



GE Medical Systems Ultrasound and Primary Care Diagnostic
c/o Lee Bush
Regulatory Affairs Director, GE HealthCare
LLC 9900 Innovation Dr.
WAUWATOSA WI 53226

November 3, 2023

Re: K232186

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: October 2, 2023

Received: October 2, 2023

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.

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

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.
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510(k) Number (if known) **K232186**

Device Name
LOGIQ e

Indications for Use (Describe)

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.

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.

510(k) Summary**K232186**

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

Date: 24 July, 2023

Submitter: GE Medical Systems Ultrasound and Primary Care Diagnostics
9900 Innovation Drive
Wauwatosa, WI 53226

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

Secondary Contact Person: Yuan Wang
Regulatory Affairs Leader
GE HealthCare

Device Trade Name: LOGIQ e

Common/Usual Name: Diagnostic Ultrasound System

Classification Names: Class II

Product Code(s): 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

Predicate Device: LOGIQ e (K151028), Diagnostic Ultrasound System

Classification Names: Class II

Product Code(s): 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

Reference Device: Vivid iq (K221148), Diagnostic Ultrasound System
Classification Names: Class II
Product Code(s): 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

Reference Device: Versana Premier (K210438), Diagnostic Ultrasound System
Classification Names: Class II
Product Code(s): 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

Reference Device: Venue Go (K202233), Diagnostic Ultrasound System
Classification Names: Class II
Product Code(s): 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 an optional 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.

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.

Intended Use/Indication 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.

Determination of Substantial Equivalence:

The proposed LOGIQ e system is substantially equivalent to the predicate device LOGIQ e and reference devices with regards to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

The following is an overview of the differences between the proposed LOGIQ e and its predicate device.

Indications for use:

The proposed LOGIQ e and predicate LOGIQ e (K151028) have similar clinical indications for use. There are no additional clinical applications, however the indications for use wording has been modified to align with FDA's new ultrasound guidance issued on 21-Feb-

2023, identify users similar to reference device Versana Premier (K210438), and provide information on the environments the system can be used in.

Transducer and modes:

- The proposed LOGIQ e and predicate LOGIQ e (K151028) have identical imaging modes.
- The proposed LOGIQ e and predicate LOGIQ e (K151028) transducers are similar, except for:
 - Addition of L4-20t-RS, which was previous cleared on Vivid iq (K221148). The clinical applications and imaging modes of L4-20t-RS are similar on the proposed LOGIQ e as they are on the reference device Vivid iq (K221148).
 - Addition of 12S-RS, which was previous cleared on Vivid iq (K221148). The clinical applications and imaging modes of 12S-RS are similar on the proposed LOGIQ e as they are on the reference device Vivid iq (K221148).
- The Thoracic/Pleural is added to the transducer C1-5-RS, based on the clearance of reference device Vivid iq (K221148).
- Pediatric are added to the transducer L10-22-RS, based on the clearance of reference device Venue Go (K202233).

Software:

- Added AutoEF – cleared in Versana Premier (K210438)
- Added Scan assistant – cleared in Versana Premier (K210438)
- Added Strain Elastography, cleared in Versana Premier (K210438)
- Added Probe check (Transducer Element Check), cleared in Versana Premier (K210438)
- Added Imaging Insights, cleared in Vivid iq (K221148)
- Added Tricefy Uplink, cleared in Vivid iq (K221148)

Hardware:

- New Product Industrial Design with 15.6inch LCD and new keyboard
- Additional option for secondary battery pack to support longer scanning time on batteries.
- Optimize thermal solution with low noise fan.

Accessories:

- Added compatible OEM biopsy guide accessory compatibility for the L4-20t-RS transducer

Summary of Non-Clinical Tests:

LOGIQ e is evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and have been found to comply 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 and Essential Performance, 2005/ A2:2012
- ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021], Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]
- IEC 60601-2-37 Edition 2.1 2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- IEC 62359 Edition 2.1 2017-09 Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields
- 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), 2021e

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, 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 as safe, effective, and performs in a substantially equivalent manner as the predicate device LOGIQ e (K151028) and reference devices Vivid iq (K221148), Versana Premier (K214038) and Venue Go (K202233).