June 17, 2025

Wuxi Hisky Medical Technologies Co., Ltd.
Defang Liao
RA
Room B401, 530 Plaza, University Science Park
Taihu International Science & Technology Park
Wuxi, Jiangsu 214135
CHINA

Re: K243880
Trade/Device Name: Shear Wave Quantificational Ultrasound Diagnostic System (Mini900, Mini990, Mini800, Mini790, Mini780, Mini560, Mini300, Mini100, FT100)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, IYN, ITX
Dated: May 16, 2025
Received: May 16, 2025

Dear Defang Liao:

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
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DHT8C: Division of Radiological
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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)*
K243880

Device Name
Shear Wave Quantificational Ultrasound Diagnostic System (Mini900, Mini990, Mini800, Mini790, Mini780, Mini560, Mini300, Mini100, FT100)

Indications for Use *(Describe)*
Shear Wave Quantificational Ultrasound Diagnostic System, Transient Elastography based device, is intended to provide 50Hz shear wave speed measurements and estimates of tissue stiffness as well as Ultrasound Attenuation Parameter (UAP) in internal structures of the body.
Shear Wave Quantificational Ultrasound Diagnostic System is indicated as a non-invasive aid for the clinical management, diagnosis, and monitoring of adult and pediatric patients with confirmed or suspected liver disease, as part of an overall assessment of the liver. Results in the pediatric population should be interpreted while considering the clinical condition and the overall patient profile
Shear Wave Quantificational Ultrasound Diagnostic System is intended for general purpose pulse echo ultrasound imaging and Doppler flow analysis of the human body. It can be used in the following applications: Abdominal, including locating of the liver.
The system must be operated by qualified and appropriately trained healthcare professionals in a professional healthcare facility environment.

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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K243880

510(k) Summary

Date of Preparation: 2025.6.13

1.Submission sponsor

Name: Wuxi Hisky Medical Technologies Co., Ltd.

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2.Identification of Proposed Device

Trade Name	Shear Wave Quantificational Ultrasound Diagnostic System
Common Name	Diagnostic Ultrasound System and Accessories
Model Name	Mini900, Mini990, Mini800, Mini790, Mini780, Mini560, Mini300, Mini100, FT100
Classification name	1) Ultrasonic Pulsed Echo Imaging System 2) Diagnostic Ultrasound Transducer 3) Ultrasonic Pulsed Doppler Imaging System
Classification	Class II
Regulation number	21 CFR 892.1560 & 21 CFR 892.1570 & 21 CFR 892.1550
Product Code	IYO, ITX , IYN

3.Identification of Predicate Device

Trade Name	Shear Wave Quantificational Ultrasound Diagnostic System
Common Name	Diagnostic Ultrasound System and Accessories
Model Name	FT9000, Mini800,FT100
510(k) number	K200136
Classification name	1) Ultrasonic Pulsed Echo Imaging System; 2) Diagnostic Ultrasound Transducer; 3) Ultrasonic Pulsed Doppler Imaging System
Classification	Class II
Regulation number	21 CFR 892.1560 & 21 CFR 892.1570 & 21 CFR 892.1550
Product Code	IYO, ITX , IYN
Manufacture	Wuxi Hisky Medical Technologies Co., Ltd.

4.Device Description

The proposed device is a general purpose, mobile, software-controlled, diagnostic ultrasound system. It consists of a fibrosis scanning probe, an imaging probe, a main unit, a probe holder,an AC/DC adapter and a foot switch. The

fibrosis scanning probe is a single element probe used for elasticity measurement, while the imaging probe is a convex probe used for ultrasound imaging. The system uses transient elastography to measure shear wave speed non-invasively and estimates of tissue stiffness as well as Ultrasound Attenuation Parameter (UAP) in internal structures of the body. A mechanical vibrator in the fibrosis scanning probe produces low-frequency shear waves at 50 Hz that travel through the skin and intercostal space into the liver. The propagation speed of the shear wave is captured using ultrasound at 2.5 MHz. Under imaging mode, the system acquires and displays ultrasound images in B,M,CFM,PWD modes. The system uses imaging probe with nominal Frequency of2.5-4.5 MHZ on abdomen for general purpose pulse echo ultrasound imaging and Doppler flow analysis of the human body. The ultrasonic imaging also helps to find a proper location for the transient elastography examination.

There are a total of 9 models in this product, all of which share the same intended use, physical design and principle of technology. The only differences among these models are software functions configuration and availability of imaging probe.

