December 16, 2024

Vinno Technology (Suzhou) Co.,Ltd
Jeff Zhou
Regulatory Registered Engineer
5F Building A,4F Building C No. 27 Xinfa Rd.
Suzhou Industrial Park
Suzhou, Jiangsu 215123
CHINA

Re: K240676
Trade/Device Name: ULTIMUS Series Ultrasound Diagnostic System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX,
Dated: June 3, 2024
Received: June 3, 2024

Dear Jeff Zhou:

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) 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240676

Device Name

ULTIMUS Series Ultrasound Diagnostic System

Indications for Use *(Describe)*

The ULTIMUS Series Ultrasound Diagnostic System is a general-purpose ultrasound system. It is intended for use by, or under the direction of a qualified and trained physician for ultrasound imaging, measurement, display and analysis of the human body and fluid. The device is intended for use in a hospitals or clinics environment.
The systems support the following clinical applications:
This device is indicated for Abdominal; Fetal/Obstetrics; Gynecology; Transvaginal; Urology(including prostate); Transrectal; Cardiac(adult and child); Peripheral Vascular; Small Organs/Parts(thyroid, breast, testicle, Musculo-skeletal Conventional and Superficial); Pediatrics(including neonatal cephalic); interventional(nerve block and vascular access); Adult Cephalic diagnostic Ultrasound applications.
Modes of operation include: 3D/4D Imaging mode, B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Combined modes: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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.

K240676 510(k) Summary

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

Date Prepared: Feb 28, 2024

Manufacturer: VINNO Technology (Suzhou) Co., Ltd
5F Building A, 4F Building C No. 27 XinFa Rd.
Suzhou Industrial Park, SuZhou 215123
Jiangsu China

Contact Person: Jeff Zhou
Regulatory Registered Engineer
VINNO Technology (Suzhou) Co., Ltd
Tel: +86 512 6287380
Fax: +86 512 62873801
email: Jeff.zhou@vinno.com

Identification of the Device:

Trade Name: ULTIMUS Series Ultrasound Diagnostic System

Model Name: ULTIMUS 9E、ULTIMUS 9P、ULTIMUS 9、ULTIMUS 8E、ULTIMUS 8P、ULTIMUS 8、ULTIMUS 7E、ULTIMUS 7P、ULTIMUS 7、ULTIMUS 6E、ULTIMUS 6P、ULTIMUS 6、ULTIMUS 5E、ULTIMUS 5P、ULTIMUS 5

Classification Name: Ultrasound Diagnostic System

Regulation Name: Ultrasonic Pulsed Doppler Imaging System

Regulatory Number: 21 CFR 892.1550, 21 CFR 892.1560, 21 CFR 892.1570

Product Code: IYN, IYO, ITX

Device Class: Class II

Review Panel: Radiology

Primary Predicate Device:

Proprietary/Trade Name: LOGIQ E10

Classification Name: Ultrasound Diagnostic System

Regulation Name: Ultrasonic Pulsed Doppler Imaging System

Regulatory Number: 21 CFR 892.1550, 21 CFR 892.1560, 21 CFR 892.1570

Product Code: IYN, IYO, ITX

Device Class: Class II

Review Panel: Radiology

Submitter/510(k) Holder: GE Medical Systems Ultrasound and Primary

	Care Diagnostics, LLC
Clearance:	K231966 (cleared Nov 07, 2022)

Device Description:
The ULTIMUS Series consists of a mobile console with a height-adjustable control panel, color LCD touch panel, LCD display monitor device. It includes a variety of electronic array transducers operating in linear, curved, sector/phase array, endocavity, and real time 3D transducer.
The ULTIMUS series is a Track 3 diagnostic ultrasound system. The system includes electronics for transmit and receive of ultrasound data, ultrasound signal processing, software computing, hardware for image storage.

Indications for Use:
The ULTIMUS Series Ultrasound Diagnostic System is a general-purpose ultrasound system. It is intended for use by, or under the direction of a qualified and trained physician for ultrasound imaging, measurement, display and analysis of the human body and fluid. The device is intended for use in a hospitals or clinics environment.

The systems support the following clinical applications:

This device is indicated for Abdominal; Fetal/Obstetrics; Gynecology; Transvaginal; Urology(including prostate); Transrectal; Cardiac(adult and child); Peripheral Vascular; Small Organs/Parts(thyroid, breast, testicle, Musculo-skeletal Conventional and Superficial); Pediatrics(including neonatal cephalic); interventional(nerve block and vascular access); Adult Cephalic diagnostic Ultrasound applications.
Modes of operation include: 3D/4D Imaging mode, B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Combined modes: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

Comparison with Predicate Device:
The ULTIMUS Series and its predicate device, the GE LOGIQ E10 Ultrasound Diagnostic System (K231966), have the equivalent intended use, and similar physical characteristics.

