June 20, 2023

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

Re: K230346
Trade/Device Name: Voluson SWIFT; Voluson SWIFT+
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: May 16, 2023
Received: May 16, 2023

Dear Bryan Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (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,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230346

Device Name

Voluson SWIFT, Voluson SWIFT+

Indications for Use *(Describe)*

The Voluson SWIFT, Voluson SWIFT+ is a general-purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals 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 SWIFT, Voluson SWIFT+ 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 (Anatomical M-Mode), PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, HD-Flow (High Definition-Flow), Harmonic Imaging, Coded Pulse, 3D/4D Imaging mode, Elastography, B-Flow and Combined modes: B/M, B/ Color, B/PWD, B/Power/PWD. The Voluson SWIFT / Voluson SWIFT+ 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.

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510(k) Summary

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

Date:	February, 8th, 2023
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:+1 262-247-5502
Alternate Contact Person:	Karim Amrouche Senior Regulatory Affairs Manager GE Healthcare T: +33620783855
Device Trade Name:	Voluson SWIFT, Voluson SWIFT+
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:	K201828 Voluson SWIFT, Voluson SWIFT+ Diagnostic Ultrasound System
Reference Device(s):	K210438 Versana Premier Diagnostic Ultrasound System K220358 Voluson E Series Diagnostic Ultrasound System K213642 Voluson S Series Diagnostic Ultrasound System
Device Description:	The subject device is a Track 3 device, primarily intended for general-purpose radiology evaluation and specialized for OB/GYN with particular features for real-time 3D/4D acquisition. The Voluson SWIFT, Voluson SWIFT+ provide digital acquisition, processing and display capability. Voluson SWIFT, Voluson SWIFT+ consist of a mobile console with control panel, full touch monitor, optional image storage and printing devices. It provides high-performance ultrasound imaging and analysis and have comprehensive networking and DICOM capability. It utilizes a variety of linear, curved linear, matrix phased array transducer including

mechanical and electronic scanning transducers which provide accurate real-time three-dimensional imaging supporting all standard acquisition modes.

Intended Use: The Voluson SWIFT, Voluson SWIFT+ is a general-purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals 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 SWIFT, Voluson SWIFT+ 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 (Anatomical M-Mode), PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, HD-Flow (High Definition-Flow), Harmonic Imaging, Coded Pulse, 3D/4D Imaging mode, Elastography, B-Flow and Combined modes: B/M, B/Color, B/PWD, B/Power/PWD. The Voluson SWIFT / Voluson™ SWIFT+ are intended to be used in a hospital or medical clinic.

Technology: The Voluson™ SWIFT, Voluson™ SWIFT+ employs the same fundamental scientific technology as its predicate device(s).

Determination of Substantial Equivalence: Comparison to Predicates

The proposed Voluson SWIFT, Voluson SWIFT+ is a new platform substantially equivalent to the predicate devices. The following is an overview of the differences between the Voluson SWIFT, Voluson SWIFT+ and the predicate Voluson SWIFT, Voluson SWIFT+ (K201828).

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The Voluson SWIFT, Voluson SWIFT+ and predicate Voluson SWIFT, Voluson SWIFT+ have the same clinical intended use.
- The Voluson SWIFT, Voluson SWIFT+ and predicate Voluson SWIFT, Voluson SWIFT+ have the similar imaging modes with the exception that the proposed Voluson SWIFT, Voluson

SWIFT+ does not include the attenuation imaging mode.

- 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 SWIFT, Voluson SWIFT+ and predicate Voluson SWIFT, Voluson SWIFT+ systems have similar capability in terms of performing measurements, capturing digital images, reviewing, and reporting studies.
- The proposed Voluson SWIFT, Voluson SWIFT+ and predicate Voluson SWIFT, Voluson SWIFT+ systems have been designed in compliance with approved electrical and physical safety standards.
- The probes supported in the proposed Voluson SWIFT, Voluson SWIFT+ and predicate Voluson SWIFT, Voluson SWIFT+ are identical except:
  - The addition of a new transducer **9L-RS** (already cleared on predicate Versana Premier K210438).
  - The addition of a new transducer **12S-RS** (already cleared on predicate Versana Premier K210438).
  - The absence of the E8C-RS transducer on the proposed Voluson SWIFT, Voluson SWIFT+

