GE Medical Systems Ultrasound and Primary Care Diagnostics
℅ Bryan Behn
Regulatory Affairs Director
GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC.
9900 Innovations Dr.
WAUWATOSA WI 53226

October 30, 2023

Re: K231965
Trade/Device Name: Voluson Expert 22, Voluson Expert 20, Voluson Expert 18
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: September 29, 2023
Received: October 2, 2023

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K231965

Device Name

Voluson Expert 22, Voluson Expert 20, Voluson Expert 18

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary K231965

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

Date:	Oct 23, 2023
Submitter:	GE Healthcare [GE Healthcare Austria GmbH & Co OG] Tiefenbach 15 Zipf, Austria 4871
Primary Contact Person:	Bryan Behn Regulatory Affairs Director GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC 9900 Innovation Dr. Wauwatosa, WI 53226 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 22, Voluson Expert 20, Voluson Expert 18
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):	K220358 Voluson Expert 22, Voluson Expert 20, Voluson Expert 18 Diagnostic 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

Reference Predicatee Device(s):	K230346 Voluson SWIFT, Voluson SWIFT+
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. The RIC12-D is a new probe and is substantially equivalent to the RIC6-12-D, it is an incremental improvement in technology.
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 E22/20/18) employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Comparison to Predicates

The proposed Voluson Expert 22/20/18 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 RIC6-12-D, eM6CG3 and RIC12-D. 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 22/20/18 and predicate Voluson Expert 22/20/18 systems have the same clinical intended use.
- The proposed Voluson Expert 22/20/18 and predicate Voluson Expert 22/20/18 systems have the same imaging modes.
- The proposed Voluson Expert 22/20/18 and predicate Voluson Expert 22/20/18 system transducers are equivalent. One new transducer RIC12-D was 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 22/20/18 and predicate Expert 22/20/18 system have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The proposed Voluson Expert Series 22/20/18 and predicate systems have been designed in compliance with approved

electrical and physical safety standards.

- There proposed Voluson Expert Series 22/20/18 and predicate Expert 22/20/18 system Software Features are equivalent. Some minor improvements to the existing Software features have been implemented into the proposed system.

- The proposed Voluson Expert Series 22/20/18 adds additional AI software features **SonoPelvicFloor2.0 (extension of existing Feature SonoPelvicFloor) , SonoAVC2.0 (extension of existing Feature SonoAVC), Fibroid Mapping (as part of Option SonoGYN)** to the system.
  Additional the existing features **SonoLyst/ Sonolyst Live have been improved.**

- The proposed Voluson Expert Series 22/20/18 adds additional software features **BSI (Blood Speckle Imaging)** and **Ophthalmic Artery Measurement** to the system.

AI Verification Summary:

SonoAVC2.0 (also described as Auto-Caliper):

The proposed Voluson Expert Series 22/20/18 BT24 feature SonoAVC2.0 migrated from already cleared (K230346) Voluson SWIFT, Voluson SWIFT+ software feature called **Auto Caliper.**

SonoPelvicFloor2.0

Summary test statistics or acceptance criteria

Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance.

• Data used for both training and validation has been collected across multiple geographical sites using different systems and probe configuration to represent the variations in target population. The distribution of test data is as follows:

Total Volumes: 94

- *Distribution by Systems*: Voluson Expert 22 (82), Voluson E8 (8), Voluson E6 (4)
- *Distribution by Probes*: RAB6-D (41), RIC5-9-D (21), RM7C (32)
- *Distribution by Countries*: Austria (36), U.S.A (47), South Africa (4), Czech Republic (7)

• The verification for the SonoPelvicFloor2.0 AI feature is performed by clinical experts following a specific Workflow:

1) Import the entire data pool into the *Archive* on the system.
2) Load the datasets one-by-one from the *Archive*
3) Assess and document the volume cine quality.
4) Check if the MHD plane can be found in the volume cine with clinically required quality. If the plane cannot be found/tracked, then mark the corresponding result as 'N/A'.
5) Press the *Init* button on the UI.
6) Enter the SonoPelvicFloor tool.
7) **Draw the OmniView line to capture the MHD plane at the first frame.** Start the Live tracking algorithm as follows 4D - SonoPelvicFloor - Live Tracking
8) Observe the automated placement of the MHD plane during live tracking on all frames of the cine loop.
9) If the result was not deemed 'N/A' in step 4), then document the assessment (by internal clinical expert) as Success/No result/Failure.
10) The final dataset obtained after these steps should be stored back to the archive.

Expected result: On datasets that were marked as Good in Image/Cine Quality (IQ) 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.

Our algorithm is shown to yield an accuracy of 96% on good IQ datasets and 93% on challenging IQ cases.

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 or *.4dv data formats. This preserves the flexibility to re-process data to our needs retrospectively during scan conversion.

