November 7, 2023

GE Medical Systems Ultrasound and Primary care Diagnostics, LLC
% Bryan Behn
Regulatory Affairs Director
9900 Innovation Drive
WAUWATOSA WI 53226

Re: K231966
Trade/Device Name: LOGIQ E10
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: October 5, 2023
Received: October 6, 2023

Dear Bryan 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
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)*

K231966

Device Name

LOGIQ E10

Indications for Use *(Describe)*

LOGIQ E10 is intended for use by a qualified physician for ultrasound evaluation of 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 (Abdominal and 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 E10 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

Date:	October 4, 2023
Submitter:	GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC 9900 Innovation Dr Wauwatosa, WI 53226
Manufacturer:	GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC 9900 Innovation Dr Wauwatosa, WI 53226
Primary Contact Person:	Bryan Behn Regulatory Affairs Director GE Healthcare E: bryan.behn@ge.com T: (262) 247-5502
Alternate Contact Person:	Elizabeth Wentworth Regulatory Affairs Leader GE Healthcare
Device: Trade Name:	LOGIQ E10
Common/Usual Name:	LOGIQ E10
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:	K211488 LOGIQ E10 Diagnostic Ultrasound System
Reference Device(s):	K211524 LOGIQ E10s and FORTIS R3 Diagnostic Ultrasound System K181685 Vivid E80/ Vivid E90/ Vivid E95 R3 Diagnostic Ultrasound System K200743 Vivid E80/ Vivid E90/ Vivid E95 R4 Diagnostic Ultrasound System K202035 Vscan Air Ultrasound Transducer K202233 L4-20t-D Ultrasound Transducer, Venue Go Diagnostic Ultrasound System K170445 P8D Ultrasound Transducer , LOGIQ S8 Diagnostic Ultrasound System
Device Description:	The LOGIQ E10 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.

Indications for Use:

LOGIQ E10 is intended for use by a qualified physician for ultrasound evaluation of 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 (Abdominal and 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 E10 is intended to be used in a hospital or medical clinic.

The LOGIQ E10 employs the same fundamental scientific technology as its predicate device(s).

Technology:

Determination of Substantial Equivalence:

Comparison to Predicates

The proposed LOGIQ E10 is substantially equivalent to the predicate devices. The following is an overview of the differences between the proposed LOGIQ E10 and the predicate LOGIQ E10 (K211488). The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.

- The LOGIQ E10 and predicate LOGIQ E10 systems 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 LOGIQ E10 and predicate LOGIQ E10 systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The LOGIQ E10 and predicate LOGIQ E10 systems have been designed in compliance with approved electrical and physical safety standards.

Probes: The probes supported in proposed LOGIQ E10, and predicate

LOGIQ E10 are identical except:

- Addition of new probes:
- L4-20t-D probe with button control (L4-20t-D probe is substantial equivalent to L4-20t-RS probe cleared on the Venue Go K202233).
- P8D probe (migrated from LOGIQ S8 K170445).

Software:

- The software features supported in proposed LOGIQ E10 and the predicate LOGIQ E10 are identical except:
- Addition of new software features:
- Auto Preset Assistant
- Auto Color Assistant
- Auto Renal Measure Assistant
- APP Launchpad
- Raw Data Streaming/Network Streaming
- Auto EF2.0 / AFI 2.0
- Vscan Air CL Support
- CEUS LI-RADS check-sheet

Hardware:

- The hardware in proposed LOGIQ E10 LOGIQ and the predicate LOGIQ E10s (K211524) are identical.
  Compatible devices:
- Addition of Vscan Air CL, wifi USB for Vscan Air CL and Wireless charger.

Appearance:

- Minor updates on device front cover. Addition of U-light.