- The following software features have been added compared to the predicate Voluson SWIFT, Voluson SWIFT+ (K201828) : **Shadow Reduction Button, Autolive, RadiantFlow, Volume with color, SpineTrace, Fractional Limb Volume, Timer for BPP, Fetal Heart Support, SonoPelvicFloor, Auto-Caliper, Reminders, SW Download, AVURI**

- The following software features have been migrated from Voluson E series (K220358): **Shadow Reduction, Fetal Heart Support, SonoPelvicFloor, SW download, AVURI**

- The following software features have been migrated from Voluson S Series (K213642) : **Radiant*flow*, Volume with color, Fractional Limb Volume.**

- The proposed Voluson SWIFT, Voluson SWIFT+ adds the following new features: **Auto*live*, Spine Trace, Time for BPP (Biophysical Profile), Auto-Caliper, reminders.**

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 SWIFT, Voluson SWIFT+ 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, 2007
- 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 SWIFT, Voluson SWIFT+, did not require clinical studies to support substantial equivalence.

AI Verification Summary

Auto-Caliper:

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

- Data used for both training and validation has been collected across multiple geographical sites using different systems and probe configuration to represent the variations in target population.
- The verification for the Auto-Caliper AI feature for 2D caliper placement is performed by clinical experts following a specific protocol :
- Visualization of the follicles on slices parallel to the A plane of acquisition from the datasets
- Click on the follicle on a slice in which the given follicle is expected to be the largest.
- The steps are repeated for all follicles in each volume.
- The output of the caliper placement on the follicles on the plane in which the clinician clicked.
- The outputs are evaluated by the clinical expert and the assessment is documented as Pass/No result/Fail
- The success rate of the AI feature is 70% or higher

Data Collection and Distribution:

- Total Datasets: 67
- Total follicles count across all volumes : 410
- Country: Germany, India, Spain, United Kingdom, USA

Quantitative evaluation:

- Values were obtained from the test pool consisting of 67 volumes, 2 follicles evaluated per volume for a total of 134 follicles.
- Mixture of small and large diameter follicles were selected for the evaluation

- The deviation of the measurements predicted by the Auto-Caliper tool from the manual measurements were calculated to obtain the accuracy of the feature.

Demographic distribution, gender, age and ethnicity :

- Data acquired from women examined in regular clinical practice
  In compliance with privacy health information.
- Data acquired from 6 countries and five systems to ensure sufficient diversity.

Information about clinical subgroups and confounders :

- Data collected from multiple system configurations and different probes from multiples geographical sites.
- The acquired datasets have a variation in shapes and size of the follicles having diameters ranging from 2mm to 25 mm.
- Data acquired from 6 countries and five systems to ensure sufficient diversity.

Equipments and protocols :

- Data is provided by external clinical partners who de-identified the data.
- Original data is collected in the form of 3D volumes to preserve the flexibility to re-process data retrospectively during scan conversion.
- A total of 223 volumes were used for training having the following distributions
  - Distribution by Systems: Voluson E8 (20), Voluson E10 (105), Voluson P8 (29), Voluson S10 (48), Voluson S8 (21)
  - Distribution by Probes: RIC5-9A-RS (98), RIC5-9-D (123), RIC6-12-D (2)
  - Distribution by Countries: India (62), Germany (29), United Kingdom (29), Spain (103).

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

- Datasets contained in the collections for training and verification are mutually exclusive and stem from a mutually exclusive list of patients.
- Data has been collected from patients from regular clinical practice from multiple sites thereby capturing the actual representative population. There is no explicit bias/preference enforced during the collection process.

- To ensure correct and reliable "truthing" process of the training, a curation protocol has been developed by clinical experts to be followed by curators, in addition, during and after the data curation process, a senior sonographer reviewed a random subset of the curated dataset for clinical accuracy.

Absolute difference between AI predicted diameter and Ground truth diameter (in mm)	Percentage of data Pool
<0.1	5.3
0.1-0.5	32.8
0.5-1.0	22.1
1.0-2.0	25.2
2.0-3.0	5.3
3.0-5.0	3.1
>5.0	6.1

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