CHISON Medical Technologies Co., Ltd.
% Liu Qifei
Regulatory Affairs Manager
No. 228, Changjiang East Road, Block 51 and 53
Phase 5, Shuofang Industrial Park
Xinwu District, Wuxi, Jiangsu 214142
CHINA

August 5, 2020

Re: K200780
Trade/Device Name: XBit 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: June 6, 2020
Received: June 6, 2020

Dear Liu Qifei:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200780

Device Name
XBit Series Digital Color Doppler Ultrasound System

Indications for Use *(Describe)*
The XBit 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 a qualified clinician for evaluation of Fetal ,Abdominal,Pediatric,Small Organ (breast, thyroid,testes), Neonatal Cephalic ,Adult Cephalic,Cardiac (adult , pediatric),Musculo-skeletal (Conventional , Superficial) ,Peripheral Vascular,Transesophageal,Trans-rectal, Trans-vaginal, OB/GYN and Urology.

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

K200780

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

1. Submitter:

Submitter: CHISON Medical Technologies Co., Ltd.
Address: No.228, Changjiang East Road, Block 51 and 53, Phase 5, Shuofang Industrial Park, Xinwu District, Wuxi, Jiangsu, China 214142
Contact: Mr. Liu Qifei
Tel: +86-510-85310019
Fax: +86-510-85310021
Date Prepared: March 12th, 2020

2. Device :

Trade Name: XBit Series Digital Color Doppler Ultrasound System

Common Name: Diagnostic Ultrasound System with Transducers

Classification: 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 ultrasonic transducer	892.1570	90-ITX

3. Predicate Device(s):

Device	Model	Product Code	510(k)Number
1.Main predicate device	CBit 9 Digital Color Doppler Ultrasound System	IYN, IYO, ITX	K180974
2.Reference device	Resona 7 Diagnostic Ultrasound System	IYN, IYO, ITX	K171233
3.Reference device	Acuson x700 Diagnostic Ultrasound System	IYN, IYO, ITX, OBJ	K141846

4. Device Description:

The XBit Series Digital Color 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 LED 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 (including Fusion Harmonic Imaging), M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Power Doppler Mode, Directional Power Doppler Mode, TDI Mode or a combination of these modes, Elastography, contrast imaging, 3D/4D.

Auto Follicle, SonoBeam, SonoColor, and SonoFusion, these four features are all semi-automated functions, they need to be modified during processing.

5. Indications for Use:

The XBit 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 a qualified clinician for evaluation of Fetal,Abdominal,Pediatric,Small Organ (breast, thyroid,testes), Neonatal Cephalic ,Adult Cephalic,Cardiac (adult , pediatric),Musculo-skeletal (Conventional, Superficial), Peripheral Vascular,Transesophageal,Trans-rectal, Trans-vaginal, OB/GYN and Urology.

6. Summary of Non-Clinical Tests:

The XBit 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.

IEC 60601-1: 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 device has been found to conform to applicable FDA medical device guidance documents titled as followings:

- Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (Document issued on: June 27, 2019)
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (Document Issued on: October 2, 2014)

- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (Document issued on: June 16, 2016)

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. Comparison to Predicate Device:

Table 1 Substantial Equivalence Comparison

Items	Main predicate device	Reference device	Reference device	Submission Device	Remark
	CBit 9 Digital Color Doppler Ultrasound System K180974	Resona 7 Diagnostic Ultrasound System K171233	Acuson x700 Diagnostic Ultrasound System K141846	XBit 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 Intra-operative(abdominal, thoracic, and vascular) Pediatric Small organ(breast, thyroid ,testes) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Musculo-skeletal(conventional, superficial), Cardiac adult Cardiac pediatric Trans-esoph. (cardiac), Peripheral vessel urology	Cardiac (Adult, Pediatric) Transesphageal (Cardiac) Intracardiac Cerebrovascular Peripheral Vessel Abdominal Renal Fetal Abdominal Intra-operative Pediatric Small Organ Neonatal Cepahalic Adult Cephalic Orthopedics Musculo-skeletal Conventional Musculo-skeletal Superficial Pelvic Obstetrical Gynecological Urological	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

