GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC
℅ Tracey Ortiz
Regulatory Affairs Director
9900 W Innovation Drive
WAUWATOSA WI 53226

September 10, 2021

Re: K210438
Trade/Device Name: Versana Premier
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: July 30, 2021
Received: August 2, 2021

Dear Tracey Ortiz:

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 and Part 809); 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

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)*

K210438

Device Name
Versana Premier

Indications for Use *(Describe)*

The Versana Premier 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 Premier 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 and Combined modes: B/M, B/Color, B/PWD, B/Color/PWD, B/Power/PWD.
Versana Premier 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

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

Date:	February 10, 2021
Submitter:	GE Medical Systems Ultrasound and Primary Care Diagnostics 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Tracey Ortiz Regulatory Affairs Director GE Healthcare T:(262)470-1003
Secondary Contact Person:	Gao Gan Regulatory Affairs GE Healthcare
Device Trade Name:	Versana Premier
Common/Usual Name:	Diagnostic Ultrasound System
Classification Names:	Class II IYN (primary), IYO (secondary), ITX
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 Premier (K200138)
Reference Device(s):	Versana Active (K200998) Versana Active (K191798) LOGIQ P9 (K181783) LOGIQ P6 (K073297) Venue (K202132) Voluson P8 (K141675) Voluson S10 Expert (K180374) Vivid S5 (K092079)

GE Healthcare

510(k) Premarket Notification Submission

Device Description:

The Versana Premier 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.

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, dual 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 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 Premier 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 Premier 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 and Combined modes: B/M, B/Color, B/PWD, B/Color/PWD, B/Power/PWD. Versana Premier is intended to be used in a hospital or medical clinic.

Technology:

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

Determination of Substantial Equivalence:

The proposed Versana Premier system is substantially equivalent to the predicate Versana Premier device with regard to intended use, imaging capabilities, technological characteristics, imaging modes, hardware, and safety effectiveness.

Indications for use

- The proposed Versana Premier and predicate Versana Premier (K200138) have similar clinical indications for use, however, the proposed Versana Premier is adding Thoracic/Pleural application which has been cleared on reference device, Versana Active (K200998).
- Gynecology and Urology are listed independently instead of within Abdominal as it was in the predicate Versana Premier (K200138). There no change in imaging or the product. No impact to safe or effective use.
- Small Organ is changed to Small Parts but there is no change in imaging or the product. It is a wording use preference change only. No impact to safe or effective use.
- Cardiac (includes Adult and Pediatric) as it was in the predicate Versana Premier (K200138) is changed to Cardiac Adult and Cardiac Pediatric; this is not a change in imaging or product. It is a wording use preference change only. No impact to safe or effective use.

Transducers and Modes:

- The proposed Versana Premier and predicate Versana Premier (K200138) systems transducers are similar, except for:
  - Addition of 9L-RS, which was first cleared on Vivid S5, K092079. The clinical indications of 9L-RS are similar on the proposed Versana Premier as they are on the reference device Versana Active, K200998.
  - Addition of L3-12-RS, which was first cleared on LOGIQ P9, K181783. The clinical indications of L3-12-RS are similar on proposed Versana Premier as they are on the reference device LOGIQ P9, K181783. However, we are adding Vascular/Peripheral Vascular, Thoracic/Pleural, Interventional guidance (includes tissue biopsy, fluid drainage, vascular access and non-vascular access) applications which were cleared with a similar linear transducer, L6-12-RS, in reference device Versana Active, K200998.
- New applications are added to transducers:
  - 4C-RS, L6-12-RS, and 12L-RS transducers: added Thoracic/Pleural application cleared with this transducer on reference device Versana Active, K200998.
  - C1-5-RS transducer: added Thoracic/Pleural cleared with this probe on the reference device Venue, K202132.
  - E8Cs-RS, BE9CS-RS and E8C-RS transducers: added Non-vascular access, cleared with this transducer on reference device Versana Active, K200998.
  - RIC5-9A-RS transducer: added Non-Vascular access, cleared with another mechanical 3D transducer RAB2-6-RS in predicate device Versana Premier, K200138.
  - 3Sc-RS transducer: added Thoracic/Pleural and Non-vascular access, cleared with this transducer on reference device Versana Active, K200998; added Vascular/Peripheral Vascular, cleared with this transducer on reference device Venue, K202132.
  - RAB2-6-RS: added Urology, cleared with this transducer on reference device Versana Active, K200998.
  - 6S-RS transducer: added Vascular/Peripheral Vascular, cleared with this transducer on reference device Venue, K202132.

- 12S-RS transducer: added Pediatric, Transcranial, cleared with this transducer on reference device Versana Active, K200998; added Vascular/Peripheral Vascular, cleared with similar sector transducer, 6S-RS, in reference device Venue, K200998; added interventional guidance (includes Fluid drainage and Non-Vascular aceess) cleared with 3Sc-RS in reference device Versana Active, K200998.
- LK760-RS transducer: added interventional guidance (includes Fluid drainage, Vascular access and Non-Vascular access), cleared with 9L-RS in reference device Versana Active, K200998.
- 8C-RS transducer: added interventional guidance (includes Fluid drainage, Non-Vascular access), cleared with this probe on reference device Venue, K202132.
- L8-18i-RS transducer: added interventional guidance (includes Fluid drainage, Vascular access and Non-Vascular access), cleared with this probe on reference device Venue, K202132.
- E7C8L-RS transducer: expanding non-vascular access to include brachytherapy, cleared with ERB transducer on reference device LOGIQ P6, K073297.

Software:

- Whizz Label is an Artificial Intelligence (AI) feature that is being added.
- Whizz Color Flow is being added, this is similar to Auto Color Optimize in reference device LOGIQ P6 (K073297).
- Whizz Easy Style is being added, this is similar to SRI cleared on reference device Voluson S10 Expert, K180374.
- V-Live is being added and is similar to HDlive cleared on reference device Voluson P8, K141675.
- TI-RADS (ACR) is being added and is the same as TI-RADS (ACR) on reference device Versana Active, K200998.
- BI-RADS (ACR) is being added based on the BI-RADS (ACR) 5th edition issued in 2013.
- Touch LGC is added and is similar to TGC on predicate Versana Premier, K200138.
- Multi-touch gestures have been added for the touch panel.
- Fast boot up is added and is similar to Standby mode in reference device Versana Active, K191798.
- Enhancements have been made to workflows and reports
- Electronic instructions for use (eIFU) are now included

Hardware:

- Fan noise optimization has been made
- Larger touch screen monitor is added
- Front paper tray is added
- Probe cable hook shape and location modified

Accessories:

- Added compatible OEM biopsy guide accessory compatibility for the 9L-RS, L3-12-RS, transducers.

Summary of Non-Clinical Tests:

Versana Premier 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 Premier 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 Premier, did not require clinical studies to support substantial equivalence.

Conclusion:

GE Healthcare considers the Versana Premier to be as safe, as effective, and performance is substantially equivalent to the predicate and reference devices.