



June 10, 2024

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

Re: K234106

Trade/Device Name: Venue Fit
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: May 8, 2024
Received: May 8, 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

Indications for Use

Submission Number (if known)

K234106

Device Name

Venue Fit

Indications for Use (Describe)

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

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
PRASStaff@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."

510(k) Summary - K234106

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

Date: December 26, 2023

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 Fit

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: K220848 Venue Fit, 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

Device Description: Venue Fit 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 Fit is a compact, portable system with a small footprint. The system can be hand carried using the integrated handle, placed on a horizontal surface (if kickstand is attached), attached to a mobile cart or mounted on the wall. 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 with full functionality and scanning.

The Venue Fit 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 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.

A barcode reader and RFID scanner are available as additional input devices. A roller bag will also be available for the customer to use when transporting the system.

Venue Fit is capable of wired or wireless internet connection. 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.

Intended Use: The Venue Fit 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 Fit is intended to be used in a hospital or medical clinic. 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.

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

Determination of Substantial Equivalence: Comparison to Predicate Device
The Venue Fit 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 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 Fit and the predicate Venue Fit:

Indications for Use:

The proposed Venue Fit and predicate Venue Fit (K220848) 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 Fit and predicate Venue Fit (K220848) have identical imaging modes.

Transducers:

The proposed Venue Fit and predicate Venue Fit (K220848) 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 Fit as they are on the reference device LOGIQ E10 K211488 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

GE HealthCare

510(k) Premarket Notification Submission

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 Fit (K220848)).

Features/Functionality:

- Vscan Air CL and Vscan Air SL probes: The proposed Venue Fit 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 Fit K220848, the only diagram that was available for MSK preset was the shoulder diagram. On the proposed Venue Fit, 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 Fit system. From the Venue Coach tab, user can configure a diagram, a reference image or both.
- Electronic delivery of SW: The proposed Venue Fit 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

GE HealthCare

510(k) Premarket Notification Submission

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 Fit system, then the cart on proposed Venue Fit is updated to include an optional connectivity solution that allows wireless and Bluetooth connectivity with the Vscan Air CL and SL probes and also provide power for the wireless charger.

Summary of Non-Clinical Tests:

The proposed Venue Fit 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 Fit 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

GE HealthCare

510(k) Premarket Notification Submission

- 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 Fit, 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 Fit to be as safe, Effective, and performs in a substantially equivalent manner as the predicate Venue Fit (K220848).