Our train data consists of 983 distinct volumes from 616 individual patients (from several patients volume were acquired in multiple phases of examination – Rest, Contraction and/or rest. Using these 983 volumes we generated 8847 images – 3 slices from each volume with three rotation angles per image. The distribution of 983 volumes is as follows:

- *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)

Demographic distribution

The data is acquired from women examined in regular clinical practice across multiple geographical sites. We do not acquire explicit information regarding age or ethnicity of each patient because of privacy constraints around PHI. Any identifying information such as age and ethnicity are removed during data anonymization step. However, acquiring data from regular practice across multiple sites/countries/clinical practices encourages implicit diversity in age and ethnicity and patient characteristics distribution in the collected datasets.

Clinical Subgroups and Confounders

The clinical subgroups/confounders present in the evaluation pool is as follows:

1. Image Quality: Good image quality and Challenging image quality
   The accuracy of algorithm on the above subgroups is:
   Good IQ: 96.2%
   Challenging IQ: 93.3%

2. Evaluation Phase: Rest, Contraction or Valsalva
   The accuracy of algorithm on the above subgroups is:
   Rest : 100%
   Contraction: 93.75%
   Valsalva: 96.55%

Equipment and protocols

The testing data was collected from hospital centers as well as private practices following the standard clinical protocol across multiple GE systems and probe configurations. Summary of the evaluation pool distribution is as follows:

*Total Volumes: 9*4

- *Distribution by Systems*: Voluson Expert 22 (82), Voluson E8 (8), Voluson E6 (4)
- *Distribution by Probes*: RAB6-D (41), RIC5-9-D (21), RM7C (32)
- *Distribution by Countries*: Austria (36), U.S.A (47), South Africa (4), Czech Republic (7)

Independence of Test-Train data

We maintain a database containing relevant information for all datasets used during training and verification of this feature in an SQL database. The datasets contained in the collections for training and verification are mutually exclusive and stem from a mutually exclusive list of patients.

In addition, we also perform testing on data acquired from site (namely U.S.A.) which did not contribute to the training data pool. The satisfactory performance on the new/unseen data distribution from these sites indicate towards the good generalizability of our models/algorithm.

Fibroid Mapping:

Summary test statistics or acceptance criteria

Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance.

• Data used for training, validation, and verification (evaluation) has been collected across multiple geographical sites using different probe configurations to represent the variations in target population.

• The verification was performed by clinical experts according to the following protocol:

1) Invoke Fibroid Pre Mapping Menu. 2D: Do a scan, find the mid sagittal plane and enter 3D pre and select “Fibroid Mapping” OR 3D Find mid sagittal plane in Volume, enter Volume analysis and select “Fibroid Mapping”.
2) Trace uterus midline on touchscreen
3) Freeze and acquire.
4) Invoke Fibroid Mapping Main
5) Start the auto segmentation after 3D acquired.
6) Check if the segmentation is satisfying. If not return to step 2). Otherwise, select “Add to Report” to save measurements to the current exam.
7) Semi-Automated Fibroid Segmentation: Position the curser over a fibroid to be measured on the section plane and click the Add/Rem button to add or remove fibroids. Repeat for all fibroids on current plane.
8) If all fibroids in the plane are segmented correctly, adjust the sectional plane with parallel shift and repeat step 7).
9) Select “Add to Report” to save the measurements to the current exam.
10) If segmentation quality of a fibroid is not satisfactory, activate manual fibroid segmentation (Add Fibroid Manually)
11) Select measurement tool “Ellipse” or “Double Caliper”. Enter the start and end point of the long and short diameter using the trackball. Measure all wanted fibroids on current plane.
12) Adjust the plane with parallel shift to achieve next slice position and continue with step 7) or 10)
13) To save measurement to the current exam select “Add to Report”.

- The success rate of each AI component of the feature (uterus, endometrium, and fibroid segmentation) should be 70% 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 are considered appropriate.

The original verification of the feature was performed on a data pool consisting of:

Total Volumes: 78

- Systems: Voluson Expert Series
- Probes: RIC5-9-D, RIC6-12-D
- Countries: Egypt, Greece, Korea, Philippines, Romania, USA.

Primary verification – qualitative results:

Uterus	95%
Endometrium	89%
Fibroids	88%

We then performed a secondary evaluation including a quantitative assessment as well as a stratified performance analysis per confounders as follows:

Total Volumes: 74

- *Systems*: Voluson Expert Series
- *Probes*: RIC5-9-D, RIC10-D
- *Countries*: Austria, Egypt, Germany, Greece, Korea, Philippines, Romania, USA

Secondary evaluation – qualitative results:

Uterus	100%
Endometrium	91%
Fibroids	88%

The clinical requirements are thus successfully met in both verification rounds.

Further details of the quantitative assessment results can be found in the dedicated subsection below. All our experiments confirm the high accuracy as well as strong generalization capabilities of the Fibroid Mapping automation feature.

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 or *.4dv data formats. This preserves the flexibility to re-process data to our needs retrospectively during scan conversion.

A total of 779 unique volumes are utilized to *train* the model. With augmentations, 7790 volumes are generated.

A total of 31 unique volumes are utilized to *validate* the model. With augmentations, 310 volumes are generated.

We collected training data of the following types from hospital centers as well as private practices. We provided a dedicated data collection protocol explaining the required data needs to each provider.

