February 15, 2023

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

Re: K223407
Trade/Device Name: Versana Essential
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: January 19, 2023
Received: January 19, 2023

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,

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)*
K223407

Device Name
Versana Essential

Indications for Use *(Describe)*

The Versana Essential 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 Essential 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 Essential 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.

510(k) Summary

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

Date:	Jan. 19, 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:	Jian Xie Regulatory Affairs Leader GE Healthcare
Device Trade Name:	Versana Essential
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 (K220446), 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 Essential 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.

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. The Video adapter is optional part which used to extend the S-Video/Composite Out interface by connecting with HDMI port. The system has a DC outlet to allow connection of a DC printer which sits in the printer box of the console and an option for external Printer USB Isolator for other commercial printers to connect.

The system allows for electronic instructions for use and software updates to be download from a GE Healthcare website.

Intended Use/Indication for Use:

Versana Essential and predicate device Versana Balance (K220446) have the same intended use:

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

Technology:
The Versana Essential employs the same fundamental scientific technology as its predicate device Versana Balance device (K220446).

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

Transducers and Modes:

- The proposed Versana Essential transducers are same as predicate Versana Balance (K220446) systems transducers
    - 4C-RS
    - E8C-RS
    - 3Sc-RS
    - L6-12-RS
    - 6S-RS
    - 8C-RS
    - E8Cs-RS
    - RAB2-6-RS
    - LK760-RS

- Versana Essential and predicate device Versana Balance (K220446) have the same imaging modes

Software:
The proposed Versana Essential has the same features and functionality as the predicate device Versana Balance (K220446). The design of all features is same as predicate device Versana Balance, the workflow is same as predicate device Versana Balance non-touchscreen version.

The key feature list as below：

- LI-RADS:
- Probe Check (transducer element check)
- Whizz Color Flow
- Lateral Gain Compensation (LGC)
- VOCAL
- V-Live
- Standby mode (Fast boot up)
- Follow up Tool
- Breast Productivity (BI-RADS)
- Thyroid productivity (TI-RADS)
- Auto Bladder
- B-Flow&B-Flow Color

- Breast Care
- Needle recognition
- Auto EF
- TUI
- Stress Echo
- Advance 3D
- Tricefy
- Elastography imaging
- e-Delivery

Note: The predicate device Versana Balance (K220446) has two additional features, whizz label and multi-touch, that are not available in the proposed Versana Essential.

Hardware:
The proposed Versana Essential and predicate Versana Balance (K2220446) non-touchscreen version have the same power input/output and similar design of internal circuits. Both of them have been designed in compliance with approved electrical and physical safety standards.
The proposed Versana Essential and predicate Versana Balance (K2220446) support the same accessories such printers, DVD, USB disk and barcode reader.

Comparison of technological characteristics with Predicate device:

Characteristic	**Proposed Device Versana Essential**	**Predicate Device Versana Balance (K220446)**	**Comment on comparison**
Scan channels	**48 Channels**	64 Channels	The number of channels on Versana Essential is less than on predicate Versana Balance, however all safety and performance requirements are met according to the device evaluation and verification. No impact to safety or effectiveness
Touch panel	**Not available**	Option (Configuration dependent)	Identical with predicate device Versana Balance non-touchscreen version.
Network / Archive:	USB, thermal b&w image printer, memory stick and Encrypt patient information store to a removable	USB, thermal b&w image printer, memory stick and Encrypt patient information store to a removable memory	The proposed device accessories for network/archive were previously available in predicate Versana Balance. An additional Bluetooth adapter was available in the predicate device but not Vesrana Essential. However, there is no

Characteristic	Proposed Device Versana Essential	Predicate Device Versana Balance (K220446)	Comment on comparison
	memory device, Ethernet/DICOM/LAN via hardware, wireless adapter, Tricefy Uplink	device, Ethernet/DICOM/LAN via hardware, wireless adapter, **Bluetooth** USB adaptor, Tricefy Uplink	impact to safety or effectiveness because the memory stick, LAN, or wireless adapter are alternative means to share patient images/data.

Summary of Non-Clinical Tests:

Versana Essential 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 Essential 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 4.1, 2020
- 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, 2020e

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 Essential, did not require clinical studies to support substantial equivalence.

Conclusion:

Based on the equipment design similarities, conformance to recognized performance

standards, and performance testing, GE Healthcare considers the Versana Essential to be as safe, effective, and performs in a substantially equivalent manner as the predicate device Versana Balance (K220446).