May 22, 2026

CHISON Medical Technologies Co., Ltd.
Qifei Liu
Regulatory Affairs Manager
#3 Changjiang S. Rd., Xinwu District
Wuxi, Jiangsu 214028
China

Re: K253949
Trade/Device Name: SonoPort Series Digital Color Doppler Ultrasound System (SonoPort 1, SonoPort 1 Exp, SonoPort 1 Pro, SonoPort 1 Elite, SonoPort 1 Plus, SonoPort 2, SonoPort 2 Exp, SonoPort 2 Pro, SonoPort 2 Elite, SonoPort 2 Plus, SonoPort 3, SonoPort 3 Exp, SonoPort 3 Pro, SonoPort 3 Elite, SonoPort 3 Plus, SonoPort 4, SonoPort 4 Exp, SonoPort 4 Pro, SonoPort 4 Elite, SonoPort 4 Plus, SonoPort 5, SonoPort 5 Exp, SonoPort 5 Pro, SonoPort 5 Elite, SonoPort 5 Plus, SonoPort 6, SonoPort 6 Exp, SonoPort 6 Pro, SonoPort 6 Elite, SonoPort 6 Plus, SonoPort 7, SonoPort 7 Exp, SonoPort 7 Pro, SonoPort 7 Elite, SonoPort 7 Plus, SonoPort 8, SonoPort 8 Exp, SonoPort 8 Pro, SonoPort 8 Elite, SonoPort 8 Plus, SonoPort 9, SonoPort 9 Exp, SonoPort 9 Pro, SonoPort 9 Elite, SonoPort 9 Plus)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: April 23, 2026
Received: April 24, 2026

Dear Qifei Liu:

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,

Daniel M. Krainak, Ph.D.
Assistant Director
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253949 ?

Please provide the device trade name(s). ?

SonoPort Series Digital Color Doppler Ultrasound System (SonoPort 1, SonoPort 1 Exp, SonoPort 1 Pro, SonoPort 1 Elite, SonoPort 1 Plus, SonoPort 2, SonoPort 2 Exp, SonoPort 2 Pro, SonoPort 2 Elite, SonoPort 2 Plus, SonoPort 3, SonoPort 3 Exp, SonoPort 3 Pro, SonoPort 3 Elite, SonoPort 3 Plus, SonoPort 4, SonoPort 4 Exp, SonoPort 4 Pro, SonoPort 4 Elite, SonoPort 4 Plus, SonoPort 5, SonoPort 5 Exp, SonoPort 5 Pro, SonoPort 5 Elite, SonoPort 5 Plus, SonoPort 6, SonoPort 6 Exp, SonoPort 6 Pro, SonoPort 6 Elite, SonoPort 6 Plus, SonoPort 7, SonoPort 7 Exp, SonoPort 7 Pro, SonoPort 7 Elite, SonoPort 7 Plus, SonoPort 8, SonoPort 8 Exp, SonoPort 8 Pro, SonoPort 8 Elite, SonoPort 8 Plus, SonoPort 9, SonoPort 9 Exp, SonoPort 9 Pro, SonoPort 9 Elite, SonoPort 9 Plus)

Please provide your Indications for Use below. ?

The Sonoport Series Digital Color Doppler Ultrasound System is intended for diagnostic ultrasound imaging in B(2D/3D/4D), B/M, M, B+CFM, B+CPA(PD), B+DPD, B+PW, B+CW, B+CFM+D(PW)/CW, B+CPA(PD) +D(PW)/CW, TDI and Fusion Harmonic Imaging modes. The device is a general-purpose ultrasonic imaging instrument intended for use by appropriately-trained qualified healthcare professionals for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, thyroid, testes), Neonatal Cephalic, Adult Cephalic, Cardiac (adult, pediatric), Musculo-skeletal (Conventional, Superficial), Peripheral Vascular, Trans-esophageal, Trans-rectal, Trans-vaginal, OB/GYN and Urology, which is intended to be used in a hospital or medical clinic.

