December 21, 2022

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: K221911
Trade/Device Name: VINNO 6PRO, VINNO 6EXP, VINNO 5PRO, VINNO 5EXP, VINNO 3, VINNO 3PRO, VINNO 3EXP
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: November 9, 2022
Received: November 21, 2022

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)*
K221911

Device Name
VINNO 6EXP, VINNO 6PRO, VINNO 5EXP, VINNO 5PRO, VINNO 3, VINNO 3EXP, VINNO 3PRO

Indications for Use *(Describe)*
The device is general purpose diagnostic ultrasound system for use by qualified healthcare professionals. It is applicable for adults, pregnant women, pediatric patients and neonates.

The device is intended for ultrasound imaging, measurement and analysis of human body and fluid for multiple clinical applications including: abdominal (GYN and Urology), Thoracic/Pleural, Fetal/Ob, small organ (including breast, thyroid, testes), peripheral vessel, neonatal cephalic, adult cephalic, pediatric, musculo-skeletal (conventional, superficial), trans-rectal, trans-vaginal, cardiac adult, cardiac pediatric, magnetic Needle guidance and imaging guidance of interventional procedures (e.g. biopsy).

This device is intended to use by, or by the order of, and under the supervision of a licensed physician qualified to direct the use of the device.

The device is used in hospital, clinics and clinical point-of-care for diagnosis of patients. 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, CBI, EI, Combine modes.

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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K221911

Section 5 510(k) summary

I Submitter

Device submitter: VINNO Technology (Suzhou) Co., Ltd.
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Email: cordelia.liu@vinno.com

Date written：2022-12-19

II Device

Trade Name of Device: VINNO 6EXP，VINNO 6PRO，VINNO 5EXP，VINNO 5PRO，VINNO 3，VINNO 3EXP，VINNO 3PRO
Regulation name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1550
Regulatory Class: II
Product code: IYN, IYO, ITX

III Predicate Devices

Trade name: VINNO 8，VINNO 6，VINNO 5
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1550
Regulatory Class: II
Product code: IYN, IYO, ITX
Premarket Notification: k190120

IV Device description

The VINNO 6EXP，VINNO 6PRO，VINNO 5EXP，VINNO 5PRO，VINNO 3，VINNO 3EXP，VINNO 3PRO ultrasound devices are laptop digital color ultrasonic diagnostic devices which transmit ultrasound waves into the body tissues and display the echo images of the tissues and blood flow accordingly. The devices are capable of digital acquisition, processing and display and operate from an integrated battery or separate power supply/charger.

V Indications for use

The device is general purpose diagnostic ultrasound system for use by qualified healthcare professionals. It is applicable for adults, pregnant women, pediatric patients and neonates.

The device is intended for ultrasound imaging, measurement and analysis of human body and fluid for multiple clinical applications including: abdominal (GYN and Urology), Thoracic/ Pleural, Fetal/Ob, small organ (including breast, thyroid, testes), peripheral vessel, neonatal cephalic, adult cephalic, pediatric, musculo-skeletal (conventional, superficial), trans-rectal, trans-vaginal, cardiac adult, cardiac pediatric, magnetic Needle guidance and imaging guidance of interventional procedures (e.g. biopsy).

This device is intended to use by, or by the order of, and under the supervision of a licensed physician qualified to direct the use of the device.

The device is used in hospital, clinics and clinical point-of-care for diagnosis of patients. 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, CBI, EI, Combine modes.

VI Comparison of technological characteristics with the predicate devices

The VINNO 6EXP，VINNO 6PRO，VINNO 5EXP，VINNO 5PRO，VINNO 3，VINNO 3EXP，VINNO 3PRO ultrasound devices have the same technological characteristics and fundamental design as the predicate devices. The VINNO 8, VINNO 6, VINNO 5 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 8, VINNO 6, VINNO 5 ultrasound devices and predicate devices do not alter suitability of the proposed device for its intended use.

See the following table for details on the comparison of technical features with the predicate device：

Technological characteristics	Subject device	Predicate device	Comparison
Indications for use	The device is intended for ultrasound imaging, measurement and analysis of human body and fluid for multiple clinical applications including:	The device is intended for ultrasound imaging, measurement and analysis of human body and fluid for multiple clinical applications including:	No difference

	abdominal (GYN and Urology), Thoracic/Pleural, Fetal/Ob, small organ (including breast, thyroid, testes), peripheral vessel, neonatal cephalic, adult cephalic, pediatric, musculo-skeletal (conventional, superficial), trans-rectal, trans-vaginal, cardiac adult, cardiac pediatric, magnetic Needle guidance and imaging guidance of interventional procedures (e.g. biopsy).	abdominal (GYN and Urology), Thoracic/Pleural, Fetal/Ob, small organ (including breast, thyroid, testes), peripheral vessel, neonatal cephalic, adult cephalic, pediatric, musculo-skeletal (conventional, superficial), trans-rectal, trans-vaginal, cardiac adult, cardiac pediatric, magnetic Needle guidance and imaging guidance of interventional procedures (e.g. biopsy).	
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.	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.	The subject device was consistent with the predicate device in terms of design, material, chemical composition, and energy source, and there was no difference
Material	The probe materials based on the biocompatibility test were all composed of a shell and a lens, the probe of the predicate device could cover the subject device, and the probe materials passed the biocompatibility test.		
Chemical composition	NA Our device does not involve the composition of chemical.		
Energy source	This device can produce and use the radiation RF energy. Ultrasound system utilizes ultrasound energy that must be coupled to the patient by direct physical contact In order to assure optimal transmission of energy between the patient and probe, a conductive gel or couplant must be applied liberally to the patient where scanning will be performed.		
Imaging features	See Table 1 of the article for details		The imaging features of the subject device can be covered by the predicated device

