

January 8, 2026

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

Re: K253370

Trade/Device Name: LOGIQ Totus
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, QIH
Dated: December 4, 2025
Received: December 4, 2025

Dear Lee Bush:

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.

K253370

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Please provide the device trade name(s).

?

LOGIQ Totus

Please provide your Indications for Use below.

?

LOGIQ Totus 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 includes: 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 Totus 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)

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510(k) Summary - K253370

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

<u>Date:</u>	January 8, 2026
<u>Submitter:</u>	GE Medical Systems Ultrasound and Primary care Diagnostics, LLC 3200 N Grandview Blvd Waukesha, WI 53188 USA
<u>Manufacturer:</u>	GE Ultrasound Korea, Ltd. 9, Sunhwan-ro 214 beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, 13204 Republic of Korea
<u>Primary Contact Person:</u>	Lee Bush Regulatory Affairs Director GE HealthCare T:(262)309-9429
<u>Alternate Contact Person:</u>	Chae-Rin, Song Regulatory Affairs Leader GE Ultrasound Korea, Ltd. T: +82-31-740-6310
<u>Device Trade Name:</u>	LOGIQ Totus
<u>Common / Usual Name:</u>	Diagnostic Ultrasound System
<u>Classification Names:</u>	Class II
<u>Product Code:</u>	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; Medical Image Management and Processing System, 21 CFR 892.2050, 90-QIH
<u>Primary Predicate Device:</u>	K232381 LOGIQ Totus Diagnostic Ultrasound System
<u>Reference Device(s):</u>	K231989 LOGIQ E10s 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 Totus is full featured, Track 3 device, primarily intended for general purpose diagnostic ultrasound system which consists of a mobile console approximately 490mm wide (monitor width: 545mm), 835mm deep and 1415~1815mm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls, 14-inch LCD touch screen and color 23.8-inch LCD & HDU image display.

Intended Use / Indications for Use:

LOGIQ Totus 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 includes: 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 Totus is intended to be used in a hospital or medical clinic.

Technology:

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

Determination of Substantial Equivalence:

The proposed LOGIQ Totus is substantially equivalent to the predicate LOGIQ Totus (K232381) with regards to intended use, imaging capabilities, technological characteristics, imaging modes, hardware, and safety effectiveness.

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

The proposed LOGIQ Totus has additional clinical applications: Transesophageal and Intraoperative.

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

The proposed LOGIQ Totus and the predicate LOGIQ Totus (K232381) have the same imaging modes.

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

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

The proposed LOGIQ Totus and the predicate LOGIQ Totus (K232381) have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.

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

The following is an overview of the differences between the proposed LOGIQ Totus and the predicate LOGIQ Totus (K232381).

Probes:

The probes supported in proposed LOGIQ Totus and the predicate LOGIQ Totus (K232381) are identical except:

- Addition of new probe C2-9-D (migrated from LOGIQ E10s K231989).
- Addition of new probe L4-20t-D (migrated from LOGIQ E10s K231989).
- Addition of new probe L3-9i-D (migrated from LOGIQ E10s K231989).
- Addition of new probe 6Tc-RS (migrated from LOGIQ E10s K231989).

Software:

The software features supported in proposed LOGIQ Totus and the predicate LOGIQ Totus (K232381) are identical except:

Addition of new software features:

- Auto Renal Measure Assistant (Cleared on LOGIQ E10s K231989). During the migration of the AI software feature from LOGIQ E10s (K231989), the algorithm was not retrained and there were no changes to the algorithmic flow or the AI components performing the inferencing. Additionally, the migrated AI feature has already been cleared on its applicable probes. GEHC confirmed that the AI feature works on the subject device after migration with regression tests.
- Ultrasound Guided Fat Fraction for adult imaging (UGFF) (Similar to Siemens UDFE 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: improvements to add Color Flow for Raw Data Streaming (cleared on LOGIQ E10s K231989).



- Public SR Template for Urology, Small Parts and Pediatrics: Support for Public DICOM Structured Reporting template for the urology, Small Parts, and Pediatrics applications.
- DICOM SR Support for Viewpoint Measurements: allows the user to transfer image tags to PACS.
- DICOM tags for AI support.
- Clean Pixel Tag: transfers a clean image to PACs that has removed annotations, measurements, calipers, color bar, and/or scale.
- Image Tagging.
- Qt UI framework for the touch panel: the Qt User Interface Refresh project transformed the current MFC UI into a modern fluid UI, with special emphasis on the touch panel interactions. A separate UI process increased responsiveness while providing fault isolation. Consolidation of UI code into one central package enhances maintainability and aligns with modern design practices. An interface driven approach with dependency injection yielded more modular software.
- Ez Touchpanel 2.0: improvement on Ez Imaging cleared in K211524. EZ Imaging provides an efficient workflow to complete exams with minimal operator button input. EZ Touch Panel allows the operator quick access to change model, flow modes and Doppler modes without searching through multiple pages or many different parameters.
- Improvements to (Continuous Tissue Optimization) CTO/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.
- Verisound Fleet Detailed Restore: improved based on Device Mgmt cleared on K231989. This allows the user to push only select preset categories to the device from the server side.
- E-delivery of base image and application software together: LOGIQ Totus has previously supported e-delivery of the application software payload. Functionality has been added to also be able to e-deliver the base image software (OS).
- Advanced Anonymization: additional anonymization option allows the user to be more selective with which data is anonymized.
- Removed Tricefy.

Hardware:

The hardware in proposed LOGIQ Totus and the predicate LOGIQ Totus (K232381) are identical except:

- GPU replacement due to end-of-life:

- NVIDIA T1000 is replaced by NVIDIA T1000E.

- Key cap variation: added new key top about "Auto" and "UGAP / UGFF" by new function requirement on OPIO as optional keys from new software features for LOGIQ Totus version R5 software.
- Sony BW 898 printer is replaced by Sony BW 899 printer.

Accessory

Addition of new accessory:

- Radio Frequency Identification (RFID) Reader
- TEE RS-DLP Adapter
- KZ200687 Bite Guard
- KZ693 Bite Guard OPR.CLIP ON
- KZ808 TEE SCAN head Protect Cover
- 086A0016 BITE Guard AD.16*27MM
- KZ800 Bite Hole Indicator

Addition of new Biopsy Kits:

- L4-20t-Verza Biopsy Starter Kit
- C2-9 Biopsy Starter Kit

Compatible Devices:

Addition of PW mode to Vscan Air CL probe (Device itself cleared with K231301; Cleared on Predicate LOGIQ Totus K232381).

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 Totus 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-PDF) 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
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BMI	21.0 – 30.8
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Skin to Capsule	9.0 – 53.0
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Distance (SCD) [mm]	

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 UGFF and MRI-PDFF values were within $\pm 8.4\%$, 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)

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Sex	
Male	5
Female	10
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BMI	21.0 – 37.5
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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 $\pm 4.6\%$, 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-PDF values were within $\pm 4.7\%$, 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 NSR.

Conclusion:

Based on the equipment design similarities, conformance to recognized performance standards, and performance testing, GE HealthCare considers the LOGIQ Totus to be as safe, effective, and performs in a substantially equivalent manner as the primary predicate LOGIQ Totus (K232381).