



May 1, 2025

GE Medical Systems Ultrasound and Primary Care Diagnostics
% Lee Bush
Director of Regulatory Affairs
3200 N Grandview Blvd
Waukesha, Wisconsin 53188

Re: K250087

Trade/Device Name: Vscan Air
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: January 13, 2025
Received: January 14, 2025

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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)

K250087

Device Name

Vscan Air

Indications for Use (Describe)

Vscan Air is a battery-operated software-based general-purpose ultrasound imaging 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. 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 device is enabling visualization and measurement of anatomical structures and fluid including blood flow.

Vscan Air's pocket-sized portability and simplified user interface enables integration into training sessions and examinations in professional healthcare facilities (ex. Hospital, clinic, medical office), home environment, road/air ambulance and other environments as described in the user manual. The information can be used for basic/focused assessments and adjunctively with other medical data for clinical diagnosis purposes during routine, periodic follow-up, and triage.

Vscan Air supports Black/ white (B-mode), Color flow (Color doppler), Pulsed wave Doppler mode, M-mode, combined (B + Color Doppler) and Harmonic Imaging modes with curved, linear and sector array transducers.

With the curved array transducer of the dual headed probe solution, the specific clinical applications and exam types include: abdominal, fetal/obstetrics, gynecological, urology, thoracic/lung, cardiac (adult and pediatric, 40 kg and above), vascular/peripheral vascular, musculoskeletal (conventional), pediatrics, interventional guidance (includes free hand needle/catheter placement, fluid drainage, nerve block and biopsy).

With the linear array transducer of the dual headed probe solution, the specific clinical applications and exam types include: vascular/peripheral vascular, musculoskeletal (conventional and superficial), small organs, thoracic/lung, ophthalmic, pediatrics, neonatal cephalic, interventional guidance (includes free hand needle/catheter placement, fluid drainage, nerve block, vascular access and biopsy).

With the sector array transducer of the dual headed probe solution, the specific clinical applications and exam types include: cardiac (adult and pediatric, 40 kg and above), abdominal, fetal/obstetrics, gynecological, urology, thoracic/ lung, pediatrics, adult cephalic, interventional guidance (includes free hand needle/catheter placement, fluid drainage, nerve block and biopsy).

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
PRAStaff@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."

K250087

510(k) Summary

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

Date: April 30, 2024

Submitter: GE Medical Systems Ultrasound and Primary Care Diagnostics
3200 N Grandview Blvd
Waukesha, WI 53188

Primary Contact Person: Lee Bush
Regulatory Affairs Director
GE Healthcare
T (262) 309-9429

Secondary Contact Person: Andrew Turner
Regulatory Affairs Leader
GE Healthcare

Device Trade Name: Vscan Air
Common/Usual Name: Diagnostic Ultrasound System
Classification Names: Class II

Product Code(s): 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: Vscan Air (K231301), Diagnostic Ultrasound System

Classification Names: Class II

Product Code(s): 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: Vscan Extend (K161588), Diagnostic Ultrasound System

Classification Names: Class II

Product Code(s): 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:

Vscan Air™ is a battery-operated general-purpose diagnostic ultrasound imaging system for use by qualified and trained healthcare professionals. It enables ultrasound imaging guidance, visualization and measurement of anatomical structures and fluid.

Vscan Air consists of an app which can be installed on Android™ or iOS devices, and 2 probes which use wireless technology for communication.

Its pocket-sized portability and simplified user interface enable integration into training sessions and examinations in professional healthcare facilities (ex. Hospital, clinic, medical office), home environment, road/air ambulance and in other environments. The information can be used for basic/focused assessments and adjunctively with other medical data for clinical diagnosis purposes during routine, periodic follow-up, and triage assessments for adult, pediatric and neonatal patients. Vscan Air can also be useful for interventional guidance.

Intended Use/Indication for Use:

Vscan Air is a battery-operated software-based general-purpose ultrasound imaging 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. 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 device is enabling visualization and measurement of anatomical structures and fluid including blood flow.

Vscan Air's pocket-sized portability and simplified user interface enables integration into training sessions and examinations in professional healthcare facilities (ex. Hospital, clinic, medical office), home environment, road/air ambulance and other environments as described in the user manual. The information can be used for basic/focused assessments and adjunctively with other medical data for clinical diagnosis purposes during routine, periodic follow-up, and triage.

Vscan Air supports Black/ white (B-mode), Color flow (Color doppler), Pulsed wave Doppler mode, M-mode, combined (B + Color Doppler) and Harmonic Imaging modes with curved, linear and sector array transducers.

With the curved array transducer of the dual headed probe solution, the specific clinical applications and exam types include: abdominal, fetal/obstetrics, gynecological, urology, thoracic/lung, cardiac (adult and pediatric, 40 kg and above), vascular/peripheral vascular, musculoskeletal (conventional), pediatrics, interventional guidance (includes free hand needle/catheter placement, fluid drainage, nerve block and biopsy).

