

July 1, 2024

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

Re: K233692

Trade/Device Name: Voluson Signature 20, Voluson Signature 18
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX

Dear Bryan Behn:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on March 7, 2024. Specifically, FDA is updating this SE Letter because FDA inadvertently indicated that the SE determination also included review and clearance of a predetermined change control plan (PCCP). However, your 510(k) submission did not include a PCCP, so FDA is providing this administrative correction. Please see the attached revised clearance letter.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Yanna Kang, OHT8: Office of Radiological Health, (301)796-6704, Yanna.Kang@fda.hhs.gov.

Sincerely,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
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



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Regulation Number: 21 CFR 892.1550
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Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: November 17, 2023
Received: November 17, 2023

Dear Bryan Behn:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on March 7, 2024.

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/pmnmn.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

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

Submission Number (if known)

K233692

Device Name

Voluson Signature 20;
Voluson Signature 18

Indications for Use (Describe)

Voluson Signature 18 / Voluson Signature 20 system 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 Signature 18 / Voluson Signature 20 system clinical applications include: Fetal/Obstetrics; Abdominal (including Renal and Gynecology/ 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, Tissue Doppler, HD-Flow, Harmonic Imaging, Coded Pulse, 3D/4D Imaging mode, Elastography, Shearwave Elastography, B-Flow, Contrast and Combined modes: B/M, B/Color, B/PWD, B/Power/PWD. The Voluson Signature 18 / Voluson Signature 20 system 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 – K233692

(Voluson Signature 20 / Voluson Signature 18)

510(k) Summary – K233692

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

Date: March 5, 2024

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, 13204 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 Signature 20, Voluson Signature 18
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: K213642 Voluson S series Diagnostic Ultrasound System
Reference Device(s): K230346 Voluson SWIFT, Voluson SWIFT+ Diagnostic Ultrasound System
K231965 Voluson Expert 22, Voluson Expert 20, Voluson Expert 18 Diagnostic Ultrasound System
K192159 Voluson E6, Voluson E8, Voluson E10
K231989 LOGIQ E10s, LOGIQ Fortis

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

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 accurate real-time three-dimensional imaging supporting all standard acquisition modes.

Indications for Use: Voluson Signature 18 / Voluson Signature 20 system 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 Signature 18 / Voluson Signature 20 system clinical applications include: Fetal/Obstetrics; Abdominal (including Renal and Gynecology/ 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, Tissue Doppler, HD-Flow, Harmonic Imaging, Coded Pulse, 3D/4D Imaging mode, Elastography, Shearwave Elastography, B-Flow, Contrast and Combined modes: B/M, B/Color, B/PWD, B/Power/PWD. The Voluson Signature 18 / Voluson Signature 20 system are intended to be used in a hospital or medical clinic.

Technology: The Voluson Signature 20 / Voluson Signature 18 employs the same fundamental scientific technology as its predicate device(s).

Determination of Substantial Equivalence: Comparison to Predicates

The proposed Voluson Signature 20 / Voluson Signature 18 is substantially equivalent to the predicate devices. The following is an overview of the differences between the Voluson Signature 20 / Voluson Signature 18 and the predicate Voluson S Series (K213642).

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The proposed Voluson Signature 20/18 and predicate Voluson S series systems have the same clinical intended use.
- The proposed Voluson Signature 20/18 and predicate Voluson S series systems have the similar imaging mode. Voluson Signature 20/18 have additional Shearwave Elastography mode cleared in Voluson Expert 22/20/18 (K231965).
- 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 Signature 20/18 and predicate Voluson S series systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The proposed Voluson Signature 20/18 and predicate Voluson S series systems have been designed in compliance with approved electrical and physical safety standards.
- The probes supported in proposed Voluson Signature 20/18 have been migrated from Voluson Expert 22/20/18(K231965) and Voluson E6 (K192159):
- The following software features have been migrated from Voluson SWIFT, Voluson SWIFT+(K230346): **Fetal Heart Support, SonoAVCfollicle-auto caliper placement, Autolive, AVURI, SpineTrace, eDelivery(SW download), BPP Clock, Reminders, Voluson Remote Update, Shadow Reduction and Flow Profiles.**
- The following software features have been migrated from Voluson Expert 22/20/18 (K231965): **Shearwave Elastography, Perspective Rendering, Advanced STIC, Slowflow HD, SonoLyst(IR/X/Live), Fibroid Mapping (part of Option SonoGYN), SonoPelvicFloor 2.0, Ophthalmic Artery, Voluson Image Portal, Augment**
- The following software feature has been migrated from LOGIQ E10s/Fortis (K231989): **Vscan Air CL Probe Support**
- The proposed Voluson Signature 20/18 adds the following new feature: **Voice command.**

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 Signature 20 / Voluson Signature 18 complies with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 2005/A2:2021
- 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 4.1, 2020
- 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, Fifth edition, 2018
- 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), 2021
- 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 Signature 20/18 did not require clinical studies to support substantial equivalence.

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