May 29, 2025

GE Medical Systems Ultrasound and Primary care Diagnostics, LLC
Bryan Behn
Senior Regulatory Affairs Director
9900 Innovation Drive
Wauwatosa, WI 53226

Re: K250543
Trade/Device Name: Voluson™ Performance 16; Voluson™ Performance 18
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, QIH
Dated: February 24, 2025
Received: February 24, 2025

Dear Bryan Behn:

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,

MARJAN NABILI -S for

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)*

K250543

Device Name

Voluson™ Performance 16;
Voluson™ Performance 18

Indications for Use *(Describe)*

Voluson™ Performance 16 / Voluson™ Performance 18 are a general-purpose diagnostic ultrasound system intended for use by a qualified and trained healthcare professional 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. Voluson™ Performance 16 / Voluson™ Performance 18 clinical applications include: Fetal/Obstetrics; Abdominal (including Renal and Gynecology/ Pelvic); Pediatric; Small Organ (Breast, Testes, Thyroid, etc.); Neonatal Cephalic; Adult Cephalic; Cardiac (Adult and Pediatric); Peripheral Vascular (PV); Musculo-skeletal Conventional and Superficial; Transrectal (including Urology/Prostate) (TR); Transvaginal (TV).

Mode of operation include: B, M, AMM, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, HD-Flow, Harmonic Imaging, Coded Pulse, 3D/4D Imaging mode, Elastography, Contrast and Combined modes: B/M, B/Color, B/PWD, B/Power/PWD. The Voluson™ Performance 16 / Voluson™ Performance 18 system are intended to be used in a hospital or medical clinic.

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.

K250543

510(k) Summary

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

Date: February 24, 2025

Submitter: GE Medical Systems Ultrasound and Primary care Diagnostics, LLC
9900 Innovation Dr
Wauwatosa, WI 53226

Manufacturer: GE Ultrasound Korea, Ltd.
9, Sunhwan-ro 214beon-gil, Jungwon-gu,
Seongnam-si, Gyeonggi-do, 13204 Republic of Korea

Primary Contact Person: Bryan Behn
Senior Regulatory Affairs Director
GE Healthcare
T:(262) 247-5502

Alternate Contact Person: Jiyeon Park
Senior Regulatory Affairs Leader
GE Healthcare
T: +82 317406307

Device Trade Name: Voluson™ Performance 18, Voluson™ Performance 16
Common/Usual Name: Diagnostic Ultrasound System
Classification Names: Class II
Product Code: IYN (primary), IYO, ITX, QIH (secondary)
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
Medical image management and processing system, 21 CFR 892.2050-QIH

Primary Predicate Device: K230346 Voluson SWIFT, Voluson SWIFT+ Diagnostic Ultrasound System

Reference Device(s): K233692 Voluson Signature 20, Voluson Signature 18 Diagnostic Ultrasound System
K242168 Voluson Expert 22, Voluson Expert 20, Voluson Expert 18 Diagnostic Ultrasound System

Classification Names:	Class II
Product Code:	IYN (primary), IYO, ITX, QIH (secondary) 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 Medical image management and processing system, 21 CFR 892.2050-QIH (*QIH is applicable for K242168 only)
Device Description:	The systems are full-featured Track 3 ultrasound systems, primarily for general radiology use and specialized for OB/GYN with particular features for real-time 3D/4D acquisition. They consist of a mobile console with keyboard control panel; color LCD/TFT touch panel, color video display and optional image storage and printing devices. They provide high performance ultrasound imaging and analysis and have comprehensive networking and DICOM capability. They utilize a variety of linear, curved linear, matrix phased array transducers including mechanical and electronic scanning transducers, which provide accurate real-time three-dimensional imaging supporting all standard acquisition modes.
Intended Use:	Voluson™ Performance 16 / Voluson™ Performance 18 are a general-purpose diagnostic ultrasound system intended for use by a qualified and trained healthcare professional 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. Voluson™ Performance 16 / Voluson™ Performance 18 clinical applications include: Fetal/Obstetrics; Abdominal (including Renal and Gynecology/ Pelvic); Pediatric; Small Organ (Breast, Testes, Thyroid, etc.); Neonatal Cephalic; Adult Cephalic; Cardiac (Adult and Pediatric); Peripheral Vascular (PV); Musculo-skeletal Conventional and Superficial; Transrectal (including Urology/Prostate) (TR); Transvaginal (TV). Mode of operation include: B, M, AMM, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, HD-Flow, Harmonic Imaging, Coded Pulse, 3D/4D Imaging mode, Elastography, Contrast and Combined modes: B/M, B/Color, B/PWD, B/Power/PWD. The Voluson™ Performance 16 / Voluson™ Performance 18 system are intended to be used in a hospital or medical clinic.
Technology:	The Voluson™ Performance 16 / Voluson™ Performance 18 employs the same fundamental scientific technology as its predicate device(s).

Determination of Substantial Equivalence:

Comparison to Predicates

The proposed Voluson™ Performance 16 / Voluson™ Performance 18 is substantially equivalent to the predicate devices. The following is an overview of the differences between the Voluson™ Performance 16 / Voluson™ Performance 18 and the predicate Voluson SWIFT Series (K230346).

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The proposed Voluson™ Performance 16/18 and predicate Voluson SWIFT series systems have the same clinical intended use.
- The proposed Voluson™ Performance 16/18 and predicate Voluson SWIFT series systems have the similar imaging mode. Voluson™ Performance 16/18 does not include the B-Flow mode.
- The systems are manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The systems have acoustic power levels which are below the applicable FDA limits.
- The proposed Voluson™ Performance 16/18 and predicate Voluson SWIFT series have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The proposed Voluson™ Performance 16/18 and predicate Voluson SWIFT series have been designed in compliance with approved electrical and physical safety standards.
- The probes supported in proposed Voluson™ Performance 16/18 and predicate Voluson SWIFT series systems are identical.
- The proposed Voluson™ Performance 16/18 has had additional AI software features which have been migrated from Voluson Expert 22/20/18 (K242168): **SonoPelvicFloor 3.0, SonoAVCfollicle 2.0, Fibroid Mapping, SonoLyst Live.** During the migration of the AI software features from Voluson Expert 22/20/18 (K242168) no changes have been made to the algorithmic flow or the AI components performing the inference. Each of the migrated AI features has already been cleared on their respective applicable probes. GEHC confirmed that the AI features work on the subject device after migration with regression tests.
- The following software features have been migrated from Voluson Expert 22/20/18 (K242168): **O-RADS, Vscan Air Probe Support**
- The following software feature has been migrated from Voluson Signature Series (K233692): **Voice Control**

Summary of Non-Clinical Tests:
The device 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 conform with applicable medical device safety standards. The Voluson™ Performance 16 / Voluson™ Performance 18 complies with voluntary standards:

- 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 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, Edition 2.1, 2015
- 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 - 3.20, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology), 2021
- 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
- AAMI TIR69:2017/(R2020), Risk management of radiofrequency wireless coexistence for medical devices and systems

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)
- Safety testing (Verification)

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, Voluson™ Performance 16/18 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 Voluson™ Performance 16/18 to be as safe, effective, and performs in a substantially equivalent manner to the predicate device(s).