June 17, 2023

VINNO Technology (Suzhou) Co., Ltd.
℅ Cordelia Liu
Regulatory Registered Engineer
5F Building A, 4F Building C No. 27 Xinfa Rd.
Suzhou Industrial Park
Suzhou, Jiangsu 215123
CHINA

Re: K223917
Trade/Device Name: VINNO E20, VINNO E10, VINNO E10P, VINNO E10E, VINNO X1, VINNO X1E, VINNO X1P, VINNO X2, VINNO X2E, VINNO X2P
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: April 12, 2023
Received: May 17, 2023

Dear Cordelia Liu:

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)*
K223917

Device Name
VINNO E20, VINNO E10, VINNO E10P, VINNO E10E, VINNO X1, VINNOX1E, VINNO X1P, VINNO X2, VINNO X2E, VINNO X2P

Indications for Use *(Describe)*
The device is intended for ultrasound imaging, measurement, display and analysis of the human body and fluid.

The operating modes supported by the device are B, M,PWD CWD, Tissue Doppler, Color Doppler, Color M Doppler, Power Doppler, Tissue Velocity Imaging, Harmonic Imaging, 3D/4D, Combine modes.

This device is indicated for Abdominal; Fetal; Obstetrics; gynecology;Trans-vaginal; Urology(including prostate); Trans-rectal; Cardiac(adult and pediatric); Peripheral Vascular; Small Organs/Parts(thyroid, breast, testicle); Musculo-skeletal(Conventional and Superficial); Pediatrics(including neonatal cephalic) and Adult Cephalic diagnostic Ultrasound applications.

This device is intended to use by, or by the order of, and under the supervision of an appropriately-trained healthcare professional qualified to direct the use of the device in hospitals or clinics.

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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Section 5 510(k) summary

K223917

I Submitter

Device submitter: VINNO Technology (Suzhou) Co., Ltd.
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Type text here

Date written：2023-06-15

II Device

Trade Name of Device: VINNO E20，VINNO E10，VINNO E10P，VINNO E10E，VINNO X1，VINNOX1E，VINNO X1P，VINNO X2，VINNO X2E，VINNO X2P

Regulation name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21 CFR 892.1550

Regulatory Class: II

Product code: IYN, IYO, ITX

III Predicate Device

Trade name: DC-30/DC-32/DC-28/DC-26/DC-25 Diagnostic Ultrasound System

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21 CFR 892.1550

Regulatory Class: II
Product code: IYN, IYO, ITX
Premarket Notification: k173369

IV Device description

VINNO E20，VINNO E10，VINNO E10P，VINNO E10E，VINNO X1，VINNOX1E，VINNO X1P，VINNO X2，VINNO X2E，VINNO X2P ultrasound devices are professional digital color ultrasonic diagnostic apparatus. It transmits ultrasound waves into the body tissues and displays the echo images of the tissues and blood flow accordingly.

V Indications for use

The device is intended for ultrasound imaging, measurement, display and analysis of the human body and fluid.

The operating modes supported by the device are B, M,PWD CWD, Tissue Doppler, Color Doppler, Color M Doppler, Power Doppler, Tissue Velocity Imaging, Harmonic Imaging, 3D/4D, Combine modes.

This device is indicated for Abdominal; Fetal; Obstetrics; gynecology;Trans-vaginal; Urology(including prostate); Trans-rectal; Cardiac(adult and pediatric); Peripheral Vascular; Small Organs/Parts(thyroid, breast, testicle); Musculo-skeletal(Conventional and Superficial); Pediatrics(including neonatal cephalic) and Adult Cephalic diagnostic Ultrasound applications.

This device is intended to use by, or by the order of, and under the supervision of an appropriately-trained healthcare professional qualified to direct the use of the device in hospitals or clinics.

VI Comparison of technological characteristics with the predicate device

The VINNO E20，VINNO E10，VINNO E10P，VINNO E10E，VINNO X1，VINNOX1E，VINNO X1P，VINNO X2，VINNO X2E，VINNO X2P ultrasound devices have the same technological characteristics and fundamental design as the predicate device. The VINNO E20，VINNO E10，VINNO E10P，VINNO E10E，VINNO X1，VINNOX1E，VINNO X1P，VINNO X2，VINNO X2E，VINNO X2P ultrasound devices and

the predicate device are all lap-top general purpose ultrasound devices designed to provide real-time images for diagnosis. The differences between the VINNO E20，VINNO E10，VINNO E10P，VINNO E10E，VINNO X1，VINNOX1E，VINNO X1P，VINNO X2，VINNO X2E，VINNO X2P ultrasound devices and predicate device do not alter suitability of the proposed device for its intended use.