Description	Subject Device ULTIMUS Ultrasound Diagnostic System	Predicate Device GE LOGIQ E10 Ultrasound Diagnostic System (K231966)
Model	ULTIMUS 9E, ULTIMUS 9P,ULTIMUS 9, ULTIMUS 8E, ULTIMUS 8P, ULTIMUS 8, ULTIMUS 7E, ULTIMUS 7P, ULTIMUS 7, ULTIMUS 6E, ULTIMUS 6P, ULTIMUS 6, ULTIMUS 5E, ULTIMUS 5P, ULTIMUS 5	LOGIQ E10
Indications for use	The ULTIMUS Series Ultrasound Diagnostic System is a general-purpose ultrasound system. It is intended for use by, or under the direction of a qualified and trained physician for ultrasound imaging, measurement, display and analysis of the human body and fluid. The device is intended for use in a hospitals or clinics environment. The systems support the following clinical applications: This device is indicated for Abdominal; Fetal/Obstetrics; Gynecology; Transvaginal; Urology(including prostate); Transrectal; Cardiac(adult and child); Peripheral Vascular; Small Organs/Parts(thyroid, breast, testicle, Musculo-skeletal Conventional and Superficial); Pediatrics(including neonatal cephalic); interventional(nerve block and vascular access); Adult Cephalic diagnostic Ultrasound applications.	LOGIQ E10 is intended for use by a qualified physician for ultrasound evaluation of Fetal / Obstetrics; Abdominal (including Renal, Gynecology/Pelvic); Pediatric; Small Organ (Breast, Testes, Thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (Adult and Pediatric); Peripheral V ascular; Musculo-skeletal Conventional and Superficial; Urology (including Prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative (Abdominal and Vascular). The LOGIQ E10 is intended to be used in a hospital or medical clinic.
User qualification	Qualified healthcare professionals	Qualified physicians or sonographers
Environment	hospitals or clinics environment	hospitals or clinics environment

Description	Subject Device ULTIMUS Ultrasound Diagnostic System	Predicate Device GE LOGIQ E10 Ultrasound Diagnostic System (K231966)
Design	This device is designed for the safety of the patient and operator. This product is designed to fully comply with the EN60601-1-2 (IEC60601-1-2), Class A, in medical electric equipment EMC regulations. And compliance with IEC60601-1, 60601-2-37	This device is designed for the safety of the patient and opeartor. This product is designed to fully comply with the EN60601-1-2 (IEC60601-1-2), Class A, in medical electric equipment EMC regulations. And compliance with IEC60601-1, 60601-2-37
Patient contact materials	Material meet ISO 10993-1 and FDA guidance	Material meet ISO 10993-1 and FDA guidance
Operating modes	• B mode • HAR mode • M mode • CF mode • Multi-Angle M mode • Color M(CM) mode • PDI mode • Tissue Doppler (TD) mode • PW mode • CW mode • Tissue Velocity Imaging (TVI) mode • Tissue Power Imaging (TPI) mode • Tissue Velocity M (TVM) mode • 3D/Free 3D mode • 4D/ STIC mode • Contrast Bubble Imaging(CBI)mode • Elastography Imaging (EI) mode • Pulse wave velocity imaging (PWV) mode • Strain and strain rate imaging mode • Shear Wave Elastography (SWE) mode (VShear)	• B-Mode (B) • Harmonics (HAR) • M-Mode (M) • Color Flow Mode (CF) • M-Mode • Color M mode • Power Doppler Imaging (PDI) • Tissue Doppler Imaging (TD) • Pulse Wave Mode (PW) • Continuous Wave Mode (CW) •Tissue Velocity Imaging (TVI) • Tissue Power •Tissue Velocity Doppler (TVD) • 3D/Easy 3D/Advance 3D/Tur 3D • 4D mode • Contrast Enhanced Ultrasound (CEUS) • Elastography (ELASTO) • PW Doppler with High PRF (PW) • Strain and strain rate imaging mode • Shear Wave Elastography (SWE) mode

