June 10, 2024

GE Medical Systems Ultrasound and Primary Care Diagnostics
% Karin Shimoni
Regulatory Affairs Manager
9900 Innovation Drive
WAUWATOSA WI 53226

Re: K240111
Trade/Device Name: Venue
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: May 9, 2024
Received: May 9, 2024

Dear Karin Shimoni:

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240111

Device Name

Venue

Indications for Use *(Describe)*

The Venue is a general purpose diagnostic ultrasound system for use by qualified and trained healthcare professionals or practitioners that are legally authorized or licensed by law in the country, state or other local municipality in which he or she practices, for ultrasound imaging, measurement, display and analysis of the human body and fluid. The users may or may not be working under supervision or authority of a physician. Users may also include medical students working under the supervision or authority of a physician during their education / training.
Venue is intended to be used in a hospital or medical clinic. Venue clinical applications include: abdominal (GYN and Urology), thoracic/pleural, ophthalmic, Fetal/OB, Small Organ (including breast, testes, thyroid), Vascular/Peripheral vascular, neonatal and adult cephalic, pediatric, musculoskeletal (conventional and superficial), cardiac (adults and pediatric), Transrectal, Transvaginal, Transesophageal, Intraoperative (vascular) and interventional guidance (includes 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 and Combined modes: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD,B/CWD, B/Color/CWD.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

GE HealthCare

510(k) Summary - K240111

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

Date:	January 15, 2024
Submitter:	GE Medical Systems Ultrasound and Primary Care Diagnostics 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Karin Shimoni Regulatory Affairs Manager GE HealthCare T: (+972) 546347710
Secondary Contact Person:	Lee Bush Regulatory Affairs Director GE HealthCare T: (262) 3099429
Device Trade Name:	Venue
Common/Usual Name:	Diagnostic Ultrasound System
Classification Names:	Class II
Product Code:	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:	K220851 Venue, Diagnostic Ultrasound System
Classification Names:	Class II
Product Code:	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(s):	K231301 Vscan Air
Classification Names:	Class II
Product Code:	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(s):	K161047 LOGIQ P9 and LOGIQ P7
Classification Names:	Class II
Product Code:	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(s):	K231989 LOGIQ E10s/LOGIQ Fortis
Classification Names:	Class II
Product Code:	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(s):	K180374 Voluson S8/ Voluson S10/ Voluson S10 Expert
Classification Names:	Class II
Product Code:	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(s):	K202035 Vscan Air
Classification Names:	Class II
Product Code:	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(s):	K200851 Vivid T8, Vivid T9
Classification Names:	Class II
Product Code:	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(s):	K203677 ViewPoint 6
Classification Names:	Class II
Product Code:	Picture archiving and communications system, 21 CFR 892.2050, 90-LLZ
Reference Device(s):	K201992 Caption Guidance
Classification Names:Product Code:	Class II QJU

Device Description:

The proposed Venue system is a general-purpose, Track 3, diagnostic ultrasound device, intended for ultrasound imaging, measurement and analysis of the human body and fluid that provides digital acquisition, processing and display capabilities. Venue can be used in offices, clinics and hospitals.

The Venue is a mobile system with a small footprint that easily fits into tight spaces and positioned to accommodate the sometimes-awkward work settings of the point of care user.

The Venue has a high resolution color LCD monitor, with a simple, multi-touch user interface that makes the system intuitive. The single surface screen provides easy cleanability. Articulated monitor arm enables flexible display positions in order to be accessible and clearly visible in both user-standing and sitting positions.

The system is capable of displaying the patient's ECG trace synchronized to the scanned image. This allows the user to view an image from a specific time of the ECG signal which is used as an input for gating during scanning. The ECG signal can be input directly from the patient or as an output from an ECG monitoring device. ECG information is not intended for monitoring or diagnosis.

Barcode reader and RFID scanner are available as additional input devices.

The Venue has a battery that allows for scanning without the need to plug in to an electrical outlet.

System meets DICOM requirements to support users image storage and archiving needs and allows for output to printing devices.

The Venue utilizes a variety of linear, convex, and phased array transducers which provide high imaging capability, supporting all standard acquisition modes. Compatible biopsy kits can be used for needle-guidance procedures.

The system includes several automated tools designed to simplify and shorten the workflow time of the healthcare professional for some common assessments.

Intended Use: The Venue is a general purpose diagnostic ultrasound system for use by qualified and trained healthcare professionals or practitioners that are legally authorized or licensed by law in the country, state or other local municipality in which he or she practices, for ultrasound imaging, measurement, display and analysis of the human body and fluid. The users may or may not be working under supervision or authority of a physician. Users may also include medical students working under the supervision or authority of a physician during their education / training. Venue is intended to be used in a hospital or medical clinic. Venue clinical applications include: abdominal (GYN and Urology), thoracic/pleural, ophthalmic, Fetal/OB, Small Organ (including breast, testes, thyroid), Vascular/Peripheral vascular, neonatal and adult cephalic, pediatric, musculoskeletal (conventional and superficial), cardiac (adults and pediatric), Transrectal, Transvaginal, Transesophageal, Intraoperative (vascular) and interventional guidance (includes 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 and Combined modes: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD,B/CWD, B/Color/CWD.

