October 2, 2026

GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC
Bryan Behn
Sr. Regulatory Affairs Director
3200 N Grandview Blvd.
Waukesha, Wisconsin 53188

Re: K261933
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: September 2, 2026
Received: September 2, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

for

MARJAN NABILI -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.	K261933

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 (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☒ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

K261933 510(k) Summary

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

Date:	Oct 2, 2026
Submitter:	GE Healthcare [GE Healthcare Austria GmbH & Co OG] Tiefenbach 15 Zipf, Austria 4871
Primary Contact Person:	Bryan Behn Regulatory Affairs Director GE Healthcare 3200N Grandview Dr, Waukesha, WI 53188 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 Automated radiological image processing software, 21 CFR 892.2050, 90-QIH
Primary Predicate Device:	K252328 Voluson Expert 18, Voluson Expert 20, Voluson Expert 22 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 Automated radiological image processing software, 21 CFR 892.2050, 90-QIH

Reference Device(s):	K251169 Vivid Pioneer Diagnostic Ultrasound System
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, eM6C G3, RSP6-16-D , RIC10-D, 6S-D and L18-18i-D, RIC12-D and RAB7-D. Support of Vscan Air SL and Vscan Air CL wireless Probes eX7C is a new probe and is substantially equivalent to the eM6C G3-D, it is an incremental improvement in technology. 6Sc-D is an already cleared probe (K251169) which has been migrated to Voluson Expert 18/20/22)
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 device.
Determination of Substantial Equivalence:	Comparison to Predicate 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:

Model names **Voluson Expert 18**, **Voluson Expert 20** and **Voluson Expert 22** are unchanged from predicate device (K252328) and Versions are generally the same in hardware . **Voluson Expert 18** is lower version, and not all probes or functions are available to use (locked). Voluson Expert 20 is middle version and product with complete configuration and is able to work with all the probes and functions of software with exception of electronic probes eM6C G3, eX7C.The high- end model Voluson Expert 22 allows all probes and functions.

- 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.
- 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 (except below Changes). Some minor improvements to the existing Software features have been implemented into the proposed system.
- The proposed Voluson Expert Series 18/20/2218/20/22 adds additional AI software features: **Uterine Wave**; **ExPress3Dface, SonoBiometry GYN (containing SonoGYN Uterus and SonoGYN Ovaries), SonoGA, SonoEFW**

Additional Updates / improvements of existing AI feature **SonoLyst/ SonoLystLive** called **SonoLyst BT27 Expansion**.; **SonoBiometry OB containing SonoBiometry 2.0 and SonoBiometryCRL; FetalHQ**

- The proposed Voluson Expert Series 18/20/22 adds additional five software features: PUL / PUV model, #Enzian, Advanced Analytics, App Launcher and Battery Support

- Improved SW feature: Coded Contrast, DICOMWeb Send/QR support, 2 Way Data streaming, Voluson Check, Auto Connect and User Profiles.

  Hardware: Implementation of **Battery Option, Linear Pulser for all Models; Two different Versions of 27 inch Monitors** have been added the to the proposed Voluson Expert Series 18/20/22

- The proposed Voluson Expert Series 18/20/22 introduces two new transducer 6Sc-D which is already cleared under predicate device K251169 and new Probe eX7C which is an electronical 4D Probe substantially equivalent to the existing eM6C G3

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.

AI Testing Summary for new **Express3dface** Feature:

<table>
<tr><td></td><td>Express3dface</td></tr>
<tr><td>Summary test Statistics</td><td>
Data Pool 1
ICC(2,1)
<table>
<tr><td>Level</td><td>Annotators</td><td>Annotators + AI</td></tr>
<tr><td>Min</td><td>0.83</td><td>0.82</td></tr>
<tr><td>Max</td><td>0.74</td><td>0.78</td></tr>
</table>
Percentage within the limits of agreement
<table>
<tr><td>Level</td><td>Percentage</td></tr>
<tr><td>Min</td><td>94.5%</td></tr>
<tr><td>Max</td><td>98.9%</td></tr>
</table>
Data Pool 2
ICC(2,1)
<table>
<tr><td>Level</td><td>Annotators</td><td>Annotators + AI</td></tr>
<tr><td>Min</td><td>0.84</td><td>0.87</td></tr>
<tr><td>Max</td><td>0.89</td><td>0.88</td></tr>
</table>
Percentage within the limits of agreement
<table>
<tr><td>Level</td><td>Percentage</td></tr>
<tr><td>Min</td><td>86.6%</td></tr>
<tr><td>Max</td><td>96.6%</td></tr>
</table>
The evaluated feature met or exceeded predefined acceptance criteria, demonstrating robust performance across intended use conditions.
</td></tr>
<tr><td>Confounders</td><td>
We perform a quantitative analysis on data covering the following confounders:
- Systems
- Regions / continents
- BMI
- Gestational trimester

