July 25, 2025

GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC
Karin Shimoni
Official Correspondent
3200 N Grandview Blvd
Waukesha, Wisconsin 53188

Re: K251322
Trade/Device Name: Venue; Venue Go; Venue Fit; Venue Sprint
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: April 29, 2025
Received: April 29, 2025

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.

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,

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

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.	K251322

Please provide the device trade name(s).

Venue;
Venue Go;
Venue Fit;
Venue Sprint

Please provide your Indications for Use below.

The Venue, Venue Go, Venue Fit and Venue Sprint are general purpose diagnostic ultrasound systems 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, Venue Go and Venue Fit are intended to be used in a hospital or medical clinic. Venue, Venue Go and Venue Fit 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.

The Venue Sprint is intended to be used in a hospital, medical clinic, home environment and road/air ambulance. Venue Sprint 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, 40 kg and above) and interventional guidance (includes free hand tissue biopsy, fluid drainage, vascular and non-vascular access). Modes of operation include: B, M, PW Doppler, Color Doppler and Harmonic Imaging.

Please select the types of uses (select one or both, as applicable).

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

K251322

510(k) Summary

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

Date:	April 29, 2025
Submitter:	GE Medical Systems Ultrasound and Primary Care Diagnostics 3200 N Grandview Blvd Waukesha, WI 53188
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, Venue Go, Venue Fit, Venue Sprint
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:	K240111 Venue, K240053 Venue Go, K234106 Venue Fit, K240206 Venue Sprint
Common/Usual Name:	Diagnostic Ultrasound Systems
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):	K231966 LOGIQ E10
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):	K223832 Vivid S70N
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):	K161588 Vscan Extend
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):	K220940 EchoPAC Software Only/EchoPAC Plug-in
Classification Names:	Class II
Product Code:	Automated Radiological Image Processing Software, 21 CFR 892.2050, QIH; Picture Archiving and Communications System, 21 CFR 892.2050, LLZ

Device Description: Venue, Venue Go, Venue Fit and Venue Sprint are general-purpose diagnostic ultrasound systems intended for use by qualified and trained healthcare professionals to evaluate the body by ultrasound imaging and fluid flow analysis.
The systems utilize a variety of linear, convex, and phased array transducers which provide high imaging capability, supporting all standard acquisition modes.
The systems have 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 is a mobile system, the Venue Go and Venue Fit are compact, portable systems that can be hand carried using an integrated handle, placed on a horizontal surface, attached to a mobile cart or mounted on the wall. Venue, Venue Go and Venue Fit have a high-resolution color LCD monitor, with a simple, multi-touch user interface that makes the systems intuitive.

The Venue Sprint is used together with the Vscan Air probes and provides the user interface for control of the probes and the needed software functionality for analysis of the ultrasound images and saving/storage of the related images and videos.

The Venue, Venue Go, Venue Fit and Venue Sprint systems can be powered through an electrical wall outlet for long term use or from an internal battery for a short time with full functionality and scanning. A barcode reader and RFID scanner are available as additional input devices. The systems meet DICOM requirements to support users image storage and archiving needs and allows for output to printing devices.

The Venue, Venue Go and Venue Fit systems are 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. Compatible biopsy kits can be used for needle-guidance procedures.

Intended Use: The Venue, Venue Go, Venue Fit and Venue Sprint are general purpose diagnostic ultrasound systems 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, Venue Go and Venue Fit are intended to be used in a hospital or medical clinic. Venue, Venue Go and Venue Fit 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.

The Venue Sprint is intended to be used in a hospital, medical clinic, home environment and road/air ambulance. Venue Sprint 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, 40 kg and above) and interventional guidance (includes free hand tissue biopsy, fluid drainage, vascular and non-vascular access). Modes of operation include: B, M, PW Doppler, Color Doppler and Harmonic Imaging.

Re. Technology: The Venue, Venue Go, Venue Fit and Venue Sprint employ the same fundamental scientific technology as their predicate (Venue, Venue Go, Venue Fit and Venue Sprint, respectively) and reference devices.

Determination of Substantial Equivalence:

Comparison to Predicate Device

The Venue, Venue Go, Venue Fit and Venue Sprint systems are substantially equivalent to the predicate devices with regards to imaging capabilities, technological characteristics and safety and effectiveness. All probes used with the proposed Venue Fit 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, Venue Go, Venue Fit and Venue Sprint and their predicates:

Indications for Use:
The proposed Venue, Venue Go, Venue Fit and Venue Sprint and predicates Venue, Venue Go, Venue Fit and Venue Sprint (K240111, K240053, K234106 and K240206, respectively) have identical clinical indications for use and imaging modes.

Transducers:
The proposed Venue Sprint and predicate Venue Sprint (K240206) system transducers are identical.
The proposed Venue, Venue Go, Venue Fit and predicates Venue, Venue Go, Venue Fit (K240111, K240053 and K234106, respectively) systems transducers are similar, except for:

- Addition of Thoracic/Pleural application on existing C2-9-RS probe. This application is already cleared with C1-5-RS in predicates Venue, Venue Go, Venue Fit, which is an equivalent transducer.
- Addition of PDI+ on existing L8-18i-RS, L4-20t-RS, ML6-15-RS, L10-22-RS, L4-12t-RS, 12L-RS, L12n-RS* probes. Both imaging mode and probes are cleared on predicates Venue (K240111), Venue Go (K240053) and Venue Fit (K234106)].
  *available on Venue only
- Addition of cNeedle feature on existing C2-9-RS probe. Both cleared on predicates Venue (K240111), Venue Go (K240053) and Venue Fit (K234106).
- Expand Caption Guidance application for Vscan Air SL probe. Caption Guidance enables the user to obtain different cardiac views through textual guidance, prescriptive graphical navigation, and reference images. Caption Guidance has its own FDA clearance (K243065) and is similar to Caption Guidance cleared on predicates Venue K240111, Venue Go K240053 and Venue Fit K234106.
- Image Quality improvements with no change to input parameters (power/frequency), no changes to core image processing (beamforming), and only changes to the postprocessing and display parameters.

