October 29, 2025

GE Medical Systems Ultrasound and Primary Care Diagnostics
Bryan Behn
Regulatory Affairs Director
3200 N Grandview Blvd
Waukesha, Wisconsin 53188

Re: K251963
Trade/Device Name: LOGIQ E10s
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, QIH
Dated: September 29, 2025
Received: September 29, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251963

Please provide the device trade name(s).

LOGIQ E10s

Please provide your Indications for Use below.

The LOGIQ E10s is intended for use by a qualified physician for ultrasound evaluation.

Specific clinical applications and exam types 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 (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 E10s is intended to be used in a hospital or medical clinic.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary- K251963

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

Date:	October 27, 2025
Submitter:	GE Medical Systems Ultrasound and Primary care Diagnostics, LLC 3200 N Grandview Blvd Waukesha, WI 53188 USA
Manufacturer:	GE Ultrasound Korea, Ltd. 9, Sunhwan-ro 214 beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, 13204 Republic of Korea
Primary Contact Person:	Bryan Behn Sr. Regulatory Affairs Director GE HealthCare T:(262)247-5502
Alternate Contact Person:	Qingmeng Chen Regulatory Affairs Leader GE HealthCare T: +86-18180590723
Device Trade Name:	LOGIQ E10s
Common / Usual Name:	Diagnostic Ultrasound System
Classification Names:	Class II
Product Code:	IYN (primary), IYO, ITX, QIH (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 automated radiological image processing software, 21 CFR 892.2050, 90-QIH
Primary Predicate Device:	K231989 LOGIQ E10s, LOGIQ Fortis Diagnostic Ultrasound System
Reference Device(s):	K232381 LOGIQ Totus Diagnostic Ultrasound System K231301 Vscan Air K201768 Voluson E10

	K220882 Vivid E80, Vivid E90, Vivid E95 K183575 Siemens Acuson S3000/S2000

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.

Intended Use / Indications for Use:

LOGIQ E10s 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; Tranesophageal 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 E10s is intended to be used in a hospital or medical clinic.

Technology:

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

Determination of Substantial Equivalence:

The proposed LOGIQ E10s is substantially equivalent to the predicate LOGIQ E10s (K231989) with regards to intended use, imaging capabilities, technological characteristics, imaging modes, hardware, and demonstrates substantial equivalence.

The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.

The proposed LOGIQ E10s and the predicate LOGIQ E10s (K231989) have the same clinical indications for use.

The proposed LOGIQ E10s employs the same fundamental scientific technology as its predicate device.

The proposed LOGIQ E10s and the predicate LOGIQ E10s (K231989) have the same imaging modes.

The proposed LOGIQ E10s is manufactured with materials which have been evaluated and found to be safe for the intended use of the device.

The proposed LOGIQ E10s has acoustic power levels which are below the applicable FDA limits.

The proposed LOGIQ E10s and the predicate LOGIQ E10s (K231989) have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.

The proposed LOGIQ E10s has been designed in compliance with approved electrical and physical safety standards.

The following is an overview of the differences between the proposed LOGIQ E10s and the predicate LOGIQ E10s (K231989).

Probes:

The probes supported in proposed LOGIQ E10s and the predicate LOGIQ E10s (K231989) are identical except:

- Addition of new probe 12S-D (migrated from LOGIQ Totus K232381).
- Addition of clinical application of Small Parts on existing L4-20t-D probe.
- Addition of Shear Wave Elastography on existing RIC5-9-D probe under clinical application of Urology.
- Addition of 4D Contrast on existing RIC5-9-D probe under clinical application of Urology

Software:

The software features supported in proposed LOGIQ E10s and the predicate LOGIQ E10s (K231989) are identical except:

- Addition of new software features:
  - Auto Abdominal Color Assistant 2.0 for adult imaging (Auto Abdominal Color Assistant 1.0 cleared on K231989)
  - Auto Abdominal Measure Assistant (AI) consists of:
    - Auto Renal Measure Assistant (Cleared on LOGIQ E10s K231989)
    - Auto Aorta Measure Assistant
    - Auto Common Bile Duct (CBD) Measure Assistant

