March 31, 2023

CHISON Medical Technologies Co., Ltd.
% Yingying Chen
RA Specialist
No.3 Changjiang South Road, Xinwu District
Wuxi, Jiangsu 214028
CHINA

Re: K223570
Trade/Device Name: SonoAir Series Digital Color Doppler Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: February 24, 2023
Received: February 27, 2023

Dear Yingying Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223570

Device Name
SonoAir Series Digital Color Doppler Ultrasound System

Indications for Use *(Describe)*
The SonoAir Series Digital Color Doppler Ultrasound System is intended for diagnostic ultrasound imaging in B(2D),B/M,M,B+CFM,B+CPA (PD), B+DPD,B+PW,B+ CFM + D (PW), B+ CPA(PD) + D (PW), Fusion Harmonic Imaging modes. The device is a general-purpose ultrasonic imaging instrument intended for use by an appropriately-trained qualified clinician for evaluation of Fetal ,Abdominal, Pediatric, Small Organ (breast, thyroid, testes),Adult Cephalic,
Cardiac Adult, Musculo-skeletal(Conventional, Superficial),Peripheral Vascular, Trans-vaginal and Urology,which is intended to be used in a hospital or medical clinic.

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

K223570

In accordance with 21 CFR 807.92 the following summary of information is provided:

1. Submitter:

Submitter: CHISON Medical Technologies Co., Ltd.
Address: No.3 Changjiang South Road, Xinwu District, Wuxi, 214028 Jiangsu, P.R. China
Contact : Mrs. Chen Yingying
Tel: +86-510-8531-0019
Fax: +86-510-8531-0021
Date Prepared: October 14th, 2022

2. Device :

Trade Name: SonoAir Series Digital Color Doppler Ultrasound System

Common Name: Diagnostic Ultrasound System with Transducers

Classfication: Regulatory Class: II
Review Category: Tier II

Classfication Name	21 CFR Section	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3. Predicate Device(s):

Device	Model	Product Code	510(k)Number
Main predicate device	EBit 90 Digital Color Doppler Ultrasound System	IYN, IYO, ITX	K162172
Reference device	XBit 90 Digital Color Doppler Ultrasound System	IYN, IYO, ITX	K200780

4. Device Description:

The SonoAir Series Digital Doppler Ultrasound System is an integrated preprogrammed color doppler ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

This system is a Track 3 device that employs a wide array of probes that include linear array, convex array and phased array.This system consists of a mobile console with keyboard control panel, power supply module, color LCD monitor and optional probes. This system is a mobile, general purpose, software controlled, color diagnostic ultrasound system. Its basic function is to acquire ultrasound echo data and to display the image B-Mode (2D), Fusion Harmonic Imaging, M-Mode, Pulsed

Doppler (PW) Mode, Color Doppler Mode, Power Doppler Mode, Directional Power Doppler Mode or a combination of these mode.

5. Indications for Use:

The SonoAir Series Digital Color Doppler Ultrasound System is intended for diagnostic ultrasound imaging in B(2D),B/M,M,B+CFM,B+CPA (PD), B+DPD,B+PW, B+ CFM + D (PW), B+ CPA(PD) + D (PW), Fusion Harmonic Imaging modes. The device is a general-purpose ultrasonic imaging instrument intended for use by an appropriately-trained qualified clinician for evaluation of Fetal ,Abdominal, Pediatric, Small Organ (breast, thyroid, testes),Adult Cephalic,Cardiac Adult, Musculo-skeletal(Conventional, Superficial),Peripheral Vascular, Trans-vaginal and Urology，which is intended to be used in a hospital or medical clinic.

6. Summary of Non-Clinical Tests:

The SonoAir Series Digital Color Doppler Ultrasound System has been evaluated for electrical, mechanical, thermal and electromagnetic compatibility safety, biocompatibility and acoustic output.

The device has been found to conform to applicable medical device safety standards in regards to thermal, mechanical and electrical safety as well as biocompatibility.

ANSI AAMI ES60601-1:2015 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance.

lEC 60601-1-2: 2014 Medical Electrical Equipment - Part 1-2: General Requirements For Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests.

lEC 60601-2-37:2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.

