GE Medical Systems Ultrasound and Primary Care Diagnostics
℅ Lee Bush
Regulatory Affairs Director
9900 W. Innovation Drive
WAUWATOSA WI 53226

May 11, 2022

Re: K220446
Trade/Device Name: Versana Balance
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: February 15, 2022
Received: February 16, 2022

Dear Lee Bush:

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)*
K220446

Device Name
Versana Balance

Indications for Use *(Describe)*
The Versana Balance is a general-purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid. Versana Balance clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Urology, Pediatric, Small Parts (includes breast, testes, thyroid), Cardiac Adult, Cardiac Pediatric, Vascular/Peripheral Vascular, Musculoskeletal Conventional, Musculoskeletal Superficial, Thoracic/Pleural, Transcranial, Transrectal, Transvaginal, Interventional guidance (includes tissue biopsy, fluid drainage, vascular and non-vascular access).

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, and Combined modes: B/M, B/Color, B/PWD, B/Color/PWD, B/Power/PWD, B Flow/B Flow Color.

Versana Balance 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary K220446

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

Date:	May 5, 2022
Submitter:	GE Medical Systems Ultrasound and Primary Care Diagnostics 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Lee Bush Regulatory Affairs Director GE Healthcare T:(262) 309-9429
Secondary Contact Person:	Andrew Turner Regulatory Affairs GE Healthcare
Device Trade Name:	Versana Balance
Common/Usual Name:	Diagnostic Ultrasound System
Classification Names:	Class II
Product Code(s):	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:	Versana Balance (K191792), Diagnostic Ultrasound System
Classification Names:	Class II
Product Code(s):	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 Device:	Versana Premier (K210438), Diagnostic Ultrasound System
Classification Names:	Class II
Product Code(s):	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 Device:	Vivid i (K121062), Diagnostic Ultrasound System
Classification Names:	Class II
Product Code(s):	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; Picture Archiving and Communication System 21 CFR 892.2050, 90-LLZ
Reference Device:	LOGIQ e (K113690), Diagnostic Ultrasound System
Classification Names:	Class II
Product Code(s):	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 Versana Balance is a general purpose, Track 3, diagnostic ultrasound system for use by qualified and trained healthcare professionals. The system is a mobile console that includes an operator control panel, display monitor and transducers.

The console provides digital acquisition, processing and display capability. The system has an internal battery to allow for acquisition while the system is not plugged into a power source. Acquisition can also be done while the system is connected to an AC power source.

The operator control panel includes function keys, trackball, an alfa-numeric keyboard and a touch panel as input sources of the device.

The variety of transducers include convex, linear, sector, and mechanical 4D transducers. The access types include trans- body surface, transrectal, transvaginal and transcranial.

Data can be imported or exported by DVD, USB, LAN or WiFi if the USB wireless adapter is connected to the system. An external ECG module has been verified to use as input for gating/triggering during scanning. The system has a HDMI port, VGA connection port, Audio out port, S-Video port, and a Composite Out port connection. The system has an external AC outlet to allow connection of a printer and sit in the printer box of the console and an option for external Printer USB Isolator for other printers to connect. The system supports one way, Bluetooth communication capability from the system to a personal device to allow for sharing of the patient's data/images when the external Bluetooth USB adapter is connected to the system.

Intended Use/Indication for Use:

The Versana Balance is a general-purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid. Versana Balance clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Urology, Pediatric, Small Parts (includes breast, testes, thyroid), Cardiac Adult, Cardiac Pediatric, Vascular/Peripheral Vascular, Musculoskeletal Conventional, Musculoskeletal Superficial, Thoracic/Pleural, Transcranial, Transrectal, Transvaginal, Interventional guidance (includes tissue biopsy, fluid drainage, vascular and non-vascular access).

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, and Combined modes: B/M, B/Color, B/PWD, B/Color/PWD, B/Power/PWD, B Flow/B Flow Color.

Versana Balance is intended to be used in a hospital or medical clinic.

Technology:
The Versana Balance employs the same fundamental scientific technology as its predicate device and reference devices.

Determination of Substantial Equivalence:
The proposed Versana Balance system is substantially equivalent to the predicate Versana Balance device with regard to intended use, imaging capabilities, technological characteristics, imaging modes, hardware, and safety effectiveness.