For this feature, the aforementioned confounding factors should be considered, as they may affect performance due to variations in image quality (IQ), anatomical size and characteristics, and imaging conditions, particularly those influenced by patient BMI.
</td></tr>
</table>

<table>
<tr><td>Data Collection</td><td>Data Pool 1:
<table>
<tr><th>Confounder</th><th>Category</th><th>Samples</th><th>Patients</th></tr>
<tr><td></td><td>All</td><td>91</td><td>91</td></tr>
<tr><td rowspan="2">System</td><td>Expert</td><td>59</td><td>59</td></tr>
<tr><td>Signature</td><td>32</td><td>32</td></tr>
<tr><td rowspan="2">Region</td><td>US</td><td>49</td><td>49</td></tr>
<tr><td>EU</td><td>42</td><td>42</td></tr>
<tr><td rowspan="2">Trimester</td><td>Second</td><td>42</td><td>42</td></tr>
<tr><td>Third</td><td>49</td><td>49</td></tr>
</table>
Data Pool 2:
<table>
<tr><th>Confounder</th><th>Category</th><th>Samples</th><th>Patients</th></tr>
<tr><td></td><td>All</td><td>30</td><td>27</td></tr>
<tr><td rowspan="3">BMI</td><td>Less than 25</td><td>10</td><td>10</td></tr>
<tr><td>Between 25 to 30</td><td>10</td><td>10</td></tr>
<tr><td>More than 30</td><td>10</td><td>7</td></tr>
</table></td></tr>
<tr><td>Truthing process for test datasets</td><td>Each sample was independently annotated by two annotators, after which an independent arbitrator selected the annotation that best represented the ground truth. Using the volume (in millimeters) derived from both annotators' segmentations and the AI-generated outputs, we computed the intraclass correlation coefficient (ICC) across all samples to assess the agreement between the AI system and human annotators. In addition, a Bland–Altman analysis was performed comparing the arbitrator-selected volumes with the corresponding AI-generated volumes, providing further insight into the level of agreement and the performance of the AI system.</td></tr>
<tr><td>Independence of Test data</td><td>A unique patient identifier is assigned to all samples derived from each patient. Data from any given patient is allocated exclusively to either the training set or the test set, ensuring no cross-usage between the two.</td></tr>
</table>

AI Testing Summary **SonoBiometryOB:**
Which includes SonoBiometry 2.0:

<table>
<tr><td></td><td>SonoBiometry2.0</td></tr>
<tr><td>Summary test Statistics</td><td>Data Pool 1:
ICC(2,1)
<table>
<tr><th>Measurement</th><th>Annotators</th><th>Annotators + AI</th></tr>
<tr><td>HC</td><td>0.98</td><td>0.98</td></tr>
</table></td></tr>
</table>

OFD	0.99	0.99
BPD (Outer-Inner)	0.99	0.99
BPD (Outer-Outer)	0.99	0.99
AC	0.99	0.99
APAD	0.99	0.99
TAD	0.99	0.99
FL, HL	0.99	0.99

Percentage within the limits of agreement

Confounder	Percentage
HC	99.5%
OFD	91.2%
BPD (Outer-Inner)	96.6%
BPD (Outer-Outer)	97.0%
AC	96.9%
APAD	93.8%
TAD	88.4%
FL, HL	94.4%

Data Pool 2:

ICC(2,1)

Measurement	Annotators	Annotators + AI
HC	0.99	0.99
OFD	0.99	0.99
BPD (Outer-Inner)	0.99	0.99
BPD (Outer-Outer)	0.99	0.99
AC	0.99	0.99
APAD	0.98	0.98
TAD	0.99	0.99
FL, HL	0.99	0.99

<table>
<tr><td></td><td>Percentage within the limits of agreement
<table>
<tr><th>Confounder</th><th>Percentage</th></tr>
<tr><td>HC</td><td>98.3%</td></tr>
<tr><td>OFD</td><td>84.7%</td></tr>
<tr><td>BPD (Outer-Inner)</td><td>96.6%</td></tr>
<tr><td>BPD (Outer-Outer)</td><td>98.3%</td></tr>
<tr><td>AC</td><td>100.0%</td></tr>
<tr><td>APAD</td><td>98.2%</td></tr>
<tr><td>TAD</td><td>98.2%</td></tr>
<tr><td>FL, HL</td><td>88.1%</td></tr>
</table></td></tr>
<tr><td>Confounders</td><td>We perform a quantitative analysis on data covering the following confounders:
- Systems
- Probe groups
- Regions / continents
- BMI
- Gestational trimester
- Anatomical plane (only for head measurements)
For this feature, the aforementioned confounding factors should be considered, as they may affect performance due to variations in image quality (IQ), imaging parameters, anatomical size and characteristics, and imaging conditions, particularly those influenced by patient BMI.</td></tr>
<tr><td>Data Collection</td><td>To cover all the required confounders, we consider two separate data pools with the following confounder distributions:

Data Pool 1:
Head
<table>
<tr><th>Confounder</th><th>Category</th><th>Samples</th><th>Patients</th></tr>
<tr><td></td><td>All</td><td>240</td><td>205</td></tr>
<tr><td rowspan="2">System</td><td>Expert</td><td>188</td><td>171</td></tr>
<tr><td>Signature</td><td>52</td><td>34</td></tr>
<tr><td rowspan="3">Probe Class</td><td>CL1</td><td>176</td><td>155</td></tr>
<tr><td>CL2</td><td>25</td><td>25</td></tr>
<tr><td>CLE</td><td>39</td><td>25</td></tr>
<tr><td rowspan="2">Region</td><td>US</td><td>135</td><td>130</td></tr>
<tr><td>EU</td><td>105</td><td>75</td></tr>
</table></td></tr>
</table>

Trimester	First	38	27
	Second	91	87
	Third	111	91
Plane	TTP	125	109
	TVP	115	106

Abdomen

Confounder	Category	Samples	Patients
	All	130	118
System	Expert	104	98
	Signature	26	20
Probe Class	CL1	80	73
	CL2	20	20
	CLE	30	25
Region	US	69	68
	EU	61	50
Trimester	First	24	19
	Second	46	45
	Third	60	54

Bone

Confounder	Category	Samples	Patients
	All	150	147
System	Expert	96	96
	Signature	54	51
Probe Class	CL1	100	98
	CL2	20	20
	CLE	30	29
Region	US	84	84
	EU	66	63
Trimester	First	41	40
	Second	51	50
	Third	58	57

Data Pool 2:
Head

Confounder	Category	Samples	Patients
	All	59	42
BMI	Less than 25	20	16
	Between 25 to 30	20	15
	More than 30	19	11

Abdomen

Confounder	Category	Samples	Patients
	All	57	42
BMI	Less than 25	20	13
	Between 25 to 30	20	15
	More than 30	17	14

Bone

Confounder	Category	Samples	Patients
	All	59	41
BMI	Less than 25	20	15
	Between 25 to 30	20	14
	More than 30	19	12

Truthing process for test datasets	Each sample has been annotated by three annotators. Using the three annotations and the AI output, we use ICC, Bland-Altman plots and Percentage within the limits of agreement to show the performance of our AI algorithms.
Independence of Test data	A unique patient identifier is assigned to all samples derived from each patient. Data from any given patient is allocated exclusively to either the training set or the test set, ensuring no cross-usage between the two.

AI Testing Summary **SonoBiometryOB:**
Which includes SonoBiometry CRL:

	Feature Name
Summary test Statistics	**Acceptability Testing** Automated calliper placements were evaluated by clinicians to assess their clinical acceptability. The placements were reviewed by clinically qualified sonographers and categorized according to pre-defined acceptance criteria. The acceptable categories were derived from independent clinical review. Overall Acceptability Rate:

	• CRL: 90.1% (requirement ≥80%) **Accuracy Testing** Measurement accuracy was evaluated by comparing AI-generated measurements (in mm), derived from automated calliper placements, against independent human expert measurements. AI–human MAE was calculated by pairing AI and human measurements for each landmark, while human–human MAE was derived from measurements between independent human readers to estimate inter-observer variability. Performance meets acceptance when AI–human MAE ≤ human–human MAE. -CRL: 3.34mm (requirement<3.90mm) All evaluated features met or exceeded predefined acceptance criteria, demonstrating robust performance across intended use conditions.
Confounders	The primary confounders presented in the data pool were as follows: - Probe type - CRL length groups (<31 mm, 31–53 mm, >53 mm) - Maternal Body Mass Index (BMI) - Geographic region
Data Collection	Data consisted of 2D ultrasound images acquired from GE Healthcare Voluson systems during routine clinical scanning. The verification dataset comprised of 180 images from 180 patients from multiple clinical sites (USA, Greece, UK, Egypt, Philippines), representing routine clinical practice. All images used for verification met the following criteria: - Gestational age between 6–14 weeks - Singleton pregnancies Acquired using CL1, CL2, or CLE probes - Clearly visible crown and rump anatomy (as determined by the expert sonographer panel)
Truthing process for test datasets	Ground truth annotations and measurement references were established by three independent qualified Subject Matter Experts (U.S. board-certified sonographers), following predefined ground truth criteria. For the MAE assessment, each sonographer performed independent manual calliper placements and derived measurements for all supported anatomical landmarks, without visibility of AI outputs. These measurements were used both to define the reference standard. For acceptability assessment, AI-generated calliper placements were reviewed by two independent experts (Reader A and Reader B) who were blinded to model outputs and not involved in model development. Disagreements were resolved through adjudication by a third independent expert (Reader C), whose decision defined the final ground truth. Only concordant or adjudicated outcomes were retained as final ground truth.