Please select the types of uses (select one or both, as applicable). ?

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary K253949

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 : Mr. Liu Qifei
Tel: +86-510-8531-0019
Fax: +86-510-8531-0021
Date Prepared: November 15th, 2025

2. Device :

Trade Name: SonoPort Series Digital Color Doppler Ultrasound System (SonoPort 1, SonoPort 1 Exp, SonoPort 1 Pro, SonoPort 1 Elite, SonoPort 1 Plus, SonoPort 2, SonoPort 2 Exp, SonoPort 2 Pro, SonoPort 2 Elite, SonoPort 2 Plus, SonoPort 3, SonoPort 3 Exp, SonoPort 3 Pro, SonoPort 3 Elite, SonoPort 3 Plus, SonoPort 4, SonoPort 4 Exp, SonoPort 4 Pro, SonoPort 4 Elite, SonoPort 4 Plus, SonoPort 5, SonoPort 5 Exp, SonoPort 5 Pro, SonoPort 5 Elite, SonoPort 5 Plus, SonoPort 6, SonoPort 6 Exp, SonoPort 6 Pro, SonoPort 6 Elite, SonoPort 6 Plus, SonoPort 7, SonoPort 7 Exp, SonoPort 7 Pro, SonoPort 7 Elite, SonoPort 7 Plus, SonoPort 8, SonoPort 8 Exp, SonoPort 8 Pro, SonoPort 8 Elite, SonoPort 8 Plus, SonoPort 9, SonoPort 9 Exp, SonoPort 9 Pro, SonoPort 9 Elite, SonoPort 9 Plus)

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	SonoMax 22 Digital Color Doppler Ultrasound System	IYN, IYO, ITX	K233697
Reference device	SonoAir 90 Digital Color Doppler Ultrasound System	IYN, IYO, ITX	K223570
Reference device	Consona N6 Diagnostic Ultrasound System	IYN, IYO, ITX	K221496

4. Device Description:

The SonoPort 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 in B(2D/3D/4D), B/M, M, B+CFM, B+CPA(PD), B+DPD, B+PW, B+CW, B+CFM+D(PW)/CW, B+CPA(PD)+D(PW)/CW, TDI, Fusion Harmonic Imaging modes or a combination of these mode.

5. Indications for Use:

The SonoPort Series Digital Color Doppler Ultrasound System is intended for diagnostic ultrasound imaging in B(2D/3D/4D), B/M, M, B+CFM, B+CPA(PD), B+DPD, B+PW, B+CW, B+CFM+D(PW)/CW, B+CPA(PD)+D(PW)/CW, TDI and Fusion Harmonic Imaging modes. The device is a general-purpose ultrasonic imaging instrument intended for use by appropriately-trained qualified healthcare professionals for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, thyroid, testes), Neonatal Cephalic, Adult Cephalic, Cardiac (adult, pediatric), Musculo-skeletal (Conventional, Superficial), Peripheral Vascular, Trans-esophageal, Trans-rectal, Trans-vaginal, OB/GYN and Urology, which is intended to be used in a hospital or medical clinic.

6. Summary of Non-Clinical Tests:

The SonoPort 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.

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

IEC 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 Basic Documentation Level, per the FDA guidance document,“Guidance for Content of Premarket Submissions for Device Software Functions Document issued on June 14, 2023”, is also included as part of this submission.