Output Indices on Diagnostic Ultrasound Equipment

ISO 10993-1:2018 Biological Evaluation of Medical Devices -- Part 1: Evaluation And Testing Within A Risk Management Process

The following quality assurance measures are applied to the development of the system:

Risk Management

Requirement review and Design reviews

Testing on unit level (Module verification)

Integration testing (system verification)

Performance testing (Verification)

Safety testing (Verification)

The biocompatibility was evaluated and meets the ISO10993 series standard and FDA guidance.

7. Clinical Test:

No clinical testing was required.

Software Documentation for a Moderate Level of Concern, per the FDA guidance document,"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document issued on May 11, 2005", is also included as part of this submission.

8. Determination of Substantially Equivalent:

Items	Main Predicate Device	Reference Device	Submission Device	Remark
	EBit 90 Digital Color Doppler Ultrasound System (K162172)	XBit 90 Digital Color Doppler Ultrasound System (K200780)	SonoAir Series Digital Color Doppler Ultrasound System	
Indications for Use	Fetal Abdominal Pediatric Small Organ (breast, thyroid ,testes) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Musculo-skeletal(Conventional, Superficial) Cardiac(adult ,pediatric) Peripheral Vascular Urology Trans-esophageal	Fetal Abdominal Pediatric Small Organ (breast, thyroid ,testes) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Musculo-skeletal(Conventional, Superficial) Cardiac(adult ,pediatric) Peripheral Vascular OB/GYN,Urology Trans-esophageal	Fetal Abdominal Pediatric Small Organ (breast, thyroid ,testes) Adult Cephalic Trans-vaginal Musculo-skeletal(Conventional, Superficial) Cardiac Adult Peripheral Vascular Urology	SE Analysis 1
Design	Autocorrelation for color processing and FFT for pulse and CW Doppler processing. Supporting Linear, Curve , Phase array and Volume probes . Cine play back capability Image file archive	Autocorrelation for color processing and FFT for pulse and CW Doppler processing. Supporting Linear, Curve , Phase array and Volume probes . Cine play back capability Image file archive	Autocorrelation for color processing and FFT for pulse and CW Doppler processing. Supporting Linear, Curve and Phase array probes. Cine play back capability Image file archive	Same
Operating Controls Items	TGC 8 slider	TGC 8 slider	TGC 8 slider	Same
	Depth Range:0-30.8 cm	Depth Range: 0-45 cm	Depth Range:0- 22.7 cm	SE Analysis 2
	256 shades of gray	256 shades of gray	256 shades of gray	Same
	B Dynamic range control: 30-180dB	B Dynamic range control: 20-180dB	B Dynamic range control: 30-180dB	Same
	Gain:0-255, 1/step	Gain:0-255, 1/step	Gain:0-255,1/step	Same

	Focal Number: adjustable	Focal Number: adjustable	Focal Number: adjustable	Same
	Focus position: adjustable	Focus position: adjustable	Focus position: adjustable	Same
	B steer: available on linear transducers	B steer: available on linear transducers	B steer: available on linear transducers	Same
	B Persistence: 7 steps	B Persistence: 7 steps	B Persistence: 7 steps	Same
	ROI size/position: adjustable	ROI size/position: adjustable	ROI size/position: adjustable	Same
	Color Wall Filter settings:8 steps	Color Wall Filter settings:8 steps	Color Wall Filter settings:4 steps	SE Analysis 2
	Color Baseline:16 steps	Color Baseline:16 steps	Color Baseline: 7 steps	
	Color Maps: 21 maps	Color Maps: 21 maps	Color Maps: 9 maps	
	PW sweeping speed: 6 steps	PW sweeping speed: 6 steps	PW sweeping speed: 3 steps	
	Color Invert: on/off	Color Invert: on/off	Color Invert: on/off	Same
	PW Wall Filter: 7 steps	PW Wall Filter: 7 steps	PW Wall Filter: 7 steps	Same
	PW sample volume: 0.5-30mm (PW only),13 steps	PW sample volume: 0.5-30mm (PW only)	PW sample volume: 1-8mm (PW only)	SE Analysis 2
	PW angle correction:-89~89degrees,1/step	PW angle correction:-89~89degrees,1/ste	PW angle correction:-70-70degrees,1/step	
	Baseline: 8steps	Baseline: 8steps	Baseline: 6steps	
	Cine control:step, play backward, play continuously	Cine control:step, play backward, play continuously	Cine control:step, play backward, play continuously	Same
	Doppler Auto Trace	Doppler Auto Trace	Doppler Auto Trace	Same
	Freeze control:Toggling freeze key	Freeze control:Toggling freeze key	Freeze control:Toggling freeze key	Same
Safety Compliance	ANSI AAMI ES60601-1 IEC 60601-1-2 ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23 IEC 60601-2-37	ANSI AAMI ES60601-1 IEC 60601-1-2 ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23 IEC 60601-2-37	ANSI AAMI ES60601-1 IEC 60601-1-2 ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23 IEC 60601-2-37	Same
Operation	B mode	B mode	B Mode	Same
	Dual mode	B/M Mode	B/B Mode	Same

