March 24, 2026

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

Re: K260673
Trade/Device Name: LOGIQ Vita; LOGIQ Vita Pro; LOGIQ Vita Express; LOGIQ Vita Plus; LOGIQ Vita Power; LOGIQ S20; LOGIQ S20 Pro; LOGIQ S20 Express; LOGIQ S20 Plus; LOGIQ S20 Power
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, QIH
Dated: March 2, 2026
Received: March 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: 2026.03.24 15:28:06 -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K260673

Device Name
LOGIQ Vita; LOGIQ Vita Pro; LOGIQ Vita Express; LOGIQ Vita Plus; LOGIQ Vita Power; LOGIQ S20; LOGIQ S20 Pro; LOGIQ S20 Express; LOGIQ S20 Plus; LOGIQ S20 Power

Indications for Use *(Describe)*
The LOGIQ Vita / S20 Series are intended for use by a qualified physician for ultrasound evaluation of Fetal / Obstetrics; Abdominal (including Renal, Gynecology/Pelvic); Pediatric; Small Organ (Breast, Testes, Thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (Adult and Pediatric); Peripheral Vascular; Musculo- skeletal Conventional and Superficial; Urology (including Prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative (Abdominal and Vascular).

Modes of operation include: B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Coded Pulse, 3D/4D Imaging mode, Elastography, Shear Wave Elastography, Attenuation Imaging and Combined modes: B/M, B/Color, B/PWD, B/Color/PWD, B/Power/PWD.

The LOGIQ Vita / S20 Series are intended to be used in a hospital or medical clinic.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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

510(k) Summary - K260673

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

Date:	March 19, 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:	Qingmeng Chen Regulatory Affairs Leader GE HealthCare T: +86-18180590723
Device Trade Name:	LOGIQ Vita, LOGIQ Vita Pro, LOGIQ Vita Express, LOGIQ Vita Plus, LOGIQ Vita Power, LOGIQ S20, LOGIQ S20 Pro, LOGIQ S20 Express, LOGIQ S20 Plus, LOGIQ S20 Power
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 Diagnostic Ultrasound System
Reference Device(s):	K250087 Vscan Air K253370 LOGIQ Totus Diagnostic Ultrasound System

Device description:

The LOGIQ Vita / S20 Series are full featured, Track 3, general purpose diagnostic ultrasound systems which consists of a mobile console approximately 530 mm wide (Caster), 835 mm deep (front and back handle) and 1314 mm high that provides digital acquisition, processing and display capability. The user interface includes a digital keyboard (physical keyboard as an option), specialized controls, 14-inch high-resolution color touch screen and 23.8-inch Wide screen High-Resolution HDU monitor and 23.8-inch Wide screen High-Resolution LCD monitor.

Intended Use / Indications for Use:

The LOGIQ Vita / S20 Series are intended for use by a qualified physician for ultrasound evaluation of Fetal / Obstetrics; Abdominal (including Renal, Gynecology/Pelvic); Pediatric; Small Organ (Breast, Testes, Thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (Adult and Pediatric); Peripheral Vascular; Musculo- skeletal Conventional and Superficial; Urology (including Prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative (Abdominal and Vascular).

Modes of operation include: B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Coded Pulse, 3D/4D Imaging mode, Elastography, Shear Wave Elastography, Attenuation Imaging and Combined modes: B/M, B/Color, B/PWD, B/Color/PWD, B/Power/PWD.

The LOGIQ Vita / S20 Series are intended to be used in a hospital or medical clinic.

Technology:

The LOGIQ Vita / S20 Series employ the same fundamental scientific technology as its predicate device(s).

Determination of Substantial Equivalence:

The proposed LOGIQ Vita / S20 Series are substantially equivalent to the predicate LOGIQ Fortis (K253366) 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 Vita / S20 Series and the predicate LOGIQ Fortis (K253366) have the same clinical indications for use.

The proposed LOGIQ Vita / S20 Series employ the same fundamental scientific technology as its predicate device.

The proposed LOGIQ Vita / S20 Series and the predicate LOGIQ Fortis (K253366) have the same imaging modes.

The proposed LOGIQ Vita / S20 Series are manufactured with materials which have been evaluated and found to be safe for the intended use of the device.

The proposed LOGIQ Vita / S20 Series have acoustic power levels which are below the applicable FDA limits.

The proposed LOGIQ Vita / S20 Series and the predicate LOGIQ Fortis (K253366) have the same capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.

The proposed LOGIQ Vita / S20 Series have been designed in compliance with approved electrical and physical safety standards.

The proposed LOGIQ Vita / S20 Series re-use 26 probes previously cleared on predicate LOGIQ Fortis (K253366) without modifications.

