



October 1, 2025

Wuxi Hisky Medical Technologies Co., Ltd.
% Siming Wang
Consultant
Shenzhen Joyantech Consulting Co., Ltd
1713A, 17th Floor, Block A
Zhongguan Times Square Nanshan District
Shenzhen, Guangdong 518000
China

Re: K250026

Trade/Device Name: Shear Wave Quantificational Ultrasound Diagnostic System
(FH9000/FH7000/FH6000/FH5000/FH3000/FH1000)

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic Pulsed Doppler Imaging System

Regulatory Class: Class II

Product Code: IYN, IYO, ITX

Dated: September 2, 2025

Received: September 2, 2025

Dear Siming Wang:

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.
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DHT8C: Division of Radiological
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K250026

Device Name

Shear Wave Quantificational Ultrasound Diagnostic System (FH9000/FH7000/FH6000/FH5000/
FH3000/FH1000)

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, Transient Elastography based device is intended to provide 100Hz shear wave speed measurements and estimates of tissue stiffness in spleen.

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 in the human body (including abdominal applications) in B, M, CFM, PWD, B/B, 4B, B+M, B+CFM, B+PWD, and B+CFM+PWD modes.

The system must be operated by qualified and appropriately trained medical 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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510(k) Summary
K250026

Date of Preparation: 2025/10/01

1. Submission sponsor

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2. Submission correspondent

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Contact person: Siming Wang

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3. Identification of Proposed Device

Trade Name	Shear Wave Quantificational Ultrasound Diagnostic System
Common Name	Diagnostic Ultrasound System and Accessories
Model Name	FH9000/ FH7000/FH6000/FH5000/FH3000/ FH1000
Submission type	Traditional 510(k) submission
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
Review Pane	Radiology

4. Identification of Predicate Device

Primary predicate	
Trade Name	Shear Wave Quantificational Ultrasound Diagnostic System
Common Name	Diagnostic Ultrasound System and Accessories
Model Name	FT9000, FT100, Mini800
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
Review Pane	Radiology
Manufacture	Wuxi Hisky Medical Technologies Co., Ltd.
Reference device	
Trade name	FibroScan® device (Models: 502 Touch, 530 Compact, 430 Mini+, 230, and 630)
Common Name	Diagnostic Ultrasound System and Accessories
Model Name	502 Touch, 530 Compact, 430 Mini+, 230, and 630
510(k) number	K223902
Classification name	1) Ultrasonic Pulsed Echo Imaging System 2) Diagnostic Ultrasound Transducer
Classification	Class II
Regulation number	21 CFR 892.1560 & 21 CFR 892.1570
Product Code	IYO, ITX
Review Pane	Radiology
Manufacture	Echosens

5. Device Description

The subject system is a general purpose, software-controlled, diagnostic ultrasound system. It is

composed of a complex probe, an imaging probe, a main unit, a power cord, a foot switch, two fuses and a protective earth wire. The complex probe is a convex array probe used for elasticity measurement and ultrasound imaging, and the imaging probe is also a convex array probe used for ultrasound imaging. The system uses transient elastography to measure shear wave speed non-invasively and estimate tissue stiffness as well as Ultrasound Attenuation Parameter (UAP) in internal structures of the body. A mechanical vibrator in the complex probe produces low-frequency shear waves at 50 Hz or 100HZ that travel through the skin and intercostal space into the liver or spleen respectively. The propagation speed of the shear wave is captured by complex probe 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 and complex probe with a frequency range of 2.5MHz to 5.0 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 6 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. The table below shows the differences among these models:

Table 1 Differences among different models

No.	Configuration Model	Complex Probe	Imaging Probe	Quick Query Function	Multiuser Management	System automatic diagnosis function	Data docking support function	Advanced search function	Automatic cleaning function	HTTP& JSON support function	Ordinary compressed storage	Advanced compressed storage
1	FH9000	√	√	√	√	√	√	√	√	√	√	√
2	FH7000	√	√	√	-	√	√	√	√	√	√	√
3	FH6000	√	√	√	√	-	√	√	√	√	√	√
4	FH5000	√	A	√	√	√	-	√	√	-	√	√
5	FH3000	√	A	√	√	√	√	-	√	√	-	√
6	FH1000	√	A	√	√	√	√	√	√	-	√	√

Note:“-”represents “not equipped”, “√” represents “equipped”, “A”represents “optional”.

6. 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, Transient Elastography based device is intended to provide 100Hz shear wave speed measurements and estimates of tissue stiffness in spleen.

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 in the human body (including abdominal applications) in B, M, CFM, PWD, B/B, 4B, B+M, B+CFM, B+PWD, and B+CFM+PWD modes..

