June 27, 2022

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

Re: K220851
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: 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 Radiation 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)*

K220851

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.

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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
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:	K202132 Venue, 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):	K210438 Versana Premier, 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):	K161706 Vivid iq, 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):	K203114 LOGIQ P10, 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):	K210426 HS40, 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):	K202658 Vivid E95, 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; Diagnostic intravascular catheter, 21 CFR 870.1200, 90-OBJ

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

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 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.

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.

System meets DICOM requirements to support users image storage and archiving needs and allows for output to printing devices.

The Venue 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 includes several automated tools designed to simplify and shorten the workflow time of the healthcare professional for some common assessments.

The user documentation is available electronically.

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

The Venue 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 system are used unchanged from the cleared predicate. They are made of the same materials and their shape is unchanged.

The proposed Venue and predicate Venue (K202132) have identical clinical indications for use.

The proposed Venue and predicate Venue (K202132) have identical imaging modes.

The following is an overview of the differences between the

proposed Venue and the predicate Venue:
The proposed Venue and predicate Venue (K202132) 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 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 (K202132) 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 (K202132), 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 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 (K202132) for adults only.
- Expanding Real-Time Ejection Fraction (EF) to pediatrics (excluding neonates). Real-Time EF tool is available on the cleared predicate Venue (K202132) for adults only.
- Updates to software related to workflow improvements.

Hardware:
New Back-End (BE) accelerated processing unit (APU), with similar functionality as computation hardware on the cleared predicate Venue K202132. The processor selected is also used on other cleared systems from the Venue family.

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 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, 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, 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.