December 20, 2024

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

Re: K242168
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: November 18, 2024
Received: November 18, 2024

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

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)*

K242168

Device Name

Voluson Expert 18;
Voluson Expert 20;
Voluson Expert 22

Indications for Use *(Describe)*

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.

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.

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K242168

510(k) Summary

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

Date:	July 24, 2024
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 F:(414)918-8275
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):	K231965 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 Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX
Product Code:	
Reference Predicatee Device(s):	K231301 Vscan Air K211488 Logiq E10 K240111: Venue
Classification Names:	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
Product Code:	
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 RAB7-D is a new probe and is substantially equivalent to the RAB6-D, it is an incremental improvement in technology. Vscan Air SL and Vscan Air CL wireless Probes are also added.
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. New RAB7-D and VscanAir SL and VscanAir CL wireless probes were added.
- 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 similar 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 (except below Changes). Some minor improvements to the existing Software features have been implemented into the proposed system.

- The proposed Voluson Expert Series 18/20/22 adds additional AI software features **SonoLyst 1st Trimester** and **Sono Pelvic floor 3.0:** which includes **MHD (valsava manoeuver detection)** and **Anal sphincter**

- The proposed Voluson Expert Series 18/20/22 updated existing AI software features **SonoLyst 2nd Trimester** and **SonoAVC follicle 2.0**

- The proposed Voluson Expert Series 18/20/22 adds additional software features
  - O-RADS=(Ovarian-Adnexal Reporting & Data System)
  - OTI live, Automation of bulk speed of sound implemented (similar method as existing ADAPT with eM6C)

- The following software feature has been migrated from Venue (K240111): Vscan Air Probe Support

- The proposed Voluson Expert Series 18/20/22 adds one new Probe: **RAB7-D** which is similar to predicate probe RAB6-D (K231965) and support of wireless Probes **Vscan Air CL** and **Vscan Air SL** Probes (K240111):

AI Testing Summary for new **Sono Pelvic floor 3.0**: which includes **MHD** (valsava manoeuver detection) and **Anal sphincter**:

<table>
<tr><th></th><th>MHD</th><th>Anal Sphincter</th></tr>
<tr><td>Summary test Statistics</td><td>Expected result.

On datasets that were marked as Good in Image/Cine Quality assessment, the success rate should be 70% or higher. On datasets that were marked as challenging in image/cine quality measure the success rate of the feature should be 60% or higher.

Rationale for clinical adequacy.

Requirements for success rates of this workflow tool were discussed with internal and external clinical experts. User scanning experience and expected image quality in clinical practice was considered and reflected in the verification data pool. Based on the expert opinion the above success rates were considered appropriate.
Verification Results on actual verification data is as follows

<table><tr><td></td><td>Good Image Quality</td><td>Challenging Image Quality</td></tr><tr><td>MHD Tracking</td><td>89.3%</td><td>77.7%</td></tr><tr><td>Minimum MHD Frame Detection</td><td>89.3%</td><td>83.3%</td></tr><tr><td>Maximum MHD Frame detection</td><td>90.66%</td><td>77.7%</td></tr></table></td><td>Expected result.

On datasets that were marked as Good in Image/Cine Quality assessment, the success rate should be 70% or higher. On datasets that were marked as challenging in image/cine quality measure the success rate of the feature should be 60% or higher.

Rationale for clinical adequacy.

Requirements for success rates of this workflow tool were discussed with internal and external clinical experts. User scanning experience and expected image quality in clinical practice was considered and reflected in the verification data pool. Based on the expert opinion the above success rates were considered appropriate.

Verification results on actual verification data is as follows

On Good IQ datasets: 81.9%</td></tr>
</table>

		On Challenging quality datasets: 60.9%
Confounders	**The primary confounders present in the data pool are as follows:** 1. Phase of examination: Rest, Contraction and Valsalva 2. Multiple probes (both Transabdominal and transvaginal) are represented in the verification pool as detailed above. 3. The data is acquired across diverse regions and sites	**Confounder:** 1. Multiple probes (both Transabdominal and transvaginal) are represented in the verification pool as detailed above. 2. The data is acquired across diverse regions and sites 3. There is also image quality variation in the data sets – marked as challenging or good IQ by clinical experts.
	4. There is also image quality variation in the data sets – marked as challenging or good IQ by clinical experts.	