5.Indication for use

Shear Wave Quantificational Ultrasound Diagnostic System, Transient Elastography based device, is intended to provide 50Hz shear wave speed measurements and estimates of tissue stiffness as well as Ultrasound Attenuation Parameter (UAP) in internal structures of the body.

Shear Wave Quantificational Ultrasound Diagnostic System is indicated as a non-invasive aid for the clinical management, diagnosis, and monitoring of adult and pediatric patients with confirmed or suspected liver disease, as part of an overall assessment of the liver. Results in the pediatric population should be interpreted while considering the clinical condition and the overall patient profile

Shear Wave Quantificational Ultrasound Diagnostic System is intended for general purpose pulse echo ultrasound imaging and Doppler flow analysis of the human body. It can be used in the following applications: Abdominal, including locating of the liver.

The system must be operated by qualified and appropriately trained healthcare professionals in a professional healthcare facility environment.

6.Substantially Equivalent (SE) Comparison

The following tables show the comparison results between subject device and predicate device and the differences between the subject device and the predicate device has been analyzed for risks in the safety and effectiveness of subject device.The comparison results show that the the subject device is determined to be Substantially Equivalent (SE) to the predicate device.

Table 2 Comparison of subject device with predicate device

Comparison item	Subject device	Predicate device(K200136)	Discussion
Device Model	Mini900, Mini990, Mini800, Mini790, Mini780, Mini560, Mini300, Mini100, FT100	FT9000,FT100,Mini800,	/
Product Code	IYO, ITX ,IYN	IYO ,ITX ,IYN	**Same**
Regulation Number	21 CFR 892.1560 & 21 CFR 892.1570 & 21 CFR 892.1550	21 CFR 892.1560 & 21 CFR 892.1570 & 21 CFR 892.1550	**Same**
Indication for use	Shear Wave Quantificational Ultrasound Diagnostic System, Transient Elastography based device, is intended to provide 50Hz shear wave speed measurements and estimates of tissue stiffness as well as Ultrasound Attenuation Parameter (UAP) in internal structures of the body. Shear Wave Quantificational Ultrasound Diagnostic System is indicated as a non-invasive aid for the clinical management, diagnosis, and monitoring of adult and pediatric patients with confirmed or suspected liver disease, as part of an overall assessment of the liver. Results in the pediatric population should be interpreted while considering the clinical condition and the overall patient profile Shear Wave Quantificational Ultrasound Diagnostic System is intended for general purpose pulse echo ultrasound imaging and Doppler flow analysis of the human body. It can be used in the following applications: Abdominal, including locating of the liver. The system must be operated by qualified and appropriately trained healthcare professionals in a professional healthcare facility environment.	Shear Wave Quantificational Ultrasound Diagnostic System (Models: FT9000, FT100 and Mini800), Transient Elastography based device, is intended to provide 50Hz shear wave speed measurements and estimates of tissue stiffness as well as Ultrasound Attenuation Parameter (UAP) in internal structures of the body. Shear Wave Quantificational Ultrasound Diagnostic System (Models: FT9000, FT100 and Mini800), is indicated for noninvasive measurement in the liver of 50 Hz shear wave speed and estimates of stiffness as well as Ultrasound Attenuation Parameter (UAP). The shear wave speed and stiffness, and UAP may be used as an aid to diagnosis and monitoring of patients with liver disease, as part of an overall assessment of the liver. Shear Wave Quantificational Ultrasound Diagnostic System (Models: FT9000), is intended for general purpose pulse echo ultrasound imaging and Doppler flow analysis of the human body. It can be used in the following applications: Abdominal, including location of the liver.	**Same** Both the subject device and the predicate device are used for: a.Liver stiffness measurement; b.Attenuation Parameter measurement c.General purpose pulse echo ultrasound imaging and Doppler flow analysis.

