GE Healthcare
% Mr. Bryan Behn
RA Director
9900 Innovation Drive
WAUWATOSA WI 53226

August 27, 2021

Re: K211524
Trade/Device Name: LOGIQ E10s, LOGIQ Fortis
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: July 30, 2021
Received: August 2, 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,

Michael D. O'Hara 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211524

Device Name
LOGIQ E10s and LOGIQ Fortis

Indications for Use *(Describe)*
The LOGIQ E10s and LOGIQ Fortis are general-purpose diagnostic ultrasound systems intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid. LOGIQ E10s and LOGIQ Fortis clinical applications include: Fetal / Obstetrics; Abdominal (including Renal, Gynecology/Pelvic); 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 (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 E10s and LOGIQ Fortis are 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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K211524

510(k) Summary

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

Date:	May 14, 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:(414)721-4214 E: bryan.behn@ge.com
Alternate Contact Person:	Qingmeng Chen Regulatory Affairs Program Manager GE Healthcare T: +86-18180590723
Device Trade Name:	LOGIQ E10s, LOGIQ Fortis
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:	K200119 LOGIQ E10s Diagnostic Ultrasound System
Reference Device(s):	K200158 LOGIQ E10 Diagnostic Ultrasound System K202658 Vivid E95 Diagnostic Ultrasound System
Device Description:	The LOGIQ E10s is a full featured, Track 3, general purpose diagnostic ultrasound system which consists of a mobile console approximately 585 mm wide (keyboard), 991 mm deep and 1300 mm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls, 12-inch high-resolution color touch screen and 23.8-inch High Contrast LED LCD monitor (or an optional 22-inch color OLED widescreen monitor).

The LOGIQ Fortis is a full featured, Track 3, general purpose diagnostic ultrasound system which consists of a mobile console approximately 575 mm wide (keyboard), 925 mm deep and 1300 mm high that provides digital acquisition, processing and display capability. The user interface includes a digital keyboard (physical keyboard as an option), specialized controls, 12-inch high-resolution color touch screen and 23.8-inch High Contrast LED LCD monitor (or 23.8-inch High Resolution LED LCD monitor as an option).

Indications for Use:

The LOGIQ E10s and LOGIQ Fortis are general-purpose diagnostic ultrasound systems intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid. LOGIQ E10s and LOGIQ Fortis clinical applications include: Fetal / Obstetrics; Abdominal (including Renal, Gynecology/Pelvic); 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 (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 E10s and LOGIQ Fortis are intended to be used in a hospital or medical clinic.

Technology:

The LOGIQ E10s and LOGIQ Fortis employ the same fundamental scientific technology as its predicate device(s).

Determination of Substantial Equivalence:

Comparison to Predicates

The proposed LOGIQ E10s and LOGIQ Fortis are substantially equivalent to the predicate devices. The following is an overview of the differences between the proposed LOGIQ E10s, LOGIQ Fortis and the predicate LOGIQ E10s (K200119). The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.

- The proposed LOGIQ E10s, LOGIQ Fortis and the predicate LOGIQ E10s have the same clinical intended use.
- The proposed LOGIQ E10s, LOGIQ Fortis and the predicate LOGIQ E10s have the same imaging modes.
- 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 proposed LOGIQ E10s, LOGIQ Fortis and the predicate LOGIQ E10s have similar capability in terms of performing measurements,

capturing digital images, reviewing and reporting studies.

- The proposed LOGIQ E10s, LOGIQ Fortis and the predicate LOGIQ E10s have been designed in compliance with approved electrical and physical safety standards.
- The probes supported in proposed LOGIQ E10s and the predicate LOGIQ E10s are identical except:
  - the following probe migrated from LOGIQ E10 (K200158): L6-24-D;
  - adding new probes ML4-20-D and ML4-20VN-D, which are equivalent to the previously cleared ML6-15-D;
  - adding Contrast and B-Flow as new modes to: L6-24-D;
  - adding UGAP as a new mode to: C2-9-D, C2-9VN-D;
  - adding Shear Wave Elastography as a new mode to: L3-12-D;
  - adding Pleural under Abdominal application use
- The probes supported in proposed LOGIQ Fortis and the predicate LOGIQ E10s are identical except:
  - the following probe migrated from LOGIQ E10 (K200158): L6-24-D;
  - adding Contrast and B-Flow as new modes to: L6-24-D;
  - adding UGAP as a new mode to: C2-9-D, C2-9VN-D;
  - adding Shear Wave Elastography as a new mode to: L3-12-D;
  - adding Pleural under Abdominal application
- The software features supported in proposed LOGIQ E10s, LOGIQ Fortis and predicate LOGIQ E10s are identical except:
  - software features added: EZ Imaging, Hepatic Assistant, Software Download, Digital Expert Remote Training, Respirometer Support;
  - other minor software improvement: Device Management 2.0, Advanced SRI-HD.
- Other minor hardware modification: adding hardware A/N keyboard as an option to the proposed LOGIQ Fortis.

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 with applicable medical device safety standards. The LOGIQ E10s, LOGIQ Fortis complies with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 2005/(R)2012 And A1:2012
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbance - Requirements

and Tests, Edition 4.0, 2014

- IEC 60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment, Edition 2.1, 2015
- ISO 10993-1, Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing Within A Risk Management Process, Fourth edition, 2018
- ISO 14971, Application of risk management to medical devices, 2007
- NEMA PS 3.1 - 3.20, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology), 2016
- 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 E10s, LOGIQ Fortis, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the LOGIQ E10s, LOGIQ Fortis to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).