GE Healthcare
% Mr. Bryan Behn
RA Director
9900 Innovation Drive
WAUWATOSA WI 53226

February 17, 2022

Re: K213689
Trade/Device Name: Voluson P6, Voluson P8
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: November 23, 2021
Received: November 23, 2021

Dear Mr. 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,

Jessica Lamb, Ph.D.
Assistant Director
Mammography Ultrasound and Imaging
Software Branch
Division of Radiological Health
OHT7: Office of in vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K213689

Device Name
Voluson P6, Voluson P8

Indications for Use *(Describe)*

Voluson P6 / Voluson P8 are a general-purpose diagnostic ultrasound system intended for use by a qualified and trained healthcare professional that are legally authorized or licensed by law in the country, state or other local municipality in which he or she practices for ultrasound imaging, measurement, display and analysis of the human body and fluid. The users may or may not be working under supervision or authority of a physician. Voluson P6 / Voluson P8 clinical applications include: Fetal/Obstetrics; Abdominal (including renal and GYN/Pelvic); Pediatric; Small Organ (Breast, Testes, Thyroid, etc.); Neonatal Cephalic; Adult Cephalic; Cardiac (Adult and Pediatric); Peripheral Vascular (PV); Musculo-skeletal Conventional and Superficial; Transrectal (including Urology/Prostate) (TR); Transvaginal (TV).

Mode of operation include: B, M, AMM, PW Doppler, CW Doppler, Color Doppler, Color M Doppler,Power Doppler, HD-Flow, Harmonic Imaging, 3D/4D Imaging mode, Contrast and Combined modes: B/M, B/Color, B/PWD, B/Power/ PWD. The Voluson P6 / Voluson P8 are 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.

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510(k) Summary

K213689

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

Date:	November 23, 2021
Submitter:	GE Medical Systems Ultrasound and Primary care Diagnostics, LLC 9900 Innovation Dr Wauwatosa, WI 53226
Manufacturer:	GE Ultrasound Korea, Ltd. 9, Sunhwan-ro 214beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea
Primary Contact Person:	Bryan Behn Regulatory Affairs Director GE Healthcare T:(262) 247-5502
Alternate Contact Person:	Jiyeon Park Senior Regulatory Affairs Leader GE Healthcare T: +82 317406307
Device Trade Name:	Voluson P6, Voluson P8
Common/Usual Name:	Diagnostic Ultrasound System
Classification Names:	Class II
Product Code:	IYN (primary), IYO, ITX (secondary) 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:	K180535 Voluson P Series Diagnostic Ultrasound System
Reference Device(s):	K201828 Voluson SWIFT, Voluson SWIFT+ 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 display, 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 accurate real-time three-dimensional imaging supporting all standard acquisition modes.

Intended Use: Voluson P6 / Voluson P8 are a general-purpose diagnostic ultrasound system intended for use by a qualified and trained healthcare professional that are legally authorized or licensed by law in the country, state or other local municipality in which he or she practices for ultrasound imaging, measurement, display and analysis of the human body and fluid. The users may or may not be working under supervision or authority of a physician. Voluson P6 / Voluson P8 clinical applications include: Fetal/Obstetrics; Abdominal (including renal and GYN/Pelvic); Pediatric; Small Organ (Breast, Testes, Thyroid, etc.); Neonatal Cephalic; Adult Cephalic; Cardiac (Adult and Pediatric); Peripheral Vascular (PV); Musculo-skeletal Conventional and Superficial; Transrectal (including Urology/Prostate) (TR); Transvaginal (TV).

Mode of operation include: B, M, AMM, PW Doppler, CW Doppler, Color Doppler, Color M Doppler,Power Doppler, HD-Flow, Harmonic Imaging, 3D/4D Imaging mode, Contrast and Combined modes: B/M, B/Color, B/PWD, B/Power/PWD. The Voluson P6 / Voluson P8 are intended to be used in a hospital or medical clinic.

Technology: The Voluson P6 / Voluson P8 employs the same fundamental scientific technology as its predicate device(s).

Determination of Substantial Equivalence:

Comparison to Predicates

The proposed Voluson P6 / Voluson P8 is substantially equivalent to the predicate devices. The following is an overview of the differences between the proposed Voluson P6 / Voluson P8 and the predicate Voluson P Series (K180535).

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The proposed Voluson P Series and predicate Voluson P Series systems have the same clinical intended use.
- The proposed Voluson P Series and predicate Voluson P Series systems have the same imaging modes.
- 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 P Series and predicate Voluson P Series systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The proposed Voluson P Series and predicate Voluson P Series

systems have been designed in compliance with approved electrical and physical safety standards.

- The probes supported in proposed Voluson P Series and predicate Voluson P Series systems are identical except
  - The following probe has been migrated from Voluson SWIFT, Voluson SWIFT+ (K201828): IC9B-RS
- The following software features have been migrated from Voluson SWIFT, Voluson SWIFT+(K201828): Sonobiometry Brain
- The following minor improvements have been made: IDEA Assessment, IOTA ADNEX, IETA Tool, Sono FHR, OS update, Security update, Measurement package updates, Refresh of connectivity, Omniview 1 Line.
- The following features is being removed: SonoMetrium

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 with applicable medical device safety standards. The Voluson P Series complies with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 2005/(R)2012 And A1:2012
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbance - Requirements and Tests, Edition 4.0, 2014
- IEC 60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment, Edition 2.1, 2015
- ISO 10993-1, Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing Within A Risk Management Process, Fourth edition, 2009
- ISO 14971, Application of risk management to medical devices, 2019
- NEMA PS 3.1 - 3.20, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology), 2016
- IEC 62359, Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, Edition 2.1, 2017

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)

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, Voluson P Series did not require clinical studies to support substantial equivalence.

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