Mode	Quad mode	M mode	4B Mode	Same
	B/M Mode	Dual mode	B/M Mode	Same
	M mode	Quad mode	M Mode	Same
	CFM mode	CFM mode	CFM Mode	Same
	PW mode	CPA Mode	PW Mode	Same
	CPA(PD) Mode	DPD Mode	CPA(PD) Mode	Same
	DPD Mode	PW mode	DPD Mode	Same
	2D Steer	2D Steer	2D Steer	Same
	Triplex Mode	Triplex Mode	Triplex Mode	Same
	Quadplex Mode	Quadplex Mode	Quadplex Mode	Same
	/	HD 3D Mode	HD 3D Mode	Same
	Free Steer M	Free Steering M	Free Steer M	Same
	HPRF Mode	HPRF Mode	HPRF Mode	Same
	FHI	FHI	FHI	Same
	Color M Mode	Color M Mode	Color M Mode	Same
	Trapezoidal Mode	Trapezoidal Mode	Trapezoidal Mode	Same
	Elastography Mode	Elastography Mode	Elastography Mode	Same
	/	Sono Contrast	Sono Contrast	Same
	Super Needle	Super Needle	Super Needle	Same
	Biopsy	/	Biopsy	Same
	Curved Panoramic	Curved Panoramic	Curved Panoramic	Same
	TGC	/	TGC	Same
	/	LGC	LGC	Same
	Chroma	Chroma	Chroma	Same
	/	X-contrast	X-contrast	Same
	Q-beam	Q-beam	Q-beam	Same
	Compound	Compound	Compound	Same
	AIO	AIO	AIO	Same
	SRA	SRA	SRA	Same
	Q-image	Q-image	Q-image	Same
	general measurement package	general measurement package	general measurement package	Same
	OB measurement package	OB measurement package	OB measurement package	Same
	GYN measurement package	GYN measurement package	GYN measurement package	Same
	URO measurement package	URO measurement package	URO measurement package	Same
	cardiac measurement package	cardiac measurement package	cardiac measurement package	Same

	vascular measurement package	vascular measurement package	vascular measurement package	Same
	small parts measurement package	small parts measurement package	small parts measurement package	Same
	Pediatric measurement package	Pediatric measurement package	Pediatric measurement package	Same
	TCD measurement package	TCD measurement package	TCD measurement package	Same
	/	Free OB	SONO OB	Same
	Bodymark	Bodymark	Bodymark	Same
	Auto IMT	Auto IMT	Auto IMT	Same
	/	SonoColor	SonoColor	Same
	Stress Echo	Stress Echo	Stress Echo	Same
	/	Strain and Strain Rate	Strain and Strain Rate	Same
Display Annotations	Logo; Hospital Name; Exam date;Exam time; AcousticPower; Mechanical index; Tissue thermal indes; ID,Last name,First Name,Middleinitial, Gender,Age; Probe model;ECG ico;Operator; TGC Corve;Focus position;Thumbnail; Imagingparameters; Dynamic Trackball indices	Logo; Hospital Name; Exam date;Exam time; Acoustic Power ; Mechanical index;Thermal indes;Probe model;ECG ico;TGC Corve;Focus position;Imaging parameters;Dynamic Trackball indices; System status;Gray/Color bar	Logo; Hospital Name; Exam date;Exam time; Acoustic Power ; Mechanical index;Thermal indes;Probe model; TGC Corve;Focus position;Imaging parameters;TTouch pad; System status;Gray/Color bar	Same