Key functionalities	Gain, Depth, Focus, TGC, B Steer, 2D Automatic Optimization, Harmonic Imaging, L/R, U/D, Frequency, PRF, Wall Filter, Packet Size, Color Level, Invert, Color Map, Line Density, Sync Display, Persistence, Flash Reduction, Base Line, Transparency, Steer, Focus Position, Focus Number, VFusion, VSpeckle, Dynamic Range	Gain, Depth, Focus, TGC, B Steer, 2D Automatic Optimization, Harmonic Imaging, L/R, U/D, Frequency, PRF, Wall Filter, Packet Size, Color Level, Invert, Color Map, Line Density, Sync Display, Persistence, Flash Reduction, Base Line, Transparency, Steer, Focus Position, Focus Number, VFusion, VSpeckle, Dynamic Range	No difference
Measurements	Depth, Distance, Perimeter, Area, Volume, Angle, Stenosis, A/B ratio, Time, Speed, Heart Rate, Stenosis, A/B ratio, Acceleration, PS, ED, TAMAX, TAMEAN, RI, PI, PS.ED ratio, ED/PS ratio, Flow volume, MaxPG, MeanPG, Stroke Volume, Heart rate	Depth, Distance, Perimeter, Area, Volume, Angle, Stenosis, A/B ratio, Time, Speed, Heart Rate, Stenosis, A/B ratio, Acceleration, PS, ED, TAMAX, TAMEAN, RI, PI, PS.ED ratio, ED/PS ratio, Flow volume, MaxPG, MeanPG, Stroke Volume, Heart rate	No difference
Probes	Convex array Linear array Phased array	Convex array Linear array Phased array	The subject device was consistent with the predicate device in terms of probes
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	No difference

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 6EXP，VINNO 6PRO，VINNO 5EXP，VINNO 5PRO，VINNO 3，VINNO 3EXP，VINNO 3PRO ultrasound devices are substantially equivalent to their predicate devices. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.

Table 1

Product	***VINNO 8***	***VINNO 6EXP***	***VINNO 6PRO***	***VINNO 5EXP***	***VINNO 5PRO***	***VINNO 3EXP***	***VINNO 3***	***VINNO 3PRO***
2D Imaging Features								
Frequency range	25Mhz	25Mhz	25Mhz	25Mhz	25Mhz	25Mhz	25Mhz	25Mhz
VFusion	X	X	X	X	X	X	X	X
VSpeckle I	X	X	X	X	X	X	X	X
VTissue	X	X	X	O	O	O	O	O
Auto optimization	X	X	X	X	X	X	X	X
Easy Compare	X	X	X	X	X	X	X	X
Duplex/Triplex	X	X	X	X	X	X	X	X
CW Mode	X	X	X	O	-	-	-	-
PW Mode	X	X	X	X	X	X	X	X
Zoom	X	X	X	X	X	X	X	X
FULL screen	X	X	X	X	X	X	X	X
B Mode	X	X	X	X	X	X	X	X
M Mode	X	X	X	X	X	X	X	X
CF Mode	X	X	X	X	X	X	X	X
PDI Mode	X	X	X	X	X	X	X	X
B+CF simultaneously	X	X	X	X	X	X	X	X
TView	X	X	X	X	X	X	X	X
Pview	O	O	O	O	O	O	O	O
TD Mode	X	X	X	-	-	-	-	-
Tissue Velocity Imaging (TVI)	O	O	O	-	-	-	-	-
Auto IMT	X	X	X	O	O	O	O	O
Auto EF	O	O	O	O	O	O	O	O
Auto Bladder	X	X	X	X	X	X	X	X
Elastography	O	O	O	-	-	-	-	-
Contrast Agent imaging	O	-	-	-	-	-	-	-
Needle enhancement	O	O	O	O	O	O	O	O
SGC (Scanline gain compensation)	O	O	O	O	O	O	X	O
Stress Echo	X	X	O	O	O	X	O	O
Flow Volume	O	O	O	O	O	O	O	O

3D/4D Imaging Features								
3D imaging	X	X	X	X	X	X	X	X
Real-time grayscale 4D	X	X	X	X	X	X	X	X
Tomographic display (Mcut)	X	X	X	O	O	O	O	O
HQ (High Quality) 3D/4D	O	O	O	O	O	O	O	O
STIC Mode	O	O	O	-	-	-	-	-
Magic cut	X	O	O	O	O	O	O	O
Free view	X	O	O	O	O	O	O	O
Free 3D	O	O	O	O	O	O	O	O
Export 3D data for 3D printer	X	O	O	O	O	O	O	O