November 13, 2020

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

Re: K202132
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: 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 and Part 809; medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or post marketing 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,

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)*

K202132

Device Name
Venue

Indications for Use *(Describe)*

The Venue 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 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.

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*"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."*

**510(k) Summary**

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

| | |
|---|---|
| Date: | July 30, 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 |
| 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 |
| Predicate Device: | Venue (K180599) |
| Reference Devices: | Venue Go (K183362)<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: 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 proposed Venue 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 is not intended for monitoring or diagnosis.

The Venue has a battery that allows for scanning without the need to plug in to an electrical outlet. The system is capable of wireless communication and a barcode reader is available to be used as an input device. System meets DICOM requirements to support users image storage and archiving needs and allows for output to printing devices. The user documentation is available via electronic media.

The Venue 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 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 for ultrasound imaging, measurement, display and analysis of the human body and fluid. 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. |
| Technology: | The Venue employs the same fundamental scientific technology as its predicate and reference devices. |
| Determination of Substantial Equivalence: | Comparison to Predicate Device<br>The Venue 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 and the predicate Venue.

- The proposed Venue and predicate Venue (K180599) have similar clinical indications for use, however the proposed Venue is adding the Intraoperative (vascular) application which has been cleared on reference device, Venue Go (K183362).
- Vascular has been added with peripheral vascular, 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. Biopsy and non-vascular access (instead of nerve block) are added as sub categories from the predicate IFU table. Fluid drainage is added as it 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 is in the proposed and 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 and predicate Venue (K180599) have identical imaging modes.
- The proposed Venue and predicate Venue (K180599) systems transducers are similar, except for:
  - Addition 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 as they are on the reference device Vivid iq, K181727.
  - Addition of 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 q, K121062.
  - Addition of 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 devices LOGIQ e, K133533.
- L4-20t-RS is a new transducer being added to the proposed Venue 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 reference 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 (K180599) which is a similar transducer.
  - L10-22-RS transducer: added Pediatric, cleared with L8-18i-RS in predicate Venue (K180599) which is a similar transducer.

  - L8-18i-RS transducer: added Ophthalmic, cleared with 12L-RS in predicate Venue (K180599) which is a similar transducer.
  - L8-18i-RS transducer: added intraoperative, cleared with this probe on reference Venue Go (K183362).
- Removed Vascular Access application from 3Sc-RS, C1-5-RS and 6S-RS. No impact to safe or effective use.
- Added 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, K180599.
- 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, K180599.
- cNeedle enhances the needle, and projects a trajectory line. Capabilities are similar to needle recognition that has been cleared on predicate Venue, K180599 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, K180599.
- Added biopsy guidzones cleared on reference Versana Premier, K200138.
- Added additional off-the-shelf SW.

Accessories:

- Added compatible OEM ECG triggering leads for pediatrics, similarly to what is on predicate Vivid iq, K181727.
- Added compatible OEM biopsy guide accessory compatibility for the C1-5-RS, and for 12L-RS, L12n-RS, & L4-12t-RS transducers.

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:

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

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