June 6, 2022

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

Re: K220358
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: April 28, 2022
Received: April 29, 2022

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

Michael D. O'Hara, Ph.D.
Deputy Director
DHT 8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT 8: 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)*

K220358

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.

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510(k) Summary (K220358)

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

Date:	April 28, 2022
Submitter:	GE Healthcare [GE Healthcare Austria GmbH & Co OG] Tiefenbach 15 Zipf, Austria 4871
Primary Contact Person:	Bryan Behn Regulatory Affairs Director GE Healthcare T:(262)247-5502 F:(414)918-8275
Secondary Contact Person:	Roland Kuntscher Regulatory Affairs Specialist GE Healthcare Austria GmbH & Co OG T:(+43)7682-3800-660 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):	K201768 Voluson E10 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 Predicate Device(s):	K192159 Voluson E10/E8/E6 K173555 LOGIQ E10
Classification Names: Product Codes:	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

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. The following have migrated from LOGIQ E10 6S-D and L18-18i-D (K173555). The RSP6-16-D was previously cleared on the Voluson E10 (K192159) and has been added back. The RIC10-D is a new probe and is substantially equivalent to the RIC5-9-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.

New Model Names and Model differences:

New model names **Voluson Expert 18**, **Voluson Expert 20** and **Voluson Expert 22** are similar 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 eM6CG3. The high-end model **Voluson Expert 22** allows to drive additionally 4D electronically probe eM6CG3.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The proposed Voluson Expert 22/20/18 and predicate Voluson E10 systems have the same clinical intended use.
- The proposed Voluson Expert 22/20/18 and predicate Voluson E10 systems have the same imaging modes.
- The proposed Voluson Expert 22/20/18 and predicate Voluson E10 system transducers are equivalent. Four new transducers RSP6-16-D, L8-18i-D, 6S-D and RIC10-D were added and three transducers removed to the proposed system.
- 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 Voluson E10 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 Voluson E10 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 **SonoPelvicFloor** and **SonoLyst/ Sonolyst Live** (workflow improvement) to the system.

- The proposed Voluson Expert Series 22/20/18 adds additional software features **Shadow Reduction** , **Adapt** and **Sono FHR** (Performance improvement) to the system.

- The proposed Voluson Expert Series 22/20/18 migrated from (K192159) the following software features **Elastography, Shear Wave Elastography** , **CW Doppler Mode** and Acquisition mode **Contrast**.

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:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 2005/(R)2012 And A1:2012
- IEC60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests, 2014
- 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- Third Edition, 2009
- 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.

AI Summary of Testing

SonoPelvic Floor:

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

- Tested on datasets marked as Good in Image Quality assessment, the success rate of each AI component of the feature (MHD plane alignment, LH contour and measurements) is expected to be 70% or higher. On datasets that are marked as challenging in image quality measure the success rate of each AI component of the feature should be 60% or higher.
- The number of individual patients images were collected from: 70+
- The number of samples, if different from above, and the relationship between the two: 110 3D/4D Volumes

Demographic distribution:

- Gender: Female
- Age: Reproductive age, specific age not collected
- Ethnicity/Country; Europe, Asia and South Africa

Information about clinical subgroups and confounders present in the dataset:

- During testing, a differentiation is made between good IQ (Image Quality) and challenging IQ datasets.

Information about equipment and protocols used to collect images:

- Mix of data from across six different probe models and five different Console variants. The data collection protocol was standardized across all data collection sites.

Information about how the reference standard was derived from the dataset (i.e. the “truthing” process)

- For the testing process, the results are generated by the AI software and the same are verified as Pass or Fail by a certified sonographer/Clinician. The results are then aggregated to yield an accuracy metric for the AI algorithm.

Description of how independence of test data from training data was ensured.

- The volumes used for test/validation purpose is completely distinct from the ones used during training process and there is no overlap between the two.

SonoLyst:

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

- For SonoLystIR the sorting accuracy is higher than 80% on a test data set containing 40000+ images. For SonoLystX the grading accuracy is higher than 80% on a test data set containing 9500+ images. For SonoLystLive the accuracy is higher than 80% on a test data set containing 5500+ images.
- The number of individual patients images were collected from: 5000+ exams
- The number of samples, if different from above, and the relationship between the two: SonoLyst was tested on 40000+ images derived from the collected exams. The exams contain multiple standard views of the fetal anatomy and cine loops.

Demographic distribution

- Gender: Female
- Age: Gestational Age of fetuses: 18-24 weeks
- Ethnicity/Country: Exams from United Kingdom, Austria, India, USA

Information about clinical subgroups and confounders present in the dataset:

- During testing, a differentiation was made between retrospective and prospective data collection from GE and non-GE scanners, evaluating the generalization performance.

Information about equipment and protocols used to collect images.

- Mix of data from across five different console variants, 4 Voluson GE, 1 non-GE. Mix of data from retrospective data collection in clinical practice and prospective data collection.

Information about how the reference standard was derived from the dataset (i.e. the “truthing” process):

1. The images were curated (sorted and graded) by a single Sonographer
2. The images were sorted and graded by SonoLyst. 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.

Description of how independence of test data from training data was ensured:

- The exams used for test/training validation purpose are separated from the ones used during training process and there is no overlap between the two.

<u>FetalHS:</u>

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

- The success rate of the 4CH view and 3VT view suggestion within cines is expected to be 70% or higher. The success rate of the suggested heart angle measurement is expected to be 80% or higher.
- The number of individual patients images were collected from: 250+ patients
- The number of samples, if different from above, and the relationship between the two: 400+ cines

Demographic distribution

- Gender: Female
- Age: Gestational age 18-25 weeks
- Ethnicity/Country : USA, India, Japan, Germany, Austria

Information about clinical subgroups and confounders present in the dataset.

- Cines were grouped into the sub-groups 4CH view present / not present, 3VT view present / not present

Information about equipment and protocols used to collect images.

- Mix of data from across six different probe models and three different console variants. The data collection protocol was standardized across all data collection sites.

Information about how the reference standard was derived from the dataset (i.e. the “truthing” process).

- For the testing process, the results are generated by the AI

software and the same are verified as Pass or Fail by certified sonographers/clinicians. The results are then aggregated to yield an accuracy metric for the AI algorithm.

Description of how independence of test data from training data was ensured.

- The data sets used for test/validation purpose are completely distinct from the ones used during training process and there is no overlap between the two.

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).