



August 9, 2024

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

Re: K233697

Trade/Device Name: SonoMax 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: July 5, 2024
Received: July 8, 2024

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 (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.

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

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

Sincerely,

Yanna S. Kang -S

Yanna Kang, Ph.D.

Assistant Director

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

Indications for Use

510(k) Number (if known)
K233697

Device Name
SonoMax Series Digital Color Doppler Ultrasound System

Indications for Use (Describe)

The SonoMax 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.

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

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: November 10th, 2023

2. Device :

Trade Name: SonoMax Series Digital Color Doppler Ultrasound System(SonoMax 1/ SonoMax 2/ SonoMax 3/ SonoMax 5/ SonoMax 6/SonoMax 7/SonoMax 7 Super/ SonoMax 7 EXP/ SonoMax 8/ SonoMax 8 Super/ SonoMax 8 EXP/SonoMax 9/ SonoMax 9 Super/ SonoMax 9 EXP/SonoMax 10/ SonoMax 11/ SonoMax 22)

Common Name: Diagnostic Ultrasound System with Transducers

Classification: Regulatory Class: II
 Review Category: Tier II

Classification 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
Predicate device	XBit 90 Digital Color Doppler Ultrasound System	IYN, IYO, ITX	K200780

4. Device Description:

The SonoMax 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 SonoMax 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 SonoMax 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	Predicate Device	Submission Device	Remark
	XBit 90 Digital Color Doppler Ultrasound System (K200780)	SonoMax 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 OB/GYN, 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	Same
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 and Phase array probes. Cine play back capability Image file archive	Same
Operating Controls Items	TGC 8 slider	TGC 10 slider	SE Analysis 1
	Depth Range: 0-45 cm	Depth Range: 0- 45 cm	Same
	256 shades of gray	256 shades of gray	Same
	B Dynamic range control: 20-180dB	B Dynamic range control: 20-180dB	Same
	Gain: 0-255, 1/step	Gain: 0-255, 1/step	Same
	Focal Number: adjustable	Focal Number: adjustable	Same
	Focus position: adjustable	Focus position: adjustable	Same

	B steer: available on linear transducers	B steer: available on linear transducers	Same
	B Persistence: 7 steps	B Persistence: 7 steps	Same
	ROI size/position: adjustable	ROI size/position: adjustable	Same
	Color Wall Filter settings:8 steps	Color Wall Filter settings:8 steps	Same
	Color Baseline:16 steps	Color Baseline: 16 steps	Same
	Color Maps: 21 maps	Color Maps: 21 maps	Same
	PW sweeping speed: 6 steps	PW sweeping speed: 6 steps	Same
	Color Invert: on/off	Color Invert: on/off	Same
	PW Wall Filter: 7 steps	PW Wall Filter: 7 steps	Same
	PW sample volume: 0.5-30mm (PW only)	PW sample volume: 0.5-30mm (PW only)	Same
	PW angle correction:-89~89degrees,1/ste	PW angle correction:-89-89degrees,1/step	Same
	Baseline: 8steps	Baseline: 8steps	Same
	Cine control:step, play backward, play continuously	Cine control:step, play backward, play continuously	Same
	Doppler Auto Trace	Doppler Auto Trace	Same
	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	Same
Operation Mode	B Mode	B Mode	Same
	FHI	FHI	Same
	B/M Mode	B/M Mode	Same
	M Mode	M Mode	Same
	Dual mode	Dual mode	Same
	Quad mode	Quad mode	Same
	CFM mode	CFM mode	Same
	CPA mode	CPA mode	Same
	DPD mode	DPD mode	Same
	PW mode	PW mode	Same

	CW mode	CW mode	Same
	B/BC mode	B/BC mode	Same
	2D Steer	2D Steer	Same
	Triplex	Triplex	Same
	Quadplex	Quadplex	Same
	Free Steer M	Free Steer M	Same
	HPRF Mode	HPRF Mode	Same
	TDI	TDI	Same
	Color M Mode	Color M Mode	Same
	TSS	TSS	Same
	Curved Panoramic	Curved Panoramic	Same
	Sono Contrast	Sono Contrast	Same
	SoundFlow	SoundFlow	Same
	SonoVector	SonoVector	Same
	Auto TGC	Auto TGC	Same
	LGC	LGC	Same
	HD 3D	HD 3D	Same
	Stress Echo	Stress Echo	Same
	Strain and Strain Rate	Strain and Strain Rate	Same
	Trapezoidal Imaging	Trapezoidal Imaging	Same
	Compound	Compound	Same
	SRA	SRA	Same
	ECG	ECG	Same
	Human Bodymark	Human Bodymark	Same
	Auto IMT	Auto IMT	Same
	Free NT	Free NT	Same
	Biopsy	Biopsy	Same
	Super Needle	Super Needle	Same
	general measurement package	general measurement package	Same
	OB measurement package	OB measurement package	Same
	GYN measurement package	GYN measurement package	Same
	URO measurement package	URO measurement package	Same
	cardiac measurement package	cardiac measurement package	Same
	vascular measurement package	vascular measurement package	Same

	small parts measurement package	small parts measurement package	Same
	Pediatric measurement package	Pediatric measurement package	Same
	TCD measurement package	TCD measurement package	Same
	4D software package	4D software package	Same
	Virtual HD	Virtual HD	Same
	SonoFusion	SonoFusion	Same
	Helpfunction	SonoHelp	Same
	Q-image	Q-image	Same
	Q-flow	Q-flow	Same
	Q-beam	Q-beam	Same
	SonoColor	SonoColor	Same
	Elastography	Elastography	Same
	SonoBeam	SonoBeam	Same
	AIO	AIO	Same
Display Annotations	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, 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;	Same
Transducer Types & Connectors	Convex Array, Phased Array, Linear Array,Volume probe 4ports	Convex Array, Phased Array, Linear Array,Volume probe 5ports	SE Analysis 2
Users / Sites	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	Same
Power Requirements	Power requirements: AC :100V- 240V, Frequenzy:50-60Hz; Operating temperature: 10-40°C; Relative humidity 30-75%; Barometric pressure:700 to 1060 hPa	Power requirements: AC :100V- 240V, Frequenzy:50-60Hz; Operating temperature: 10-40°C; Relative humidity 30-75%; Barometric pressure: 700 to 1060 hPa	Same

SE Analysis 1:

Operation Controls, compared with the predicate device, the submission device employs the same operation controls design ,but has different TGC slider. 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 2:

Compared with the predicate device, the submission device has different number of probe ports. But 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 SonoMax Series Digital Color Doppler Ultrasound System is substantially equivalent to the predicate device with regard to safety and effectiveness.