Items	Main predicate device	Reference device	Reference device	Submission Device	Remark
	CBit 9 Digital Color Doppler Ultrasound System K180974	Resona 7 Diagnostic Ultrasound System K171233	Acuson x700 Diagnostic Ultrasound System K141846	XBit Series Digital Color Doppler Ultrasound System	
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	Transmit ultrasonic energy into patients, then perform post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body.	The ACUSON X700 ultrasound system features a sophisticated imaging engine migrated from our premium imaging products as well as technology to bolster compatibility across systems.	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
Operating Controls	TGC 8 slider	TGC 8 slider	TGO: 8 controls	TGC 8 slider	Same
	Depth Range: 0 to 45 cm	Depth Range: 1.5 to 40 cm	Depth Range: 1 to 30 cm	Depth Range: 0 to 45 cm	Same
	256 shades of gray	NA	NA	256 shades of gray	Same
	B Dynamic range control: 20-280dB	B Dynamic range control: 30-260dB	B Dynamic range selection: 30-90dB	B Dynamic range control: 20-280dB	Same
	Gain:0-255,1/step	Gain:0-100,1/step	Gain:-30-+30,1/step	Gain:0-255,1/step	Same
	Focal Number: adjustable	No physical focus to adjust	Focal Number: adjustable	Focal Number: adjustable	Same
	Focus position: adjustable	No physical focus to adjust	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	B steer: available on linear transducers	Same
	B Persistence: 7 steps	B Persistence: 7 steps	B Persistence:5 levels	B Persistence: 7 steps	Same
	ROI size/position: adjustable	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	Wall filter：4 selections	Color Wall Filter settings:8 steps	Same
	Color Baseline: 16 steps	Color Baseline: 16 steps	Color Baseline: 9 steps	Color Baseline: 16 steps	Same
	Color Maps: 21 maps	Color Maps: 21 maps	Color maps: 16 maps	Color Maps: 21 maps	Same
	Color Invert:	Color Invert:	Color	Color Invert:	Same

Items	Main predicate device	Reference device	Reference device	Submission Device	Remark
	CBit 9 Digital Color Doppler Ultrasound System K180974	Resona 7 Diagnostic Ultrasound System K171233	Acuson x700 Diagnostic Ultrasound System K141846	XBit Series Digital Color Doppler Ultrasound System	
	on/off	on/off	invert :on/off	on/off	
	PW sweeping speed: 6 steps	PW sweeping speed: 6 steps	Sweep speed: 8 selections	PW sweeping speed: 6 steps	Same
	PW Wall Filter: 7 steps	PW Wall Filter: 8 or 9 steps	Wall filter: 25 – 3906 Hz, 8 steps	PW Wall Filter: 7 steps	Same
	PW sample volume: 0.5-30mm (PW only)	PW sample volume: 0.5-30mm (PW only)	Gate size: 0.2 – 20 mm	PW sample volume: 0.5-30mm (PW only)	Same
	PW angle correction:-89~89degrees,1/step	PW angle correction:-89~89degrees,1/step	Angle correction: 0 – 89° in 1° increments	PW angle correction:-89~89degrees,1/step	Same
	Baseline: 8steps	Baseline: 9steps	Baseline shift: 17 levels	Baseline: 8steps	Same
	Cine control: step, play backward, play continuously	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	Autotrace Function	Doppler Auto Trace	Same
	Freeze control:Toggling freeze key	Freeze control:Toggling freeze key	Freeze control:Toggling freeze key	Freeze control:Toggling freeze key	Same
Safety Compliance	IEC60601-1 IEC60601-1-2 ISO 10993-1 ISO 10993-5 ISO 10993-10 IEC 60601-2-37	IEC60601-1 IEC60601-1-2 ISO 10993-1 ISO 9001 ISO 13485 IEC 60601-2-37	EN/IEC 60601-1 EN/IEC 60601-1-1 EN/IEC 60601-1-2 EN/IEC 62304 EN/IEC 62366 EN/IEC 60601-2-18 EN/IEC 60601-2-25	IEC60601-1 IEC60601-1-2 ISO 10993-1 ISO 10993-5 ISO 10993-10 IEC 60601-2-37	Same
Operation Mode	B mode	B mode	B mode	B mode	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	Dual mode	Dual mode	Same
	Quad mode	Quad mode	Quad mode	Quad mode	Same
	CFM mode	CFM mode	CFM mode	CFM mode	Same
	CPA mode	CPA mode	PD mode	CPA mode	Same
	DPD mode	DPD mode	DPD mode	DPD mode	Same
	PW mode	PW mode	PW mode	PW mode	Same