The compatible device Vscan Air CL probe has its own clearance with K250087 and is also cleared on Predicate LOGIQ Fortis K253366).

The software features supported on proposed LOGIQ Vita / S20 Series and the predicate LOGIQ Fortis (K253366) are identical except that proposed device do not support the use with Koios Lite, Koios DS Connectivity, and Digital Expert.

The hardware and accessories in proposed LOGIQ Vita / S20 Series and the predicate LOGIQ Fortis (K253366) are similar. The major difference between the proposed LOGIQ Vita / S20 Series and the predicate LOGIQ Fortis (K253366) is the operation panel, monitors and appearance.

> The LOGIQ Vita / S20 Series were developed and designed based on LOGIQ Fortis (K253366) and LOGIQ Totus (K253370) as shown in the figure below. It uses the LOGIQ Forits Trolley console base and the LOGIQ Totus Operator Panel (OPIO). The software of LOGIQ Vita / S20 Series is based on LOGIQ Fortis R5.0.1. The LOGIQ Vita series uses the 23.8inch HDU monitor from predicate LOGIQ Fortis (K253366) as its main display and the LOGIQ S20 series uses the 23.8inch LCD monitor from LOGIQ Totus (K253370) as its main display. The industrial design has been refreshed and the covers have been recolored.
>
> Some accessories are not supported with LOGIQ Vita / S20 relative to the predicate: Digital Expert associated tablets, UPS (Uninterruptible Power Supply) kit, B/W Printer, and color printer.

Comparison table of technological characteristics with predicate device(s):

Characteristic	**Proposed Device LOGIQ Vita / S20 Series**	**Predicate Device LOGIQ Fortis (K253366)**	**Comparison**
Touch Panel	**14-inch touch panel**	12.1-inch touch panel	Proposed devices use 14-inch Touch Panel from LOGIQ Totus (K253370).
Monitors	23.8" High Resolution **HDU** monitor 23.8-inch High Resolution **LCD** monitor	23.8" High contrast LED LCD monitor (or 23.8-inch High Resolution LED LCD monitor as an option)	The proposed LOGIQ Vita uses 23.8inch HDU monitor from predicate LOGIQ Fortis (K253366) and the proposed LOGIQ S20 uses the 23.8inch LCD monitor from LOGIQ Totus (K253370).
Key Software features	Ultrasound-Guided Attenuation Parameter (UGAP), Ultrasound Guided Fat Fraction (UGFF), Auto Preset Assistant, Auto Abdominal Color Assistant 2.0, Auto Abdominal Measure Assistant (Renal, Aorta, CBD)	Ultrasound-Guided Attenuation Parameter (UGAP), Ultrasound Guided Fat Fraction (UGFF), Auto Preset Assistant, Auto Abdominal Color Assistant 2.0, Auto Abdominal Measure Assistant (Renal, Aorta, CBD), **KOIS Lite**	Identical* except proposed devices do not support Koios Lite.
Options/Utilities	Biopsy w/guidelines, Scan Assistant, ECG, Footswitch, Histogram,	Biopsy w/guidelines, Scan Assistant, ECG, Footswitch, Histogram,	Identical except proposed devices do not support UPS.

Characteristic	Proposed Device LOGIQ Vita / S20 Series	Predicate Device LOGIQ Fortis (K253366)	Comparison
	Video out, Service Modem, Respirometer, RFID reader	Video out, Service Modem, Respirometer, RFID reader, **UPS**	
Connectivity and Archive	DVR, CD/RW & DVD; IP/DICOM, USB; DICOM Compression, Modem, Ethernet network, Multiple and Multiple Frame send, memory stick, Vscan Air CL support, Send Images via Email, ViewPoint on LOGIQ	**B/W & Color printing**, DVR, CD/RW & DVD; IP/DICOM, USB; DICOM Compression, Modem, Ethernet network, Multiple and Multiple Frame send, memory stick, **Koios DS Connectivity**, Vscan Air CL support, Send Images via Email, ViewPoint on LOGIQ, **Digital Expert Connectivity**	Identical except proposed devices do not support Koios DS Connectivity, Digital Expert Connectivity, or integrated printers.

* There were no modifications or retraining of the liver assessment features (UGAP/UGFF) or the features utilizing AI algorithms since the frontend beamforming hardware, backend processing hardware, and compatible probes are the same as on predicate LOGIQ Fortis (K253366)

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 Vita / S20 Series comply 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 60601-2-37 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 of Clinical Tests:

The subject of this premarket submission, the LOGIQ Vita / S20 Series, leverages the same clinical data as the predicate and no changes to the features, accessories, or components that require new 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 Vita / S20 Series to be as safe, effective, and performs in a substantially equivalent manner as the predicate LOGIQ Fortis (K253366).