Data Collection	Data is provided by external clinical partners who de-identified the data before sharing it with us. Original data is collected in the form of 4D volume Cines in *.vol[5] or *.4dv[6] data formats. This preserves the flexibility to re-process data to our needs retrospectively during scan conversion[7]. A standardized data collection protocol was followed for all acquisitions.	Data is provided by external clinical partners who de-identified the data before sharing it with us. Original data is collected in the form of 4D or 3D volume acquisitions in *.vol[2] or *.4dv[3] data formats. This preserves the flexibility to re-process data to our needs retrospectively during scan conversion[4]. A standardized data collection protocol was followed for all acquisitions.
	Distribution of train data is as follows *Total Volumes:* 983 *Distribution by Systems*: V730 (116), Voluson E10 (482), Voluson E6 (21), Voluson E8 (90), Voluson P8 (274) *Distribution by Probes*: RAB 4-8L (116), RAB2-6-RS (38), RAB6-D (111), RIC5-9A-RS (236), RIC5-9-D (8), RM6C (474) *Distribution by Countries*: Australia (116), Austria (8), Belgium (465), Czech Republic (100), Japan (236), Italy (37), South Africa (21) **Distribution of Test data is as follows**	**Distribution of train data is as follows** *Total Volumes:* 828 *Distribution by Systems*: Voluson E6 (118), V730 (160), Voluson E10 (149), Voluson S10 (120), Voluson SWIFT (28), Voluson E8 (83), Voluson P8 (155), Voluson S8 (8), SWIFT + (7) *Distribution by Probes*: RAB 4-8L (160), RAB6 (409) RIC5-9 (132), RM7C (42), em6C (2), RM6C (83) *Distribution by Countries*: Belgium (116), Australia (186), Egypt (136), Japan (132), Germany (125), South Africa (124), Italy (9) **Distribution of Test data is as follows**

	Total Volumes: 93 *Distribution by Systems*: Voluson Expert 22 (59), Voluson Expert 20 (4), V730 (5), Voluson E10 (12), Voluson E8 (2), Voluson S10 (10), Voluson Signature 20 (1) *Distribution by Probes*: RAB6-D (21), RIC5-9-D (14), RM7C (26), RAB 4-8L (5), RIC10-D (21), RM6C (6) *Distribution by Countries*: Italy (21), U.S.A (29), Australia (5), Germany (15), Czech Republic (6), France (2), India (15)	Total Volumes: 106 *Distribution by Systems*: Voluson E10 (37), Voluson Expert 22 (57), Voluson Expert 20 (7), Voluson Signature 20 (5) *Distribution by Probes*: RAB6-D (12), RAB7-D (2), RIC10-D (9), RIC5-9 (62), RM6C (2), RM7C (19) *Distribution by Countries*: Italy (21), U.S.A (18), France (32), Germany (12), India (23)
Truthing process for training datasets	We undertake a two-stage curation process. In the first stage, curators identify the MHD plane in the relevant frame of the cine. In the next stage, the anatomical structures are marked on the MHD plane. The curated datasets are reviewed by expert arbitrators and changes/edits made if necessary to maintain correctness and consistency in curations,	We undertake a 3D segmentation of the Anal Canal using VOCAL tool in the 4D View[5] Software. Curation protocol is as follows: 1. Align the volume to ensure full visualization of the Anal Canal 2. Segment the Anal Canal in 3D using VOCAL tool. Curation is done on only volumes that have proper visualization of the relevant anatomy Each volume was reviewed by a skilled arbitrator for correctness. If any error was found, the volume was re-worked
Truthing process for Test datasets	For Evaluation pool: The evaluation was based on interpretation of the AI output by reviewing clinicians. The evaluation was conducted by three	For Evaluation pool: The evaluation was based on interpretation of the AI output by reviewing clinicians. The evaluation was conducted by three

