GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC
% Tracey Ortiz
Regulatory Affairs Director
9900 W. Innovation Drive
WAUWATOSA WI 53226

September 18, 2020

Re: K200852
Trade/Device Name: EchoPAC Software Only, EchoPAC Plug-In
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 21, 2020
Received: August 25, 2020

Dear Tracey Ortiz:

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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200852

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, 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:	March 27, 2020
Submitter:	GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Tracey Ortiz Regulatory Affairs Director GE Healthcare T:(262)676-6120
Secondary Contact Person:	Charlotte K. Munthe Jørgensen Senior Regulatory Affairs Leader GE Vingmed Ultrasound AS
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:	Picture archiving and communications system, 21 CFR 892.2050, LLZ
Primary Predicate Device(s):	EchoPAC Software Only / EchoPAC Plug-in (K170847)
Reference Predicate Device(s):	Vivid S70N (K182450) Vivid E95 (K181685) Vivid E95 (K200743)

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 Vivid family of ultrasound scanners by GE Healthcare. The EchoPAC Software Only / EchoPAC Plug-in software is an integral component of each Vivid system, providing the post-acquisition image management and reporting functions of the scanner. EchoPAC Software Only will be offered as SW-only to be installed directly on customer PC hardware, and EchoPAC Plug-in will be offered as an accessory to image management workstations. EchoPAC Software Only / EchoPAC Plug-in is DICOM compliant, transferring images and data via LAN between scanners, 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, 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 EchoPAC Software Only / EchoPAC Plug-in is substantially equivalent to the predicate device with regards to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

The following is an overview of the difference between the proposed EchoPAC Software Only / EchoPAC Plug-in and its predicates.

Features/Functionality additions:

- AI Auto Measure – 2D: same feature as cleared on Vivid E95 (K200743). It is AI (Artificial Intelligence) based Cardiac Auto 2D feature that enables semi-automated measurements on a PLAX image.
- AI Auto Measure – Spectrum Recognition: same feature as cleared on Vivid E95 (K200743). It is AI based Spectrum Recognition feature that enables automated recognition of common Doppler spectra and automatically starts the Auto Doppler measurement or opens the appropriate manual measurement folder.
- AFI 3.0: same feature as cleared on Vivid E95 (K200743), based on AFI 2.0 (cleared in Vivid E95, K181685), adds the ability to analyze the left ventricle on both GEHC raw data images and DICOM images from 3rd party ultrasound scanners.
- Auto EF 3.0: same feature as cleared on Vivid E95 (K200743), based on Auto EF 2.0 (cleared in Vivid E95, K181685), adds the ability to assess LV function on raw data images acquired with GEHC scanners as well as on DICOM images from other vendors systems.
- AFI RV: same feature as cleared on Vivid E95 (K200743), based on AFI 2.0 (cleared in Vivid E95, K181685) but modified for the right ventricle (RV). It is a parametric tool giving quantitative data for right ventricular longitudinal global strain, free wall strain and segmental strain derived from the apical 4-chamber RV focused view.
- AFI LA: same feature as cleared on Vivid E95 (K200743), based on AFI 2.0 (cleared in Vivid E95, K181685) but modified for the left atrium. It provides quantitative data for left atrial (LA) global strain. The tool also supports measurements of LA volumes and emptying fraction (EF).
- Launchpad: same feature as cleared on Vivid E95 (K200743), allows the display and launch/starting of third-party software apps. The offered apps are verified to be compatible with EchoPAC Software Only / EchoPAC Plug-in.

- FlexiLight and HD Color: same features as cleared on Vivid E95 (K200743), are visualization tools enhancing depth and color perception respectively of 3D objects on a 2D monitor
- 4D Auto TVQ: same feature as cleared on Vivid E95 (K200743), based on 4D Auto MVQ (cleared in EchoPAC Software Only/EchoPAC Plug-in, K170847), but modified for quantification of tricuspid annulus and valve in 4D echocardiographic data.
- DICOM PDF Read: same feature as cleared on Vivid E95 (K200743). The system supports read-only access to DICOM PDF reports created on a DICOM server
- The new feature "Open 4D" loads 3D or 4D ultrasound images from 3rd party vendors and allows user to do measurements and analysis.
- Z-score enhancement: same enhancements as cleared on Vivid E95 (K200743). More Z-score sets of values added based on published literature - are being added to those previously cleared in predicate EchoPAC Software Only / EchoPAC Plug-in.
- 4D marker enhancement: same feature as cleared on Vivid E95 (K200743). Feature cleared in predicate Vivid E95 (K181685), is modified to allow user to modify individual markers.

Indications for use:

- Adding clinical applications Obstetrics, Intra-luminal and Intra-Cardiac which were cleared with Vivid S70N (K182450).
- Clarified Real time 3D as 4D and listed 3D.

Summary of Non-Clinical Tests:

The EchoPAC Software Only / EchoPAC Plug-in and its applications comply with voluntary standards:

1. ISO 14971:2007 - Medical devices - Application of risk management to medical devices
2. NEMA PS 3.1 -3.20 Digital Imaging and Communications in Medicine (DICOM) Set, (Radiology), 2016
3. IEC 62304:2006 A1 2015 - Medical device software - Software life cycle process
4. 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

Summary of Clinical Tests: Conclusion:

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

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