Indications for use

- Vascular has been added with peripheral vascular, this clarifies vessels and is not a change in imaging or product. No impact to safe or effective use. This is the same as on reference device Versana Premier (K210438).
- Removal of the wording "Cephalic" as this is covered by "Transcranial" and to align indications with the reference device Versana Premier (K210438). No impact to safe or effective use.
- Gynecology and Urology are listed independently instead of within Abdominal as it was in the predicate Versana Balance (K191792). There is no change in imaging or the product. No impact to safe or effective use.
- Small Organ is changed to Small Parts, it is a wording use preference change only. There is no change in imaging or the product. No impact to safe or effective use. This is the same as on reference device Versana Premier (K210438).
- Cardiac (includes Adult and Pediatric) in the predicate Versana Balance (K191792) is changed to Cardiac Adult and Cardiac Pediatric; it is a wording use preference change only. There is no change in imaging or the product. No impact to safe or effective use. This is the same as on reference device Versana Premier (K210438).

Transducers and Modes:

- The proposed Versana Balance and predicate Versana Balance (K191792) systems transducers are similar, except for:
  - Addition of L8-18i-RS, which was first cleared on LOGIQ e (K113690). The clinical indications and modes of L8-18i-RS are the same as on the proposed Versana Balance as they are on the reference device Versana Premier (K210438).
  - Addition of 12S-RS, which was first cleared on Vivid i, (K121062). The clinical indications and modes of 12S-RS are the same as on proposed Versana Balance as they are on the reference device Versana Premier (K210438).
  - Elastography mode has been added to the following existing transducers for Versana Balance for same clinical indications as the reference device Versana Premier (K210438):
    - 4C-RS
    - E8Cs-RS
    - L6-12-RS
    - 12L-RS

Software:

- Addition of Whizz Label: an Artificial Intelligence (AI) feature that identifies key anatomies/organs during ultrasound imaging. Whizz Label was first cleared with Versana Premier (K210438).
- Addition of LI-RADS: Liver Imagining Reporting and Data System, based on the ACR (American College of Radiology) published literature. LI-Rads enables the user to enter categorization, standardized reporting, and data collection for the liver.
- Addition of Probe Check (transducer element check): a tool that evaluates the probe performance and provides the user with an indication of the potential impact to the diagnostic image if it is compromised due to a transducer malfunction.
- Addition of Whizz Color Flow: Whizz Color Flow is used to optimize color flow by adjusting Color Flow parameters (gain and frequency) automatically. Whizz Color Flow is the same feature as on reference device Versana Premier (K210438).
- Addition of Lateral Gain Compensation (LGC): Lateral Gain Compensation (LGC) amplifies returning signals to correct for the attenuation due the beam penetrating through tissue. This is a similar feature as on reference device Versana Premier (K210438).
- Addition of VOCAL: a function to visualize and calculate the volume of anatomical structures running under 3D/4D mode for volume calculation.
- Addition of Standby mode (Fast boot up): a power saving functionality and is the same feature as on Versana Premier (K210438).
- Addition of V-Live: a feature that allows the user to rotate a single light source by track ball to easily highlight details in otherwise darkened areas within a region of interest. This is the same feature as on reference device Versana Premier (K210438).

Mechanical and Industrial Design Change:

Optimization of the industrial design, no change in the materials themselves

Hardware:

- Addition of an optional 13.3’ multi-touch panel
- Addition of an optional cable tray
- Updated high level internal computer components (Hard drive, CPU, etc)
- Addition of optional barcode reader

Summary of Non-Clinical Tests:

Versana Balance 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 comply with applicable medical device safety standards. The Versana Balance complies with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance - 2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests - Edition 4.0, 2014
- IEC 60601-2-37, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance 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
- 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
- ISO 14971, Medical devices - Application of risk management to medical devices, 2019
- NEMA PS 3.1 - 3.20, Digital Imaging and Communications in Medicine (DICOM) Set, 2016

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 material and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, Versana Balance, did not require clinical studies to support substantial equivalence.

Conclusion:

GE Healthcare considers the Versana Balance to be as safe, effective, and performs in a substantially equivalent manner as the predicate and reference devices.