GE Healthcare
c/o Bryan Behn
RA Director
9900 Innovation Drive
WAUWATOSA, WI 53226

August 29, 2019

Re: K192159
Trade/Device Name: Voluson E6, Voluson E8, Voluson E10
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: August 7, 2019
Received: August 9, 2019

Dear Mr. 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

Thalia T. Mills, Ph.D.
Director
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

Section 4: Indications for Use Statement

Voluson E Series
(Voluson E6 / Voluson E8 / Voluson E10)

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)*
K192159

Device Name
Voluson E6, Voluson E8, Voluson E10

Indications for Use *(Describe)*
The device is a general-purpose ultrasound system. 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; Peripheral Vascular; Transvaginal (including GYN); Transrectal.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

Section 5: 510(k) Summary

Voluson E Series
(Voluson E6 / Voluson E8 / Voluson E10)

**510(k) Summary K192159**

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

| | |
|---|---|
| Date: | Aug 7, 2019 |
| Submitter: | GE Healthcare [GE Healthcare Austria GmbH & Co OG]<br>Tiefenbach 15<br>Zipf, Austria 4871 |
| Primary Contact Person: | Bryan Behn<br>Regulatory Affairs Director<br>GE Healthcare<br>T:(262)247-5502<br>F:(414)918-8275 |
| Secondary Contact Person: | Roland Kuntscher<br>Regulatory Affairs Specialist<br>GE Healthcare Austria GmbH & Co OG<br>T:(+43)7682-3800-660<br>F:(+43)7682 3800-47 |
| Device: Trade Name: | Voluson E6, Voluson E8, Voluson E10<br>Models: Voluson E6 / Voluson E8 / Voluson E10 |
| Common/Usual Name: | Ultrasound system |
| Classification Names: | Class II |
| Product Code(s): | IYN (primary), IYO, ITX (secondary)<br>Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550, 90-IYN |
| Primary Predicate Device(s): | K181985 Voluson E6_E8_E10 Diagnostic Ultrasound System |
| Product Code(s): | IYN (primary), IYO, ITX (secondary)<br>Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550, 90-IYN |
| 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. Voluson E10 is identical in hardware and software compared to the Voluson E8 and Voluson E6 with the exception of scan channels. Voluson E10 has more than Voluson E8 and E6. Voluson E10 also has additional hardware for the 4D electronic probes: eM6C and eM6C G2. The basic software is the same as the predicate and no additional software functions were added in this submission.

Intended Use: The device is a general-purpose ultrasound system. 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; Peripheral Vascular; Transvaginal (including GYN); Transrectal

Technology: The Voluson E Series (Voluson E6 / Voluson E8 / Voluson E10) employs the same fundamental scientific technology as its predicate devices. The updated version of the Voluson E Series (Voluson E6 / Voluson E8 / Voluson E10) consists of improved hardware and improvements to existing software features compared to the predicate version.

Determination of Substantial Equivalence:

Comparison to Predicates

The proposed Voluson E Series (Voluson E6 / Voluson E8 / Voluson E10) is substantially equivalent to the predicate devices with regards to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The proposed Voluson E Series and predicate Voluson E Series systems have the same clinical intended use.
- The proposed Voluson E Series and predicate Voluson E Series systems have the same imaging modes.
- The proposed Voluson E Series and predicate Voluson E Series systems transducers are equivalent. No new transducers were

added 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 E Series and predicate Voluson E Series systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The proposed Voluson E Series and predicate systems have been designed in compliance with approved electrical and physical safety standards.
- There proposed Voluson E Series and predicate Voluson E series Software Features are identical. Some minor improvements to the existing Software features have been implemented into the proposed system.

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 E Series 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:

Second edition 2007

- NEMA PS 3.1 - 3.20 (2016), 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.

Summary of Clinical Tests:

The subject of this premarket submission, Voluson E Series (Voluson E6 / Voluson E8 / Voluson E10), did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Voluson E Series (Voluson E6 / Voluson E8 / Voluson E10) to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).