Independence of Test data	Verification datasets were collected from independent clinical sites and remained fully segregated from training data throughout development. Sites used for verification were not involved in model training, ensuring no contamination between training and evaluation datasets.

AI Testing Summary **SonoBiometryGYN**
Which includes SonoBiometry Ovary:

<table>
<tr><td></td><td>SonoBiometry Ovary</td></tr>
<tr><td>Summary test Statistics</td><td>
Bland-Altman Analysis
Automated measurements were assessed for agreement against the Limits of Agreement (LoA) derived from measurements performed by three independent sonographers.
Percentage within the limits of agreement
<table>
<tr><th colspan="2">Percentage</th></tr>
<tr><th>Ovary Height</th><th>Ovary Width</th></tr>
<tr><td>91.42</td><td>92.99</td></tr>
</table>
ICC
Automated measurements were assessed using the intraclass correlation coefficient model ICC(2,1) in combination with the measurements from three human annotators.
<table>
<tr><th rowspan="2">Confounder</th><th colspan="2">ICC(2,1)</th></tr>
<tr><th>Annotators</th><th>Annotators + AI</th></tr>
<tr><td>Ovary Hight</td><td>0.84</td><td>0.83</td></tr>
<tr><td>Ovary Width</td><td>0.86</td><td>0.87</td></tr>
</table>
</td></tr>
<tr><td>Confounders</td><td>
The primary confounders presented in the data pool are as follows:
- Region (USA, Europe)
- Device
- Stimulated / unstimulated follicles
- Pre- / Postmenopause
- Menstrual Phase
</td></tr>
<tr><td>Data Collection</td><td>
Data is collected by hospital sites as 2D images during routine scans.
Data is provided in anonymized form and in accordance with a data collection protocol.
The confounder distribution of the data is given below:
<table>
<tr><th></th><th># Patients</th><th>#Exams</th><th># Images</th></tr>
<tr><td>Total number</td><td>137</td><td>139</td><td>361</td></tr>
</table>
</td></tr>
</table>

	# cases from USA	61	63	210
	# cases from Europe	76	76	151
	# cases collected with Expert systems	37	39	152
	# cases collected with Signature systems	75	75	150
	# cases collected with SWIFT systems	25	25	59
	# cases with stimulated follicles	16	16	45
	# cases with unstimulated follicles	119	121	276
	# pre menopause cases	126	127	310
	# post menopause cases	22	22	43
	# follicular phase cases	60	61	117
	# ovulatory phase cases	47	47	92
	# luteal phase cases	43	43	65
Truthing process for test datasets	Three independent, experienced US sonographers manually placed calipers to measure ovarian height and width.			
Independence of Test data	Data from each patient is used exclusively for training or for verification but not both.			

AI Testing Summary **SonoBiometryGYN**
Which includes SonoBiometry Uterus:

	Feature Name
Summary test Statistics	**Acceptability Testing** Automated calliper placements were evaluated by clinicians to assess their clinical acceptability. The placements were reviewed by clinically qualified sonographers and categorized according to pre-defined acceptance criteria. The acceptable categories were derived from independent clinical review. Overall Acceptability Rate: - Sagittal uterus: 95.8% (requirement ≥80%) - Transverse uterus: 97.0% (requirement ≥80%) **Accuracy Testing** Measurement accuracy was evaluated by comparing AI-generated measurements (in mm), derived from automated calliper placements, against independent human expert measurements. AI–human MAE was calculated by pairing AI and human measurements for each landmark, while human–human MAE was derived from measurements between independent human readers to estimate inter-observer variability. Performance meets acceptance when AI–human MAE ≤ human–human MAE.

