April 2, 2026

Xuzhou Yongkang Electronic Science Technology Co., Ltd.
% Rachel Yu
Official Correspondent
ZHIHE Info-Tech Co., Ltd.
Room 616, Building 1, No. 1 Huayun Road, Industrial Park
Suzhou, Jiangsu 215134
CHINA

Re: K252709
Trade/Device Name: Wireless Probe Type Ultrasound Scanner
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: August 25, 2025
Received: August 27, 2025

Dear Rachel Yu:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Digitally signed by
Kaitlyn Mcdonald -S for

Yanna Kang, Ph.D.
Assistant Director
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
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.

510(k) Number *(if known)*
K252709

Device Name
Wireless Probe Type Ultrasound Scanner

Indications for Use *(Describe)*

The Wireless Probe Type Ultrasound Scanner is a portable and software-based ultrasound imaging system, indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications:
PIU1A,PEU1A,PIU1C,PEU1C,PAU2C: Small Organ, Musculo-skeletal(Conventional and Superficial) , Peripheral vessels
PIU1B,PEU1B: Fetal, Abdominal, Pediatric, Ob/GYN, Urology;
PIU1D,PEU1D: Fetal, Abdominal, Pediatric, Ob/GYN, Urology, Cardiac Adult, Cardiac Pediatric;
PIU2A,PEU2A, PAU2A: Small Organ, Musculo-skeletal(Conventional and Superficial) , Peripheral vessels, Fetal, Abdominal, Pediatric, Ob/GYN, Urology;
PIU2B,PEU2B, PAU2B: Small Organ, Musculo-skeletal(Conventional and Superficial), Peripheral vessels, Fetal, Abdominal, Pediatric, Ob/GYN, Urology, Cardiac Adult, Cardiac Pediatric;

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
K252709

I Submitter

Device Submitter:	Xuzhou Yongkang Electronic Science Technology Co., Ltd.
Address:	2nd & 3rd Floor, Building 5, Block B, Huaihai Biomedical Industry Park, No. 5 Tengzhai North Road, Xuzhou High-tech Industrial Development Zone, Xuzhou, Jiangsu 221000, P.R. China
Contact Person:	Xiao Wan Title: +86 150 6214 9600 E-mail: wanxiao@yonker.cn
Date Prepared:	March 10, 2026

II Device

Trade/Device Name:	Wireless Probe Type Ultrasound Scanner
Regulation Number:	21 CFR 892.1550
Regulation Name:	Ultrasonic pulsed doppler imaging system
Regulation Class:	Class II
Product code:	IYN, ITX, IYO
Review Panel:	Radiology

III Predicate Device

Items	Device Name	510(k) Number
Primary Predicate	NUSONO Handheld Ultrasound Scanner (NUSONO-C35); NUSONO Handheld Ultrasound Scanner (NUSONO-L75); NUSONO Handheld Ultrasound Scanner (NUSONO-P25)	K242681
Reference	Leltek Ultrasound Imaging System (Model: LU700 Series)	K222365
Reference	Clarius Ultrasound Scanner	K192107
Reference	SonoMe Wireless Probe Type Ultrasound Scanner (Model: 5C, 5CB, H5C, 10L, 14L, 10LB, H10L, H5C10L) and SonoFinder Wireless Probe Type Ultrasound Scanner (Model: SF14L25)	K220169

IV Description of the Device:

The Wireless Probe Type Ultrasound Scanner is a portable, software-controlled diagnostic ultrasound system used to acquire and display high-resolution, real-time ultrasound data through an off-the-shelf (OTS) Windows 11 Pro, Android 10 or higher, and iOS 17.6.1 or higher based mobile or PC device. The system consists of a series of wireless transducers employing Wi-Fi-based technology to communicate with the Wireless Probe Type Ultrasound Scanner App on standard smartphone, tablet, or PC devices via direct Wi-Fi connection, with Bluetooth supported for device discovery. The application provides the interface for mode/setting control and image display, acquisition, measurement, and storage functions. The 32-channel digital beamformer with 96 or 128 array elements (depending on the probe model) and advanced image signal processing technology maximize the performance of all imaging

transducer elements to enhance diagnostic utility and confidence.