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

7. Substantially Equivalent (SE) Comparison

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

Table 2 Comparison of subject device with primary predicate device

Comparison item	Subject device	Primary predicate device(K200136)	Discussion
Device Model	FH9000, FH7000, FH6000, FH5000, FH3000, FH1000	FT9000	/
Regulation Number	21 CFR 892.1560 & 21 CFR 892.1570 & 21 CFR 892.1550	21 CFR 892.1550 & 21 CFR 892.1560 & 21 CFR 892.1570	Same
Product Code	IYO, ITX, IYN	IYO, ITX, IYN	Same
Indications 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, Transient Elastography based device is intended to provide 100Hz	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	Similar Both the subject device and the primary predicate device are used for: - a.Liver stiffness measurement; - b.Attenuation Parameter measurement - c.General purpose pulse echo ultrasound imaging and Doppler flow analysis.

	shear wave speed measurements and estimates of tissue stiffness in spleen. 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 in the human body (including abdominal applications) in B, M, CFM, PWD, B/B, 4B, B+M, B+CFM, B+PWD, and B+CFM+PWD modes. The system must be operated by qualified and appropriately trained medical professionals in a professional healthcare facility environment	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.	The difference is that the subject device has an additional indication for use for spleen stiffness measurement, which is included in the indication for use of the reference device. Therefore, the difference doesn't raise new risks in regard to safety and effectiveness of the subject device.
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Patient population		adults, and pediatric patients.	adults	Different Although the patient population of the subject device is different from the primary predicate, this technical characteristic is same as the reference device. The performance applied to pediatric patients is verified, this difference does not raise any questions related to safety and effectiveness.
TE Probe	Nominal Frequency	FH-C1 complex probe:2.5MHz	FT-2.5D9 fibrosis scanning probe:2.5MHz	Same
	Type	Multiple array element transducer	Single element transducer	Different As multiple array element transducer of the complex probe FH-C1 can electronically focus the sound beam at different depths and angles by controlling the timing and amplitude of the electrical signals sent to each element. So the complex probe offers better image quality, resolution and penetration depth compared to single-element transducers. Therefore, the difference doesn't raise different questions of safety and

				effectiveness than the predicate device
	Function	a.Stiffness measurement of liver and spleen; b.UAP measurement of liver; c.General purpose pulse echo ultrasound imaging and Doppler flow analysis of the human body	a.Stiffness measurement of liver b.UAP measurement of liver	Similar The subject device and the primary predicate device have the same functions of liver stiffness and UAP measurement. But the subject device has the following additional functions: <i>1.spleen stiffness measurement;</i> This function is same with the reference device. And the function is verified. Therefore, the difference doesn't raise new risks in regard to safety and effectiveness of the subject device.
	Mode	Vibration-Controlled Transient Elastography mode	A mode and M mode	Similar Although the mode of the subject device and the predicate device is different, they can execute the same Transient Elastography measurement function. Therefore, the difference doesn't raise different questions of safety and effectiveness than the predicate device

	Source of Mechanical Vibration	External electromechanical Vibrator	External electromechanical Vibrator	Same
	Ultrasound Source	Piezoelectric ultrasound source	Piezoelectric ultrasound source	Same
	Measurement depth	15-85mm	15-85mm	Same
Ultrasound imaging Probe	Nominal Frequency	FH-C1 complex probe:2.5MHz FH-C2 imaging probe :3.5MHz	FT-3.5R65 imaging probe:3.5MHz	Similar Although the probe frequency of the subject device is different from that of the predicate device, they can execute the same ultrasound imaging function. Therefore, the difference doesn't raise different questions of safety and effectiveness than the predicate device
	Mode	B, M, CFM, PWD, B/B,4B,B+M, B+CFM, B+PWD, B+CFM+PWD	B, B/B, B/D, CFM and PWD mode	Similar The subject device has broader range of application of M mode, which is a widely 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
	Function	General purpose pulse echo ultrasound imaging and Doppler flow analysis of the human body	General purpose pulse echo ultrasound imaging and Doppler flow analysis of the human body	Same
	Ultrasound Source	Piezoelectric ultrasound source	Piezoelectric ultrasound source	Same
TE display		Liver Shear wave speed (0.8-5.2m/s) Spleen Shear wave speed (0.8-5.8 m/s) Liver Stiffness (2.0-80 kPa) Spleen Stiffness(2kPa -100kPa) 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	Similar Both the subject device and the primary predicate device have the same TE display in terms of liver stiffness, except that the subject device has additional display for spleen stiffness, which is equivalent to the function of the reference device's TE probe. Therefore, the difference doesn't raise new risks in regard to safety and

				effectiveness of the subject device.
TE Bias	Liver stiffness	(-5.2%) – (4.2%)	(-4.7%) - (2.4%)	Similar Both the subject device and the primary 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. And the subject device has additional function of spleen stiffness, which is equivalent to the function of the reference device's TE probe. Therefore, the difference doesn't raise new risks in regard to safety and effectiveness of the subject device.
	Spleen stiffness	(-5.2%) – (4.2%)	/	
TE Precision	Liver stiffness	(0.0%) – (0.67%)	(0.0%) – (1.6%)	
	Spleen stiffness	(0.0%) – (0.67%)	/	
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		(-1.8%) - (0.3%)	(-3.3%) – (2.0%)	Similar