8. Determination of Substantially Equivalent：

Items	Submission Device	Main predicate device	Reference device	Reference device	Remark
	SonoPort Series Digital Color Doppler Ultrasound System	SonoMax 22 Digital Color Doppler Ultrasound System (K233697)	SonoAir 90 Digital Color Doppler Ultrasound System (K223570)	Consona N6 Diagnostic Ultrasound System (K221496)	
Indications for Use	Fetal Abdominal Pediatric Small Organ (breast, thyroid ,testes) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-esophagea l Musculo-skeletal(Conventional, Superficial) Cardiac(adult,pediatric) Peripheral Vascular OB/GYN Urology	Fetal Abdominal Pediatric Small Organ (breast, thyroid ,testes) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-esophageal Musculo-skeletal(Conventional, Superficial) Cardiac(adult,pediatric) Peripheral Vascular OB/GYN Urology	Fetal Abdominal Pediatric Small Organ (breast, thyroid, testes) Adult Cephalic Cardiac Adult Musculo-skeletal (Conventional, Superficial) Peripheral Vascular Trans-vaginal Urology	Fetal Abdominal Intra-operative Pediatric Small organ(breast, thyroid, testes) Neonatal cephalic Adult cephalic Trans-rectal Trans-vaginal Trans-esoph Musculo-skeletal(conventional), musculo- skeletal(superficial), Thoracic/Pleural Cardiac(adult,pediatric)Peripheral vessel Urology exams.	Same
Design	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	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 , Phase array and Volume probes . Cine play back capability Image file archive	Same
Safety Compliance	ANSI AAMI ES60601-1 IEC 60601-1-2	ANSI AAMI ES60601-1 IEC 60601-1-2	ANSI AAMI ES60601-1 IEC 60601-1-2	ANSI AAMI ES60601-1 IEC 60601-1-2	Same

Items	Submission Device	Main predicate device	Reference device	Reference device	Remark
	SonoPort Series Digital Color Doppler Ultrasound System	SonoMax 22 Digital Color Doppler Ultrasound System (K233697)	SonoAir 90 Digital Color Doppler Ultrasound System (K223570)	Consona N6 Diagnostic Ultrasound System (K221496)	
	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23 IEC 60601-2-37	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23 IEC 60601-2-37	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23 IEC 60601-2-37	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23 IEC 60601-2-37	
Operation Mode	B Mode	B Mode	B Mode	B Mode	Same
	FHI	FHI	FHI	/	Same
	B/M Mode	B/M Mode	B/M Mode	B/M Mode	Same
	M Mode	M Mode	M Mode	M Mode	Same
	Dual mode	Dual mode	B/B mode	/	Same
	Quad mode	Quad mode	4B mode	/	Same
	CFM mode	CFM mode	CFM mode	Color Doppler	Same
	CPA mode	CPA mode	CPA mode	Amplitude Doppler	Same
	DPD mode	DPD mode	DPD mode	/	Same
	PW mode	PW mode	PW mode	PWD	Same
	CW mode	CW mode	/	CWD	Same
	B/BC mode	B/BC mode	/	/	Same
	2D Steer	2D Steer	2D Steer	/	Same
	Triplex	Triplex	Triplex	/	Same
	Quadplex	Quadplex	Quadplex	/	Same
	Curved Panoramic	Curved Panoramic	Curved Panoramic	iScape View	Same
	Auto TGC	Auto TGC	TGC	/	Same
	Biopsy	Biopsy	Biopsy	iNeedle	Same
	Free Steer M	Free Steer M	Free Steer M	Free Xros M	Same
	HPRF Mode	HPRF Mode	HPRF Mode	/	Same
	TDI	TDI	/	Tissue Doppler Imaging	Same
	Color M	Color M	Color M	Color M	Same
	TSS	TSS	/	/	Same
	Sono Contrast	Sono Contrast	Sono Contrast	Contrast imaging	Same
	SoundFlow	SoundFlow	/	/	Same