The comparison and discussion between the subject device and the predicate device are listed in below table:

Device feature	**VINNO E20，VINNO E10，VINNO E10P，VINNO E10E，VINNO X1，VINNO X1E，VINNO X1P，VINNO X2，VINNO X2E，VINNO X2P(subject device)**	**Shenzhen Mindray Bio-medical Electronics Co.LTD DC-30 k173369 (predicate device)**
Indications for use	The device is intended for ultrasound imaging, measurement, display and analysis of the human body and fluid. The operating modes supported by the device are B, M,PWD CWD, Tissue Doppler, Color Doppler, Color M Doppler, Power Doppler, Tissue Velocity Imaging, Harmonic Imaging, 3D/4D, Combine modes. This device is indicated for Abdominal; Fetal; Obstetrics; gynecology;Trans-vaginal; Urology(including prostate); Trans-rectal; Cardiac(adult and pediatric); Peripheral Vascular; Small Organs/Parts(thyroid, breast, testicle); Musculo-skeletal(Conventional and Superficial); Pediatrics(including neonatal cephalic) and Adult Cephalic diagnostic Ultrasound applications. This device is intended to use by, or by the order of, and	Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ(breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans vaginal,musculo-skeletal(conventional, superficial), cardiac(adult, pediatric) , peripheral vessel and urology exams.

	under the supervision of an appropriately-trained healthcare professional qualified to direct the use of the device in hospitals or clinics.	
User qualification	Qualified healthcare professionals	Qualified physicians or sonographers
Physical Specification	Width:520mm； Depth: 835mm； Height: 1350mm； Keyboard：Adjustable：+120mm（E20 applies） Monitor：Adjustable：+150mm Weight: Basic unit without accessories approx: 55kg；	Height: 1265 ~ 1415mm (with adjustable height) ; 1315mm（without adjustable height） Width: 520mm ; Depth: 670 mm ; Weight:approx.55kg（with battery）;
Patient contact materials	Probe housing: ABS Probe lens: Silicon rubber Comply with ISO10993 series	Probe housing: ABS Probe lens: Silicon rubber Comply with ISO10993 series
Operating modes	B Mode、HAR Mode、CF Mode、PDI Mode、PW Mode、CW Mode、Tissue Doppler（TD）mode、Tissue velocity imaging（TVI）mode、M Mode、Color M（CM）mode、4D	B-Mode、Tissue Harmonic and PSH、M-Mode、Color Doppler Imaging 、 Power Doppler Imaging and Directional PDI、Pulsed Wave Doppler、Continuous Wave Doppler、Free Xros M、TDI、UWN、Natural Touch Elastography Imaging、Smart 3D、Real-time 4D、iScape View、Tissue Velocity/Energy Imaging
Operating controls	Gain、Depth、TCG slides controls、B steer、2D Automatic Optimazation 、 Harmonic Imaging 、 Frequency 、 Focus Position、Focus #、VFusion、VSpeckle、Dynamic Range、Line Density、L/R and U/D	B-Mode、THI and PSH、M-Mode、Color Doppler Imaging、Power Doppler Imaging and Directional PDI、Pulsed Wave Doppler、iClear、iBeam、iTouch、Zoom/iZoom、FCI、B steer、ExFOV Imaging、iStation、iVision、Integrated 1 TB and hard drive、3 active transducer connectors、DVD-RW driver、3 USB ports、Auto Doppler Calculation、Shared

		Service Package、Medsight、iStorage、Tutorial function、Smart Installment Reminder
Measurements	Distance（Lateral、Axial、Depth）、Perimeter（L&W、Ellipse、Polygon、Spline、Trace）、Area（L&W、Ellipse、Polygon、Spline、Trace）、Volume（L&W&H）、Angle、Time、Slope（Velocity、Acceleration）、SV Depth、Velocity、Angle Correction	Depth、Distance、Angle、Area（Ellipse、Trace、Spline、Cross）、Trace Length、Double Distance、Parallel、Volume（3-Distance、Ellipse、Ellipse+ Distance）、Length ratio、Area Ratio、IMT、B Histogram、B Profile、Volume Flow、Color Velocity、Time、Slope、Heart Rate、Velocity、Accleration、D Trace、PS/ED
Comments	Comments and bodymarks	Comments and bodymarks
Probe types	Convex array Linear array Phased array Volume convex array Endocavity array Micro convex array	Convex array Linear array Phased array
Display monitor	15.6 inch monitor	15-inch/17-inch high resolution clor LED monitor
Acoustic output	Comply with Track 3 limits: Ispta.3≤720mW/cm^2 MI≤1.9	Comply with Track 3 limits: Ispta.3≤720mW/cm^2 MI≤1.9
Conformity standards	IEC60601-1 IEC60601-1-2 IEC60601-2-37 NEMA UD 2	IEC60601-1 IEC60601-1-2 IEC60601-2-37 NEMA UD 2
Peripherals	Color thermal printer Black&White thermal printer	Analog Black/white video printer Analog Color video printer

	USB DVDRW ECG S-Video Output Cable Blutooth dongle Wireless adapter External Foot switch	Digital Black and White Video Printer Graph/text printer Footswitch ECG Built-in Battery Bulit-in DVD R/W

VII Performance data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

Biocompatibility of the probes was evaluated in accordance with ISO 10993-1:2009. All evaluation acceptance criteria were met.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Ultrasound System. The system complies with the IEC 60601-1 and IEC 60601-2-37 for safety and the IEC 60601-1-2 for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

Acoustic output testing

Acoustic output testing was performed according to NEMA UD2 and IEC60601-2-37.

VIII Conclusion

The VINNO E20，VINNO E10，VINNO E10P，VINNO E10E，VINNO X1，VINNOX1E，VINNO X1P，VINNO X2，VINNO X2E，VINNO X2P ultrasound devices are substantially equivalent to the predicate device. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.