- Ultrasound Guided Fat Fraction (UGFF) for adult imaging (Similar to Siemens UDFF feature cleared on
  Acuson S3000/S2000 K183575)
- AppAPI RoundTrip (AppAPI cleared on K231989)
- Viewpoint on LOGIQ (Viewpoint 6 cleared on K241300)
- Send Images via Email (migrated from Voluson E10 K201768)
- RFID Reader Login
- KOIOS Lite (KOIOS DS cleared on K242130)
- Auto EF without ECG (migrated from Vivid E80 / Vivid E90 / Vivid E95 K220882)

- Other minor software modifications/improvements:
  - Data Streaming Color Flow Support
  - Public SR Template for Urology, Small Parts and Pediatrics
  - DICOM SR Support for Viewpoint Measurements
  - DICOM tags for AI support.
  - Clean Pixel Tag
  - Image Tagging.
  - Additional OB Measurements/Charts: added support for authors Acharya (UMB A), Schaffer (Uterine A, UMB A, MCA), and Chitty (HL).
  - Qt UI framework for the touch panel
  - Ez Touchpanel 2.0
  - Improvements to CTO (Continuous Tissue Optimization)/CATO (Continuous Auto Tissue Optimization): Improvements of functionality already available on previous clearance K231989.
  - Adding availability of ACE (Adaptive Contrast Enhancement) to Thyroid application: Expansion of functionality already available on previous clearance K231989.
  - Adding PW mode to the Vscan Air CL probe cleared on K231301.
  - Expanded redesigned Color Flow.
  - Added raw data collection for Shear Wave Elastography.
  - Verisound Fleet Detailed Restore: improved based on Device Mgmt cleared on K231989.
  - E-delivery of base image and application software together.
  - Advanced Anonymization.
  - Removed Tricefy.

<u>Hardware:</u>

The hardware in proposed LOGIQ E10s and the predicate LOGIQ E10s (K231989) are identical except:

- GPU replacement due to end-of-life
- Key cap variation: added new keys for new software features for LOGIQ E10s R5.

Accessory

Addition of new accessory: RFID Reader.

Compatible device:

Addition of PW mode to Vscan Air CL probe (Device itself cleared with K231301; Cleared on Predicate LOGIQ E10s K231989).

AI Testing Summary:

Auto Abdominal Color Assistant 2.0:

Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance	• The overall model detection accuracy (sensitivity and specificity) and DICE score for the Aorta, Kidney, Liver/Spleen/inferior vena cava (IVC), Gallbladder (GB)/Urinary Bladder, Pancreas, and Air view is expected to be as follows: ➢ Detection accuracy ≥ 80% (0.80) ➢ Sensitivity (True Positive Rate): ≥ 80% (0.80) ➢ Specificity (True Negative Rate): ≥ 80% (0.80) ➢ DICE Similarity Coefficient (Segmentation Accuracy): ≥ 0.80 • The number of individual subjects: 49 • The number of annotation images: 1186 • The model achieved accuracy of 94.8%, with sensitivity of 0.91, specificity of 0.98, and a DICE score of 0.82, all of which meet the predefined acceptance criteria.
Information about clinical subgroups and confounders present in the dataset	• Gender: Male 24.2% (8), Female 75.8% (25) • Age: 60 ±15.7 (average and standard deviation) (24 Min, 83 Max) • BMI: 27±5.6 (average and standard deviation) (16 Min, 38 Max) • Ethnicity: not hispanic 96.4%(27), hispanic 3.6% (1) • Race : Asian 12.9% (4), White 77.4% (24), Black 9.7% (3) • Country: USA (100%)
Information about equipment and protocols used to collect images	Mix of data from across three different probe models and three different Console variants. The data collection protocol was standardized.