Items	Submission Device	Main predicate device	Reference device	Reference device	Remark
	SonoPort Series Digital Color Doppler Ultrasound System	SonoMax 22 Digital Color Doppler Ultrasound System (K233697)	SonoAir 90 Digital Color Doppler Ultrasound System (K223570)	Consona N6 Diagnostic Ultrasound System (K221496)	
	SonoVector	SonoVector	/	/	Same
	LGC	LGC	LGC	/	Same
	HD 3D	HD 3D	HD 3D	Smart 3D	Same
	Stress Echo	Stress Echo	Stress Echo	Stress Echo	Same
	Strain and Strain Rate	Strain and Strain Rate	Strain and Strain Rate	/	Same
	Zoom	Zoom	Zoom	/	Same
	DICOM	DICOM	DICOM	DICOM Basic	Same
	Trapezoidal Imaging	Trapezoidal Imaging	Trapezoidal	/	Same
	Compound	Compound	Compound	/	Same
	SRA	SRA	SRA	/	Same
	ECG	ECG	ECG	ECG	Same
	Human Bodymark	Human Bodymark	Human Bodymark	/	Same
	Auto IMT	Auto IMT	Auto IMT	IMT	Same
	Free NT	Free NT	/	Smart NT	Same
	Super Needle	Super Needle	Super Needle	/	Same
	general measurement package	general measurement package	general measurement package	Abdomen/General Package	Same
	OB measurement package	OB measurement package	OB measurement package	Obstetrics Package	Same
	GYN measurement package	GYN measurement package	GYN measurement package	Gynecology Package	Same
	URO measurement package	URO measurement package	URO measurement package	Urology Package	Same
	cardiac measurement package	cardiac measurement package	cardiac measurement package	Cardiology Package	Same
	vascular measurement package	vascular measurement package	vascular measurement package	Vascular Package	Same
	small parts measurement package	small parts measurement package	small parts measurement package	Small Parts Package	Same
	Pediatric measurement	Pediatric measurement	Pediatric measurement	Pediatrics Package	Same

Items	Submission Device	Main predicate device	Reference device	Reference device	Remark
	SonoPort Series Digital Color Doppler Ultrasound System	SonoMax 22 Digital Color Doppler Ultrasound System (K233697)	SonoAir 90 Digital Color Doppler Ultrasound System (K223570)	Consona N6 Diagnostic Ultrasound System (K221496)	
	package	package	package		
	TCD measurement package	TCD measurement package	TCD measurement package	/	Same
	4D software package	4D software package	/	4D	Same
	Virtual HD	Virtual HD	/	/	Same
	SonoOB	/	SonoOB	Smart OB	Same
	SonoFusion	SonoFusion	/	/	Same
	Q-image	Q-image	Q-image	/	Same
	Q-flow	Q-flow	/	/	Same
	Q-beam	Q-beam	Q-beam	/	Same
	SonoColor	SonoColor	SonoColor	/	Same
	SonoNeedle	/	SonoNeedle	/	Same
	Extended Imaging	/	Convex Array Extended	/	SE Analysis 1
	Intelligent doppler	/	Intelligent doppler	/	Same
	Volume Flow	Volume Flow	Volume Flow	Glazing Flow	Same
	Elastography	Elastography	Elastography	Strain Elastography	Same
	SonoBeam	SonoBeam	/	/	Same
	AIO	AIO	AIO	/	Same
Display Annotations	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	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	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	Same

Items	Submission Device	Main predicate device	Reference device	Reference device	Remark
	SonoPort Series Digital Color Doppler Ultrasound System	SonoMax 22 Digital Color Doppler Ultrasound System (K233697)	SonoAir 90 Digital Color Doppler Ultrasound System (K223570)	Consona N6 Diagnostic Ultrasound System (K221496)	
Measurements	**2D mode:** Depth,Distance, Area:Ellipse, Trace, Spline, Trace, Length ,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, ED/PS, Volume Flow;	**2D mode:** Depth,Distance, Area:Ellipse, Trace, Spline, Trace, Length ,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, ED/PS, Volume Flow;	**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;	/	Same
Transducer Types & Connectors	Convex Array, Phased Array, Linear Array,Volume probe 5ports	Convex Array, Phased Array, Linear Array,Volume probe 5ports	Convex Array, Phased Array, Linear Array, 4ports	Convex Array, Phased Array, Linear Array,Volume probe 4ports	Same
Users / Sites	Hospitals, clinics usage	Hospitals, clinics usage	Hospitals, clinics usage	Hospitals, clinics usage	Same
Acoustic Output	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	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	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/cm2 max	$I_{spta.3}$ (mW/cm2) $\leqslant$ 720, $I_{sppa.3}$ (W/cm2) $\leqslant$ 190 or MI $\leqslant$ 1.9	Same