UAP Precision	(0.1%) – (1.0%)	(0.2%) – (1.5%)	Similar
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Table 3 Comparison of subject device with Reference device

Comparison item	Subject device	Reference device(K223902)	Discussion
Device Model	FH9000, FH7000, FH6000, FH5000, FH3000, FH1000	630	/
Regulation Number	21 CFR 892.1560 & 21 CFR 892.1570 & 21 CFR 892.1550	21 CFR 892.1560 & 21 CFR 892.1570	Similar The reference device doesn't have pulsed Doppler imaging function, so 21 CFR 892.1550 is inapplicable.
Product Code	IYO, ITX, IYN	IYO, ITX	Similar The reference device doesn't have pulsed Doppler imaging function, so IYN is inapplicable.
Indications 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, Transient Elastography based device is intended to provide 100Hz shear wave speed measurements and estimates	The FibroScan® device (Models: 502 Touch, 530 Compact, 430 Mini+, 230, and 630) is intended to measure liver stiffness (E) using Vibration Controlled Transient Elastography™ (VCTE™) at 50 Hz shear wave frequency and liver ultrasound attenuation coefficient (CAP™)* at 3.5 MHz. FibroScan® 630 Expert is also intended to measure spleen stiffness using VCTE™ at 100 Hz shear wave frequency.	Similar Both the subject device and the reference device are used for: a. Measurement of stiffness and Ultrasound Attenuation Parameter of liver b. Measurement of stiffness of spleen The difference is that the subject device has an additional indication for use for general purpose pulse echo ultrasound imaging and Doppler flow analysis of the human body, which is included in the

	of tissue stiffness in spleen. 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 in the human body (including abdominal applications) in B, M, CFM, PWD, B/B, 4B, B+M, B+CFM, B+PWD, and B+CFM+PWD modes. The system must be operated by qualified and appropriately trained medical professionals in a professional healthcare facility environment.	FibroScan liver stiffness measurements (LSM) by VCTE™ may aid the physician in determining the likelihood of cirrhosis and may be used, taken in context with other clinical and laboratory data, as an aid in the assessment of liver fibrosis. FibroScan CAP™ measurements may be used, taken in context with other clinical and laboratory data, as an aid in the assessment of hepatic steatosis. FibroScan® 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. The FibroScan® device is intended for use by healthcare professionals in hospitals, clinics or any facility where healthcare is provided. * CAP™ refers to ultrasound attenuation coefficient (originally defined as	indication for use of the primary predicate device. Therefore, the difference doesn't raise new risks in regard to safety and effectiveness of the subject device.
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			Controlled Attenuation Parameter). CAP™ on S+ probe is only available with SmartExam capability.	
Patient population		adults, and pediatric patients.	adults, and pediatric patients.	Same
TE Probe	Nominal Frequency	FH-C1 complex Probe: (2.5MHz)	M+probe :3.5 MHz XL+ probe:2.5 MHz S+ probe :5 MHz	Similar FH-C1 applies to both adult and pediatric patients, however, S ⁺ and M ⁺ probe apply to pediatric patients and XL ⁺ probe applies to adult patients, which indicates that the probe of subject device has a broader range of application. Therefore, the difference doesn't raise different questions of safety and effectiveness than the reference device.
	Type	Multiple array element transducer	Single element transducer	Different As multiple array element transducer of the complex probe FH-C1 can electronically focus the sound beam at different depths and angles by controlling the timing and amplitude of the electrical signals sent to each element. So the complex probe offers better image quality, resolution and penetration depth compared to single-element transducers.

				Therefore, the difference doesn't raise different questions of safety and effectiveness than the reference device
	Function	a. Stiffness measurement of liver and spleen; b. UAP measurement of liver; c. General purpose pulse echo ultrasound imaging and Doppler flow analysis of the human body	a. Stiffness measurement of liver and spleen b. CAP measurement of liver	Similar The subject device and the reference device have the same functions of liver stiffness and Ultrasound Attenuation Parameter measurement. But the subject device has the following additional functions: <i>General purpose pulse echo ultrasound imaging and Doppler flow analysis of the human body.</i> This additional function is equivalent to the imaging function of the primary predicate device's ultrasound imaging probe. Therefore, the difference doesn't raise new risks in regard to safety and effectiveness of the subject device.
	Mode	Vibration-Controlled Transient Elastography mode	A-mode / M-mode Transient Elastography/ Shear Wave / (CAP™)	Similar Although the probe mode of the subject device and the reference device is different, they can execute the same Transient Elastography measurement

