August 7, 2026

GE Medical Systems Ultrasound and Primary care Diagnostics, LLC
Karin Shimoni
Regulatory Affairs Manager
3200 N Grandview Blvd.
Waukesha, Wisconsin 53188

Re: K261668
Trade/Device Name: Venue Go
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, ITO, ITX, QIH
Dated: May 20, 2026
Received: May 20, 2026

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 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: 2026.08.07 08:48:40 -04'00'

For

Yanna Kang
Assistant Director
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.	K261668

Please provide the device trade name(s).

Venue Go

Please provide your Indications for Use below.

The Venue Go 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 Go is intended to be used in a hospital or medical clinic.
Venue Go 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.

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)

K261668

510(k) Summary

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

Date:	May 20, 2026
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 Go
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; Automated Radiological Image Processing Software, 21 CFR 892.2050, 90-QIH
Primary Predicate Device:	K251322 Venue Go Diagnostic Ultrasound System
Reference Device(s):	K241201 TEX20
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; Automated Radiological Image Processing Software, 21 CFR 892.2050, 90-QIH

Reference Device(s):	K250818 Nerveblox
Classification Names:	Class II
Product Code:	QRG Real-Time Ultrasound Anatomy Visualization And Labeling Device For Ultrasound Guided Regional Anesthesia. 21 CFR 868.1980-QRG

Device Description:

Venue Go is a general-purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals to evaluate the body by ultrasound imaging and fluid flow analysis.
The system utilize a variety of linear, convex, and phased array transducers which provide high imaging capability, supporting all standard acquisition modes.
The system 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 Go has a high-resolution color LCD monitor, with a simple, multi-touch user interface that makes the system intuitive.
The Venue Go system 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 system meets DICOM requirements to support users image storage and archiving needs and allows for output to printing devices.

The Venue Go 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. Compatible biopsy kits can be used for needle-guidance procedures.

Indications for Use:

The Venue Go 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 Go is intended to be used in a hospital or medical clinic.

Venue Go 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.

Technology: The Venue Go employs the same fundamental scientific technology as its predicate K251322.

Determination of Substantial Equivalence:

Comparison to Predicate Device

The Venue Go 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 Go 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 Go and its predicate:

Indications for Use:

The Venue Go and predicate Venue Go (K251322) have identical clinical indications for use and imaging modes.

Transducers:

The proposed Venue Go and predicate Venue Go (K251322) system transducers are similar, except for:

- 4Sc-RS and L8-18t-RS which are new transducers being added to the proposed Venue Go system. 4Sc-RS has identical clinical indications and modes of operation as the 3Sc-RS cleared with predicate Venue Go K251322. L8-18t-RS has similar clinical indications for use and modes of operations as the L8-18i-RS cleared with predicate Venue Go K251322.

- Adding PW (Pulse Wave Doppler) mode to ophthalmic application on L8-18t-RS, 12L-RS, L4-12t-RS and L4-20t-RS.

Features/Functionality:

- Auto Gastric Volume (AGV): provides a simplified workflow for gastric volume calculations and content assessment. The tool helps the user to obtain a gastric view of the antrum during live scanning, presents the content assessment of the gastric content and calculates the cross-sectional area (CSA). The tool then displays additional calculations: Gastric Volume and Volume to Weight ratio. These calculations may support anesthesia providers in assessing risk of aspiration. The workflow is similar to cleared features on predicate Venue Go with Nerveblox K250818 and on reference TEX20 with Auto GA K241201, respectively.
- cNeedle: the proposed Venue Go system supports a new version of the cNeedle feature (known as cNeedle 2.0). cNeedle 2.0 has an improved robustness compared to the cNeedle on predicate, due to improvements in the accuracy of the algorithm. The previous version of cNeedle available on predicate Venue Go K251322 was first cleared on Venue Go K202233.
- Auto Catheter Vessel Ratio (CVR): a semi-automated tool intended to measure vessel's diameter and present the Catheter to Vessel Ratio calculations (when the catheters' diameters are selected from a predefined list). These ratios appear in Green/Red. The tool displays a visual representation of the compatible catheter with the largest diameter out of the “Green range”. Auto CVR is similar to Catheter to Vessel Ratio tool cleared on predicate Venue Go K251322 and first cleared on Venue Go K220800.
- Aesthetic Toolkit: The Aesthetic Toolkit feature provides a simplified workflow for scanning and documenting a facial aesthetic procedure. This feature is similar to MSK Diagrams cleared on predicate Venue Go K251322.
- Operating System (OS) updated from Windows 10 to Windows 11
- Adding Auto Depth on Caption guidance: automatically adjusts the imaging depth in real time to optimize visualization. Caption Guidance has its own FDA clearance with approved PCCP (K243065) and cleared instructions for use which is also provided to customers who order this optional application. Caption guidance

