GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC
% Tracey Ortiz
Regulatory Affairs Director
9900 Innovation Drive
WAUWATOSA WI 53226

November 20, 2020

Re: K202035
Trade/Device Name: Vscan Air
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: ITX, IYN, IYO
Dated: October 16, 2020
Received: October 19, 2020

Dear Tracey Ortiz:

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 and Part 809); 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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K202035

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), Combined (B + Color Doppler) and Harmonic imaging modes with both the curved and linear 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).

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

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

Date: July 22, 2020

Submitter: GE Medical Systems Ultrasound and Primary Care Diagnostics
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Jiangsu China

Trade Name: Vscan Air
Common/Usual Name: Diagnostic Ultrasound Imaging System
Classification Names: Class II
Product Code: Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX;
Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550 90-IYN;
Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO

Predicate Device: Vscan Extend (K180995)
Product Code: Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX;
Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550 90-IYN;
Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO

Reference Devices: Clarius Ultrasound Scanner (K192107)

Product Code:

Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX;
Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550 90-IYN;
Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO

Venue Go (K183362)
Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX;
Ultrasonic Pulsed Doppler Imaging System. 21CFR, 892.1550 90-IYN;
Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO

Versana Active (K200998)
Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX;
Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550 90-IYN;
Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO

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 a probe which uses 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: 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), Combined (B + Color Doppler) and Harmonic imaging modes with both the curved and linear 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).

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.

The systems are intended for diagnostic ultrasound imaging and fluid flow analysis

The proposed Vscan Air and the predicate Vscan Extend(K180995) have the similar clinical intended use and clinical applications however the following are being added to Vscan Air:

- Ophthalmic, musculoskeletal (superficial) and neonatal cephalic that are found in cleared Venue Go (K183362).
- Vascular is added to peripheral vascular for clarity to include all the vessels that was also cleared in Versana Active (K200998).
- Interventional guidance (biopsy and nerve block) already cleared in Venue Go (K183362).
- Imaging guidance for foreign bodies

The proposed Vscan Air and the predicate Vscan Extend have the same imaging modes.

The proposed Vscan Air probe and the predicate Vscan Extend 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 Extend have linear array transducer for shallow scanning and a similar transducer for deep scanning. Vscan Air uses a curved array for the deep scanning, like is cleared in Versana Active (K200998) and a linear array for shallow scanning like is cleared in Venue Go (K183362).

The proposed Vscan Air has acoustic power levels that are below FDA applicable limits.

The proposed Vscan Air has additional presets based on the indications for use. The proposed Vscan Air supports same

distance measurement as predicate Vscan Extend and adds ellipse measurement like in reference device Versana Active (K200998).

The proposed Vscan Air has 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 like is done for cleared Clarius Ultrasound System (K192107).

The proposed Vscan Air does not have a physically wired probe but uses Wi-Fi technology (Wi-Fi direct) to communicate between the probe and the mobile device with the installed Vscan Air app similar to cleared Clarius Ultrasound System (K192107).

The proposed Vscan Air and predicate Vscan Extend have been designed in compliance with approved electrical and physical safety standards.

The proposed Vscan Air and predicate Vscan Extend have difference in charging method, Vscan Air probe battery shall be charged via a wireless charging pad where the Vscan required the charging cable to be plugged into it.

Summary of Non-Clinical Tests:

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/A2:2012
- IEC 60601-1-2, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests, 2014

- 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- Third Edition, 2009
- ISO 14971, Application of risk management to medical devices, 2012
- IEC 62359, Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 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, 2015
- 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, 2014

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.

Summary of Clinical Tests:

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

Conclusion: GE Healthcare considers the Vscan Air to be as safe, as effective, and performance is substantially equivalent to the predicate devices.