November 24, 2025

GE Medical Systems Ultrasound and Primary Care Diagnostics
Behn Bryan
Regulatory Affairs Director
9900 Innovation Drive
Wauwatosa, Wisconsin 53226

Re: K252328
Trade/Device Name: Voluson Expert 18; Voluson Expert 20; Voluson Expert 22
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, QIH
Dated: July 24, 2025
Received: July 25, 2025

Dear Behn Bryan:

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252328

Please provide the device trade name(s).

Voluson Expert 18;
Voluson Expert 20;
Voluson Expert 22

Please provide your Indications for Use below.

The device is a general purpose ultrasound system intended for use by qualified and trained healthcare professionals. Specific clinical applications remain the same as previously cleared: Fetal/OB; Abdominal (including GYN, pelvic and infertility monitoring/follicle development); Pediatric; Small Organ (breast, testes, thyroid etc.); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Musculo-skeletal Conventional and Superficial; Vascular; Transvaginal (including GYN); Transrectal

Modes of operation include: B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Coded Pulse, 3D/4D Imaging mode, Elastography, Shear Wave Elastography and Combined modes: B/M, B/Color, B/PWD, B/Color/PWD, B/Power/ PWD, B/Elastography. The Voluson™ Expert 18, Voluson™ Expert 20, Voluson™ Expert 22 is intended to be used in a hospital or medical clinic.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K252328 510(k) Summary

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

Date:	Novenmber 21, 2025
Submitter:	GE Healthcare [GE Healthcare Austria GmbH & Co OG] Tiefenbach 15 Zipf, Austria 4871
Primary Contact Person:	Bryan Behn Regulatory Affairs Director GE Healthcare 9900 Innovation Drive, Wauwatosa, WI 53226 USA T:(262)247-5502
Secondary Contact Person:	Thomas Reisenberger Sr. Regulatory Affairs Leader GE Healthcare Austria GmbH & Co OG T:(+43)7682-3800-332 F:(+43)7682 3800-47
Device: Trade Name:	Voluson Expert Series Models: Voluson Expert 18, Voluson Expert 20, Voluson Expert 22
Common/Usual Name:	Ultrasound 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
Primary Predicate Device(s):	K242168 Voluson Expert 18, Voluson Expert 20, Voluson Expert 22 Diagnostic Ultrasound System

Classification Names:	Class II Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550, 90-IYN
Product Code:	Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX Automated radiological image processing software, 21 CFR 892.2050, 90-QIH

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 highly accurate real-time three-dimensional imaging supporting all standard acquisition modes.

The following probes are the same as the predicate: RIC5-9-D, IC5-9-D, RIC6-12-D, 9L-D, 11L-D, ML6-15-D, RAB6-D, C1-6-D, C2-9-D, M5Sc-D, RM7C, eM6CG3, RSP6-16-D , RIC10-D, 6S-D and L18-18i-D, RIC12-D.
The existing cleared Probe C1-6-D is being added to previously cleared SW- AI Feature Sonolyst 1st Trimester.

Intended Use:

The device is a general purpose ultrasound system intended for use by qualified and trained healthcare professionals. Specific clinical applications remain the same as previously cleared:

Fetal/OB; Abdominal (including GYN, pelvic and infertility monitoring/follicle development); Pediatric; Small Organ (breast, testes, thyroid etc.); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Musculo-skeletal Conventional and Superficial; Vascular; Transvaginal (including GYN); Transrectal

Modes of operation include: B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Coded Pulse, 3D/4D Imaging mode, Elastography, Shear Wave Elastography and Combined modes: B/M, B/Color, B/PWD, B/Color/PWD, B/Power/PWD, B/Elastography. The Voluson™ Expert 18, Voluson™ Expert 20, Voluson™ Expert 22 is intended to be used in a hospital or medical clinic.

Technology:

The Voluson Expert Series (Voluson Expert 18/20/22) employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Comparison to Predicates

The proposed Voluson Expert 18/20/22 is substantially equivalent to the predicate device with regards to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

Model Names and Model differences:

Voluson Expert 18, **Voluson Expert 20** and **Voluson Expert 22** are same in hardware . **Voluson Expert 18** is lower version and not all probes or functions are available. **Voluson Expert 20** is mid version and product with complete configuration with all the probes and functions of software with exception of 4D electronically probe eM6C G3, 4d realtime Probes: RIC6-12-D, and RM7C. The high-end model **Voluson Expert 22** supports all probes including electronical 4D probe eM6C G3.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The proposed Voluson Expert 18/20/22 and predicate Voluson Expert 18/20/22 systems have the same clinical intended use.
- The proposed Voluson Expert 18/20/22 and predicate Voluson Expert 18/20/22 systems have the same imaging modes.
- The proposed Voluson Expert 18/20/22 and predicate Voluson Expert 18/20/22 system transducers are equivalent.
- There is no change to the system indications for use.
- 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 Expert Series 18/20/22 and predicate Expert 18/20/22 system have same capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The proposed Voluson Expert Series 18/20/22 and predicate systems have been designed in compliance with approved electrical and physical safety standards.