Re. Technology: The Venue employs the same fundamental scientific technology as its predicate and reference devices.

Determination of Substantial Equivalence: Comparison to Predicate Device

The Venue system is substantially equivalent to the predicate device with regards to imaging capabilities, technological characteristics and safety and effectiveness. All probes used with the proposed Venue system are used unchanged from the cleared predicate. They are made of the same materials and their shape is unchanged.

The following is an overview of the differences between the proposed Venue and the predicate Venue:

Indications for Use:
The proposed Venue and predicate Venue (K220851) have similar clinical indications for use, however the IFU statement is updated to add details to the operator qualification/profile for clarity. No change to the product and no impact to safe or effective use.
The proposed Venue and predicate Venue (K220851) have identical imaging modes.

Transducers:
The proposed Venue and predicate Venue (K220851) systems transducers are similar, except for

- Addition of C2-9-RS which was first cleared on Voluson S8/ Voluson S10/ Voluson S10 Expert K180374. This probe is unchanged from the cleared reference device (K180374). It is made of the same materials and its shape is unchanged. The clinical indications of C2-9-RS are the same on the proposed Venue as they are on the reference device LOGIQ E10s/LOGIQ Fortis K231989 with 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. The transducer body is identical between the two.
- Addition of Vscan Air CL and SL probes. The Vscan Air CL was first cleared in K202035 and the Vscan Air SL was first cleared in K231301. The clinical indications of the Vscan Air CL and SL are identical as on the reference device Vscan Air K231301. The Vscan Air CL probe is cleared also on reference LOGIQ E10s/LOGIQ Fortis K231989.
- Addition of neonatal cephalic application on existing L10-22-RS probe. This application was already cleared with this probe on reference device LOGIQ P9 and LOGIQ P7 (K161047).
- Addition of PDI+ on existing ML6-15-RS probe (both imaging mode and probe are cleared on predicate Venue (K220851).

Features/Functionality:

- Vscan Air CL and Vscan Air SL probes: The proposed Venue system supports the Vscan Air CL and Vscan Air SL cleared in K231301. The Vscan Air CL probe is cleared also on reference LOGIQ E10s/LOGIQ Fortis K231989.

- Auto Volume Flow (AVF): The AVF tool is a semi-automated tool intended to measure inflow in the vessel. It enables the user to perform a quick assessment, especially when measuring inflow in the artery of the fistula of a dialysis patient. The rate of volume flow is calculated using pulsed wave (PW) Doppler flow measurement.
- Bladder Volume Tool: Bladder Volume Tool provides a simplified workflow for bladder volume measurement.
- MSK diagrams The MSK Diagram enables documenting and summarizing MSK exam in an anatomical view. On predicate Venue K220851, the only diagram that was available for MSK preset was the shoulder diagram. On the proposed Venue, diagrams are also added for the knee, wrist/hand, hip, elbow and ankle/foot.
- Venue Coach: Venue Coach contains all the diagrams and reference images available in the proposed Venue system. From the Venue Coach tab, user can configure a diagram, a reference image or both.
- Electronic delivery of SW: The proposed Venue system now 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.
- Expanding cleared Auto Inferior Vena Cava (IVC), Auto B-Lines, Real Time ejection fraction (RT-EF) and cNerve for Vscan Air CL and SL probes. These probes are already cleared on predicate Vscan Air K231301. The Vscan Air CL probe is cleared also on reference device LOGIQ E10s/LOGIQ Fortis K231989.
- AppAPI functionality: to facilitate future integration of multiple software components.

Hardware:
When Vscan Air CL and SL probes are to be used with the proposed Venue system, then the Venue system is updated to include WiFi and Bluetooth dongles that allow wireless connectivity with the Vscan Air CL and SL probes. Power to the wireless charger of Vscan Air CL and SL probes is supplied from the Main Power Board (MPB).

Summary of Non-Clinical Tests:
The proposed Venue 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 comply with applicable medical device safety standards. The Venue complies with voluntary standards:

- Marketing Clearance of Diagnostic Ultrasound Systems and Transducers- Guidance for Industry and Food and Drug Administration Staff, issued on February 21, 2023
- 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 Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests, 2020
- IEC 60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment, 2015
- IEC 62359, Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2017
- ISO 10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing Within a Risk Management Process, Fifth edition, 2018
- ISO 14971, Application of risk management to medical devices, 2019
- NEMA PS 3.1 - 3.20e, Digital Imaging and Communications in Medicine (DICOM) Set, 2021
- AAMI TIR69, Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems, 2020

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 material and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, Venue, 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 Venue to be as safe, Effective, and performs in a substantially equivalent manner as the predicate Venue (K220851).