	independent reviewers, with at least two being US Certified sonographers, with extensive clinical experience.	independent reviewers, with at least two being US Certified sonographers, with extensive clinical experience.
Independence of Test data	To ensure separation of train and test data, following steps were undertaken: Post model development, we acquired consecutive data from previously unseen sites to test the robustness of the algorithm on new data distributions. We also collected consecutive data (separately) from sites that had contributed to the train pool as well.	To ensure separation of train and test data, following steps were undertaken: Post model development, we acquired data from previously unseen (in train pool) systems as well as new/unseen sites to test the robustness of the algorithm on new data distributions.

AI Testing Summary for updated feature **SonoAVC Follicle 2.0**:

	SonoAVC Follicle 2.0
Summary test Statistics	**Expected result** The success rate for AI feature should be 70% or higher. **Rational for Clinical Adequacy** Requirements for success rates of this workflow tool were discussed with internal and external clinical experts. User scanning experience and expected image quality in clinical practice was considered and reflected in the verification data pool. Based on the expert opinion the above success rates were considered appropriate. **Verification Results on actual verification data is as follows:** Accuracy: On test data acquired together with train cohort: 94.73% On test data, acquired consecutively post model development: 92.8% Overall Accuracy: 93.6%

<table>
<tr><td></td><td>For various confounders the individual accuracy numbers are as follows:
<u>Probe wise distribution:</u>
RIC5-9 – 94.6%
RIC10 – 93,6%
RIC6-12 – 90.6%
<u>Geographical distribution:</u>
Germany – 92.2%
India – 95.1%
Spain – 94.7%
U.K. – 95.5%</td></tr>
<tr><td>Confounders</td><td>The test cohort consists of multiple sets – Set 1 is acquired together with the train data set and remaining sets (2-5) are acquired post model development.

For set 1 – the size distribution of follicles (measured as the largest 3D diameter) is detailed below:
3-5 mm: 31%
5-10 mm: 40%
10-15 mm: 21%
>15 mm: 8%

The above is in line with the clinical prevalence of the follicle sizes.

The above, together with data from diverse probes and different sites ensure sufficient diversity is captured in terms of acquisition settings, image quality as well as patient demographics.

The performance matrix for the various size ranges for follicles is as follows.
<table>
<tr><th>Size Range (mm)</th><th>Dice Coefficient</th></tr>
<tr><td>3-5</td><td>0.937619</td></tr>
<tr><td>5-10</td><td>0.946289</td></tr>
<tr><td>10-15</td><td>0.962315</td></tr>
<tr><td>>15</td><td>0.93206</td></tr>
</table>
</td></tr>
</table>

Data Collection	Data is provided by external clinical partners who de-identified the data before sharing it with us. Original data is collected in the form of 3D volumes in *.vol[1] or *.4dv[2] data formats. This preserves the flexibility to re-process data to our needs retrospectively during scan conversion[3]. Train Data Distribution: *Total Volumes:* 249 - *Distribution by Systems*: Voluson E8 (20), Voluson E10 (131), Voluson P8 (29), Voluson S10 (48), Voluson S8 (21) - *Distribution by Probes*: RIC5-9A-RS (98), RIC5-9-D (149), RIC6-12-D (2) - *Distribution by Countries*: India (62), Germany (29), United Kingdom (29), Spain (103) Test Data Distribution *Total Datasets:* 138 Total follicle count across all volumes: 2708 - *Distribution by Systems*: Voluson E22 (63), E10 (32), Voluson E8 (20), Voluson P8 (8), Voluson S10 (12), Voluson S8 (3) - *Distribution by Probes*: RIC5-9 (84), RIC10 (37), RIC6-12 (17) - *Distribution by Countries*: Germany (54), India (11), Spain (43), United Kingdom (7); USA (23)
Truthing process for training dataset	To ensure correct and reliable "truthing" process of the training data we followed a two-step approach. In the 1st step, a detailed curation protocol (developed by clinical experts) was shared with the curators, and they were trained and instructed to follow the same. As an automated quality control step, we confirm the availability of all the required masks/markings in each of the curated views. Missing masks or inconsistent labels are reported back to the curators and the datasets not used for training/development until all masks are available and consistently labelled. In addition, during and after the data curation process, a arbitrator reviews all the datasets and curations from each curator's completed data pool for their clinical accuracy. In case that any inconsistencies are detected, an optimal curation strategy is discussed and communicated back to the entire curation team. ,