Items	Main predicate device	Reference device	Reference device	Submission Device	Remark
	CBit 9 Digital Color Doppler Ultrasound System K180974	Resona 7 Diagnostic Ultrasound System K171233	Acuson x700 Diagnostic Ultrasound System K141846	XBit Series Digital Color Doppler Ultrasound System	
	B/BC mode	B/BC mode	B/BC mode	B/BC mode	Same
	2D Steer	2D Steer	NA	2D Steer	Same
	Triplex mode	Triplex mode	Triplex mode	Triplex mode	Same
	Quadplex	Quadplex	NA	Quadplex	Same
	HD 3D	NA	Freehand 3D	HD 3D	Same
	CW mode	CW mode	CW mode	CW mode	Same
	Free Steering M mode	Free Xros M	Anatomical M mode	Free Steering M mode	Same
	HPRF	NA	NA	HPRF	Same
	S-flow	NA	NA	S-flow	Same
	Auto TGC	NA	TGO	Auto TGC	Same
	Stress echo	Stress echo	Stress echo	Stress echo	Same
	TDI	TDI	TDI	TDI	Same
	Color M mode	Color M mode	Color M mode	Color M mode	Same
	Curved Panoramic	iScape view	SieScape	Curved Panoramic	Same
	Trapezoidal image	ExFov	Trapezoidal Mode	Trapezoidal image	Same
	compound	NA	SieClear	compound	Same
	SRA	iClear	Speckle Reduction(SRI)	SRA	Same
	Chroma	NA	NA	Chroma	Same
	Elastography	Elastography	Strain-based Elastography	Elastography	Same
	ECG	ECG	ECG	ECG	Same
	LV tracking Strain and Strain Ratio	TT QA(Tissue Tracking)	Auto LH Strain and Strain Rate	LV tracking Strain and Strain Ratio	Same
	LGC	LGC	Na	LGC	Same
	Auto IMT	Auto IMT	Auto IMT	Auto IMT	Same
	Free NT	Smart NT	NA	Free NT	Same
	Super Needle	iNeedle	NA	Super Needle	Same
	NA	TSI	NA	TSS	Same
	NA	Contrast Imaging	Contrast Agent Image	SonoContrast	Same
	S-Flow	NA	NA	SoundFlow	Same
	NA	V Flow	NA	SonoVector	Same
	NA	NA	Syno Auto Follicle	Auto Follicle	**SE Analysis 1**
	NA	Smart OB	Syno Auto OB	Free OB	same
	NA	Fusion Imaging	NA	SonoFusion	**SE Analysis 2**
	NA	Color Vel	NA	SonoColor	**SE**

Items	Main predicate device	Reference device	Reference device	Submission Device	Remark
	CBit 9 Digital Color Doppler Ultrasound System K180974	Resona 7 Diagnostic Ultrasound System K171233	Acuson x700 Diagnostic Ultrasound System K141846	XBit Series Digital Color Doppler Ultrasound System	
					Analysis 3
	general measurement package	general measurement package	NA	general measurement package	Same
	OB measurement package	OB measurement package	Obstetrics measurement package	OB measurement package	Same
	GYN measurement package	GYN measurement package	Gynecology measurement package	GYN measurement package	Same
	URO measurement package	URO measurement package	Urology measurement package	URO measurement package	Same
	cardiac measurement package	cardiac measurement package	cardiac measurement package	cardiac measurement package	Same
	vascular measurement package	vascular measurement package	Venous measurement package Cerebrovascular measurement package Peripheral Vascular measurement package	vascular measurement package	Same
	small parts measurement package	small parts measurement package	NA	small parts measurement package	Same
	Pediatric measurement package	Pediatric measurement package	Orthopedic measurement package	Pediatric measurement package	Same
	TCD measurement package	TCD measurement package	Cerebrovascular measurement package	TCD measurement package	Same
	4D software package	4D software package	4D software package	4D software package	Same
	Breast measurement package	Breast measurement package	Breast measurement package	Breast measurement package	Same
	Virtual HD	iLive	NA	Virtual HD	Same
	X-Contrast	iBeam	NA	X-Contrast	Same
	FHI	THI	THI	FHI	Same
	Q-image	NA	NA	Q-image	Same

