations for each other. A consensus reading was first done whereby the two cardiologists discussed if they agreed on or not. A panel of experienced experts further reviewed annotations that the two cardiologists could not agree on.
- Hence, the ground truth used are the annotations that the two cardiologists agreed with Each other, and the consensus annotations achieved in the review meeting by a panel of experienced experts.

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

- To ensure that the testing dataset is not mixed with the training data, we used datasets from different clinical sites for testing as compared to the clinical sites for training.

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:
GE Healthcare considers the EchoPAC Software Only / EchoPAC Plug-in to be as safe, as effective, and performance is substantially equivalent to the predicate and reference devices.