Description	Subject Device ULTIMUS Ultrasound Diagnostic System	Predicate Device GE LOGIQ E10 Ultrasound Diagnostic System (K231966)
Functions	• Har mode • Steer • Vfusion • Vspeckle • Vsharpen • Persistence • GrayFilter • Smooth • Vtissue • 2D Automatic Optimization • PW automatic optimization • Auto spectrum trace • Auto trace • Tview • Pview • Dual & Quad view • Image rotation, invert and zoom • Duplex and Triplex • Stress echo • 4D rendering • Mcut • Color 3D • Light Lab • VLuminous flowing • MCP(Micro Contrast Perfusion) • SMF (Super Micro Flow)	• Coded Harmonic Imaging, • Steering, • CrossXBeam • SRI • Edge Enhance, • Frame Averaging, • Rejection, • B Softener, • Suppression • Auto Tissue Optimization: ATO, • Auto Spectrum Optimization: ASO, • Doppler auto trace • Auto trace • Virtual Convex, • LOGIQView, • Independent Dual B/PW Display, Quad Screen Display • Zoom: Write/Read/Pan, Image Rotation • Duplex, Real-time Triplex Mode at any Depth and PRF, • Stress echo, • Render, Texture • Tomographic Ultrasound Imaging (TUI), • HDlive Flow • HDlive Studio • Radiantflow™ • MVI(CEUS) • Micro Vascular Imaging

Description	Subject Device ULTIMUS Ultrasound Diagnostic System	Predicate Device GE LOGIQ E10 Ultrasound Diagnostic System (K231966)
Measurement	Measurements: • Abdominal measurements • Obstetrics Measurements • Gynecology Measurements • Cardiac Measurements • Vessel measurements • Urology Measurements • Small organ measurements • Pediatric Measurements	Categories include the following: • Abdomen • Obstetrics • Gynecology • Cardiology • Vascular • Urology • Small Parts • Pediatrics
Probe types	Phased array S1-6P Convex array X2-6C Micro convex (Endocavity) X4-9E Linear array X6-16L Volume convex array D2-6C	Sector Phased Array Convex Array Micro convex Array Linear Array Volume Probes (4D)
Acoustic output	Track 3; Ispta.3 ≤ 720 mW/cm2 MI ≤ 1.9 TI ≤ 6.0	Track 3; Ispta.3 ≤ 720 mW/cm2 MI ≤ 1.9 TI ≤ 6.0
Labeling	Conforms to 21 CFR Part 801	Conforms to 21 CFR Part 801

Technology:
The ULTIMUS Series employs the same fundamental scientific technology as its predicated device.

Determination of substantial equivalence:
The Proposed ULTIMUS Series system are substantially equivalent to the predicate GE LOGIQ E10 Ultrasound Diagnostic System (K231966) with regards to intended use, indication for use, image capabilities, technological characteristics, image mode, and safety effectiveness.
The following is an overview of the differences between the proposed ULTIMUS Series and its predicate device.
Comparison Analysis
Note 1: Indications for use
Both the subject and predicate devices are used for the diagnostic ultrasonic imaging. The indications for use of the subject devices - ULTIMUS 9E, ULTIMUS 9P,ULTIMUS 9, ULTIMUS 8E, ULTIMUS 8P, ULTIMUS 8, ULTIMUS 7E, ULTIMUS 7P,

ULTIMUS 7, ULTIMUS 6E, ULTIMUS 6P, ULTIMUS 6, ULTIMUS 5E, ULTIMUS 5P, ULTIMUS 5 are covered by the indications for use of the predicate device. Transesophageal and Intraoperative are not intended to be used with the subject device. The less indication for use of the subject device does not impact safety and effectiveness.

Note2: Patient Contact Materials.
The Patient Contact Materials of probes is equivalent to the predicated device, both the subject and predicated device probe material meet ISO 10993-1 and FDA guidance requirement. They can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

The subjected device and the predicted device are identical in the indications for use, patient population, use environment, biocompatibility and electrical safety. They are similar in technical specification. The differences between the proposed device and the predicate device will not raise any new issues of safety or effectiveness.

Summary of Non-clinical test:
The ULTIMUS Series were evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and have been found to comply with applicable medical device safety standard, The ULTIMUS Series complies with voluntary standards:

1. ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
2. IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
3. IEC/TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
4. IEC 60601-2-37 Edition 2.1 2015 Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
5. IEC62359, Ultrasonics-Field characterization- Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2017.

6. ISO10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
7. ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
8. ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
9. ISO10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation
10. ISO14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices
11. NEMAPS 3.1 - 3.20 2022d Digital Imaging and Communications in Medicine (DICOM) Set.
12. IEC60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
13. IEC62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION Medical devices - Part 1: Application of usability engineering to medical devices
14. IEC62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes
15. ISTA 3E 2017 Similar Packaged-Products in Unitized Loads for Truckload Shipment
16. IEC 62133-2:2017+AMD1:2021 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

Summary of Clinical Tests:
The subject of this premarket submission, did not require clinical studies to support substantial equivalence.

Conclusion:
VINNO Technology (Suzhou) Co., Ltd Considers the ULTIMUS Series Ultrasound Diagnostic System to be as safe, as effective, and performance is substantially equivalent to the predicate device.