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

July 30, 2026

Re: K261835
Trade/Device Name: LOGIQ Focus
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, QIH
Dated: June 2, 2026
Received: June 2, 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: 2026.07.30 14:23:31 -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.	K261835

Please provide the device trade name(s).

LOGIQ Focus

Please provide your Indications for Use below.

LOGIQ Focus is a general-purpose diagnostic ultrasound system intended for qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid.

The system is intended for use for the following Part of Body or Type of Tissue: Fetal/Obstetrical, Abdominal (including Renal, Gynecology/Pelvic, Thoracic/Pleural), Pediatric, Small Organ (Breast, Testes, Thyroid), Neonatal Cephalic, Adult Cephalic, Cardiac (Adult and Pediatric), Peripheral Vascular, Musculoskeletal Conventional and Superficial, Urology (including prostate), Transrectal, Transvaginal, Transesophageal and Intraoperative (Vascular), Interventional Guidance (including tissue biopsy, fluid drainage, vascular and nonvascular access).

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.

LOGIQ Focus 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 (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 - K261835

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

Date: May 29, 2026

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

Manufacturer: GE Medical Systems (China) Co., Ltd.
No. 19, Changjiang Road,
Wuxi National High-Tech Development Zone,
214028 Jiangsu P. R. China

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

Alternate Contact Person: Jian Sophie Xie
Regulatory Affairs Manager
GE HealthCare
T: +86-13338113925

Device Trade Name: LOGIQ Focus

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
Medical Image Management and Processing System, 21 CFR 892.2050, 90-QIH

Primary Predicate Device: K253366 LOGIQ Fortis

Reference Device(s): K242005 Versana Premier, Versana Premier Lotus, LOGIQ F
K214039 LOGIQ P10, LOGIQ P9, LOGIQ P8
K253370 LOGIQ Totus

Device Description:

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

The system consists of a mobile console, operator control panel, display monitor and some transducers. The operator control panel includes an ultrasound keyboard, an alfa-numeric key and a Touch panel as input sources of the device.

The variety of compatible transducers include convex, linear, sector, mechanical 4D, and wireless probes.

LOGIQ Focus is available in two configurations, LOGIQ Focus X and LOGIQ Focus S, which share an identical user interface design and layout. The primary differences between the two configurations are the display type and trackball design: LOGIQ Focus X features an HDU display with an illuminated trackball, while LOGIQ Focus S is equipped with an LCD display and a non-illuminated trackball.

Intended Use/Indications for Use:

LOGIQ Focus is a general-purpose diagnostic ultrasound system intended for qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid.

The system is intended for use for the following Part of Body or Type of Tissue: Fetal/Obstetrical, Abdominal (including Renal, Gynecology/Pelvic, Thoracic/Pleural), Pediatric, Small Organ (Breast, Testes, Thyroid), Neonatal Cephalic, Adult Cephalic, Cardiac (Adult and Pediatric), Peripheral Vascular, Musculoskeletal Conventional and Superficial, Urology (including prostate), Transrectal, Transvaginal, Transesophageal, Intraoperative (Vascular), Interventional Guidance (including tissue biopsy, fluid drainage, vascular and non-vascular access).

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.

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

Technology:

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

Determination of Substantial Equivalence:

The proposed LOGIQ Focus is substantially equivalent to the predicate device, The following is an overview of the differences between the LOGIQ Focus and the predicate device LOGIQ Fortis (K253366).

Indications for Use

The proposed LOGIQ Focus and predicate device LOGIQ Fortis (K253366) have similar clinical indications for use. Addition of Thoracic/Pleural under Abdominal and Interventional Guidance (including tissue biopsy, fluid drainage, vascular and non-vascular access) in the indications for use. Although Thoracic/Pleural and interventional guidance applications were not explicitly called out in the indications for use of LOGIQ Fortis, the capability to perform pleural imaging has already been clinically established and cleared on predicate device LOGIQ Fortis (K253366), and Interventional Guidance (including tissue biopsy, fluid drainage, vascular and non-vascular access) is enabled by existing probe capabilities that support biopsy and needle guidance.

Transducers:

The proposed LOGIQ Focus and predicate device LOGIQ Fortis (K253366) transducers are similar, except for:

- Addition of 9L-RS, L3-12-RS, L4-20t-RS, L8-18i-RS and M5Sc-RS with identical indications for use and modes of operation as the predicate transducers 9L-D, L3-12-D, L4-20t-D, L8-18i-D and M5Sc-D cleared with LOGIQ Fortis (K253366), These transducers are identical to the corresponding predicate transducers except for the use of an RS connector instead of a D connector and were previously cleared on the reference device Versana Premier (K242005).
- Addition of ML6-15-RS with identical indications for use and modes of operation as the predicate transducer ML6-15-D cleared with LOGIQ Fortis (K253366), The ML6-15-RS transducer is the same as the ML6-15-D transducer except it uses RS connector instead of D connector. ML6-15-RS was previously cleared on reference device Cleared on LOGIQ P10, LOGIQ P9, LOGIQ P8 (K214039).
- Addition of RAB2-6-RS with identical indications for use and modes of operation as the predicate transducer RAB6-D cleared with LOGIQ Fortis (K253366). RAB2-6-RS was previously cleared on reference device Versana Premier (K242005).
- Addition of C1-5-RS with identical indications for use and similar modes of operation as previously cleared on reference device Versana Premier (K242005). Additional modes Shear Wave Elastography and Attenuation Imaging are being added, these modes were previously cleared on the similar transducer C1-6-D on LOGIQ Fortis (K253366).
- Addition of IC9-RS with identical indications for use and modes of operation as previously cleared on reference device LOGIQ P10, LOGIQ P9, LOGIQ P8 (K214039).
- Addition of E8Cs-RS, 12L-RS and 3Sc-RS with identical indications for use and modes of operation as previously cleared on reference device Versana Premier (K242005).