Fibrosis Scanning Probe	Model name	XW-01	Mini800:XW-01 FT9000,FT100: FT-2.5D9	/
	Nominal Frequency	2.5 MHz	2.5 MHz	**Same**
	Mode	A mode and M mode	A mode and M mode	**Same**
	Type	Single element transducer	Single element transducer	**Same**
	Source of Mechanical Vibration	External electromechanical Vibrator	External electromechanical Vibrator	**Same**
	Ultrasound Source	Piezoelectric ultrasound source	Piezoelectric ultrasound source	**Same**
	Function	a.Stiffness measurement of live b.UAP measurement of liver	a.Stiffness measurement of liver b.UAP measurement of liver	**Same**
	TE measurement depth	15-85mm	15-85mm	**Same**
Imaging Probe	Model name	YD-U	FT9000: FT-3.5R65	/
	Nominal Frequency	3.5 MHz	3.5 MHz	**Same**
	Mode	B, CFM,PWD,M	B, B/B, B/D, CFM and PWD mode	**Similar:** The subject device has broader range of application of M mode, which is a wildly used mode in ultrasound device. Therefore, the difference doesn't raise different questions of safety and effectiveness than the predicate device.
	Type	Multiple array element transducer	Multiple array element transducer	**Same**
	Ultrasound Source	Piezoelectric ultrasound source	Piezoelectric ultrasound source	**Same**
	Function	a. locating of live ; b. General purpose pulse echo ultrasound imaging and Doppler flow analysis of the human body	a. locating of liver ; b. General purpose pulse echo ultrasound imaging and Doppler flow analysis of the human body	**Same**

TE display		Liver Shear wave speed (0.8-5.2m/s) Liver Stiffness (2.0-80 kPa) Interquartile range (IQR) and IQR/median ratio	Liver Shear wave speed (0.8-5.2 m/s) Liver Stiffness (2.0-80 kPa) Interquartile range (IQR) and IQR/median ratio	**Same**
TE Bias	Liver stiffness	(-2.1%) – (3.5%)	FT9000:(-4.7%) - (2.4%) Mini800:(-5.3%)– (1.2%) FT100:(-2.1%) – (3.5%)	**Similar** Both the subject device and the predicate device have similar performance parameters in terms of liver stiffness and the difference is slight and doesn't raise different questions of safety and effectiveness than the predicate device.
TE Precision	Liver stiffness	(0.0%) – (3.8%)	FT9000:(0.0%) – (1.6%) Mini800:(0.0%) – (1.8%) FT100: (0.0%) – (3.8%)	
UAP display		UAP (90-450 dB/m) Interquartile range (IQR) and IQR/median ratio	UAP (90-450 dB/m) Interquartile range (IQR) and IQR/median ratio	**Same**
UAP Bias		(-1.6%) – (6.5%)	FT9000:(-3.3%) – (2.0%) Mini800:(-6.9%) - (4.8%) FT100: (-1.6%) – (6.5%)	**Similar** Both the subject device and the predicate device have similar performance parameters and the difference is slight and doesn't raise different questions of safety and effectiveness than the predicate device.
UAP Precision		(0.3%) – (2.0%)	FT9000:(0.2%) – (1.5%) Mini800:(0.2%) – (2.0%) FT100: (0.3%) – (2.0%)	

7.Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards and regulations:

1) Biocompatibility

- ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2021 Biological evaluation of medical devices – Part 10: Tests for skin sensitization
- ISO 10993-23:2021 Biological evaluation of medical devices – Part 23: Test for irritation

2) Reprocessing

- FDA Guidance for industry and Food and Drug Administration Staff Reprocessing medical devices in healthcare setting: Validation Methods and Labeling
- 17664-2:2021: Processing of health care products — Information to be provided by the
- medical device manufacturer for the processing of medical devices —Part 2:Non-critical medical devices

3) EMC

- IEC 606601-1-2:2014/AMD1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essentialperformance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC TR 60601-4-2:2024 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagneticimmunity: performance of medical electrical equipment and medical electrical systems

4) Electrical Safety and essential performance

- IEC 60601-1 :2005+A1:2012+A2:2020 Medical electrical equipment Part 1: General requirements for basic safety and essentialperformance
- IEC 60601-2-37:2015 Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 62359:2017 Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields

5) Lithium Battery safety

- IEC 62133-2:2021 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

6) Ultrasound Performance

- Marketing Clearance of Diagnostic Ultrasound Systems and Transducers Guidance for Industry and Food and Drug Administration Staff :2023

7) Software function

- IEC 62304-2015 Medical device software Software life cycle processes
- General Principles of Software Validation Final Guidance for Industry and FDA Staff: 2002
- Content of Premarket Submissions for Device Software Functions Guidance for Industry and Food and Drug Administration Staff: 2023

8) Cybersecurity

- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration Staff: 2023

8. Clinical investigation

Not applicable

9.Conclusion

In summary, the above information demonstrates that Shear Wave Quantificational Ultrasound Diagnostic System is substantially equivalent to its predicate device and the differences raise no risks in regard to safety and effectiveness of the proposed device.