Items	Submission Device	Main predicate device	Reference device	Reference device	Remark
	SonoPort Series Digital Color Doppler Ultrasound System	SonoMax 22 Digital Color Doppler Ultrasound System (K233697)	SonoAir 90 Digital Color Doppler Ultrasound System (K223570)	Consona N6 Diagnostic Ultrasound System (K221496)	
		Isppa: 190 W/cm^2 max			
Power Requirements	Power requirements: AC :100V- 240V, Frequenzy:50-60Hz Operating temperature: 10-40℃; relative humidity 30-75%; Barometric pressure: 700 to 1060 hPa	Power requirements: AC :100V- 240V, Frequenzy:50-60Hz Operating temperature: 10-40℃; 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	Power requirements: AC :100V- 240V, Frequenzy:50-60Hz Operating temperature: 0-40℃; relative humidity 20-85%; Barometric pressure: 700 to 1060 hPa	Same

SE Analysis 1：

Operation mode: Compared with equivalent devices, the submitting device adopts the same operation mode, only with a different name description. But both comply with the requirements of ANSI AAMI ES60601-1 and IEC60601-2-37, and meet clinical requirements. Therefore, they can be considered as essentially equivalent in terms of safety and effectiveness, without creating new risks, and therefore SE will not be affected.

Probes Comparison:

Subject device SonoPort Series has the same/similar probes as the predicate device SonoMax Series (K233697).

Submission Device	Main predicate device	Remark
SonoPort Series Digital Color Doppler Ultrasound System	SonoMax 22 Digital Color Doppler Ultrasound System (K233697)	
L4-10 Linear probe,L3-10 Linear probe,L6-18 Linear probe,L4-15B Linear probe,L6-15i Linear probe,L4-10R Linear probe,L3-8 Linear probe,L5-14 Linear probe,L11-20 Linear probe,ML4-6 Linear probe,LA1-15 Linear probe	L4-10 Linear probe,L3-10 Linear probe,L6-18 Linear probe,L4-15B Linear probe,L6-15i Linear probe,L4-10R Linear probe,L3-8 Linear probe,L5-14 Linear probe,L11-20 Linear probe,ML4-6 Linear probe,LA1-15 Linear probe	Same
E4-10 Micro convex probe,C1-5 Convex probe,MC1-5 Convex probe,C1-7 Convex probe,C1-7P Convex probe,C1-6 Convex probe,C2-6 Convex probe,C4-11 Micro convex probe,E4-13 Micro convex probe,BL3-12 Bi-plane probe	E4-10 Micro convex probe,C1-5 Convex probe,MC1-5 Convex probe,C1-7 Convex probe,C1-7P Convex probe,C1-6 Convex probe,C2-6 Micro Convex probe,C4-11 Micro convex probe,E4-13 Micro convex probe,BL3-12 Micro convex probe	Same
S1-5P Phased array probe,S1-5 Phased array probe,S2-8 Phased array probe,S4-12 Phased array probe,MS1-5 Phased array probe	S1-5P Phased array probe,S1-5 Phased array probe,S2-8 Phased array probe,S4-12 Phased array probe,MS1-5 Phased array probe	Same
V2-6 Volume probe,VE4-10 Volume probe	V2-6 Volume probe,VE4-10 Volume probe	Same
CW2 Pencil probe	CW2 Pencil probe	Same
T4-6 Tee probe,MT4-6 Tee probe	T4-6 Tee probe,MT4-6 Tee probe	Same

The 31 transducers(probes) are same,and have been cleared in the SonoMax Series Digital Color Doppler Ultrasound System (K233697) , manufactured by CHISON Medical Technologies Co., Ltd.Therefore, they can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised.