	- Sagittal uterus: AI–human MAE 66.9mm vs human–human MAE 72.7 mm (Pass) - Transverse uterus: AI–human MAE 131.0 mm vs human–human MAE 210.0 mm (Pass) All evaluated features met or exceeded predefined acceptance criteria, demonstrating robust performance across intended use conditions.
Confounders	The primary confounders presented in the data pool were as follows: - Geographic region (USA, Europe, International sites) - Uterine view (sagittal, transverse) - Uterine orientation (anteverted, retroverted, anteflexed, retroflexed) - Menopausal status (peri-menopausal, post-menopausal) - Menstrual phase (secretory, proliferative, post-menstrual, fluid/SIS) - Presence of intra-uterine device (IUD) (sagittal view only)
Data Collection	Data consisted of 2D transvaginal ultrasound images acquired during routine pelvic examinations using GE Healthcare Voluson systems. The verification dataset comprised of 422 images from 261 patients collected from multiple clinical sites (USA, Greece, UK, Egypt, Philippines), representing routine clinical practice. All images used for verification met the following criteria: - Women aged 21–65 with normal uterine morphology - Acquired using CLE probes - Standard sagittal and transverse uterine views - Images contained visible and annotatable anatomical landmarks necessary to support automated measurement (as determined by the expert sonographer panel) Datasets were curated to ensure representation across clinically relevant confounders.
Truthing process for test datasets	Ground truth annotations and measurement references were established by three independent qualified Subject Matter Experts (U.S. board-certified sonographers), following predefined ground truth criteria. For the MAE assessment, each sonographer performed independent manual calliper placements and derived measurements for all supported anatomical landmarks, without visibility of AI outputs. These measurements were used both to define the reference standard and to compute human–human variability. For acceptability assessment, AI-generated calliper placements were reviewed by two independent experts (Reader A and Reader B) who were blinded to model outputs and not involved in model development. Disagreements were resolved through adjudication by a third independent expert (Reader C), whose decision defined the final ground truth. Only concordant or adjudicated outcomes were retained as final ground truth.
Independence of Test data	Verification datasets were collected from independent clinical sites and remained fully segregated from training data throughout development. Sites used for verification were not involved in model training, ensuring no contamination between training and evaluation datasets.

AI Testing Summary for new **Uterine Wave** Feature:

<table>
<tr><td></td><td>Uterine Wave</td></tr>
<tr><td>Summary test Statistics</td><td>The primary evaluation metric is Area similarity. The anterior and posterior boundary curves are combined to form a closed anatomical region.
Bland-Altman Analysis
Automated measurements were assessed for agreement against the Limits of Agreement (LoA) derived from measurements performed by three independent sonographers.
Mean Percentage within the limits of agreement: 93.6%

Dice Similarity
Automated measurements were assessed for agreement against measurements performed by three independent sonographers. The closed anatomical region is rasterized into a binary mask, and Dice similarity is computed as the normalized overlap between two masks.
<table>
<tr><td>Median model-expert Dice (included model-expert pairs)</td><td>0,7921</td></tr>
<tr><td>Median inter-expert area Dice</td><td>0,8483</td></tr>
</table>
All evaluated features met or exceeded predefined acceptance criteria, demonstrating robust performance across intended use conditions.</td></tr>
<tr><td>Confounders</td><td>The primary confounders presented in the data pool are as follows:
- Region (USA, non-USA)
- Uterus orientation
- Pre- / Postmenopause
- Menstrual Phase</td></tr>
<tr><td>Data Collection</td><td>Data is collected as 2D images during routine scans. Data is provided in anonymized form and in accordance with a data collection protocol.
The dataset consists of 2D ultrasound images containing mid-sagittal uterus views.
The confounder distribution of the data is given below:
<table>
<tr><th>Confounder</th><th>Group</th><th># Patients</th><th># Exams</th><th># Images</th></tr>
<tr><td>Country</td><td>USA</td><td>108</td><td>108</td><td>109</td></tr>
<tr><td>Country</td><td>non-USA</td><td>101</td><td>101</td><td>160</td></tr>
<tr><td>menopause_status</td><td>post-menopausal</td><td>44</td><td>44</td><td>47</td></tr>
<tr><td>menopause_status</td><td>premenopausal</td><td>50</td><td>50</td><td>54</td></tr>
<tr><td>menopause_status</td><td>unknown</td><td>115</td><td>115</td><td>168</td></tr>
<tr><td>menstrual_phase</td><td>fluid/sis</td><td>7</td><td>7</td><td>7</td></tr>
<tr><td>menstrual_phase</td><td>post-menstrual</td><td>27</td><td>27</td><td>28</td></tr>
<tr><td>menstrual_phase</td><td>proliferative</td><td>89</td><td>89</td><td>129</td></tr>
</table></td></tr>
</table>

	menstrual_phase	secretory	53	53	66
	menstrual_phase	unknown	33	33	39
	uterus_orientation	anteflexed/anteverted	115	115	161
	uterus_orientation	other/unable to tell	40	40	40
	uterus_orientation	retroflexed/retroverted	54	54	68
Truthing process for test datasets	Three independent, experienced US sonographers manually annotate structures in the images. They mark the endometrial tip and delineate anterior/posterior endometrial borders separately.				
Independence of Test data	A unique patient identifier is assigned to all samples derived from each patient. Data from any given patient is allocated exclusively to either the training set or the test set, ensuring no cross-usage between the two				