Software Features/Functionality:

The software features supported in proposed LOGIQ Focus and the predicate LOGIQ Fortis (K253366) are similar except:

- Auto Abdominal Color Assistant 2.0: migrated from predicate device LOGIQ Fortis (K253366) and expanded to support probe C1-5-RS, which is similar to the previously cleared C1-6-D

transducer on the predicate device LOGIQ Fortis (K253366).

- Auto Preset Assistant: migrated from predicate device LOGIQ Fortis (K253366) and expanded to support the 9L-RS, L3-12-RS, and ML6-15-RS transducers. The supported transducers L3-12-RS, and ML6-15-RS differ only in connector type compared to those used with predicate device LOGIQ Fortis (K253366) and the supported transducer 9L-RS differs only in connector type compared to 9L-D on reference device LOGIQ Totus (K253370).
- Ultrasound-Guided Fat Fraction (UGFF)/Ultrasound-Guided Attenuation Parameter (UGAP): migrated from reference device LOGIQ Totus (K253370) and expanded to support C1-5-RS, which is similar to the previously cleared C1-6-D transducer on the predicate device LOGIQ Totus (K253370).
- IOTA (International Ovarian Tumor Analysis): a worksheet-based ovary measurement and analysis tool, same as cleared on LOGIQ P10, LOGIQ P9, LOGIQ P8 (K214039)

Accessories:

- Added the SONY UP-D899DC printer
- Added compatible OEM biopsy guide accessory compatibility for the C1-5-RS, 3Sc-RS, 12L-RS, IC9-RS Transducers
- Added new hardware options: Gel Warmer, Charge Box with Battery Kit, Battery Pack, Charge Box, 4D Module, ECG Module, Lemo Module
- Added new connectivity option Wi-Fi and Bluetooth 2 in 1 USB Stick Kit
- Added new peripherals: UP-D899DC Printer Shelf, UP-D899DC Printer Kit, DVD Shelf, DVD Kit
- Added new accessories: 64G USB Stick, USB Barcode Reader Honeywell, Operator Panel Rear Storage, Trolley Base Storage, Trolley Rear Storage, Trolley Top Storage, P6D Probe Holder, Vertical Endo Probe Holder Adapter for Cardiac Probe

AI Testing Summary:

Auto Preset Assistant

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: 67 patients • The number of samples, if different from above, and the relationship between the two: 1253 images
Information about clinical subgroups and confounders present in the dataset	• Gender: Male & Female: 32 (48%), 35 (52%) • Country: USA (100%) • Age: 58±17.1 • BMI: 27.1±8.9 • Ethnicity: Hispanic (5), Not Hispanic (61) • Race: Asian (8), Black (14), Hispanic/Latino (1), White (44)

Information about equipment and protocols used to collect images	Mix of data from across 3 different probe models (L3-12-RS, ML6-15-RS, 9L-RS) and 1 Console (LOGIQ Focus) 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 [7] 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 purposes are separated from the ones used during training process and there is no overlap between the two.

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: 67 • The number of annotation images: 728 • The model achieved a detection accuracy of 93.8%, with sensitivity of 0.94, specificity of 0.99, and a DICE score of 0.85, all of which meet the predefined acceptance criteria.
Information about clinical subgroups and confounders present in the dataset	• Gender: Male & Female: 32 (48%), 35 (52%) • Country: USA (100%) • Age: 58±17.1 • BMI: 27.1±8.9 • Ethnicity: Hispanic (5), Not Hispanic (61) • Race: Asian (8), Black (14), Hispanic/Latino (1), White (44)
Information about equipment and protocols used to collect images	Data from 1 probe model (C1-5-RS) and 1 Console (LOGIQ Focus) variants. The data collection protocol was standardized.

Information about how the reference standard was derived from the dataset (i.e. the "truthing" process)	Reference Standard and Ground Truthing Process for Testing Dataset • Prior to annotation, all device-displayed information was removed to ensure unbiased evaluation. Only raw B-mode ultrasound images were used for analysis. • Independent clinical readers reviewed the static B-mode images to identify and annotate anatomical structures, establishing the reference standard ("ground truth") before any AI inference was performed. • The AI model was then executed on the same dataset, and its predictions were compared against the ground truth annotations. • A confusion matrix was generated to evaluate the model's performance across each anatomical class. • Detection accuracy metrics—including sensitivity, specificity, and DICE similarity coefficient—were calculated based on this comparison.
Description of how independence of test data from training data was ensured	The exams used for test/training validation purposes 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 Focus 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, Edition 3.0, 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 Focus, 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 Focus to be as safe, effective, and performs in a substantially equivalent manner as the predicate LOGIQ Fortis (K253366).