Compared with the predicate device, there are 8 new transducers(probes) asfollowed: P2WS,P2,C3-12, 3C,P5,C2-9,S3-7,S4-10 which is similar with the probes cleared with predicate device SonoMax Series(K233697) and SonoAir Series(K223570).
The engineering drawings of the new function transducers(probes) (P2WS,P2,C3-12, 3C,P5,C2-9,S3-7,S4-10), and the further comparison are provided as followed.

Table 1) Further Comparison for P2WS Probe

Comparison Items	Subject Device SonoPort Series (K253949)	Reference Device Legally marketed SonoMax Series (K233697)	Remark
Probe1	P2WS	L5-10W	/
Photo			/
Probe Type	Linear probe	Linear probe	Same
Frequency	4.5-10.0MHz	4.0-10.0MHz	SE Analysis 2
Indication for use	Pediatric,Small Organ (breast,thyroid,testes),Musculo-skeletal (Conventional, Superficial), Peripheral Vascular	Pediatric,Small Organ (breast,thyroid,testes), Musculo-skeletal (Conventional, Superficial), Peripheral Vascular	Same
Operation Mode	B Mode	B Mode	Same
	B/M Mode	B/M Mode	
	M Mode	M Mode	
	Dual mode	Dual mode	
	Quad mode	Quad mode	
	CFM mode	CFM mode	
	CPA mode	CPA mode	
	DPD mode	DPD mode	
	PW mode	PW mode	
	B/BC mode	B/BC mode	
	2D Steer	2D Steer	
	Triplex	Triplex	
	Quadplex	Quadplex	
	HPRF Mode	HPRF Mode	
	Sono Contrast	Sono Contrast	
	HD 3D	HD 3D	
	Zoom	Zoom	
	Trapezoidal Imaging	Trapezoidal Imaging	
	Elastography	Elastography	
Acoustic Output	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	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

Table 2) Further Comparison for P2 Probe

Comparison Items	**Subject Device** SonoPort Series (K253949)	**Reference Device Legally marketed** SonoMax Series (K233697)	Remark
Probe1	P2	L5-10W	/
Photo			/
Probe Type	Linear probe	Linear probe	Same
Frequency	4.5-10.0MHz	4.0-10.0MHz	SE Analysis 2
Indication for use	Pediatric,Small Organ (breast,thyroid,testes),Musculo-skeletal (Conventional, Superficial), Peripheral Vascular	Pediatric,Small Organ (breast,thyroid,testes), Musculo-skeletal (Conventional, Superficial), Peripheral Vascular	Same
Operation Mode	B Mode	B Mode	Same
	B/M Mode	B/M Mode	
	M Mode	M Mode	
	Dual mode	Dual mode	
	Quad mode	Quad mode	
	CFM mode	CFM mode	
	CPA mode	CPA mode	
	DPD mode	DPD mode	
	PW mode	PW mode	
	B/BC mode	B/BC mode	
	2D Steer	2D Steer	
	Triplex	Triplex	
	Quadplex	Quadplex	
	HPRF Mode	HPRF Mode	
	Sono Contrast	Sono Contrast	
	HD 3D	HD 3D	
	Trapezoidal Imaging	Trapezoidal Imaging	
	Elastography	Elastography	
Acoustic Output	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	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

Table 3) Further Comparison for C3-12 Probe

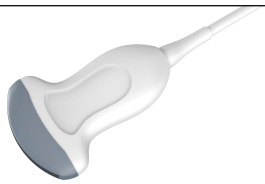
Comparison Items	**Subject Device** SonoPort Series (K253949)	**Reference Device Legally marketed** SonoMax Series (K233697)	Remark
Probe1	C3-12	C2-6	/
Photo			/
Probe Type	Convex probe	Convex probe	Same
Frequency	2.0-8.0MHz	2.0-5.3MHz	SE Analysis 2
Indication for use	Fetal, Abdominal, OB/GYN, Urology	Fetal, Abdominal, OB/GYN, Urology	Same
Operation Mode	B Mode	B Mode	SE Analysis 3
	B/M Mode	B/M Mode	
	M Mode	M Mode	
	Dual mode	Dual mode	
	Quad mode	Quad mode	
	CFM mode	CFM mode	
	CPA mode	CPA mode	
	DPD mode	DPD mode	
	PW mode	PW mode	
	B/BC mode	B/BC mode	
	Triplex	Triplex	
	Quadplex	Quadplex	
	HPRF Mode	HPRF Mode	
	Sono Contrast	Sono Contrast	
	HD 3D	HD 3D	
	Extended Imaging	/	
	Elastography	Elastography	
Acoustic Output	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	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