- *Systems*: Voluson E10, E8, E6, S10, S8, S6, P8.
- *Probes*: RIC5-9-D, RIC6-12-D, RM6C, RIC5-9A-RS, RIC5-9W-RS.
- *Countries*: Austria, Egypt, France, Greece, Korea, Poland, Romania, USA.

For an overview of the data used for *verification* (evaluation), please see the preceding subsection of this summary.

Demographic distribution

The data is acquired from women examined in regular clinical practice across multiple geographical sites. We do not acquire explicit information regarding age or ethnicity of each patient because of privacy constraints around PHI. Any identifying information such as age and ethnicity are removed during data anonymization step. However, acquiring data from regular practice across multiple sites/countries/clinical practices encourages implicit diversity in age and ethnicity and patient characteristics distribution in the collected datasets.

Information about clinical subgroups and confounders

We considered the following relevant confounders to analyze the performance of our algorithms on subgroups: uterus position, endometrial phase, fibroid location, probes, and geographic regions. Our analysis shows that our algorithms perform consistently well across all the subgroups.

Quantitative evaluation

The data pool for quantitative analysis consists of 74 volumes. Data is provided by external clinical partners who de-identify the data before sharing it with GE HealthCare. Original data is collected in the form of 3D volumes in *.vol data format. This preserves the flexibility to re-process data to our needs retrospectively during scan conversion. The results show high accuracy of the algorithms and a correlation between DICE scores (i.e., Dice coefficient) and qualitative assessment by independent clinical experts.

Anatomy	DICE when successful	DICE when failed
Uterus	0.89 ± 0.03	n/a
Endometrium	0.70 ± 0.18	0.29 ± 0.27
Fibroids	0.70 ± 0.13	0.48 ± 0.17

Equipment and protocols

• Data is provided by external clinical partners who de-identified the data.

• Original data is collected in the form of 3D/4D volumes to preserve the flexibility to re-process data retrospectively during scan conversion.

• A data collection protocol is provided to each site to explain the required data needs.

Independence of Test-Train data

We maintain a database containing relevant information for all datasets used during training and verification of this feature in an SQL database. The datasets contained in the collections for training and verification are mutually exclusive and stem from a mutually exclusive list of patients.

In addition, we also perform testing on data acquired from sites (namely, in Germany and Austria) which did not contribute to the training data pool. The satisfactory performance on the new/unseen data distribution from these sites indicate towards the good generalizability of our models/algorithm.

Sonolsyt/Sonolyst Live (existing Features was improved and extended)

The basic functionality of SonoLyst/SonoLyst Live feature were already submitted as AI feature and cleared with the submission K220358.

With this submission (K231965) the following changes occurred compared to (K220358):

- Added views
  - Lower Limb, with following criteria: Magnification, Upper leg visible, Lower leg visible, foot visible,
  - Upper Limb, with following criteria: Magnification, Upper arm visible, Forearm visible
- User Interface changes
  - The sagittal spine view contained the grading criteria “Sacrum visible”, “Lumbar visible”, “Thoracic visible”, and “Cervical visible”. In order to simply the workflow for the user, these criteria are directly accessible to the user at view level as “Spine Sacrum”, “Spine Lumber” “Spine Thoracic”, and “Spine Cervical”, without changing the underlaying AI algorithm.
  - The Lower Limb view contains the grading criteria “Upper Leg visible”, “Lower leg visible”, “Foot visible”. In order to simply the workflow for the user, these criteria are directly accessible to the user at view level as “Upper Leg”, “Lower Leg” and “Sagittal foot”, without changing the algorithm.
  - The Upper Limb view contains the grading criteria “Upper Arm visible” and “Forearm visible”. In order to simply the workflow for the user, these criteria are directly accessible to the user at view level as “Upper Arm”, and “Forearm”, without changing the algorithm.
  - Manual Indication of left/right hands/feet/extremities added.
  - Status hexagon shown also while in Scan Assistant.
  - Automatically stores images in real-time during exam.

Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance.

- 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.
- The average success rate of SonoLyst 2nd Trimester IR and X and overall traffic light accuracy is 80% or higher.

Data Collection and Distribution:

- Systems: GE Voluson V730, E6, E8, E10, Siemens Acuson 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: 2570

Quantitative evaluation:

For SonoLyst 2nd Trimester IR in total 42102 images are used for quantitative evaluation

For SonoLyst 2nd Trimester X in total 10424 images are used for quantitative evaluation

For SonoLystLive 2nd Trimester in total 5666 images are used for quantitative evaluation

Information about clinical subgroups and 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.

Equipment and protocols

Equipment: GE Voluson V730, E6, E8, E10, Siemens Acuson S2000 and Hitachi Aloka

Data was collected from routine clinical practice in hospitals and private practice during mid-trimester examinations, with a gestational age range of 18-24 weeks.

Information about the reference standard and dataset ("truthing process"):

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 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.

C**onclusion: GE Healthcare considers the Voluson Expert 18, Expert 20 and Expert 22 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).**

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 22/20/18 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 (2022a), Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)

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 22/20/18 did not require clinical studies to support substantial equivalence.

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