AI Testing Summary **Fetal HQ Feature:**

	FetalHQ
Summary test Statistics	**Bland Altman Analysis** Automated measurements were assessed for agreement against the Limits of Agreement (LoA) derived from measurements performed by three independent sonographers. ***Cardiac Phase detection*** Systolic and diastolic phases are automatically detected and compared to expert phase annotations. Percentage within the LoA: **98.2%** ***Caliper placements of ventricle valve inserts and apex*** Caliper locations in systolic phase are automatically determined. Areas are calculated which are formed by the triangle between the apex and valve calipers for each ventricle. And compared to areas from expert annotations. **Percentage within LoA** **Left ventricle** / **Right Ventricle** **98.1** / **97.2** All evaluated features met or exceeded predefined acceptance criteria, demonstrating robust performance across intended use conditions.
Confounders	**The primary confounders presented in the data pool are as follows:** - Probes - Regions (USA, Europe)

<table>
<tr><td></td><td>
- Trimester (2nd, 3rd)
- Heart orientation (Septal acquisition; Apical / Basal acquisition)
- BMI
</td></tr>
<tr><td>Data Collection</td><td>
Data is collected as 2D cine sequences acquired during heart examinations.
Data is provided in anonymized form and in accordance with a data collection protocol.
The confounder distribution of the data is given below:
<table>
<tr><th>Category</th><th>Confounder</th><th>#Patients</th><th>#Exams</th><th># cases</th></tr>
<tr><td>Orientation</td><td>Apical / Basal</td><td>84</td><td>86</td><td>117</td></tr>
<tr><td>Orientation</td><td>Septal</td><td>29</td><td>29</td><td>31</td></tr>
<tr><td>Orientation</td><td>Not annotated</td><td>6</td><td>6</td><td>6</td></tr>
<tr><td>Trimester</td><td>Second Trimester</td><td>51</td><td>51</td><td>65</td></tr>
<tr><td>Trimester</td><td>Third Trimester</td><td>64</td><td>64</td><td>82</td></tr>
<tr><td>Trimester</td><td>not known</td><td>2</td><td>2</td><td>7</td></tr>
<tr><td>Region</td><td>Region USA</td><td>56</td><td>58</td><td>81</td></tr>
<tr><td>Region</td><td>Region Europe</td><td>59</td><td>59</td><td>73</td></tr>
<tr><td>Probe</td><td>Probe Group CL1</td><td>103</td><td>103</td><td>113</td></tr>
<tr><td>Probe</td><td>Probe Group CL2</td><td>18</td><td>18</td><td>41</td></tr>
<tr><td>BMI</td><td>BMI < 25</td><td>28</td><td>28</td><td>30</td></tr>
<tr><td>BMI</td><td>25<=BMI<30</td><td>17</td><td>17</td><td>18</td></tr>
<tr><td>BMI</td><td>BMI >= 30</td><td>13</td><td>13</td><td>19</td></tr>
</table>
</td></tr>
<tr><td>Truthing process for test datasets</td><td>
Three independent, experienced US sonographers manually annotate cine data.
Cardiac Phase:
- They mark diastolic and systolic frames in a 4CH view cine sequence
Caliper placements:
- In systolic frames, the sonographers mark the valve inserts and apex of the left and right ventricle with caliper points.
</td></tr>
<tr><td>Independence of Test data</td><td>A unique patient identifier is assigned to all samples derived from each patient. Data from any given patient is allocated exclusively to either the training set or the test set, ensuring no cross-usage between the two</td></tr>
</table>

AI Testing Summary **SonoLyst BT27 Expansion:**
Including: SonoLyst 1st Trimester and SonoLyst 2nd & 3rd Trimester

SonoLyst 1st Trimester

	Feature Name
Summary test Statistics	**Accuracy Testing** The performance of the SonoLyst AI algorithms was evaluated by comparing model outputs (view classification, grading, and image acceptability) against predefined reference labels derived from independent clinical review. Performance was assessed as percentage agreement with acceptance criteria for each feature.

	Overall Performance Results: • SonoLyst IR: 94.1% (requirement ≥90%) • SonoLyst X: 82.4% (requirement ≥80%) • SonoLyst Live: 82.5% (requirement ≥80%) • SonoLyst Labeling: 83.7% (requirement ≥80%) All evaluated features met or exceeded predefined acceptance criteria, demonstrating robust performance across intended use conditions.
Confounders	The primary confounders presented in the data pool were as follows: - Probe type - Maternal Body Mass Index (BMI) - Gestational age - Ultrasound console family - Geographic region
Data Collection	Data consisted of retrospective 2D obstetric ultrasound images acquired during routine clinical practice using GE Healthcare Voluson systems. The verification datasets comprised of the following number of images (patients), collected from multiple international clinical sites (USA, Austria, Germany, Netherlands), representing real-world conditions: -SonoLyst 1st Trimester IR: 7970 (571) -SonoLyst 1st Trimester X: 4931 (392) -SonoLyst 1st Trimester Live: 9111 (571) -SonoLyst 1st Trimester Labeling: 386 (231) All data met the following criteria: - Gestational age between 11–14 weeks (1st trimester) - Singleton pregnancies with normal fetal anatomy - Acquired using CL1, CL2 and CLE probes Datasets were curated to ensure balanced representation across clinically relevant confounders and imaging conditions.
Truthing process for test datasets	Ground truth reference labels were established using a controlled, independent multi-reader expert annotation process. Qualified Subject Matter Experts (U.S. board-certified sonographers) independently annotated each image following predefined, annotation protocols aligned to regulatory performance endpoints. Each image was reviewed by two independent experts (Reader A and Reader B) who were blinded to model outputs and not involved in model development. Disagreements were resolved through adjudication by a third independent expert (Reader C), whose decision defined the final ground truth. Only concordant or adjudicated outcomes were retained as final ground truth. **View classification:** assignment of each image to the intended anatomical or protocol view **Criterion-level grading:** evaluation of specific protocol criteria (met / not met)

