GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC
% Tracey Ortiz
Regulatory Affairs Director
9900 W. Innovation Drive
WAUWATOSA WI 53226

November 18, 2020

Re: K202233
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, IYO, ITX
Dated: October 8, 2020
Received: October 13, 2020

Dear Tracey Ortiz:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K202233

Device Name
Venue Go

Indications for Use *(Describe)*

The Venue Go 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. 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.

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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GE Healthcare
510(k) Premarket Notification Submission

**510(k) Summary**

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

| | |
|---|---|
| Date: | August 6, 2020 |
| Submitter: | GE Medical Systems Ultrasound and Primary Care Diagnostics<br>9900 Innovation Drive<br>Wauwatosa, WI 53226 |
| Primary Contact Person: | Tracey Ortiz<br>Regulatory Affairs Director<br>GE Healthcare<br>T:(262)470-1003 |
| Secondary Contact Person: | Karin Shimoni<br>Regulatory Affairs Leader<br>GE Healthcare |
| Device Trade Name: | Venue Go |
| 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: | Venue Go (K183362) |
| Reference Device(s): | Venue (K180599)<br>Versana Premier (K200138)<br>Vivid iq (K181727)<br>LOGIQ e (K133533)<br>LOGIQ e (K151028)<br>Voluson S8 (K120741)<br>Vivid q (K121062)<br>Venue 50 (K152758)<br>Vscan Extend (K180995)<br>Vivid S70N (K182450) |
| 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 Venue Go is a compact, portable system with a small footprint. The system can be hand carried using an |

integrated handle, placed on a horizontal surface, attached to a mobile cart or wall mounted. It has a high resolution color LCD monitor, with a simple, multi-touch user interface that makes the system intuitive. The system can be powered through an electrical wall outlet for long term use or from an internal battery for a short time.

The Venue Go utilizes a variety of linear, convex, and phased array transducers which provide high imaging capability, supporting all standard acquisition modes. Some transducers are compatible with OEM biopsy kits to support needle-guidance procedures.

The system has the capability for 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. The ECG signal can be input directly from the patient leads or as an output from an ECG monitoring device. ECG information is not intended for monitoring or diagnosis.

A barcode reader is available to be used as an input device.

Venue Go is capable of wireless communication through a built-in Wireless LAN device. The system meets DICOM requirements to support users image storage and archiving needs (local PACS or products such as Q-Path) and allows for output to printing devices. The user documentation is available electronically.

An additional accessory that will also be available for the customer will be a roller bag.

Intended Use: The Venue Go 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. 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 and reference devices.

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.

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

- The proposed Venue Go and predicate Venue Go (K183362) have similar clinical indications for use.
- Vascular has been added with peripheral vascular and for intraoperative, this clarifies vessels and does not change imaging or the product. No impact to safe or effectiveness use.
- Imaging guidance of interventional procedures is changed to interventional guidance as it was in the IFU tables in the predicate. Non-vascular access (instead of nerve block) is added as subcategory from the predicate IFU table. Fluid drainage is added as it is part of intended use. There is no change to the intended use from the predicate, no change to the product and no impact to safe or effective use.
- The IFU statement is updated to add "trained" to the operator qualification for clarity however it was stated in the predicate product documentation. No change to the product and no impact to safe or effective use.
- Device use settings and modes of operation are added as required in the 2019 ultrasound guidance. There was no change in the system modes or the use environment from the predicate.

Transducers and Modes:

- The proposed Venue Go and predicate Venue Go (K183362) have identical imaging modes.
- The proposed Venue Go and predicate Venue Go (K183362) systems transducers are similar, except for:
    - Adding of ML6-15-RS which was first cleared on Voluson S8, K120741. The clinical indications of ML6-15-RS are similar on the proposed Venue Go as they are on the reference device Vivid iq, K181727.

  - Adding 12S-RS, which was first cleared on Vivid q, K121062. The clinical indications of 12S-RS are the same on the proposed Venue as they are on the reference device Vivid iq, K121062.
  - Adding L10-22-RS which was first cleared on LOGIQ e, K133533. The clinical indications of L10-22-RS are similar on the proposed Venue as they are on the reference device LOGIQ e, K133533.
- L4-20t-RS is a new transducer being added to the proposed Venue Go system. The L4-20t-RS has similar clinical indications for use as the predicate L4-12t-RS transducer which was first cleared on LOGIQ e K133533. L4-20t-RS is a surface, linear array transducer which operates in a wider range of frequencies compared to the predicate L4-12t-RS. The clinical indications of L4-20t-RS are the same as the L4-12t-RS transducer cleared with predicate device Venue Go, K183362.
- New applications are added to transducers:
  - ML6-15-RS transducer: added Ophthalmic, Cardiac (Pediatric and Adult), Thoracic/Pleural, Vascular and Non-vascular access, cleared with 12L-RS in predicate Venue Go (K183362) which is a similar transducer.
  - L10-22-RS transducer: added Pediatric, cleared with L8-18i-RS in predicate Venue Go (K183362) which is a similar transducer.
  - L8-18i-RS transducer: added Ophthalmic, cleared with 12L-RS in predicate Venue Go (K183362) which is a similar transducer.
  - 8C-RS transducer: added Musculoskeletal (Conventional and Superficial) and Adult cephalic, cleared with reference Venue (K180599).
- Removed Vascular Access application from 3Sc-RS, C1-5-RS and 6S-RS. No impact to safe or effective use.
- Adding Coded Pulse mode to Vascular/Peripheral Vascular, Vascular Access and Non-vascular on L10-22-RS.

Features/Functionality:

- Simple Screen is a modification of Full Screen that is on predicate Venue Go (K183362).
- Follow-up feature is being added with minor modifications to what has been cleared on Versana Premier, K200138.
- Venue View is being added and is a different name for LOGIQ View that has been cleared on Versana Premier, K200138.
- Lung Sweep allows multiple lung scans to play simultaneously during review. Lung scanning was available also on predicate Venue Go (K183362).
- cNeedle enhances the needle, and projects a trajectory line. Capabilities are similar to needle recognition that has been cleared on predicate Venue Go, K183362 and Pinpoint GT feature on reference Venue 50, K152758, respectively.
- Real-Time Ejection Fraction (EF) is being added and is similar to the Auto EF feature on reference Vivid S70N, K182450.
- Renal Diagram is similar to the eFAST Navigation Tool cleared on predicate Venue Go, K183362.
- Added biopsy guidzones cleared on reference Versana Premier, K200138.
- Added additional off-the-shelf SW.

Accessories:

- Adding compatible OEM ECG triggering leads for pediatrics, similarly to what is on predicate Vivid iq K181727.
- Adding compatible OEM biopsy guide accessory compatibility for the C1-5-RS, and for 12L-RS and L4-12t-RS transducers.

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 comply with 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/ A2:2012
- IEC 60601-1-2, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests, 2014
- IEC 60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment, 2015
- ISO 10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Third Edition, 2009
- IEC 62359, Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2017
- ISO 14971, Application of risk management to medical devices, 2019
- NEMA PS 3.1 - 3.20, Digital Imaging and Communications in Medicine (DICOM) Set, 2016

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 Go, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Venue Go to be as safe, as effective, and performance is substantially equivalent to the predicate device.