GE Medical Systems Ultrasound and Primary Care Diagnostics
GE Healthcare
% Mr. Bryan Behn
Regulatory Affairs Director
9900 Innovation Drive
WAUWATOSA WI 53226

March 22, 2022

Re: K214039
Trade/Device Name: LOGIQ P10, LOGIQ P9, LOGIQ P8
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: December 22, 2021
Received: December 23, 2021

Dear Mr. Behn:

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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K214039

Device Name
LOGIQ P10, LOGIQ P9, LOGIQ P8

Indications for Use *(Describe)*
The LOGIQ P8/P9/P10 is intended for use by a qualified physician for ultrasound evaluation of Fetal/Obstetrics; Abdominal; Pediatric; Small Organ(Breast, Testes, Thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac(adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology(including Prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative(Abdominal, Vascular).
Modes of operation include: B, M, PW, Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Coded Pulse, 3D/4D Imaging mode, Elastography, Shear Wave Elastography, Attenuation Imaging and Combined modes: B/M, B/Color, B/PWD, B/Color/PWD, B/Power/PWD.
The LOGIQ P8/P9/P10 is intended to be used in a hospital or medical clinic.

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 K214039

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

Date:	December 22, 2021
Submitter:	GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC. 9900 Innovation Dr Wauwatosa, WI 53226
Manufacturer:	GE Ultrasound Korea, Ltd. 9, Sunhwan-ro 214 beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea
Primary Contact Person:	Bryan Behn Regulatory Affairs Director GE Healthcare T:(262)-247-5502
Alternate Contact Person:	Chae-Rin, Song Regulatory Affairs Specialist GE Healthcare GE Ultrasound Korea, Ltd. T: +82-31-740-6310
Device: Trade Name:	LOGIQ P10, LOGIQ P9 and LOGIQ P8
Common/Usual Name:	Diagnostic Ultrasound System
Classification Names:	Class II
Product Code:	IYN(primary), IYO, ITX(secondary) 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
Primary Predicate Device:	**K203114** LOGIQ P10/P9/P8 Diagnostic Ultrasound System
Classification Names:	Class ll; IYN(primary), IYO, ITX(secondary)
Product Codes:	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 Predicate Device(s):	**K210438 Versana Premier**

Classification Names:	Class II
Product Code:	IYN(primary), IYO, ITX(secondary) 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:	The LOGIQ P10, LOGIQ P9 and LOGIQ P8 are full featured, Track 3 device, primarily intended for general purpose diagnostic ultrasound system which consists of a mobile console approximately 55 cm wide, 74 cm deep and 160 cm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls, 10.4-inch LCD touch screen and color 23.8-inch LCD image display with HDMI audio function. All probes on the subject device have been previously cleared on the predicate K203114 with the exception of the E7C8L-RS which was previously cleared on predicate K210438. All probes available as accessories for the subject systems LOGIQ P Series uses are unchanged from the cleared predicates. They are made of the same materials and their shape is unchanged The primary differences between the difference models are the the LOGIQ P10 is the highest configuration offering all the features and probes available on the P Series and the other models offer a subset of them.
Intended Use:	The LOGIQ P10, LOGIQ P9, LOGIQ P8 are general purpose diagnostic ultrasound system intended for use by a qualified and trained healthcare professional physician for ultrasound imaging, measurement, display and analysis of the human body and fluid. The LOGIQ P10, LOGIQ P9 and LOGIQ P8 clinical applications include: evaluation of Fetal/Obsteterics; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative (abdominal, vascular). Modes of operation include: B, M, PW, Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Coded Pulse, 3D/4D Imaging mode, Elastography, Shear Wave Elastography, Attenuation Imaging and Combined Modes: B/M, B/Color, B/PWD, B/Color/PWD, B/Power/PWD. The LOGIQ P8/P9/P10 is intended to be used in a hospital or medical clinic.

Technology: The LOGIQ P10, LOGIQ P9 and LOGIQ P8 employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Comparison to Predicates

The proposed LOGIQ P10, LOGIQ P9 and LOGIQ P8 systems are substantially equivalent to the predicate devices. The following is an overview of the differences between the proposed LOGIQ P10, LOGIQ P9 and LOGIQ P8(Software version R4.5) and the predicate LOGIQ P10, LOGIQ P9 and LOGIQ P8(Software version R4)(K203114).

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The LOGIQ P10/P9/P8 and predicate LOGIQ P10/P9/P8 systems have the same clinical intended uses.
- The LOGIQ P10/P9/P8 and predicate LOGIQ P10/P9/P8 systems transducers are identical except for the addition of 1 new transducer, E7C8L-RS. E7C8L-RS has been migrated from Versana Premier(K210438).
- The LOGIQ P10/P9/P8 and predicate LOGIQ P10/P9/P8 systems have the same indications for use.
- The systems are manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The systems have acoustic power levels which are below the applicable FDA limits.
- The LOGIQ P10/P9/P8 and predicate LOGIQ P10/P9/P8 systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The LOGIQ P10/P9/P8 and predicate LOGIQ P10/P9/P8 systems have been designed in compliance with approved electrical and physical safety standards.
- The LOGIQ P10/P9/P8 and predicate LOGIQ P10/P9/P8 systems are identical except:
  - E7C8L-RS(ERB) probe is migrated from Versana Premier k210438 and it can be attached to a stepper to be used for urological procedures including transperineal needle guidance, transperineal grid biopsy and prostate brachytherapy.
  - Stepper Volume Measurement(STVOL) is migrated from Versana Premier(K210438). This is the method used to calculate the volume of an organ using urology

software, a transaxial probe and a mechanical stepping device that moves the probe in fixed increments.
- "EZ DICOM Viewer" is Class I MD, which enables export DICOM(Digital Imaging and Communications in Medicine) to external medias along with standalone software.
- "Probe Health Test" which is to check for element integrity and function for all compatible probes when a transducer is connected to the main system or is activated is added according to the FDA guidance.
- KOIOS SW(KOIOS Breast), which is cleared on KOIOS DS for Breast(K190442), enables LOGIQ P8, P9 and P10 system connects via DICOM to PACs running KOIOS DS and is configured similar to a DICOM service.
- HDU monitor(LCD) for LOGIQ P10 only. LOGIQ P10 has two configurations. One is with 23.8inch bezel-less LCD monitor and the other one is with 23.8inch HDU monitor has much more high contrast image. Both of monitor has HDMI audio functions.

The following minor improvements have been made: Hepatic Assistant, week/day OB for SR, Hide date and time, Quick Patient Change, UPS support, HDMI Audio signal for external monitor, DICOM Viewer SR storage and Digital Expert.

Summary of Non-Clinical Tests:

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform to applicable medical device safety standards. The LOGIQ P10, LOGIQ P9 and LOGIQ P8 and its applications comply with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 2005/(R)2012 And A1:2012
- IEC60601-1-2, Medical Electrical Equipment – Part 1-2:General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbance - Requirements and Tests, Edtion 4.0, 2014

- IEC60601-2-37, Medical Electrical Equipment – Part 2-37:Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment, Edition 2.1, 2015
- ISO10993-1, Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing- Third Edition, 2009
- ISO14971, Application of risk management to medical devices: 2019
- NEMA PS 3.1 - 3.20 (2016), Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)
- IEC 62359, Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, Edition 2.1, 2017

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)

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, LOGIQ P10, LOGIQ P9 and LOGIQ P8, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the LOGIQ P10, LOGIQ P9 and LOGIQ P8 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).