				function. Therefore, the difference doesn't raise different questions of safety and effectiveness than the reference device
	Source of Mechanical Vibration	External electromechanical Vibrator	External electromechanical Vibrator	Same
	Ultrasound Source	Piezoelectric ultrasound source	Piezoelectric ultrasound source	Same
	Measurement depth	15-85mm	S1 exam: 15-40 mm S2 exam: 20-50 mm M exam: 25-65 mm XL exam: 35-75 mm	Similar
Ultrasound imaging Probe	Nominal Frequency	FH-C2 imaging probe :3.5MHz FH-C1 complex Probe :2.5MHz	ES-C5-2R60S-3 B-Mode ultrasound localization probe: 3.5 MHz	Similar Although the probe frequency of the subject device is different from that of the reference device, they can execute the same ultrasound imaging function. Therefore, the difference doesn't raise different questions of safety and effectiveness than the reference device
	Mode	B, M, CFM, PWD, B/B, 4B, B+M, B+CFM, B+PWD, B+CFM+PWD Note:CFM equates C and PWD equates D	B	Similar: The subject device has broader range of application of M, CFM, PWD mode, which are widely used mode in ultrasound device. Therefore, the addition of M,

				CFM, PWD mode doesn't raise different questions of safety and effectiveness than the reference device
	Type	Multiple array element transducer	Multiple array element transducer	Same
	Function	a.locating of liver and spleen b.General purpose pulse echo ultrasound imaging and Doppler flow analysis of the human body	locating of liver and spleen	Similar Both the subject device and the reference device have the same function in locating, except that the subject device has additional function of general purpose pulse echo ultrasound imaging and Doppler flow analysis of the human body, which is equivalent to the function of the primary predicate device's ultrasound imaging probe. Therefore, the difference doesn't raise new risks in regard to safety and effectiveness of the subject device.
	Ultrasound Source	Piezoelectric ultrasound source	Piezoelectric ultrasound source	Same
TE display		Liver Shear wave speed (0.8-5.2m/s) Spleen Shear wave speed (0.8-5.8 m/s) Liver Stiffness (2.0-80 kPa) Spleen Stiffness(2kPa -100kPa) Interquartile range (IQR) and IQR/median	Liver Shear wave speed (0.8-5.0 m/s) Spleen Shear wave speed (1.4-5.8 m/s) Liver Stiffness (2.0-75 kPa) Spleen Stiffness(6kPa -100kPa) Interquartile range (IQR) and IQR/median	Similar

		ratio	ratio	
TE measurement depth		15-85mm	S1 exam: 15-40 mm S2 exam: 20-50 mm M exam: 25-65 mm XL exam: 35-75 mm	Similar
TE Bias	Liver	(-5.2%) – (4.2%)	(-10%) – (-38%)	Similar
	Spleen	(-5.2%) – (4.2%)	(-31%) – (-44%)	Similar
TE Precision	Liver	(0.0%) – (0.67%)	$\leq 3\%$	Similar
	Spleen	(0.0%) – (0.67%)	$\leq 1\%$	Similar
Attenuation display		UAP (90-450 dB/m) Interquartile range (IQR) and IQR/median ratio	CAP (100-400 dB/m) CAP median and interquartile range (IQR)	Similar The UAP measurement range of the subject device is larger than that of the reference device. And they have different way of statistic, which doesn't raise different questions of safety and effectiveness than the

			reference device.
UAP Bias	(-1.8%) - (0.3%)	(1.0%) – (12.4%)	Similar
UAP Precision	(0.1%) – (1.0%)	(0.2%) – (6.9%)	Similar

8. 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 essential performance - Collateral
Standard: Electromagnetic disturbances - Requirements and tests

IEC TR 60601-4-2:2024 Medical electrical equipment - Part 4-2: Guidance and interpretation – Electromagnetic immunity: 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 essential performance

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) Ultrasound Performance

Following the requirements of FDA ultrasound guidance: *Marketing Clearance of Diagnostic Ultrasound Systems and Transducers Guidance for Industry and Food and Drug Administration Staff:2023*, bench performances testing were conducted to assure the subject devices' safety and effectiveness:

- Vibration-Controlled Triggered Transient Elastography (TE) and Ultrasound Attenuation Parameter (UAP) measurement accuracy testing including TE detection range, bias, precision; UAP detection range, bias, precision.
- Ultrasound image performance testing including Examination depth, spatial resolution, Geometric Accuracy, detection depth, dead zone, slice thickness, measuring error of circumference and area, time display error, Doppler accuracy and detection depth.

6) 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

7) Cybersecurity

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

9. Clinical investigation

Not applicable

10. Conclusion

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