This transportable system is intended for use in environments where healthcare is provided by trained healthcare professionals. Intended users will be qualified and appropriately trained healthcare professionals with ultrasound experience.

The Wireless Probe Type Ultrasound Scanner product includes:

a) Scanner models:
   - PIU1A; PIU1B; PIU1C; PIU1D; PIU2A; PIU2B
   - PEU1A; PEU1B; PEU1C; PEU1D; PEU2A; PEU2B
   - PAU2A; PAU2B; PAU2C

b) Components:
   - Software:
     - Wireless Probe Type Ultrasound Scanner App for Windows 11 Pro and compatible
     - Wireless Probe Type Ultrasound Scanner App for Android 10 or higher
     - Wireless Probe Type Ultrasound Scanner App for iOS 17.6.1 or higher
   - Wireless charging dock
   - USB Type-C charging cable (integrated with charging dock)
   - Power adapter

V Intended Use of the Device

Diagnostic ultrasound imaging and fluid flow analysis of the human body.

Indication for Use:

The Wireless Probe Type Ultrasound Scanner is a portable and software-based ultrasound imaging system, indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications:

PIU1A,PEU1A,PIU1C,PEU1C,PAU2C: Small Organ, Musculo-skeletal(Conventional and Superficial) , Peripheral vessels

PIU1B,PEU1B: Fetal, Abdominal, Pediatric, Ob/GYN, Urology;

PIU1D,PEU1D: Fetal, Abdominal, Pediatric, Ob/GYN, Urology, Cardiac Adult, Cardiac Pediatric;

PIU2A,PEU2A, PAU2A: Small Organ, Musculo-skeletal(Conventional and Superficial) , Peripheral vessels, Fetal, Abdominal, Pediatric, Ob/GYN, Urology;

PIU2B,PEU2B, PAU2B: Small Organ, Musculo-skeletal(Conventional and Superficial), Peripheral vessels, Fetal, Abdominal, Pediatric, Ob/GYN, Urology, Cardiac Adult, Cardiac Pediatric

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The Wireless Probe Type Ultrasound Scanner provides diagnostic ultrasound imaging in B mode, M mode, Color Doppler mode, PW mode and combine mode (B+M,B+PW,B+CF,B+PDI,B+DPDI,B+PW+CF), intended for use in environments where healthcare is provided by trained healthcare professionals. The environments where the system can be used include physician offices, clinics, hospitals, and clinical point of care for diagnosis of patients except environments where intensity of electromagnetic disturbances is high.

VI Determination of SE

The subject device, " Wireless Probe Type Ultrasound Scanner," is a Track 3 system that utilizes the same fundamental scientific technology as the primary predicate device, NUSONO Handheld Ultrasound Scanner (NUSONO-C35); NUSONO Handheld Ultrasound Scanner (NUSONO-L75); NUSONO Handheld Ultrasound Scanner (NUSONO-P25)(K242681),along with the reference devices: Leltek Ultrasound Imaging System (Model: LU700 Series (K222365), Clarius Ultrasound Scanner (K192107), and SonoMe Wireless Probe Type Ultrasound Scanner/H5C10L (K220169). The Wireless Probe Type Ultrasound Scanner shares identical indications for use with the primary predicate device and at least one model of the reference devices. A detailed comparison between the predicate device and the subject device is provided below:

Items	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device
510k number	Current submission	K242681	K222365	K192107	K220169
Device name	Wireless Probe Type Ultrasound Scanner	NUSONO Handheld Ultrasound Scanner (NUSONO-C35); NUSONO Handheld Ultrasound Scanner (NUSONO-L75); NUSONO Handheld Ultrasound Scanner (NUSONO-P25)	Leltek Ultrasound Imaging System (Model: LU700 Series)	Clarius Ultrasound Scanner	SonoMe Wireless Probe Type Ultrasound Scanner / H5C10L
Product code	IYN, IYO, ITX	IYN, IYO, ITX	IYN, IYO, ITX	IYN, IYO, ITX	IYN, IYO, ITX
Intended use	Diagnostic ultrasound imaging and fluid flow analysis of the human body.	Diagnostic ultrasound imaging and fluid flow analysis of the human body.	Diagnostic ultrasound imaging or fluid flow analysis of the human body.	Diagnostic ultrasound imaging and fluid flow analysis.	SonoMe is indicated for examining the adult, pregnant woman, and children. This products is intended for use by, or by the order of, and under the supervision of, a licensed physician who is qualified for direct use of medical devices. An appropriately trained healthcare professionals can have operator qualifications. The device use settings are intended in hospital clinic, and medical office settings. The general clinical applications include fetal/obstetrics(OB), gynecology(GYN), abdominal, small organ and peripheral vessel imaging. The modes of operation are B-mode, PDI(Power Doppler Imaging) mode, PW(Pulse Wave Spectral Doppler) mode and Harmonic mode.
Indications for use	- - Fetal - Abdominal - - Pediatric - Small organ - - - Musculoskeletal (conventional)	- - Fetal - Abdominal - - Pediatric - Small organ - - - Musculoskeletal (conventional)	- Ophthalmic - Fetal - Abdominal - - Pediatric - Small organ - Neonatal cephalic - - Musculoskeletal (conventional)	- - Fetal - Abdominal - Intra-operative - Pediatric - - - Adult cephalic -	- - Fetal - Abdominal - - - Small organ - - -

Items	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device
	- Musculoskeletal (superficial) - Urology -Obstetrics(OB)/ Gynecology(GYN) - Cardiac adult - Cardiac pediatric - Peripheral vessel - - -	- Musculoskeletal (superficial) - Urology - Gynecology - Cardiac adult - Cardiac pediatric - Peripheral vessel - Carotid - Lung -	- Musculoskeletal (superficial) - - - Cardiac adult - Cardiac pediatric - Peripheral vessel - Carotid - Pulmonary - interventional guidance(includes free handneedle/catheter)	Musculoskeletal(conventional) - - Urology - Gynecology - Cardiac adult - Cardiac pediatric - Peripheral vessel - -	- - - Obstetrics(OB) , Gynecology(GYN) - - - Peripheral vessel - -
Modes of operation	- B mode - M mode - Color Doppler - - PW - Combined mode (B+M, B+PW, B+ Color Doppler, B+PDI, B+DPDI, B+PW+ Color Doppler mode)	- B mode - M mode - Color doppler (CD) - Power doppler(PD) - - - Combined mode (B+M, B+CD, B+PD)	- B mode - M mode - Color doppler (CD) - Power doppler(PD) - PWD - - Combined mode (B+M, B+CD,B+PWD)	- B mode - M mode - Color doppler (CD) - Power doppler(PD) - PWD - - Combined mode (B+M, B+CD,B+PD, B+PWD)	- B mode - B/M mode - Color - PDI - PW - -
Wireless capability	Wi-Fi Bluetooth	Wi-Fi	Wi-Fi	Wi-Fi Bluetooth	Wireless
Transducer types	- Convex(PIU1B, PEU1B, PIU1D, PEU1D,) - Linear (PIU1A, PEU1A, PIU1C, PEU1C, PAU2C) - - Convex & Linear (PIU2A, PEU2A, PIU2B, PEU2B, PAU2A, PAU2B)	- Convex (NUSONO-C35) - Linear (NUSONO-L75) - Phased array (NUSONO-P25) -	- - Linear(LU710L) - Phased array(LU710PA) -	- Convex(C3 HD) - -	- - - Convex & Linear
Power source	Rechargable battery (Li-ion)	Rechargable battery (Li-ion)	Rechargable battery (Li-ion)	Rechargable battery (Li-ion)	Rechargable battery
Display	iOS or Android mobile device and Windows	iOS or Android mobile device	iOS or Android mobile device and Windows	iOS or Android mobile device	iOS / Android /Windows
510(k) Track	Track 3	Track 3	Track 3	Track 3	Track 3
Standards	- IEC 60601-1 (2020) - IEC 60601-1-2(2020) - IEC 60601-1-6(2020) - - IEC 60601-2-37(2015) - IEC TS 60601-4-2(2024) - - - IEC 62359(2017) - IEC 62133-2 (2022) - IEC 62366-1 (2020)	- IEC 60601-1 (2020) - IEC 60601-1-2(2020) - IEC 60601-1-6(2020) - - IEC 60601-2-37(2015) - IEC 60601-4-2(2016) - UD 2-2004 (R2009) - - - IEC 62133-2 (2017) - IEC 62366-1 (2020)	- ANSI/AAMI ES60601-1 (2012) - IEC 60601-1-2 (2014) - IEC 60601-1-6 (2013) - - IEC 60601-2-37(2015) - - UD 2-2004 (R2009) - UD 3-2004 (R2009) - - IEC 62133 (2012) - IEC 62366 (2014)	- ANSI/AAMI ES60601-1 (2012) - IEC 60601-1-2 (2014) - IEC 60601-1-6 (2013) - IEC 60601-1-12 (2014) - IEC 60601-2-37 (2015) - - UD 2-2004 (R2009) - - IEC 62133 (2012) -	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-37

