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

May 26, 2026

Re: K260398
Trade/Device Name: LOGIQ e
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: February 6, 2026
Received: February 6, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Digitally signed by Michael D. O'hara -S
Date: 2026.05.26 10:10:15 -04'00' For

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.	K260398

Please provide the device trade name(s).

LOGIQ e

Please provide your Indications for Use below.

The LOGIQ e is a general-purpose diagnostic ultrasound system for use by qualified and trained HealthCare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid.
LOGIQ e is intended to be used in a hospital or medical clinic.

LOGIQ e clinical application include Ophthalmic, Fetal/OB, Abdominal (GYN & Urology), Pediatric, Small organ (Breast, Testes, Thyroid), Neonatal and Adult cephalic, Cardiac (Adult & Pediatric), Peripheral vascular, Musculoskeletal conventional & superficial, Transrectal, Transvaginal, Transesophageal, Intraoperative (Abdominal, Thoracic and Peripheral), Thoracic/pleural for motion and fluid detection and imaging guidance of interventional procedures (e.g. Nerve block; vascular access).
Mode of operation include B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Coded Pulse and Combined modes: B/M, B/PWD, B/Color/PWD, B/Power/PWD.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☒ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary – K260398

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

Date: May 4, 2026

Submitter: GE Medical Systems Ultrasound and Primary Care Diagnostics
3200 N Grandview Blvd
Waukesha, WI 53188, USA

Manufacturer: GE Medical Systems (China) Co., Ltd.
No.19, ChangJiang Road, WuXi National Hi-Tech Dev. Zone,
214028 Jiangsu China

Primary Contact Person: Lee Bush
Regulatory Affairs Director
GE HealthCare
T:(262) 309-9429

Alternate Contact Person: Cui Fang
Regulatory Affairs Specialist
GE HealthCare

Device Trade Name: LOGIQ e
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: K232186 LOGIQ e Diagnostic Ultrasound System
Reference Device(s): K242005 Versana Premier
K250087 Vscan Air
K251322 Venue
K223832 Vivid S70N, Vivid S60N
K200278 Vivid iq
K232381 LOGIQ Totus
K251963 LOGIQ E10s

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 proposed LOGIQ e system is a general-purpose, Track 3, diagnostic ultrasound device, intended for ultrasound imaging, measurement, display and analysis of the human body and fluid.

It is an ultrasound imaging & analysis system, consisting of a compact console with LCD, and control panel with new keyboard.

The system has digital acquisition, processing and display capability and operates from an integrated battery or AC/DC power adapter. It has one battery pack as standard configuration and also with an optional battery pack to be provided for additional power for longer scanning time.

The system also has two optional carts. The primary LOGIQ e cart is height-adjustable cart for comfortable standing and sitting positions. The cart is approx. 510mm length, 510mm width and adjustable height from 830 to 1130mm with optional battery box consisting of a charger box and 4pcs battery Packs to supply the system power from the cart. The LOGIQ e simple cart is approx. 555mm length, 545mm width and fixed height 875mm without powered electrical components or functions.

LOGIQ e utilizes a variety of electronic array transducers operating in linear, curved, sector/phased array, TEE.

The system includes electronics for transmit and receive of ultrasound data, ultrasound signal processing, software computing, hardware for image storage, printing, and network access to the facility through both LAN and wireless (supported by use of a wireless LAN USB-adapter) connection.

The system supports electronic delivery of software. The system allows the user, in addition to service personnel, to update the SW by logging into a GEHC website to download SW available to them and install it on the system. Download from the GEHC website requires an account.

Indications for Use:

The LOGIQ e is a general-purpose diagnostic ultrasound system for use by qualified and trained HealthCare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid.

LOGIQ e is intended to be used in a hospital or medical clinic.

LOGIQ e clinical application include Ophthalmic, Fetal/OB, Abdominal (GYN & Urology), Pediatric, Small organ (Breast, Testes, Thyroid), Neonatal and Adult cephalic, Cardiac (Adult & Pediatric), Peripheral vascular, Musculoskeletal conventional & superficial, Transrectal, Transvaginal, Transesophageal, Intraoperative (Abdominal, Thoracic and Peripheral), Thoracic/pleural for motion and fluid detection and imaging guidance of interventional procedures (e.g. Nerve block; vascular access). Mode of operation include B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Coded Pulse and Combined modes: B/M, B/PWD, B/Color/PWD, B/Power/PWD.