Information about how the reference standard was derived from the testing 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 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 Aorta Measure Assistant:

Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance	Long View Aorta: • The average keystrokes to obtain the Anteroposterior (AP) measurement (diameter) of the aorta in the long view is 4.132 +/- 0.291 without AI and 1.236 +/-0.340 with AI. Short View Aorta: • The average keystrokes to obtain the AP and Trans measurement (diameter) of the aorta in the short view is 7.05 +/-0.158 without AI and 2.307 +/- 1.0678 with AI. Long View AP Measurement Accuracy: • Average accuracy is 87.2% with 95% CI of +/- 1.98% and average absolute error of 0.253 cm and 95% CI of 0.049 cm. • Limits of Agreement in centimeters are (-0.15, 0.60) with 95% CI of (-0.26, 0.71). Short View AP Measurement Accuracy: • Average accuracy is 92.9% with a 95% CI of +/- 2.02% and an average absolute error of 0.128 cm and 95% CI of 0.037 cm. • Limits of Agreement in centimeters are (-0.21, 0.36) with 95% CI of (-0.29, 0.45). Short View Trans Measurement Accuracy: • Average accuracy is 86.9% with 95% CI of +/- 6.25% and average absolute error of 0.235 cm and 95% CI of 0.110 cm. • Limits of agreement in centimeters are (-0.86, 0.69) with 95% CI (-1.06, 0.92).

Information about clinical subgroups and confounders present in the dataset	Long View Aorta: • Gender: 11 Male, 25 Female • Country: 16 Japan, 20 USA • Age: 60.50 ±14.24 (average and standard deviation) (23 Min – 81 Max) • BMI: 25.11 ±5.69 (average and standard deviation) (16.65 – 37.60) Short View Aorta: • Gender: 11 Male, 24 Female • Country: 15 Japan, 20 USA • Age: 61.11 ±14.46 (average and standard deviation) (23 Min – 81 Max) • BMI: 25.24 ±5.97 (average and standard deviation) (16.65 – 37.60)
Information about equipment and protocols used to collect images	Validation images were collected on LOGIQ Fortis with the C1-6 probe with a standardized protocol. Images acquired on LOGIQ Fortis are acceptable for validation of LOGIQ E10 because the transmit, receive, and back-end processing hardware are the same. The acquisition software architecture is also the same. Therefore, the image quality of the two systems is comparable.
Information about how the reference standard was derived from the testing 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 to ground truth the AP measurement of the aorta long view and the AP and Trans measurement of the aorta short view – Number of keystrokes measured. • Readers to ground truth the AP measurement of the aorta long view and the AP and Trans measurement of the aorta short view using AI - Number of keystrokes measured. • Number of Keystrokes with and without AI is compared for each reader. • Arbitrator to select most accurate measurement among all readers. • Arbitrator selected measurement is compared to AI baseline measurement with and without on segmentation editing for accuracy.
Description of how independence of test data from training data was ensured	The exams used for regulatory validation purpose are separated from the ones used during model development process by exam site origin ensuring there is no overlap between the two.

Auto Common Bile Duct (CBD) Measure Assistant:

Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance	• The average reduction between keystrokes for measurements (diameter) made manually and with AI is 1.62±0.375 (mean and standard deviation) Porta Hepatis measurement accuracy without segmentation scroll edit: • Average accuracy is 59.85% with 95% CI of +/- 17.86% and average absolute error of 1.66 mm and 95% CI of 1.02 mm. • Limits of Agreement in millimeters are (-4.75,4.37) with 95% CI of (-6.17, 5.79). Porta Hepatis measurement accuracy with segmentation scroll edit: • Average accuracy is 80.56% with a 95% CI of +/- 8.83% and an average absolute error 0.91 mm and 95% CI of 0.45 mm. • Limits of Agreement in millimeters are (-1.96, 3.25) with 95% CI of (-2.85,4.14).
Information about clinical subgroups and confounders present in the dataset	• Gender: Male 44% (11), Female 56% (14) • Age: 62 ±16.03 (average and standard deviation) (23 Min – 83 Max) • BMI: 23.48 ± 4.94 (average and standard deviation) (16.65 min – 36.73 max) • Race: Asian 64% (16), White 36% (9) • Country: USA (40%), Japan (60%)
Information about equipment and protocols used to collect images	Validation images were collected on LOGIQ Fortis with the C1-6 probe with a standardized protocol. Images acquired on LOGIQ Fortis are acceptable for validation of LOGIQ E10 because the transmit, receive, and back-end processing hardware are the same. The acquisition software architecture is also the same. Therefore, the image quality of the two systems is comparable.
Information about how the reference standard was derived from the testing 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 to ground truth the diameter of the CBD in the Porta Hepatis – Number of keystrokes measured. • Readers to ground truth the diameter of the CBD in the Porta Hepatis using AI - Number of keystrokes measured. • Number of Keystrokes with and without AI is compared for each reader. • Arbitrator to select most accurate measurement among all readers. • Arbitrator selected measurement is compared to AI baseline measurement with and without on segmentation editing for accuracy.