AI Testing Summary

Auto Renal Measure Assistant : Al Summary of Testing

Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance	• For Longitudinal model the accuracy of measurement is expected to be higher than 80% and for the Transverse model it is expected to be higher than 70% • The number of individual patients' images were collected from: 30 Patients. • The number of samples is 60 with 30 Longitudinal views and 30 Transverse view
Information about clinical subgroups and confounders present in the dataset	• Gender: Male & Female • Age: range 26-81 yrs old • Ethnicity/Country; USA (58%) and Japan (42%)
Information about equipment and protocols used to collect images	The datasetused for final verification was collected prospectively on 30 demographically diverse patients at 2 sites: Japan and the USA exclusively with the system under consideration GE Logiq Fortis after the Auto Renal Measure Assistant function was developed using C1-6-D probe in Abdomen application;
Information about how the reference standard was derived from the dataset (i.e. the "truthing" process)	• The Validation set of 30 patient (60 images) were loaded onto the LOGIQ validation system. • 2 Readers (certified sonographer/Clinician) to ground truth the measurements: Length on the Longitudinal views and the Height and Width Measurements on the Transverse views. • Board Certified Nephrologist arbitrated the ground truth between the above two readers to establish the reference standard for the dataset • Summary of Results: The Longitudinal model for length measurements has average accuracy of 96.45 with 95% CI of ± 1.26% and average absolute error of 0.35cm at 95% CI of ±0.12 cm. The Transverse model for width measurements has average accuracy of 92.94% with 95% CI of ± 3.02% and average absolute error of 0.38cm at 95% CI of ±0.14 cm. The Transverse model for width measurements has average accuracy of 93.13% with 95% CI of ± 3.63% and average

	absolute error of 0.37cm at 95% CI of ±0.14 cm.
Description of how independence of test data from training data was ensured	The verification data was acquired independently during validation process after the development of the model as described above.

Auto Abdominal Color Assistant : AI Summary of Testing

Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance	• The overall model success rate of the Aorta, Kidney, Liver, GB, and Pancreas view suggestion is expected to be 80% or higher. • The number of individual patients' images were collected from: 50+ patients • The number of samples, if different from above, and the relationship between the two: 1100+ images
Information about clinical subgroups and confounders present in the dataset	• Gender: Male & Female • Age: Wide range, but specific age not collected • Ethnicity/Country; USA (77%) and Australia (23%)
Information about equipment and protocols used to collect images	Mix of data from across three different probe models and two 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)	• Before the process of data annotation, all information displayed on the device is removed and performed on information extracted purely from Ultrasound B-mode images. • Readers (certified sonographer/Clinician) to ground truth the "anatomy" visible in static B-Mode image. (Before running AI) • Ran AI and created confusion matrix of ground truth vs AI predictions. • Calculated the accuracies of the algorithm against each class.
Description of how independence of test data from training data was ensured	The exams used for test/training validation purpose are separated from the ones used during training process and there is no overlap between the two.

Auto Preset Assistant : AI Summary of Testing

Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance	• The overall model success rate of the Abdomen, Air, Breast, Carotid, Leg, MSK, Scrotal, Thyroid and Carotid/Thyroid (Mixed) view suggestion is expected to be 80% or higher. • The number of individual patients' images were collected from: 110+ patients • The number of samples, if different from above, and the relationship between the two: 2600+ images
Information about clinical subgroups and confounders present in the dataset	• Gender: Male & Female • Age: Wide range, but specific age not collected • Ethnicity/Country; USA (41.2%) , Austria (3.8%), Australia (1.1%), Japan (41.3%), Italy (0.7%) and Greece (12%).
Information about equipment and protocols used to collect images	Mix of data from across five different probe models and three 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)	• Before the process of data annotation, all information displayed on the device is removed and performed on information extracted purely from Ultrasound B-mode images. • Readers (certified sonographer/Clinician) to ground truth the "anatomy" visible in static B-Mode image. (Before running AI) • Ran AI and created confusion matrix of ground truth vs AI predictions. • Calculated the accuracies of the algorithm against each class.
Description of how independence of test data from training data was ensured	The exams used for test/training validation purpose are separated from the ones used during training process and there is no overlap between the two.

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 E10 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
- 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, 2014
- IEC 60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment, 2015
- ISO 10993-1, Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing Within A Risk Management Process, 2018
- ISO 14971, Application of risk management to medical devices, 2012
- NEMA PS 3.1 - 3.20, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology) 2016

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 E10, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the LOGIQ E10 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).