June 27, 2022

GE Medical Systems
℅ Lee Bush
Regulatory Affairs Director
Ultrasound and Primary Care Diagnoistics, LLC
9900 W. Innovation Drive
WAUWATOSA WI 53226

Re: K220848
    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 24, 2022
    Received: May 25, 2022

Dear Lee Bush:

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

Michael D. O'Hara, Ph.D.
Deputy Director
DHT8C: Division of Radiological Imaging
 and Rediation Therapy Devices
OHT8: Office of 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)*

K220848

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 for ultrasound imaging, measurement, display and analysis of the human body and fluid. 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.

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: June 17, 2022

Submitter: GE Medical Systems Ultrasound and Primary Care Diagnostics
9900 Innovation Drive
Wauwatosa, WI 53226

Primary Contact Person: Lee Bush
Regulatory Affairs Director
GE Healthcare
T: (262) 3099429

Secondary Contact Person: Karin Shimoni
Regulatory Affairs Manager
GE Healthcare

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: K203137 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

<u>Reference</u> <u>Device(s)</u>:	K210438 Versana Premier, Diagnostic Ultrasound System
<u>Classification</u> <u>Names</u>:	Class II
<u>Product</u> <u>Code</u>:	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

<u>Reference</u> <u>Device(s)</u>:	K161706 Vivid iq, Diagnostic Ultrasound System
<u>Classification</u> <u>Names</u>:	Class II
<u>Product</u> <u>Code</u>:	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

<u>Reference</u> <u>Device(s)</u>:	K203114 LOGIQ P10, Diagnostic Ultrasound System
<u>Classification</u> <u>Names</u>:	Class II
<u>Product</u> <u>Code</u>:	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

<u>Reference</u> <u>Device(s)</u>:	K210426 HS40, Diagnostic Ultrasound System
<u>Classification</u> <u>Names</u>:	Class II
<u>Product</u> <u>Code</u>:	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

<u>Reference</u> <u>Device(s)</u>:	K202658 Vivid E95, Diagnostic Ultrasound System
<u>Classification</u> <u>Names</u>:	Class II
<u>Product</u> <u>Code</u>:	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; Diagnostic intravascular catheter, 21 CFR 870.1200, 90-OBJ

<u>Reference</u> <u>Device(s)</u>:	K182234 Optima XR240amx, Mobile X-ray system
<u>Classification</u> <u>Names</u>:	Class II
<u>Product</u> <u>Code</u>:	Mobile x-ray system 21 CFR 892.1720 IZL, Solid state x-ray imager 892.1680 MQB

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.

The user documentation is available electronically.

Intended Use: The Venue Fit 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 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.

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 proposed Venue Fit and predicate Venue Fit (K203137) have identical clinical indications for use.

The proposed Venue Fit and predicate Venue Fit (K203137) have identical imaging modes.

The following is an overview of the differences between the proposed Venue Fit and the predicate Venue Fit:
The proposed Venue Fit and predicate Venue Fit (K203137) systems transducers are similar, except for:

- Additions of M5Sc-RS which was first cleared on Vivid iq K161706. This probe is used unchanged from the cleared reference device (K161706). It is made of the same materials and its shape is unchanged. The clinical indications of M5Sc-RS are the same on the proposed Venue Fit as they are on the reference device Vivid E95 K202658 with M5Sc-D probe. The M5Sc-RS probe is the

same as the M5Sc-D except it uses an RS connector instead of a D connector. The transducer body is identical between the two.

- New applications are added to the following transducers:
  - M5Sc-RS transducer: added Ophthalmic application. This application was already cleared with 3Sc-RS in predicate Venue Fit (K203137) which is a similar transducer.
  - 3Sc-RS, E8C-RS, 6S-RS, 12S-RS: added Nonvascular access to the Interventional guidance application which was already cleared with these probes on reference device Versana Premier (K210438).