Technology:

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

Determination of Substantial Equivalence:

Comparison to Predicates

The proposed LOGIQ e is substantially equivalent to the predicate devices. The following is an overview of the differences between the LOGIQ e (K232186).

Transducers:

The proposed LOGIQ e and predicate LOGIQ e (K232186) are similar, except for:

- Addition of L6-12-RS previously cleared on Versana Premier (K242005). The clinical applications and imaging modes of L6-12-RS are similar to those available on the reference device Versana Premier (K242005).
- Addition of IC9-RS: previously cleared on Versana Premier (K242005). The clinical applications and imaging modes of IC9-RS are similar to those available on the reference device Versana Premier (K242005).
- Addition of C2-9-RS: previously cleared on Venue (K251322). The clinical applications and imaging modes of C2-9-RS are similar to those available on the reference device Venue (K251322). However, the additional application of Abdominal, Fetal/Obstetrics and Urology are also being added， these applications were cleared on Vivid S70N, Vivid S60N (K223832) with the C2-9-D probe. The C2-9-RS probe is the same as the C2-9-D except it uses an RS connector instead of a D connector. Furthermore, the application of

Thoracic/Pleural is also being added, which was already cleared with a similar curved transducer C1-5-RS on predicate device LOGIQ e (K232186).

- Addition of Vscan Air CL and Vscan Air SL probes, which were cleared on Vscan Air (K250087). The clinical applications and imaging modes are similar with reference device Vscan Air (K250087). The Vscan Air CL and Vscan Air SL have also been cleared on several other consoles such as Venue (K251322)
- Addition of High-Res PDI imaging mode on existing probe ML6-15-RS, both imaging mode and probe are cleared on predicate device LOGIQ e (K232186)

Software Features/Functionality:

- B Flow: same as cleared on Versana Premier (K242005), it is intended to provide a more intuitive representation of non-quantitative hemodynamics in vascular structures.
- AFI: similar to AFI on cleared device Vivid iq (K200278), it is a tool for global and regional assessment of the systolic function of the left ventricle (LV), right ventricle (RV), and left atrium (LA). AFI calculates the myocardial tissue deformation based on feature tracking on 2D grey scale loops.
- SonoBiometry: same as cleared on Versana Premier (K242005), it is an alternative to the common fetal biometry measurements.
- Voice Control: similar to Voice Control on cleared device LOGIQ Totus (K232381), it lets users activate certain functions by speaking recognized commands.
- MyPreset: same as cleared on Versana Premier (K242005), allows users to customize and save frequently used scanning presets.
- Fleet Management: same as cleared on LOGIQ E10s (K251963),is a remote device management tool that enables bi-directional management capabilities on the device which allows cloud management of system preset configurations to a fleet of systems on network, as well as one to one system preset configuration cloud backup and restore functions.
- Connection Manager: similar to Connection Manager cleared on LOGIQ E10s (K251963), it is a wizard tool to set up connectivity step-by-step, the configuration progresses through Network, Remote devices, Print Flow, Dataflow, and Local devices setup screens.
- APP API: same as cleared on Venue (K251322), it is a standardized interface tool to facilitate the integration of multiple software components.
- OS updated from Windows 10 to Windows 11

Hardware:

- CPU was updated to Intel I5-125U
- Added two-probe port option
- CWI board was updated to support Voice Control

Accessories:

- Added Digital Expert Connect
- Added wireless chargers for Vscan Air CL and Vscan Air SL probes
- Added WiFi-Bluetooth USB adaptor to allow wireless connectivity with the Vscan Air CL and Vscan Air SL probes
- Added LOGIQ e Simple Cart
- Added compatible OEM biopsy guide accessory compatibility for the L6-12-RS, C2-9-RS and IC9-RS Transducers
- Added the SONY UP-D899MD printer

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 e complies with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 2005/A2:2021
- 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 4.1, 2020
- IEC 60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment, Edition3.0, 2024
- ISO 10993-1, Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing Within Risk Management Process, Fifth edition, 2018
- ISO 14971, Application of risk management to medical devices, 2019
- NEMA PS 3.1 - 3.20, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology), 2024e
- 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
- AAMI TIR69, Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems, 2017(R2020)

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

Conclusion:
Based on the equipment design similarities, conformance to recognized performance standards, and performance testing, GE HealthCare considers the proposed LOGIQ e to be substantially equivalent to the predicate LOGIQ e (K232186).