Measurements	**2D mode:** Depth , Distance ,Area: Ellipse, Trace, Spline, Cross, Trace Length, Double Distance, Parallel, Volume: Distance, Ellipse, Ellipse + Distance, Length Ratio, Area Ratio, IMT, B Histogram, B Profile, Volume Flow, Color Velocity; **M mode:** Distance, Time, Slope, Heart Rate, Velocity; **Doppler mode:** D Velocity, Time, Heart Rate, Acceleration, D Trace, PS/ED, Volume Flow;	**2D mode:** Depth , Distance ,Area: Ellipse, Trace, Spline, Trace Length , Double Distance , Parallel ,Volume :Distance, Ellipse, Ellipse + Distance, Distance Ratio ,Area Ratio , IMT, Volume Flow, Color Velocity; **M mode:** Distance,Time, Slope, Heart Rate,Velocity; **Doppler mode:** D Velocity ,Time ,Heart Rate,Acceleration ,D Trace,PS/ED , Volume Flow;	**2D mode:** Depth , Distance ,Area: Ellipse, Trace, Spline, Trace, Length ,Volume :Distance, Ellipse, Ellipse + Distance, Distance Ratio, Area Ratio , IMT, Volume Flow; **M mode:** Distance,Time, Slope,Heart Rate,Velocity; **Doppler mode**: D Velocity ,Time , Heart Rate, Acceleration ,D Trace,ED/PS, Volume Flow;	Same
Transducer Types & Connectors	Convex Array, Phased Array, Linear Array, Volume probe 2 ports	Convex Array, Phased Array, Linear Array,Volume probe 4ports	Convex Array, Phased Array, Linear Array, 4ports	Same
Users / Sites	Hospitals, clinics usage	Hospitals, clinics usage	Hospitals, clinics usage	Same
Acoustic Output	Track 3; MI, TIS, TIC, TIB Derated Ispta: 720mW/cm^2 maximum, TIS/TIB/TIC:0.1-4.0 Range, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190 W/cm^2 max	Track 3; MI, TIS, TIC, TIB Derated Ispta: 720mW/cm^2 maximum, TIS/TIB/TIC:0.1-4.0 Range, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190 W/cm^2 max	Track 3; MI, TIS, TIC, TIB Derated Ispta: 720mW/cm2 maximum,TIS/TIB/TIC:0.1-4.0 Range, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190 W/cm^2 max	Same
Power Requirements	Power requirements: AC :100V- 240V, Frequenzy:50-60Hz Operating temperature: 10-40° C; relative humidity 30-75%; Barometric pressure: 700 to 1060hPa	Power requirements: AC :100V- 240V, Frequenzy:50-60Hz Operating temperature: 0-40℃; relative humidity 30-75%; Barometric pressure: 700 to 1060 hPa	Power requirements: AC :100V- 240V, Frequenzy:50-60Hz Operating temperature: 10-38℃; relative humidity 30-75%; Barometric pressure: 700 to 1060 hPa	SE Analysis 3

SE Analysis 1：

Compared with the predicate device, the submission device has some differences in

indications for use. Principles of operation transducer configuration is the same, the only difference is the number of probe. Both of the predicate and submission device comply with the requirements of ANSI AAMI ES60601-1& IEC 60601-2-37 and meet clinical requirements.Therefore they can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

SE Analysis 2：

Operation Controls, compared with the predicate device, the submission device employs the same operation controls design ,but has some differences in setting range. But both of them comply with the requirements of ANSI AAMI ES60601-1 & IEC60601-2-37 and meet clinical requirements. Therefore they can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

SE Analysis 3：

Compared with the predicate device, the submission device has some differences in operating temperature. But the operating temperature of the device is contained within the scope of the predicate device. Both them comply with the requirements of ANSI AAMI ES60601-1. Therefore they can be considered Substantially Equivalent in safety, and no new risk is raised, so the SE is not affected.

9. Conclusion

In accordance with the Act. 21 CFR Part 807 and based on the information provided in this premarket notification, CHISON Medical Technologies Co., Ltd. concludes that the SonoAir Series Digital Color Doppler Ultrasound System is substantially equivalent to the predicate device with regard to safety and effectiveness.