With the linear array transducer of the dual headed probe solution, the specific clinical applications and exam types include: vascular/peripheral vascular, musculoskeletal (conventional and superficial), small organs, thoracic/lung, ophthalmic, pediatrics, neonatal cephalic, interventional guidance (includes free hand needle/catheter placement, fluid drainage, nerve block, vascular access and biopsy).

With the sector array transducer of the dual headed probe solution, the specific clinical applications and exam types include: cardiac (adult and pediatric, 40 kg and above), abdominal, fetal/obstetrics, gynecological, urology, thoracic/ lung, pediatrics, adult cephalic, interventional guidance (includes free hand needle/catheter placement, fluid drainage, nerve block and biopsy).

Technology:

The Vscan Air employs the same fundamental scientific technology as its predicate device.

Determination of Substantial Equivalence:

The proposed Vscan Air system is substantially equivalent to the predicate Vscan Air and reference devices with regards to intended use, indications for use, imaging capabilities, technological characteristics, imaging modes, hardware, and safety effectiveness.

The following is an overview of the differences between the proposed Vscan Air and its currently marketed predicate.

Indications for use:

- Identical

Imaging Modes:

- Identical

Transducers/Hardware:

- Identical

Software Features/Functionality:

- Added Auto bladder volume which is a protocol-based measurement tool for calculating urinary bladder volumes. The measurement workflow is similar to Bladder Volume Application cleared in reference device Vscan Extend (K161588), however, Auto bladder volume uses a deep learning algorithm to automatically place the measurement calipers in transverse and longitudinal views when using the Vscan Air CL probe instead of traditional image analysis.
- Added compatibility with Caption AI which provides real-time user guidance to assist medical professionals in the acquisition of cardiac ultrasound images and provides an automated estimation of left ventricular ejection fraction. Caption AI incorporates two separately cleared software features: Caption Guidance (K201992) and Caption Interpretation AutoEF (K210747).
- Added service tools and quality improvements to existing features/functionality.

Accessories:

- Identical

Summary of Non-Clinical Tests:

Vscan Air was 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 Vscan Air complies with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety and Essential Performance, 2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]
- IEC 60601-1-2, Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbance – Requirements and Tests, Edition 4.1, 2020
- IEC 60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment, Ed. 2.1, 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
- ISO 10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing Within A Risk Management Process, 2018-08
- 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, Edition 2.1 2020-07 CONSOLIDATED VERSION
- 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, Edition 1.1 2020-07 CONSOLIDATED VERSION

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.

Auto bladder volume Summary of Testing:

Bladder volume measurement accuracy was validated to the distance measurement accuracy and associated volumetric calculation accuracy specified in the user manual.

Summary test statistics and other results including acceptance criteria and information supporting the appropriateness of the characterized AI caliper placement performance are provided below.

Verification dataset:

- Verification dataset representative of the range of bladder volumes which Auto Bladder Volume supports was assessed by experts for accuracy.
- Verification dataset included 1,817 images from 142 individuals.

Demographic distribution of verification dataset:

- Gender: Male and Female
- Age: 13-95 years
- Ethnicity/Country: USA, Germany, UK, Japan, India
- BMI: (Normal <25, Overweight >25)
- Ultrasound Console: Vscan Air

Information about clinical subgroups and confounders present in the verification dataset:

- The algorithm performance was verified across a range of demographic subgroups: Gender (M/F), Age (13-95), Ethnicity/Country (USA, Germany, UK, Japan, India), BMI (Normal <25, Overweight >25).

Expected performance:

- At least 90% success rate in automatic caliper placement for bladder volume measurements when bladder wall is entirely visualized.

Performance demonstrated on verification dataset:

- Automatic caliper placement success rate: 92.24% with a 90% confidence level
- Further analysis demonstrated consistent performance across key subgroups including subjects with known BMI:

BMI	Success Rate
Overweight >25	92%
Normal <25	95%

The number of total samples, if different from above, and the relationship between the two:

- Each individual was scanned in two views: Transverse and Longitudinal.
- Total dataset included 4,014 images from 301 individuals, 1,817 were used for verification dataset and the rest for training/validation.

Information about equipment and protocols used to collect images:

- Mix of data collected from three different Console variants: Vscan Air, Logiq E, and Logiq F. 86% of the total dataset was collected on Vscan Air.

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:

- In training/validation and verification datasets, annotators performed manual annotation on images converted from vscanet files.
- The annotators chose 4-6 images that represent different bladder volume status. On each view the annotation included 4 different landmarks, which represent the bladder edges:
Transverse: Anterior, Posterior, left and right.
Longitudinal: Head, Foot, Anterior and Posterior.
- These points would correspond to the locations where the measurement calipers would be placed for Bladder Volume Measurement.

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

- The data used for the verification dataset is exclusive, comprising of completely independent subjects from data used during training/validation (tuning) processes and there is no overlap between the two.

Summary of Clinical Tests:

The subject of this premarket submission, Vscan Air, 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 Vscan Air to be as safe, effective, and performs in a substantially equivalent manner as the predicate Vscan Air (K231301).