Features/Functionality:

- Scribble: assists the user during system training and teaching by providing a touch-operated pointer and free drawing capabilities.
- Power Doppler Imaging+ (PDI+): is intended for slow blood flows like those found in wrists, ankles, hands, and feet.
- Catheter Vessel Ratio: a measurement that supports clinicians in selecting the appropriate sized catheter based on vessel diameter.
- Probe Check: provides an automated probe element check and notifies user of potential probe issue.
- Shoulder Diagram: simplifies documentation and assists the clinician in the follow up for patients with suspected shoulder disorders. Is similar to the Renal Diagram feature previously available on the cleared predicate Venue Fit (K203137), except it does not contain an anatomical organ drawing and the question/request that appears to the user is tailored to the shoulder region.
- cNerve: may help the user to detect and track nerves during the scouting stage of a nerve block procedure, prior to inserting the needle to inject the anesthetic material. Is similar to the NerveTrack tool on cleared reference HS40 system by Samsung (K210426). The cNerve tool on proposed Venue Fit system is available for adults only.
- Expanding B-lines tool for pediatrics (excluding neonates). This allows Lung sweep and Lung Diagram to pediatrics (excluding neonates) as well. B-lines tool is

available on the cleared predicate Venue Fit (K203137) for adults only.

- Expanding Real-Time Ejection Fraction (EF) to pediatrics (excluding neonates). Real-Time EF tool is available on the cleared predicate Venue Fit (K203137) for adults only.
- Updates to software related to workflow improvements.

Accessories:
- Adding compatible OEM biopsy guides (for 3Sc-RS, E8C-RS and M5Sc-RS transducers).
- Adding RFID scanner that enables easy login/logout using a badge. This capability is similar to RFID option on reference device Optima XR240amx, K182234.

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:

- 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, 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 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.

AI Summary of Testing

cNerve:
Summary test statistics and other results including acceptance criteria and information supporting the appropriateness of the characterized performance
Dataset:
- Test dataset representative of the Nerve block scouting procedures which cNerve supports was assessed for accuracy.
- Test dataset included 124 sequences, and 3776 frames.

Appropriateness of the characterized performance:
- Success criteria were based on conformance of the cNerve detections to ground truth annotations of nerve bundles in individual frames. Since the intended use is nerve tracking during scouting rather than nerve segmentation accuracy, success criteria were derived via a preliminary survey. The target of the survey was to identify thresholds for pixel accuracy in frames and for frame accuracy in sequences that are appropriate for the intended use.
- cNerve performance requirements.
- Sequence accuracy requirement – for testing overall cNerve performance: At least 70% of the sequences are meaningfully detected, and at least 80% of the meaningfully detected sequences are successfully detected (meeting frame accuracy criteria).

The number of individuals images were collected from:

- A total of 44 individuals contributed to the verification dataset.

The number of samples, if different from above, and the relationship between the two:
- Each individual contributed up to 2 sequences per view location. Often both laterals (left and right) were scanned.
- Test dataset included 124 sequences, and 3776 frames.

Demographic distribution including:
- Gender: Male and Female
- Age: 18-82 years
- Ethnicity/Country: USA, Japan, Israel

Information about clinical subgroups and confounders present in the dataset:
- The algorithm performance was verified via frame accuracy on all demographic subgroups: Gender (M/F), Age (<60 / >=60), BMI (<=25 / >25).
- Similarly, it was tested for all supported nerve block locations and all supported probe types.

Information about equipment and protocols used to collect images:

- Mix of data from across five different probes in the appropriate nerve mode, and three different Console variants.

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: Frames from scouting sequences were annotated by a single clinical expert, where the anatomical area of the nerves was marked in each frame.

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

- The data used for verification is completely distinct from that used during training process and there is no overlap between the two.

Summary of Clinical Tests:

The subject of this premarket submission, Venue Fit, did not require clinical studies to support substantial equivalence.

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