Features/Functionality:

- Contrast Imaging: The contrast imaging technique, facilitated by the use of a contrast agent, detects non-linear signals while suppressing linear signals from surround tissue. Blood containing the contrast agent stands out brightly against a dark background of normal tissue. The Contrast Imaging on proposed Venue, Venue Go and Venue Fit is similar to Contrast Imaging available on the cleared reference LOGIQ E10 (K231966).
- Automated Function Imaging (AFI): an automated tool for global and regional assessment of the systolic function of the left ventricle (LV), right ventricle (RV), and left atrium (LA). The AFI tool on proposed Venue and Venue Go is similar to AFI with Easy AFI LV tool available on the cleared references Vivid S70N (K223832) and EchoPAC Software Only/EchoPAC Plug-in (K220940)

and includes AI Auto ROI algorithm that automatically detects the myocardium.

- Auto Bladder Volume (ABV): provides a simplified workflow and automated measurements of bladder's height, width and length, for calculating bladder volume. The workflow is similar to Bladder Volume cleared on predicates Venue K240111, Venue Go K240053, Venue Fit K234106 and Venue Sprint K240206 and the automated calipers placement is similar to Bladder Volume Application on reference Vscan Extend K161588, however, Auto Bladder Volume uses a deep learning algorithm instead of traditional image analysis.
- Added 'Maximize image' - an option to automatically increase the image size, when scanning in Shallow Depth.

Summary of Non-Clinical Tests:
The proposed Venue, Venue Go, Venue Fit and Venue Sprint have been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and have been found to conform to applicable medical device safety standards.

The Venue, Venue Go, Venue Fit and Venue Sprint comply 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 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: Second edition 2019
- NEMA PS 3.1 - 3.20e, Digital Imaging and Communications in Medicine (DICOM) Set, 2023
- AAMI TIR69, Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems, 2020

The Venue Sprint complies with the additional voluntary standards:

- IEC 60601-1-11, Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment, 2020
- IEC 60601-1-12, Medical Electrical Equipment - Part 1-12: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Intended For Use In The Emergency Medical Services Environment, 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.

AI Summary of Testing

Auto Bladder Volume (ABV):

Summary verification statistics and other results including acceptance criteria and information supporting the appropriateness of the characterized performance are provided below.

Verification dataset:

- Verification dataset representative of the range of bladder volumes which Auto Bladder Volume supports was assessed by experts for accuracy.
- Verification dataset included 1874 images from 101 individuals.

Demographic distribution of verification dataset:

- Gender: Male and Female
- Age (18-82 years)
- Ethnicity/Country: USA and Israel
- BMI (18.7-42.5)
- Ultrasound Console: Venue Family (Venue, Venue Go, Venue Fit)

Information about clinical subgroups and confounders present in the verification dataset:

- The algorithm performance was verified across a range of demographic subgroups:
  Gender (M/F), Age (18-82 years), Ethnicity/Country (USA and Israel), BMI (18.7-42.5)

Expected performance:

- At least 90% success rate in automatic caliper placement for bladder volume measurements when bladder wall is entirely visualized.

Performance demonstrated on verification dataset:

- Automatic caliper placement success rate: 95.09% with a 95% confidence level
- Further analysis demonstrated consistent performance across key subgroups including subjects with known BMI:

BMI	Success Rate
healthy weight (18.5-24.9)	95.64%
Obese (25-29.9)	95.59%
overweight (Over 30)	92.6%

The number of total samples, if different from above, and the relationship between the two:

- Each individual was scanned in two views: Transverse and Longitudinal.
- Total dataset included 8,392 images from 496 individuals, 1,874 were used for verification dataset and the rest for training/validation.

Information about equipment and protocols used to collect images:

- For training we used mix of data collected from several different Console variants: Venue Go, Venue Fit, LOGIQ e, LOGIQ F and Vscan air.
- For verification we used mix of data collected from several different Console variants: Venue, Venue Go and Venue Fit.

Information about how the reference standard was derived from the dataset (i.e. the "truthing" process):

Ground truth annotations of the verification dataset were obtained as follows:

- In all Training/Validation and Verification datasets, annotators performed manual annotation on images converted from DICOM files.
- The annotators chose 4-6 images that represent different bladder volume status. On each view the annotation included 4 different landmarks, which represent the bladder edges:
  Transverse: Anterior, Posterior, left and right.
  Longitudinal: Head, Foot, Anterior and Posterior.
- These points would correspond to the locations where the measurement calipers would be placed for Bladder Volume Measurement.

Description of how independence of verification data from training data was ensured:

- The data used for the verification dataset is exclusive, comprising of completely independent subjects from data used during training/validation (tuning) processes and there is no overlap between the two.

Summary of Clinical Tests:

The subjects of this premarket submission, Venue, Venue Go, Venue Fit and Venue Sprint, 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, Venue Go, Venue Fit and Venue Sprint to be as safe, Effective, and performs in a substantially equivalent manner as the predicates Venue, Venue Go, Venue Fit and Venue Sprint (K240111, K240053, K234106 and K240206, respectively).