VINNO Technology (Suzhou) Co., Ltd.
℅ Ms. Sherry Zhang
Regulatory Affairs
5F Building A, 4F Building C No. 27 XinFa Rd.
Suzhou Industrial Park
Suzhou, Jiangsu 215123
CHINA

January 23, 2020

Re: K190120
Trade/Device Name: VINNO 8, VINNO 6, VINNO 5
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: December 6, 2019
Received: December 9, 2019

Dear Ms. Zhang:

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,

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

Indications for use

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190120

Device Name
VINNO 8, VINNO 6, VINNO5

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.

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

I Submitter

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

Contact person: Sherry Zhang
Regulatory Affairs
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Email: Sherry.Zhang@vinno.com

Date of preparation: Dec 5th, 2019

II Device

Trade Name of Device: 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

III Predicate Devices

Trade name: LOGIQ e
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1550
Regulatory Class: II
Product code: IYN, IYO, ITX
Premarket Notification: k151028

Trade name: CX50 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: k162329

Trade name: eZono™ 4000 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: k140254

IV Device description

The VINNO 8, VINNO 6, VINNO 5 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.

Mode of operations for each probe supported by the VINNO 8, VINNO 6, VINNO 5 ultrasound devices is listed in below table.

Probe	Mode of Operation														Device Model		
	B	M	PWD	CWD	Tissue Doppler	Color Doppler	Color M Doppler	Power Doppler	Tissue Velocity Imaging	Harmonic Imaging	3D/4D	CBI	EI	Combine modes[1]	VINNO 5	VINNO 6	VINNO 8
G2-5C	N	N	N			N	N	N		N		N	N	N			X
U5-15LE	N	N	N			N	N	N		N		N	N	N			X
S1-6P	N	N	N	N	N	N	N	N	N	N		N	N	N			X
F2-5C	N	N	N			N	N	N		N		N	N	N	X	X	X
F4-9E	N	N	N			N	N	N		N		N	N	N	X	X	X
G4-9M	N	N	N			N	N	N		N		N	N	N	X	X	X
F4-12L	N	N	N			N	N	N		N		N	N	N	X	X	X
D3-6C	N	N	N			N	N	N		N	N	N	N	N	X	X	X
G1-4P	N	N	N	N	N	N	N	N	N	N		N	N	N	X	X	X
X4-12L	N	N	N			N	N	N		N		N	N	N		X	X
X6-16L	N	N	N			N	N	N		N		N	N	N		X	X
X6-16LG	N	N	N			N	N	N		N		N	N	N		X	X

Note:

N = new indication; P = previously cleared by FDA

[1] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD;

The systems also provide for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

The VGuide NGS function detects the position and orientation of magnetized needles in

the presence of the probe and displays this information relative to the ultrasound image. Spatial positioning of the needle, with respect to the ultrasound image, is then updated in real time. This guides the operator to better visualize the needle in the ultrasound image during ultrasound guided needling procedures.

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 detail indications for use of each probe are listed below.

Transducer	Clinical Application																		
	Anatomy/Region of Interest												Exam Type, Means of Access					Interventional Guidance	
	Fetal	Abdominal	Pediatric	Small Organ [2]	Neonatal Cephalic	Adult Cephalic	Cardiac Adult	Cardiac Pediatric	Peripheral vessel	Musculo-skeletal (Conventional)	Musculo-skeletal (Superficial)	Thoracic/Pleural	Trans-rectal	Trans-vaginal	Trans-urethral	Transesophageal	Intraoperative	Vascular Access	Nonvascular [1]
G2-5C	N	N	N																N
U5-15LE		N	N	N					N	N	N								
S1-6P		N	N		N	N	N	N											N
X6-16L		N	N	N					N	N	N								N
X6-16LG		N	N	N					N	N	N								N
F2-5C	N	N	N																N
F4-9E	N	N											N	N					N
G4-9M		N	N		N		N	N											
F4-12L		N	N	N					N	N	N								N
X4-12L		N	N	N					N	N	N								N
D3-6C	N	N																	
G1-4P		N	N		N	N	N	N											N

Notes:

N = new indication; P = previously cleared by FDA

[1] Nonvascular means Biopsy Guidance

[2] Small organs include breast, testes, thyroid

VI Comparison of technological characteristics with the predicate devices

The VINNO 8, VINNO 6, VINNO 5 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.