feature is already cleared on predicate Venue Go K251322. On the proposed Venue Go, we are expanding SW scanning capability to support Auto Depth. This is identical to Auto Depth on Caption guidance as implemented on cleared Vscan Air K250087.

- New User interface (UI): The new user interface represents a more contemporary visual appearance of the predicate device's UI with no introduction of new functionality. The design has been updated to align with GE HealthCare guidelines.

Accessories:

- Adding compatible OEM biopsy guides (for 4Sc-RS and L8-18t-RS new transducers).
- Adding a compatible printer.

Summary of Non-Clinical Tests:
The proposed Venue Go 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 to applicable medical device safety standards.

The Venue Go 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 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, 2024
- 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 - 3.20, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology), 2024e
- 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.

AI Summary of Testing

1. Auto Gastric Volume (AGV)

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

Verification Dataset:

- Independent verification dataset representative of the intended adult use population and supported gastric assessment workflows was evaluated by clinical experts.
- Verification dataset included multiple dedicated evaluation sets per algorithmic component:
    - Antrum Segmentation: 6,276 frames from 295 subjects
    - Content Classification: 241 clips from 143 subjects
    - Quality Indicator: 9,094 frames from 332 subjects
    - Landmark Detection: 8,553 frames from 339 subjects

Demographic Distribution of Verification Dataset:

The verification dataset represented a broad demographic and technical range:

- Geography: USA (4 sites), Spain, Germany
- Age: (12 to 88)
- BMI: Underweight to Obese
- Gender: Male and Female
- Scan Position: Supine and Right Lateral Decubitus (RLD)
- Ultrasound Systems: Venue, Venue Go
- Probe Type: Curved and Sector

Clinical Subgroups and Confounders:

Algorithm performance was evaluated across clinically relevant subgroups and potential confounders, including:

- Age (<18, 18-39, 40-59, >60)
- BMI (underweight, normal, overweight, obese, severely obese)
- Gender (Female, Male)
- Scan position (Supine, RLD)
- Probe type (Curved, Sector)

Performance remained consistent across evaluated subgroups, including higher-BMI and older-subject subsets.

Expected Performance (Acceptance Criteria):

Predefined acceptance criteria included:

- Antrum Segmentation:
  - Mean Dice Similarity Coefficient (DSC) ≥ 0.85 for all measurable frames
  - Mean DSC ≥ 0.90 for clinically suitable clear-fluid frames

- Content Classification:
  - ≥70% of cases classified
  - ≥80% classification accuracy among classified cases

- Quality Indicator:
  - ≥85% enabling measurement on suitable frames
  - ≥90% prevention of measurement on non-measurable frames

- Landmarks Detection:
  - ≥80% weighted average precision
  - ≥80% weighted average recall

Performance Demonstrated on Verification Dataset:

All predefined acceptance criteria were met or exceeded:

- Antrum Segmentation:
  - Mean DSC (all frames): 0.876
  - Mean DSC (clear fluid subset): 0.913

- Content Classification:
  - Percentage of cases classified for content type (i.e. Sensitivity): 82.57%
  - Content classification correctness rate (i.e. Accuracy): 86.93%

- Quality Indicator:
  - Measurement enabling on suitable frames: 91.18%
  - Correct green frame identification: 96.27%
  - Prevention on non-measurable frames: 94.32%

- Landmarks Detection:
  - Precision: 90.33%
  - Recall: 85.94%

Clinical Evaluation of Quality Indicator Results:

- Five expert physicians evaluated 195 clips across green, red/gray, and combined quality categories.
- Acceptance criterion: ⩾90% of clips rated acceptable (majority expert agreement).
- Overall, 95.9% of clips met the acceptance criterion.
- High acceptance observed across subgroups (91.7%–98.7%).