Items	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device
	- ISO 10993-1 (2018) - - - - - IEC 62304 (2015) - ISO 15223-1 (2021) - ISO 14971 (2019) - ISO 13485 (2016)	- ISO 10993-1 (2018) - ISO 10993-5 (2009) - ISO 10993-10 (2021) - - ISO 10993-23 (2021) - IEC 62304 (2015) - ISO 15223-1 (2021) - ISO 14971 (2019) - ISO 13485 (2016	- ISO 10993-1 (2009) - ISO 10993-5 (2009) - ISO 10993-10 (2010) - - - IEC 62304 (2006) - ISO 15223-1 (2016) - ISO 14971 (2019) - ISO 13485 (2016)	- - ISO 10993-5 (2009) - ISO 10993-10 (2010) - ISO 10993-11 (2017) - - IEC 62304 (2006) - ISO 15223-1 (2012) - ISO 14971 (2007) -	

The subject device provides additional combined modes (e.g., B+PW+Color Doppler, B+PDI, B+DPDI) that are not fully covered in all predicate devices. However, these combined modes are constructed solely from individual imaging modes (B-mode, M-mode, Color Doppler, Power Doppler, PW Doppler) that are already present in the predicates. The combination does not introduce new diagnostic functionality but instead facilitates user workflow by enabling simultaneous display. Since the underlying acoustic output and image generation remain unchanged from the individual modes, these differences do not raise new questions of safety or effectiveness, and the subject device is therefore considered substantially equivalent with respect to modes of operation.

The subject device conforms to IEC 62359:2017 for the measurement and calculation of acoustic output indices (MI, TI), whereas the predicate devices list compliance with UD 2-2004 (R2009) and UD 3-2004 (R2009). IEC 62359:2017 is internationally recognized and encompasses the same technical principles as UD 2/UD 3, providing equivalent requirements for acoustic output characterization and display. Therefore the difference in standards does not raise new questions of safety or effectiveness.

As a result, it is reasonable to conclude that subject device (Wireless Probe Type Ultrasound Scanner) is substantial equivalent with predicate device.

VI Non-clinical Performance Test

The subject device was tested/analyzed according to the following standards in order to ensure its effectiveness and safety:

Test	Title/Test Method Summary	Result
Thermal, Electrical, and Mechanical Safety		
Electrical Safety	IEC 60601-1	Pass
Electromagnetic Compatibility	IEC 60601-1-2 ANSI AAMI IEC 60601-1-2 IEC TS 60601-4-2	Pass
Battery Safety	IEC 62133-2	Pass
Wireless Coexistence	ANSI IEEE USEMCSC C63.27	Pass
FCC Certification	FCC 15, FCC 18	Certified
Acoustic Output	IEC 60601-2-37 IEC 62359	Pass, Track 3
Software Verification and Validation		
Software Verification and Validation	IEC 62304	Pass
Cybersecurity		
Cybersecurity Assessment and testing	Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions	Pass
Non-Clinical Verification Testing		
Measurement Accuracy	Internal test methods	Pass

VII Clinical Performance Test

The Wireless Probe Type Ultrasound Scanner did not require clinical testing to establish substantial equivalence.

VIII Conclusion

The Wireless Probe Type Ultrasound Scanner is substantially equivalent to the predicate device. The Wireless Probe Type Ultrasound Scanner functions in a manner similar to and is intended for the same use as the predicate device. Based on the predicate device comparison of indications for use, acoustic output and general safety and effectiveness information, as well as the non-clinical performance test results, it is concluded that this device is as safe and effective as the predicate device for its intended use and performance, and is substantially equivalent to the predicate device.