Truthing process fortest data	For Evaluation pool: The evaluation was based on interpretation of the AI output by reviewing clinicians. The evaluation was conducted by three independent reviewers, with at least two being US Certified sonographers, with extensive clinical experience.
Independence of Test data	To ensure separation of train and test data, following steps were undertaken: 1. Post acquiring the data at the start of the model development – the entire data pool was split into train / validation and test datasets ensuring that there is uniqueness in the patient representation in each set – i.e. a single patient is present only in one of the three groups. Also, it was attempted that there is a representation of as many geographical sites as possible in both the test and train pool. Beyond these two constraints, the data was split randomly. 2. Post model development, we acquired consecutive data from previously unseen (in train pool) systems as well as new/unseen probe to test the robustness of the algorithm on new data distributions.

AI Testing Summary for updated feature **2nd Trimester SonoLyst/SonoLystlive**

	2nd Trimester SonoLyst/SonolysLive
Summary test Statistics	• 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 2nd 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 2nd 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) • The average success rate of SonoLyst 2nd Trimester IR and X and overall traffic light accuracy is 80% or higher

Confounders	In order to demonstrate the generalization performance of the algorithm, the quantitative evaluation is performed for two subgroups: a data set containing of a variety of ultrasound systems and data formats against a data set containing the target platform. For both subgroups the acceptance criteria are met.
Data Collection	- Systems: GEHC Voluson V730, E6, E8, E10, Siemens S2000 and Hitachi Aloka - Formats: Still images were obtained in DICOM & JPEG format, cine loops in RAW data format. - Countries: UK, Austria, India and USA - Total number of images: 2.2M - Total number of cine loops: 3595
Truthing process for training datasets	To ensure the quality of the curated data for verification, the following strategy is employed: employed 1. The images were curated (sorted and graded) by a single sonographer 2. The images were sorted and graded by ScanNav AutoCapture Second Trimester. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. 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

Truthing process for Test datasets	For Evaluation pool: The evaluation was based on interpretation of the AI output by reviewing clinicians. The evaluation was conducted by three independent reviewers, with at least two being US Certified sonographers, with extensive clinical experience.
Independence of Test data	All training data is independent from the test data at a patient level.

AI Testing Summary for updated feature **1st Trimester SonoLyst/Sonolystlive**

	1st Trimester SonoLyst/SonolysLive
Summary test Statistics	• 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) • 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 •
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.

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: 5271 SonoLyst 1st Trim X: 2400 SonoLyst 1st Trim Live: 6000 SonoBiometry CRL: 110
Truthing process for test datasets	To ensure the quality of the curated data for verification, the following strategy is employed: employed 1. The images were curated (sorted and graded) by a single sonographer 2. The images were sorted and graded by ScanNav AutoCapture First Trimester. This process resulted in some images being reclassified during sorting. 3. Where they differed from the ground truth, the sorted images from step 2 were reviewed by a 5-sonographer review panel, in order to determine the sorting accuracy of the system. The sorting process resulted in some images being reclassified based upon the majority view of the panel. 4. 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.
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.

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: GE Healthcare considers the Voluson Expert Series 18/20/22 to be as safe, as effective, and performance is substantially equivalent to the primary predicate device.