August 15, 2023

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

Re: K231301
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: August 1, 2023
Received: August 1, 2023

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K231301

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 probesolution, 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.

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510(k) Summary K231301

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

Date:	May 4, 2023
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)309-9429
Secondary Contact Person:	Liwen Wei Regulatory Affairs Leader GE Healthcare
Trade Name:	Vscan Air
Common/Usual Name:	Diagnostic Ultrasound Imaging System
Classification Names: Product Code:	Class II 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
Predicate Device: Product Code:	Vscan Air (K202035) 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 Devices: Product Code:	Vscan Extend (K180995) 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 Venue Go (K220800) 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/ Indications 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 and reference devices.
Determination of Substantial Equivalence:	Comparison to Predicate Devices The Vscan Air system is substantially equivalent to the predicate and reference devices with regards to intended use, capabilities, technological characteristics, safety and effectiveness. Intended Use/Indications for Use The systems are intended for diagnostic ultrasound imaging and fluid flow analysis The proposed Vscan Air and the predicate Vscan Air (K202035) have the similar clinical intended use and clinical applications however the following applications are being added to the proposed Vscan Air: • Adult Cephalic, which can be found in reference device Vscan Extend (K180995). Modes and Transducers The proposed Vscan Air and the predicate Vscan Air (K202035) both support Black/white (B-mode), Color flow (Color doppler), combined (B + Color Doppler) and Harmonic Imaging modes. In addition, the proposed Vscan Air also supports Pulsed wave Doppler mode and M-mode, which are cleared in reference device Venue Go (K220800). The proposed Vscan Air probes and the predicate Vscan Air (K202035) probe are manufactured with materials which have been evaluated and found to be safe for the intended use of the device. The proposed Vscan Air and the predicate Vscan Air (K202035) use the same linear array transducer for shallow scanning and curved array transducer for deep scanning. In addition, by introducing the new Vscan Air SL probe, the proposed Vscan Air adds a sector array for deep scanning, which is similar to the sector array that is cleared in reference device Vscan Extend (K180995). Software The proposed Vscan Air uses a software app which can be installed on user's mobile device that provides some of the processing and uses the screen of the mobile device as the display, same as the predicate device Vscan Air (K202035). The proposed Vscan Air has additional TCD (Transcranial Doppler) preset for Adult Cephalic application which is cleared in reference device Vscan Extend (K180995). The proposed Vscan Air supports same distance and

	ellipse measurement as predicate Vscan Air (K202035) and adds velocity, time and angle measurements and OB measurement display, which are cleared in reference device Venue Go (K220800) The proposed Vscan Air adds an annotation function to software app to add/delete/modify free text as labels on image, which is used in reference device Venue Go (K220800). The proposed Vscan Air and the predicate Vscan Air (K202035) both have a transducer element check function, however, the proposed Vscan Air made improvements to quickly assess health of transducers as soon as the probe starts up. The proposed Vscan Air software app allows probes to be on low-power-connected mode while probe is in freeze mode or charging, for power saving and convenience of continuous scanning after probe charging. The proposed Vscan Air adds more basic patient information fields, configuration settings, and basic calculations, which are used in reference device Venue Go (K220800). <u>Hardware</u> The proposed Vscan Air uses Wi-Fi technology (Wi-Fi direct) to communicate between the probe and the mobile device with the installed Vscan Air app, same as predicate device Vscan Air (K202035). The proposed Vscan Air uses wireless charging technology to charge the Vscan Air CL and Vscan Air SL Probe batteries, same as predicate device Vscan Air (K202035). The proposed Vscan Air and predicate Vscan Air (K202035) have been designed in compliance with approved electrical and physical safety standards. <u>Summary of Non-Clinical Tests</u> The Vscan Air device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection as well as thermal, electrical, electromagnetic, mechanical safety and wireless, and has been found to conform to applicable medical device safety standards. The Vscan Air and its applications comply 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 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, 2015 • ISO 10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Fifth edition 2018-08 • ISO 14971, Application of risk management to medical devices, 2019 Edition 2.1 • IEC 62359, Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, Edition 2.1, 2017 • 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) Probe materials are biocompatible. <u>Summary of Clinical Tests:</u> 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 device Vscan Air (K202035).