Table 1 Substantial equivalence discussion

Device feature	**VINNO 8, VINNO 6, VINNO 5 (subject device)**	**GE Healthcare LOGIQ e k151028 (predicate device)**	**Philips CX50 Diagnostic Ultrasound System k162329 (predicate device)**
Indications for use	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).	The LOGIQ e is intended for ultrasound imaging, measurement and analysis of the human body for multiple clinical applications including: ophthalmic: fetal/ob; abdominal (gyn & urology); pediatric; small organ (breast, testes, thyroid); neonatal and adult cephalic; cardiac (adult & pediatric); peripheral vascular; musculoskeletal conventional & superficial; transrectal; transvaginal; transesophageal; intraoperative (abdominal, thoracic and peripheral); thoracic/pleural for motion and fluid detection and imaging guidance of interventional procedures (e.g. Nerve block; vascular access).	Ophthalmic, Intraoperative, Laparascopic, Fetal, Abdominal, Pediatric, Small Organ, Adult Cephalic, Neonatal Cephalic, Trans-vaginal, Musculoskeletal, Gynecological, Cardiac Adult, Cardiac Pediatric, Trans-esoph, Intracardiac echo, Peripheral Vessel, Other (Carotid)
User	Qualified healthcare	Qualified physicians or	Qualified physicians or

qualification	professionals	sonographers	sonographers
Physical Design	Laptop design with lithium battery, also available to be used with a mobile cart 1 probe port	Laptop design with lithium battery, also available to be used with a mobile cart 1 probe port	Laptop design with lithium battery, also available to be used with a mobile cart 1 probe port
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	Probe housing: ABS Probe lens: Silicon rubber Comply with ISO10993 series
Operating modes	B, M, Color Flow, PDI, PWD, CWD, Harmonic, 3D/4D, Color M, Elastography, TVI/TVD, Contrast agent imaging	B, M, M-Color Flow, Anatomical M, Color Anatomical M, CFM, PDI, High-Res PDI, CWD, PWD, TVI/TVD, Needle Recognition, 3D	B, M, Anatomical M, Color M, Color, CWD, Harmonic, PDI, PWD, TDI, Power/Dirpower, 3D/4D, Elastography, Stress Echo, Contrast agent imaging
Operating controls	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	Depth, Gain, Focus, Auto Optimize, MD cursor, Frequency, CrossXBeam, TGC, Tilt, Reserve, Dynamic Range, Line Density, Grey Maps, Frame Average, Colorize, Edge Enhance, Steer, Rotation, Virtual Convex, SRI HD, Virtual Apex, Centerline, Rejection, Suppression, Scan Area, LOGIQ View, Fusion Background Area,	Depth, Gain, Dynamic Range, TGC, Angle, Color Gain, Wall Filter, Baseline, Sweep Speed, Doppler DR, Colorize, iBeam, iClear, TSI, Sync Display, Steer, Focus Position, Focus Number, iTouch
Measurements	Depth, Distance, Perimeter, Area,	Depth, Distance, Circumference,	Depth, Distance, Circumference,

	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	Area, Angle, Stenosis, A/B ratio, Slope, Heart Rate, Velocity, Time, Acceleration, Frequency, TAMAX, TAMEAN, RI, PI, Ratios, Heart rate, Auto Doppler Trace function with automatic calculations	Area, Time, Heart Rate, Angle, Stenosis, A/B ratio, Volume, Auto volume measurements, Auto NT measurements, Auto OB measurement, Color Speed, Orthopaedic surgery
Comments	Comments and bodymarks	Comments and bodymarks	Comments and bodymarks
Probe types	Convex array Linear array Phased array	Convex array Linear array Sector array	Curved array Linear array Phased array
Display monitor	15.6 inch LCD monitor	15 inch LCD monitor	15.6 inch LCD 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	Comply with Track 3 limits: Ispta.3≤720mW/cm^2 MI≤1.9
Conformity standards	IEC6061-1 IEC60601-1-2 IEC60601-2-37 NEMA UD 2	IEC6061-1 IEC60601-1-2 IEC60601-2-37 NEMA UD 2	IEC6061-1 IEC60601-1-2 IEC60601-2-37 NEMA UD 2
Peripherals	LAN, USB storage device, HDMI, Footswitch, Printers, ECG lead, Mobile Cart, USB Bluetooth	LAN, USB storage device, HDMI, Footswitch, Printers, USB ECG, Barcode Scanner, External DVD R/W, Mobile Cart	LAN, USB storage device, HDMI, Footswitch, Printers, USB ECG, Barcode Scanner, External DVD R/W, Mobile Cart

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 8, VINNO 6, VINNO 5 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.