



October 2, 2024

GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC  
Lee Bush  
Regulatory Affairs Director  
3200 N Grandview Blvd  
Waukesha, WI 53188

Re: K242005

Trade/Device Name: Versana Premier; Versana Premier Lotus; LOGIQ F  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic Pulsed Doppler Imaging System  
Regulatory Class: Class II  
Product Code: IYN, IYO, ITX  
Dated: July 9, 2024  
Received: July 9, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

 Marjan Nabili -S<sup>for</sup>

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

## Indications for Use

Submission Number (if known)

K242005

Device Name

Versana Premier;  
Versana Premier Lotus;  
LOGIQ F

Indications for Use (Describe)

The Versana Premier/Versana Premier Lotus/LOGIQ F 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/Versana Premier Lotus/LOGIQ F 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, Transesophageal, 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/Versana Premier Lotus/LOGIQ F 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.

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510(k) Summary

K242005

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

Date: July 10, 2024

Submitter: GE Medical Systems Ultrasound and Primary care Diagnostics, LLC  
3200 N Grandview Blvd  
Waukesha, WI 53188

Manufacturer: GE Medical Systems (China) Co., Ltd.  
No.19, ChangJiang Road, WuXi National Hi-Tech Dev. Zone,  
214028 Jiangsu China

Primary Contact Person: Lee Bush  
Regulatory Affairs Director  
GE HealthCare  
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Alternate Contact Person: Jian Xie  
Senior Regulatory Affairs Manager  
GE HealthCare  
T: +86 13338113925

Device Trade Name: Versana Premier, Versana Premier Lotus, LOGIQ F  
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: K210438 Versana Premier, Diagnostic Ultrasound System  
Reference Device(s): K220446 Versana Balance, Diagnostic Ultrasound System  
K231989 LOGIQ E10s, LOGIQ Fortis  
K214039 LOGIQ P10, LOGIQ P9, LOGIQ P8  
K221147 Vivid T8, Vivid T9  
K220800 Venue Go  
K213642 Voluson S6, Voluson S8, Voluson S8t,  
Voluson S10, Voluson S10 Expert

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

Device Description: The Versana Premier, Versana Premier Lotus and LOGIQ F 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, and a touch panel with a digital keyboard (physical keyboard as an option) as input sources of the device. The variety of transducers include convex, linear, sector, Bi-plane probe and mechanical 4D transducers. The access types include trans- body surface, transrectal, transvaginal, transcranial and transesophageal.

The Versana Premier, Versana Premier Lotus and LOGIQ F share a common software and hardware platform. There may be different configurations commercially offered, however they are all within the overall design of the product.

Intended Use: The Versana Premier/Versana Premier Lotus/LOGIQ F 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/Versana Premier Lotus/LOGIQ F 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, Transesophageal, 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/Versana Premier Lotus/LOGIQ F is intended to be used in a hospital or medical clinic

Technology: The Versana Premier/Versana Premier Lotus/LOGIQ F employs the same fundamental scientific technology as its predicate device(s).

Determination of  
Substantial  
Equivalence:

Comparison to Predicates

The proposed Versana Premier/Versana Premier Lotus/LOGIQ F is substantially equivalent to the predicate devices. The following is an overview of the differences between the Versana Premier/Versana Premier Lotus/LOGIQ F and the predicate Versana Premier (K210438).

Indications for Use:

The proposed Versana Premier/Versana Premier Lotus/LOGIQ F and predicate Versana Premier (K210438) have similar clinical indications for use, however the proposed device is adding Transesophageal application which has been cleared on reference device Venue Go (K220800).

Transducers:

The proposed Versana Premier/Versana Premier Lotus/LOGIQ F and predicate Versana Premier (K210438) transducers are similar, except for:

- Addition of IC9-RS: previously cleared on LOGIQ P9 (K214039). The clinical applications and imaging modes of IC9-RS are similar to those available on the reference device LOGIQ P9 (K214039).
- Addition of L4-20t-RS: previously cleared on Venue Go (K220800). The clinical applications and imaging modes of L4-20t-RS are similar to those available on the reference device Venue Go (K220800).
- Addition of 6Tc-RS: previously cleared on Venue Go (K220800). The clinical applications and imaging modes of 6Tc-RS are similar to those available on the reference device Venue Go (K220800).

Software:

- V-live 2.0: similar feature as HD Live in reference device LOGIQ P9 (K214039).
- Whizz RenderLive: similar feature as SonoRenderLive in reference device LOGIQ P9 (K214039).
- Whizz Follicle: similar feature as SonoAVC in reference device LOGIQ P9 (K214039)
- Whizz Report: creates report templates on personal computer to include data, images, and cine loop.
- Whizz Note: allows user to import and display clinical datasheets for reference quickly and easily while scanning.
- Strain and Strain Rate: similar features as reference device Vivid T9 (K221147).
- Intensity Ratio: a measurement tool to calculate the intensity ratio of two sample areas on a frozen B-mode image.

- LI-RADS: liver Imaging Reporting and Data System, based on the ACR (American College of Radiology) published literature, same feature as reference device Versana Balance (K220446)
- Digital TGC: similar feature as touch TGC in LOGIQ Fortis (K231989)
- V-zoom: zoom the full screen for selected ROI. Similar feature as Voluson S10 (K213642).
- Scan coach with voice comments: a quick method to add or play audible guidance/comments during using scan coach for the clinical guidance of scan plane acquisition and anatomical structures.
- Imaging insights: automatically optimizes system and probe fleet investment plans, identify staff assignment and training needs, and monitor variability of staff usage patterns, similar feature as LOGIQ Fortis (K231989)
- Insite Auto Connect: a service feature to accomplish fully automatic connection of installed consoles to GE Insite without any user operation, similar feature as LOGIQ Fortis (K231989)
- Probe check (transducer element check): same feature as reference device Versana Balance (K220446)
- eDelivery: allows the user, in addition to service personnel, to update the SW by logging into a GE HealthCare website to download SW available to them and install it on the system, same feature as reference device Versana Balance (K220446)

#### Hardware:

New Product Industrial Design with additional 23.8-inch LCD and 15.6-inch touch panel, 5 probe ports, Lower the control panel height, handbrake control on height adjustment, indication light, cable management, Endo probe holder, Drawer, and Accessory tray.

#### Accessories:

- Added compatible OEM biopsy guide accessory compatibility for the IC9-RS and L4-20t-RS Transducers
- Added Digital Expert and Barcode reader.
- ECG module was revised to new version.
- Added new wireless adapter.

#### 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 Versana Premier/Versana Premier Lotus/LOGIQ F complies with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 2005/A2:2021
- 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 4.1, 2020
- 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 Risk Management Process, Fifth edition, 2018
- ISO 14971, Application of risk management to medical devices, 2019
- NEMA PS 3.1 - 3.20, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology), 2021
- 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, Versana Premier/Versana Premier Lotus/LOGIQ F 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 proposed Versana Premier/Versana Premier Lotus/LOGIQ F to be as safe, effective, and performs in a substantially equivalent manner as the predicate Versana Premier



GE HealthCare

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510(k) Premarket Notification Submission

(K210438).