Table 4) Further Comparison for 3C Probe

Comparison Items	Subject Device SonoPort Series (K253949)	Reference Device Legally marketed SonoAir Series (K223570)	Remark
Probe1	3C	3C	/
Photo			/
Probe Type	Convex probe	Convex probe	Same
Frequency	1.8-4.0MHz	1.8-4.0MHz	Same
Indication for use	Fetal, Abdominal, OB/GYN, Urology	Fetal, Abdominal, OB/GYN, Urology	Same
Operation Mode	B Mode	B Mode	SE Analysis 3
	FHI	FHI	
	B/M Mode	B/M Mode	
	M Mode	M Mode	
	Dual mode	B/B mode	
	Quad mode	4B mode	
	CFM mode	CFM mode	
	CPA mode	CPA mode	
	DPD mode	DPD mode	
	PW mode	PW mode	
	B/BC mode	/	
	Triplex	Triplex	
	Quadplex	Quadplex	
	HPRF Mode	HPRF Mode	
	Sono Contrast	Sono Contrast	
	HD 3D	HD 3D	
	Extended Imaging	Convex Array Extended	
	Elastography	Elastography	
Acoustic Output	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	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

Table 5) Further Comparison for P5 Probe

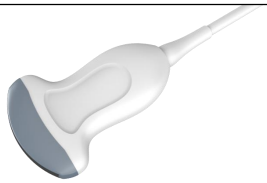
Comparison Items	Subject Device SonoPort Series (K253949)	Reference Device Legally marketed SonoMax Series (K233697)	Remark
Probe1	P5	C2-6	/
Photo			/
Probe Type	Convex probe	Convex probe	Same
Frequency	2.0-4.0MHz	2.0-5.3MHz	SE Analysis 2
Indication for use	Fetal, Abdominal, OB/GYN, Urology	Fetal, Abdominal, OB/GYN, Urology	Same
Operation Mode	B Mode	B Mode	Same
	B/M Mode	B/M Mode	
	M Mode	M Mode	
	Dual mode	Dual mode	
	Quad mode	Quad mode	
	CFM mode	CFM mode	
	CPA mode	CPA mode	
	DPD mode	DPD mode	
	PW mode	PW mode	
	B/BC mode	B/BC mode	
	Triplex	Triplex	
	Quadplex	Quadplex	
	HPRF Mode	HPRF Mode	
	Sono Contrast	Sono Contrast	
	HD 3D	HD 3D	
	Extended Imaging	Extended Imaging	
	Elastography	Elastography	
Acoustic Output	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	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

Table 6) Further Comparison for C2-9 Probe

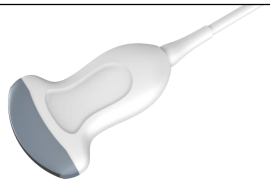
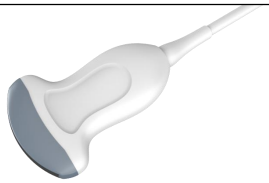
Comparison Items	Subject Device SonoPort Series (K253949)	Reference Device Legally marketed SonoMax Series (K233697)	Remark
Probe1	C2-9	C2-6	/
Photo			/
Probe Type	Convex probe	Convex probe	Same
Frequency	2.0-9.0MHz	2.0-5.3MHz	SE Analysis 2
Indication for use	Fetal, Abdominal, OB/GYN, Urology	Fetal, Abdominal, OB/GYN, Urology	Same
Operation Mode	B Mode	B Mode	Same
	B/M Mode	B/M Mode	
	M Mode	M Mode	
	Dual mode	Dual mode	
	Quad mode	Quad mode	
	CFM mode	CFM mode	
	CPA mode	CPA mode	
	DPD mode	DPD mode	
	PW mode	PW mode	
	B/BC mode	B/BC mode	
	Triplex	Triplex	
	Quadplex	Quadplex	
	HPRF Mode	HPRF Mode	
	Sono Contrast	Sono Contrast	
	HD 3D	HD 3D	
	Elastography	Elastography	
Acoustic Output	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	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

