DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC
% Ms. Renee Webb
Regulatory Affairs Manager
9900 W. Innovation Drive
WAUWATOSA WI 53226

June 14, 2017

Re: K170847
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: May 15, 2017
Received: May 16, 2017

Dear Ms. Webb:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170847

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 and Real time 3D.

Clinical applications include: Fetal; 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); and Intraoperative (abdominal, thoracic and vascular).

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.

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510(k) Summary

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

Date:	March 16, 2017
Submitter:	GE Healthcare 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Renee Webb Regulatory Affairs Manager GE Healthcare T:847-277-6078 F:847-277-4506
Secondary Contact Person:	Charlotte Kaas Munthe Jørgensen 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:	LLZ
Primary Predicate Device:	K150085 - EchoPAC
Secondary Predicate Device(s):	K150122 - TomTec Arena TTA2 K161706 – Vivid iq
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 selected 3rd party 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:	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 and Real time 3D. Clinical applications include: Fetal; 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); and Intraoperative (abdominal, thoracic and vascular).
Technology:	EchoPAC Software Only / EchoPAC Plug-in employ the same fundamental scientific technology as its predicate devices.
Determination of Substantial Equivalence:	Comparison to Predicate Devices 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 proposed EchoPAC Software Only / EchoPAC Plug-in and the predicate EchoPAC Software Only / EchoPAC Plug-in are all intended for diagnostic review and analysis of ultrasound images, patient record management and reporting.
- The proposed EchoPAC Software Only / EchoPAC Plug-in and the predicate EchoPAC Software Only / EchoPAC Plug-in have the same capabilities in term of performing measurements and analysis/reviewing the images, except:.
- The new feature “Myocardial Work” builds on the functionality of the existing “2D-Strain” functionality available with the predicate EchoPAC Software Only / EchoPAC Plug-in (K150085).
- The new features “4D Auto RVQ” and “4D Auto MVQ” are both alternative implementation of functionality offered with TomTec Arena (K150122) as available on the predicate EchoPAC Software Only / EchoPAC Plug-in (K150085).

- "Cardiac AutoDoppler" is workflow improvements of functionality already available on the predicate EchoPAC Software Only / EchoPAC Plug-in (K150085)
- 3rd party DICOM SR Read builds on the capability of the existing DICOM SR support available with the predicate EchoPAC Software Only / EchoPAC Plug-in (K150085).
- The proposed EchoPAC Software Only / EchoPAC Plug-in and the predicate EchoPAC Software Only / EchoPAC Plug-in use ultrasound images acquired via the same imaging modes.
- The proposed EchoPAC Software Only / EchoPAC Plug-in and the predicate EchoPAC Software Only / EchoPAC Plug-in have the same processing and display features.
- The proposed EchoPAC Software Only / EchoPAC Plug-in and the predicate EchoPAC Software Only / EchoPAC Plug-in have the same indications and clinical.applications, except Musculo-skeletal Superficial which was cleared with Vivid iq (K161706).

Summary of Non-Clinical Tests:

EchoPAC Software Only / EchoPAC Plug-in and its applications comply with voluntary standards. The following quality assurance measures were applied to the development of the system:

1. IEC 62366:2007 + A1:2014, Medical devices – Application of usability engineering to medical devices
2. IEC 62304:2006, Medical device software - Software life cycle process.
3. NEMA PS 3.1 - 3.20 (2011), Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)
4. ISO 14971:2007 Medical Devices – Application of risk management to medical devices

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:

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 devices.