	Image acceptability / quality grading: expert assessment of image suitability **Anatomy labelling:** region-level identification of applicable anatomical structures
Independence of test data	Verification datasets were collected from independent clinical sites and remained fully segregated from training data throughout development. Sites used for verification were not involved in model training, ensuring no contamination between training and evaluation datasets.

AI Testing Summary **SonoLyst BT27 Expansion:**
Including: SonoLyst 2nd & 3rd Trimester

	Feature Name
Summary test Statistics	**Accuracy Testing** The performance of the SonoLyst AI algorithms was evaluated by comparing model outputs (view classification, grading, and image acceptability) against predefined reference labels derived from independent clinical review. Performance was assessed as percentage agreement with acceptance criteria for each feature. The GA range was 18-24 weeks (2nd trimester) for non-biometry views and 18-36 weeks (2nd, 3rd trimester) for biometry views (Head TV, Head TT, AC, FL). **Overall Performance Results:** - SonoLyst IR: 92.5% (requirement ≥90%) - SonoLyst X: 86.9% (requirement ≥80%) - SonoLyst Live: 83.3% (requirement ≥70%) - SonoLyst Labeling: 84.4% (requirement ≥80%) All evaluated features met or exceeded predefined acceptance criteria, demonstrating robust performance across intended use conditions.
Confounders	The primary confounders presented in the data pool were: - Probe type - Maternal Body Mass Index (BMI) - Gestational age - Ultrasound console family - Geographic region
Data Collection	Data consisted of retrospective 2D obstetric ultrasound images acquired during routine clinical practice using GE Healthcare Voluson systems. The verification datasets comprised of the following number of images (patients), collected from multiple international clinical sites (USA, Austria, Germany, Netherlands), representing real-world conditions. -SonoLyst 2nd/3rd Trimester IR: 4,128 (464) -SonoLyst 2nd/3rd Trimester X: 4,128 (464) -SonoLyst 2nd/3rd Trimester Live: 4,128 (464) -SonoLyst 2nd/3rd Trimester Labeling: 266 (201)

	All data met the following criteria: - Gestational age between 18–36 weeks (2nd and 3rd trimester) (note, views restricted to 2nd trimester were only evaluated on 2nd trimester images) - Singleton pregnancies with normal fetal anatomy - Acquired using CL1 and CL2 probes Datasets were curated to ensure balanced representation across clinically relevant confounders and imaging conditions.
Truthing process for test datasets	Ground truth reference labels were established using a controlled, independent multi-reader expert annotation process. Qualified Subject Matter Experts (U.S. board-certified sonographers) independently annotated each image following predefined, annotation protocols aligned to regulatory performance endpoints. Each image was reviewed by two independent experts (Reader A and Reader B) who were blinded to model outputs and not involved in model development. Disagreements were resolved through adjudication by a third independent expert (Reader C), whose decision defined the final ground truth. Only concordant or adjudicated outcomes were retained as final ground truth. **View classification:** assignment of each image to the intended anatomical or protocol view **Criterion-level grading:** evaluation of specific protocol criteria (met / not met) **Image acceptability / quality grading:** expert assessment of image suitability **Anatomy labelling:** region-level identification of applicable anatomical structures
Independence of test data	Verification datasets were collected from independent clinical sites and remained fully segregated from training data throughout development. Sites used for verification were not involved in model training, ensuring no contamination between training and evaluation datasets.