These results demonstrate accurate and reliable AGV quality Indicator across clinical use cases.

Total Dataset and Relationship Between Training and Verification Data:

- Development datasets (training, tuning, holdout) and verification datasets were strictly separated.
- Verification datasets consisted of independent subjects not used for training or tuning.
- 4 sites were completely separated from the training and tuning datasets. In 2 sites, limited overlap was controlled via subject level separation and, where applicable, temporal partitioning.

Reference Standard (Ground Truth):

- Ground truth annotations were created according to standardized gastric ultrasound protocols developed by internationally recognized clinical experts in perioperative gastric ultrasound.
- Annotations were performed by trained US-certified sonographers and reviewed by US-based physicians.
- Frame-based and clip-based annotation strategies were applied depending on algorithm component.

Independence of Verification Data:

- Verification datasets were composed of independent subjects relative to training and validation data.
- No subject overlap was permitted between training and verification datasets.

2. cNeedle

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

Verification Dataset:

- Independent verification dataset representative of ultrasound-guided needle visualization workflows was assessed.

- Verification dataset included:
  - 11,784 frames
  - 105 subjects
- Data was collected across multiple clinical sites.

Demographic Distribution of Verification Dataset:

- Geography: USA (2 sites) and Spain
- Age: 16 to 85
- BMI: Underweight to Obese
- Gender: Male and Female
- Ultrasound Systems: Venue Go, Venue Fit
- Probe Type: Linear and Curved
- Needle Type: Echogenic and Non-echogenic

Clinical Subgroups and Confounders:

Performance was evaluated across relevant demographic and technical subgroups, including:

- Age (<18, 18-39, 40-59, >60)
- BMI (underweight, normal, overweight, obese, severely obese)
- Gender (Female, Male)
- Probe type (Curved, Sector)
- Needle type (Echogenic, Non-echogenic)

Subgroup analysis demonstrated consistent performance across evaluated factors.

Expected Performance (Acceptance Criteria):

The predefined accuracy requirements were:

- Positive Frames (frames containing needle):
  - Sensitivity $\geqslant$ 80%
  - Specificity $\geqslant$ 90%
- Negative Frames (frames without needle):
  - Specificity $\geqslant$ 80%

Additionally, a clinical evaluation acceptance rate target of ≥90% was defined for needle visualization quality relative to B-mode imaging.

Performance Demonstrated on Verification Dataset:

Algorithm performance met or exceeded all predefined acceptance criteria:

- Sensitivity (needle in tissue): 85.82%
- Specificity (needle in frame, positive clips): 98.35%
- Overall Specificity: 90.67%

All results met acceptance criteria with 95% statistical confidence.

Clinical Evaluation Results:

- A blinded clinical evaluation compared cNeedle to standard B-mode imaging.
- 100% of evaluated cases met the predefined acceptance criterion (majority expert rating ≥ "as good as" B-mode).
- Overall, 94% of expert ratings favored cNeedle as better than or equal to B-mode.

Total Dataset and Relationship Between Training and Verification Data:

- Development dataset included >70,000 frames from clinical and non-clinical sources.
- Verification dataset consisted of independent subjects not included in training or tuning.
- 2 sites were completely separated from the training and tuning datasets. In the third site, dataset separation was enforced by subject ID and acquisition period.

Reference Standard (Ground Truth):

- Ground truth annotations were generated following standardized ultrasound-guided needle protocols.
- Annotations included manual marking of the full visible needle path or designation of "no needle."
- All annotations were reviewed and approved by experienced US-based clinicians.

Independence of Verification Data:

- Verification data was fully independent from the training and holdout (tuning) datasets.
- No frames from verification recordings were used during model training or tuning.
- No subject overlap was permitted between training and verification datasets.

Summary of Clinical Tests:

The subject of this premarket submission, Venue Go, 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 Go to be as safe, Effective, and performs in a substantially equivalent manner as the predicate Venue Go K251322.