Table 7) Further Comparison for S3-7 Probe

Comparison Items	Subject Device SonoPort Series (K253949)	Reference Device Legally marketed SonoMax Series (K233697)	Remark
Probe1	S3-7	S2-8	/
Photo			/
Probe Type	Phased array probe	Phased array probe	Same
Frequency	3.0-7.0MHz	3.0-8.0MHz	SE Analysis 2
Indication for use	Cardiac (adult, pediatric)	Cardiac (adult, pediatric)	Same
Operation Mode	B Mode	B Mode	Same
	B/M Mode	B/M Mode	
	M Mode	M Mode	
	Dual mode	Dual mode	
	Quad mode	Quad mode	
	CFM mode	CFM mode	
	CPA mode	CPA mode	
	DPD mode	DPD mode	
	PW mode	PW mode	
	CW mode	CW mode	
	B/BC mode	B/BC mode	
	Triplex	Triplex	
	Quadplex	Quadplex	
	Free Steer M	Free Steer M	
	HPRF Mode	HPRF Mode	
	TDI	TDI	
	Color M	Color M	
	Sono Contrast	Sono Contrast	
	HD 3D	HD 3D	
	ECG	ECG	
	Elastography	Elastography	
Acoustic Output	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	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

Table 8) Further Comparison for S4-10 Probe

Comparison Items	Subject Device SonoPort Series (K253949)	Reference Device Legally marketed SonoMax Series (K233697)	Remark
Probe1	S4-10	S4-12	/
Photo			/
Probe Type	Phased array probe	Phased array probe	Same
Frequency	4.0-10.0MHz	4.0-10.0MHz	Same
Indication for use	Cardiac (adult, pediatric)	Cardiac (adult, pediatric)	Same
Operation Mode	B Mode	B Mode	Same
	B/M Mode	B/M Mode	
	M Mode	M Mode	
	Dual mode	Dual mode	
	Quad mode	Quad mode	
	CFM mode	CFM mode	
	CPA mode	CPA mode	
	DPD mode	DPD mode	
	PW mode	PW mode	
	CW mode	CW mode	
	B/BC mode	B/BC mode	
	Triplex	Triplex	
	Quadplex	Quadplex	
	Curved Panoramic	Curved Panoramic	
	Free Steer M	Free Steer M	
	HPRF Mode	HPRF Mode	
	TDI	TDI	
	Color M	Color M	
	Sono Contrast	Sono Contrast	
	ECG	ECG	
	Elastography	Elastography	
Acoustic Output	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	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

SE Analysis 2

Although the frequency is different, all of them comply with the requirements of IEC 60601-1 & IEC 60601-1-2 & IEC 60601-2-37 and meet clinical requirements, and no new risk is raised.

SE Analysis 3

Although the operation mode is different, the new operation modes are both comply with the requirements of ANSI AAMI ES60601-1 and IEC60601-2-37, and meet clinical requirements.

Moreover, compared with predicate device, the subject device (SonoPort Series) complies with the same regulation and safety standards and has the consistent acoustic output levels.

The clinical application is the same, the performance or frequency is similar,and the difference of these doesn't affect the safety, effectiveness and clinical use.Therefore, they can be considered Substantially Equivalent in safety and effectiveness, 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 SonoPort Series Digital Color Doppler Ultrasound System is substantially equivalent to the predicate device with regard to safety and effectiveness.