- There proposed Voluson Expert Series 18/20/22 and predicate Expert 18/20/22 system Software Features are equivalent.

- **Main difference: Transducer C1-6-D was added to existing Feature Sonolyst 1st Trimester**
- **Minor Software Improvements, Bug Fixes**

AI Testing Summary for feature **Sonolyst 1st Trimester**
Note: Update to predicate Device only in Section Data Collection:

<table>
<tr><th></th><th>SonoLyst/SonolysLive 1st Trimester</th></tr>
<tr><td>Summary test Statistics</td><td>

Data used for both training and validation has been collected across multiple geographical sites using different systems to represent the variations in target population.
The verification for the SonoLyst 1st Trim IR&X feature is based on computing confusion matrices for the sorting (SonoLyst IR) and grading (SonoLyst X) features
The verification of the SonoLystLive 1st Trim Trimester features is based on the average agreement between a sonographer panel and the output of the algorithm regarding Traffic light quality (green/amber/none).
A verification of the binary results regarding protocol adherence (SonoLyst X) and view suitability (SonoLystLive) was performed on a dedicated data set.
The verification of the SonoBiometry CRL feature is based on the acceptability rate for the placement of CRL callipers
The average success rate of SonoLyst 1st Trimester IR, X and SonoBiometry CRL and overall traffic light accuracy is 80% or higher

Functionality accuracy
<table>
<tr><th>Functionality</th><th>CL2 probe group</th><th>Acceptance Criteria</th></tr>
<tr><td>SonoLystIR</td><td>0.93</td><td>0.80</td></tr>
<tr><td>SonoLystX</td><td>0.84</td><td>0.80</td></tr>
<tr><td>SonoLystLive</td><td>0.84</td><td>0.70</td></tr>
</table>
</td></tr>
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Confounders

For SonoLyst 1st Trimester the following confounder is used: the algorithmic performance is tested on two sub data sets: 1) data acquired with transabdominal probes 2) data acquired with transvaginal probes. By choosing transabdominal vs transvaginal probes as confounder for the data analysis, the robustness of the algorithm against the influence of the abdominal wall, the transducer geometry and frequency is evaluated.

For both subgroups the acceptance criteria are met. This demonstrates the generalization performance of the algorithm.

Subgroup and potential confounders analysis has been completed were appropriate and data allows. All patients within the dataset includes pregnancies between 11 and 14 weeks of gestation, with no known fetal abnormalities at the time of imaging, in line with the intended use.

Table : Results from transabdominal and transvaginal scanning

(%)	Transabdominal (TA)			Transvaginal (TV)	Difference (TA_{mean} -TV)	95% Confidence Interval
	CL1	CL 2	Mean	CLE		
SonoLyst IR	93.7	94.5	94.1	97.3	-3.2	(-4.6, 1.8)
SonoLyst X	91.6	93.1	92.4	92.6	-0.3	(-2.1, 1.7)
SonoLyst Live	82.9	82.1	82.5	81.9	0.6	(-1.2, 2.6)

Table: performance across regions

%	USA	European	Difference (USA-European)	95% Confidence Interval
SonoLyst IR	95.6	94.8	0.8	(-1.1, 2.7)
SonoLyst X	92.9	92.4	0.5	(-1.9,2.9)

	SonoLyst Live | 83.2 | 84.9 | -1.7 | (-5.0,1.6)
Data Collection	- Systems: GE Voluson V730, P8, S6/S8, E6, E8, E10, Expert 22, Philips Epiq 7G - Formats: Still images were obtained in DICOM & JPEG format, cine loops in RAW data format. - Countries: UK, Austria, India and USA - For training 122,711 labelled source images from 35,861 patients - For testing the following number of images were used: SonoLyst 1st Trim IR: **7970** SonoLyst 1st Trim X: **4931** SonoLyst 1st Trim Live: **9111** SonoBiometry CRL: **243** - For Probegroup CL2 (which includes C1-6-D Probe) Data was collected from 396 patients. Data was sampled so that a maximum of one sample was taken per patient per view. The final samples evaluated were:

View Category	Images per dataset for CL2 Probetypes	
	SonoLystIR & X	SonoLyst Live
Sagittal Fetus (Crown rump length)	133	164
Sagittal Bladder	140	142
Sagittal Head	153	164
	148	164
Trans-thalamic	132	164
Axial orbits	149	164
Coronal orbits	164	164
Coronal palate	150	164
Coronal lips	147	165
Axial heart	155	165
Axial cord insertion	163	163
Axial abdomen	133	164
Axial kidneys	164	164
Axial bladder	161	164
Coronal kidneys	122	164
Sagittal spine	72	164

	<table><tr><td>Upper limbs</td><td>115</td><td>164</td></tr><tr><td>Lower limbs</td><td>130</td><td>164</td></tr><tr><td>Others</td><td>168</td><td>180</td></tr><tr><td>Total images</td><td>2699</td><td>3111</td></tr></table> - Demographic distribution including Gender, Age, and Ethnicity: We are not able to provide exact demographic distributions due to data privacy constraints. Where collected, patient age is grouped into <20, 20-29, 30-39, 40-49, >50. The data set contains known patient ages from <20 till 30-39 and has been limited to reproductive ages of at least 18 years of age. Data was collected from 396 patients for CL2 evaluation, with 201 (51%) patients from USA sites and 195 (49%) from European sites. From our earlier evaluation across the probe groups, we also conducted a subset evaluation across different regions. In all cases the confidence intervals cross zero, indicating no statistically significant difference. These findings demonstrate that the algorithm performs consistently across regions. *See also Table: "performance across regions"*
Truthing process for test datasets	In general for Sonolyst Software: To ensure the quality of the curated data for verification, the following strategy is employed: 1. The images were curated (sorted and graded) by a single sonographer 2. The images were sorted and graded by SonoLyst IR/X First Trimester. This process resulted in some images being reclassified during sorting. 3. The sorting process resulted in some images being reclassified based upon the majority view of the panel.Where they differed from the ground truth, the graded images from step 1 were reviewed by a 5-sonographer review panel, in order to determine the grading accuracy of the system <u>especially for C1-6-D probe impmentation:</u> A standardized imaging protocol was used based on internationally recognized guidelines to ensure consistency and quality across all scans. Specifically, the following sources were used to inform the protocol:

	• **AIUM Practice Parameter for the Performance of Standard Diagnostic Obstetric Ultrasound** This U.S.-based guideline defines the minimum criteria for a complete first-trimester scan, with flexibility for transabdominal or transvaginal approaches. • **AIUM Detailed Protocol (12 Weeks 0 Days to 13 Weeks 6 Days)** Used in cases where abnormalities were suspected or in high-risk pregnancies, this protocol provides more detailed criteria for diagnostic imaging. • **ISUOG Practice Guidelines: Performance of First-Trimester Fetal Ultrasound Scan** This guideline outlines the standard approach for confirming fetal viability, accurately establishing gestational age and determining the number of fetuses. • **ISUOG Detailed Protocol** Applied in cases involving higher-risk pregnancies, this protocol provides additional detail to ensure comprehensive assessment during the first-trimester scan. • **Routine First-Trimester Ultrasound Screening Using a Standardized Anatomical Protocol (Yimei Liao et al.)** This study informed the development of a routine first-trimester scan protocol for detecting structural abnormalities. Test data was collected on: GEHC Voluson Expert 22 GEHC Voluson Expert 10
Independence of Test data	All training data is independent from the test data at a patient level. A statistically significant subset of the test data is independent from the training data at a site level, with no test data collected at the site being used in training. Independence of the test data has been insured by collecting test data only from sites which were not involved in the collection of data used for training.

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 to applicable medical device safety standards. The Voluson Expert Series 18/20/22 and its applications comply with voluntary standards:

- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests, Edition 4.1 CONSOLIDATED VERSION 2020
- IEC60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment, 2015
- ISO10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, 2018
- ISO14971, Application of risk management to medical devices: Third Edition 2019
- NEMA PS 3.1 - 3.20 (2023e), Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)
- AAMI TIR69:2017/(R2020), Risk management of radio-frequency wireless coexistence for medical devices and systems
- IEC62359 Edition 2.1 2017-09 Consolidated Version; Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields

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)
- Final Acceptance Testing (Validation)

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, Voluson Expert Series 18/20/22 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 Expert Series 18/20/22 performs in a substantially equivalent manner to the predicate device(s).