AI Testing Summary **SonoGA:**

	Feature Name
Summary test Statistics	**Accuracy Assessment** The performance of the SonoGA AI algorithm was evaluated by comparing AI-estimated gestational age (GA) against the ground truth gestational age. Ground truth gestational age was established using clinical reference standards. For early gestation (8–14 weeks), gestational age was determined based on the dating CRL measurement taken during routine clinical practice. For later gestation, gestational age was derived from the dating CRL measurement combined with elapsed time from this examination. SonoGA estimates were compared against these reference values, and mean absolute error (MAE) was calculated across the dataset to assess performance. **Performance by trimester:** - 1st trimester: MAE 1.42 days (95% CI: 1.22–1.62), bias −0.21 days (clinical benchmark 3 days)

	- 2nd trimester: MAE 3.09 days (95% CI: 2.56–3.63), bias 0.91 days (clinical benchmark 5 days) - 3rd trimester: MAE 4.76 days (95% CI: 4.12–5.42), bias 1.17 days (clinical benchmark 7 days) All results were within clinically acceptable limits and met predefined performance requirements, demonstrating accuracy comparable to or better than standard clinical methods across gestations.
Confounders	The primary confounders presented in the data pool were as follows: - Probe type (CL1, CL2, CLE) - Maternal Body Mass Index (BMI) - Gestational age (1st, 2nd, 3rd trimester) - Geographic region - Ultrasound console family
Data Collection	Data consists of 2D ultrasound image streams acquired during routine obstetric examinations using GE Voluson machines. The verification dataset comprised of multiple independent datasets comprising 312 patient streams collected across several countries (USA, UK, Spain, Romania). All data met the following criteria: - Gestational age range 8–36 weeks - Acquired using CL1, CL2, or CLE probes - Representative of scanning during routine clinical practice Datasets were structured to ensure balanced representation across trimesters and other clinically relevant confounders.
Truthing process for test datasets	Ground truth gestational age was established using clinical reference standards. For early gestation (8–14 weeks), gestational age was determined based on the dating CRL measurement taken during routine clinical practice. For later gestation, gestational age was derived from the dating CRL measurement combined with elapsed time from this examination. SonoGA estimates were compared against these reference values and mean absolute error (MAE) was calculated across the dataset to assess performance.
Independence of Test data	Verification datasets were collected from independent clinical sites and remained fully segregated from training data throughout development. Sites used for verification were not involved in model training, ensuring no contamination between training and evaluation datasets.

AI Testing Summary **SonoEFW:**

	SonoEFW
Summary test Statistics	**Published study [1].** Mean relative error (±SD) was 7.31±6.47% for small, 6.49±5.02% for appropriate and 7.31±5.71% for large fetuses for gestational age, using birthweight projected to scan date with the Marsál curve. **Supplementary verification.** Comparing SonoEFW results against Hadlock estimated fetal weight (EFW) from image-based biometry in 128 exams, the average relative error was 9% (SD 7 percentage points; 95% CI 7.72%–10.20%). **Paired reference analysis.** For 103 of these exams, ICC(2,1) was 0.97 between image-derived and metadata-derived Hadlock EFW, and 0.96 for both references plus SonoEFW. ICC used a two-way random-effects, absolute-agreement, single-measurement model. These results assess agreement between weight estimates.
Confounders	**Published study:** gestational age, BMI, parity, conception mode, ethnicity and ultrasound model. **Supplementary verification:** region, BMI, gestational age and probes. BMI and gestational-age strata covered 47 and 38 exams. Subgroup ICCs including SonoEFW ranged from 0.88 to 0.99.
Data Collection	**Published study:** retrospective singleton data from 17 Danish hospitals (2008–2018); 433,096 images from 65,752 patients across development and evaluation; third-trimester testing. **Supplementary verification:** 128 exams (35 Europe, 93 US). A paired subset of 103 had routine clinical biometry metadata (34 Europe, 69 US).
Truthing process for test datasets	**Published study:** birthweight projected to scan date provided the reference; clinical biometry provided the Hadlock comparator. **Exported images:** Clinical experts measured HC, BPD, AC and FL under a predefined protocol, blinded to SonoEFW. Each exam had one reader; Hadlock EFW was calculated from the measured lengths. **Metadata:** international physicians and sonographers recorded lengths during routine clinical scans without the study annotation protocol. Measurement calipers were unavailable. These lengths provided the second Hadlock reference for the paired ICC analysis.
Independence of Test data	**Published study:** patient-level training/validation/test split of 85%/5%/10%, without overlap. **Supplementary verification:** The dataset was collected after all model training was completed and excluded patients and exams used for training or tuning.

[1] Mikołaj KW et al. Predicting abnormal fetal growth using deep learning. npj Digital Medicine. 2025;8:318. doi:10.1038/s41746-025-01704-0.

Definitions and Abbreviations

- **CL1, CL2, CLE**: Ultrasound probe models used with GE Healthcare Voluson systems.
  - CL1: Curved linear transducer designed for transabdominal obstetric imaging
  - CL2: Curved linear transducer with higher frequency range for improved resolution in obstetric applications
  - CLE: Endocavitary (transvaginal) transducer used for early gestation and gynecological imaging

Conclusion: Based on the equipment design similarities, conformance to recognized performance standards, and performance testing, GE Healthcare considers that the Voluson Expert Series 18/20/22 performs in a substantially equivalent manner to the predicate device.