Description of how independence of test data from training data was ensured	The exams used for regulatory validation purpose are separated from the ones used during model development process by exam site origin ensuring 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 E10s complies with voluntary standards:

- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]
  Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION
  Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-37 Edition 3.0 2024
  Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION
  Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 62359 Edition 2.1 2017-09 CONSOLIDATED VERSION
  Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields
- ISO 10993-1 Fifth edition 2018-08
  Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 14971 Third Edition 2019-12
  Medical devices - Application of risk management to medical devices
- NEMA PS 3.1 - 3.20 2024e
  Digital Imaging and Communications in Medicine (DICOM) Set
- AAMI TIR69:2017/(R2020)
  Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems

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 & Validation)
- Safety testing (Verification)

Transducer materials and other patient contact materials are biocompatible.

Summary discussion of the clinical tests submitted, referenced, or relied on for a determination of substantial equivalence.

UGFF Clinical Study: Acoustic property measurements including the Attenuation Coefficient (AC), Back scatter Coefficient (BSC), and Signal-to-Noise Ratio (SNR) were obtained from the liver of five hundred and eighty-two (582) participants in an external clinical study in Japan. The UGFF index is based on a least squares fit (estimation) between the acoustic property measurements and the corresponding MRI Proton Density Fat Fraction (MRI-PDFF %) measurements.

Table 1 summarizes baseline demographic information from the clinical study including sex, age, BMI, race, and ethnicity. There were no adverse effects or complications in the acquisition of the ultrasound clinical data.

Table 1 Clinical patient data

Population	Asian
Age	65±14.1
Sex	
Male	308
Female	274
Etiology	
HBV	91
HCV	67
NAFLD	300

ALD	35
Other	89
BMI	21.0 – 30.8
Skin to Capsule Distance (SCD) [mm]	9.0 – 53.0

Strong correlation was confirmed between UFF values and MRI-PDFF. The correlation coefficient was 0.87. Bland-Altman analysis between UGFF and MRI-PDFF was conducted. The offset was -0.32% and the limit of agreement (LOA) was -6.0% to 5.4%. The differences between UFF and MRI-PDFF values were within ±8.4%, and results in 91.6% patients were smaller than the LOA.

A second confirmatory study was conducted on 15 US and 5 EU patients using the same least squares fit (estimation) to ensure performance was maintained on an independent dataset.

Table 2 summarizes the demographic information from the confirmatory study conducted on US and EU patients. Demographic information on the 5 EU patients was unavailable.

Table 2 Clinical patient data (US adults)

Sex	
Male	5
Female	10
BMI	21.0 – 37.5
SCD [mm]	13.9 – 26.9

Strong correlation between UFF values and MRI-PDFF (correlation coefficient: 0.90) was also demonstrated in European and American populations. Bland-Altman analysis between UGFF and MRI-PDFF was conducted. The offset was -0.1%, and the limit of agreement (LOA) was -3.6% to 3.4%. The differences between UFF and MRI-PDFF values were within ±4.6%, and results in 95.0% patients were smaller than the LOA.

A third confirmatory study comparing UGFF with Ultrasound-Derived Fat Fraction (UDFF, Siemens) was conducted on 24 EU patients using the same least squares fit (estimation) to ensure performance was maintained on an independent dataset.

Strong correlation between UGFF and UDFF (correlation coefficient: 0.88) was also demonstrated. Bland-Altman analysis between UGFF and UDFF was conducted. The offset was -

1.2%, and the limit of agreement (LOA) was -5.0% to 2.6%. The differences between UFF and MRI-PDFF values were within ±4.7%, and results in all patients were smaller than the LOA.

The results of the clinical study indicate that BMI, SCD, and other demographic confounders do not have a statistically significant effect on measurements of the AC, BSC, and SNR.

Conclusion:

Based on the equipment design similarities, conformance to recognized performance standards, and performance testing, GE Healthcare considers the LOGIQ E10s to be as safe, effective, and performs in a substantially equivalent manner to the primary predicate device.