June 10, 2024

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

Re: K240206
Trade/Device Name: Venue Sprint
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: January 25, 2024
Received: May 9, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240206

Device Name

Venue Sprint

Indications for Use *(Describe)*

Venue Sprint 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.
The Venue Sprint is intended to be used in a hospital, medical clinic, home environment and road/air ambulance.
Venue Sprint 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, 40 kg and above) and interventional guidance (includes free hand tissue biopsy, fluid drainage, vascular and non-vascular access). Modes of operation include: B, M, PW Doppler, Color Doppler and Harmonic Imaging.

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) Summary - K240206

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

Date:	January 25, 2024
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 Sprint
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):	K170714 Venue
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
Reference Device(s):	K203137 Venue Fit
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):	K200851 Vivid T8, Vivid T9
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 Sprint 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 Sprint is used together with the Vscan Air probes and provides the user interface for control of the probes and the needed software functionality for analysis of the ultrasound images and saving/storage of the related images and videos.
Intended Use:	Venue Sprint 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.
The Venue Sprint is intended to be used in a hospital, medical clinic, home environment and road/air ambulance.
Venue Sprint 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, 40 kg and above) and interventional guidance (includes free hand tissue biopsy, fluid drainage, vascular and non-vascular access).
Modes of operation include: B, M, PW Doppler, Color Doppler and Harmonic Imaging.

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

Determination of Substantial Equivalence:

Comparison to Predicate Device

The Venue Sprint system is substantially equivalent to the predicate device with regards to intended use, imaging capabilities, technological characteristics and safety and effectiveness. All probes used with the proposed Venue Sprint 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 Sprint and the predicate Venue Fit:

Indications for Use:

- The proposed Venue Sprint and predicate Venue Fit (K220848) have similar clinical indications for use, however the IFU statement is updated to be consistent with the wording cleared for predicate Vscan Air K231301:
  - Add details to the operator qualification/profile
  - Add “free hand”, as the method for tissue biopsy
  - Add “40 kg and above” for cardiac (pediatric) application
- The proposed Venue Sprint and predicate Venue Fit (K220848) have similar use-environments, however Venue Sprint is to be used also in home environment and road/air ambulance. No impact to safe or effective use. This is consistent with the use-environments of the cleared predicate Vscan Air K231301

- The proposed Venue Sprint and predicate Venue Fit (K220848) have similar imaging modes.

Transducers:
Vscan Air CL and SL probes on proposed Venue Sprint: The Vscan Air CL was first cleared in K202035 and the Vscan Air SL was first cleared in K231301. The clinical indications of the Vscan Air CL and SL are identical as on the reference device Vscan Air K231301.

Features/Functionality:

- Vscan Air CL and Vscan Air SL probes: The proposed Venue Sprint system supports the Vscan Air CL and Vscan Air SL cleared in K231301.
- 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 Sprint, 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 Sprint system. From the Venue Coach tab, user can configure a diagram, a reference image or both.
- Electronic delivery of SW: The proposed Venue Sprint system 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 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:
The Venue Sprint software can be installed on a Windows-based off-the-shelf (OTS) consumer display device (tablet). Similar to predicate Venue Fit K220848, the tablet can be attached to a

mobile cart. The cart of proposed Venue Sprint provides power for the wireless charger of Vscan Air CL and SL probes.

Summary of Non-Clinical Tests:
The proposed Venue Sprint 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 Sprint 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
- 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
- IEC 60601-1-11, Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment, 2020

- IEC 60601-1-12, Medical Electrical Equipment - Part 1-12: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Intended For Use In The Emergency Medical Services Environment, 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 are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, Venue Sprint, 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 Sprint to be as safe, Effective, and performs in a substantially equivalent manner as the predicate Venue Fit (K220848).