Items	Main predicate device	Reference device	Reference device	Submission Device	Remark
	CBit 9 Digital Color Doppler Ultrasound System K180974	Resona 7 Diagnostic Ultrasound System K171233	Acuson x700 Diagnostic Ultrasound System K141846	XBit Series Digital Color Doppler Ultrasound System	
	Q-flow	NA	NA	Q-flow	Same
	Q-beam	NA	NA	Q-beam SonoBeam	**SE Analysis 4**
	AIO	iTouch	NA	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;ECG ico;TGC Corve; 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;ECG ico;TGO 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;ECG ico;TGC Corve;Focus position;Imaging parameters;Dynamic Trackball indices; System status;Gray/Color bar	Same
Measurements	**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	**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	**2D mode:** Depth, Distance, Angle, Area and circumference: ellipse, trace, Volume: 1 distance, 2 distance, 3 distance, 1 ellipse and 1 distance Flow volume: 1 velocity and 1 distance, 1 velocity and 1ellipse, Stenosis: 2 ellipse, 2 distance; **M mode:** Distance, Time, Slope, Heart Rate; **Doppler mode:**	**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	Same

Items	Main predicate device	Reference device	Reference device	Submission Device	Remark
	CBit 9 Digital Color Doppler Ultrasound System K180974	Resona 7 Diagnostic Ultrasound System K171233	Acuson x700 Diagnostic Ultrasound System K141846	XBit Series Digital Color Doppler Ultrasound System	
	Rate,Acceleration ,D Trace,PS/ED , Volume Flow;	Rate,Acceleration ,D Trace,PS/ED , Volume Flow;	Velocity/Frequency/Pressure Gradient, Heart rate/Heart cycle/Time, PS, ED, TAMx, TAMn, PI, RI, S/D, TAV, VTI, Acceleration/Deceleration, Flow volume	Rate,Acceleration ,D Trace,PS/ED , Volume Flow;	
Transducer Types & Connectors	Convex Array, Phased Array, Linear Array,Volume probe 4ports	Convex Array, Phased Array, Linear Array,Volume probe 4ports	Convex Array, Phased Array, Linear Array,Volume probe 3ports	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/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/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:50-60 Hz Operating temperature:10-40 ℃ ; 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	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	Same

Comparison Analysis

SE Analysis 1:
Operation Controls, compared with the predicate device--Acuson x700 Diagnostic Ultrasound System, the subject device employs the same operation controls design and has some differences in analyzed object.
The syngo® Auto Follicle measurement option of predicate device is an automated measurement tecnique that enables fast and acurate assessment of multiple follicles. Follicles measurement methods supported Distance, 2Dist + Avg,-- 3Dist + Avg,-- 2Dist Avg,-- 3Dist Avg,-- Area,-- Volume,-- Circumference.
Auto Follicle Detection of subject device can automatically identify, trace, and calculate the area and circumference of the follicle after the user moves the square ROI to the follicle area. It is operated in a semi-automated fashion since the output value of area and circumference can be modified.
But both of them can get area and circumference of follicle. so the SE is not affected.

SE Analysis 2:
Operation Controls, compared with the predicate device, the subject device employs the same operation controls design and has some differences in navigation device and navigation bracket. But both of them can make real-time ultrasound image match with CT/MR image. Both of them can improve the diagnostic efficiency. so the SE is not affected.

SE Analysis 3:
Operation Controls, compared with the predicate device, the subject device employs the same operation controls design and has some differences in angle acquisition. subject device recognizes the vessel angle automatically. The predicate reference device recognizes the vessel angle by user control. But both of them can get point velocity and meet clinical requirements. so the SE is not affected.

SE Analysis 4:
Operation Controls, the sonobeam function is a type of image optimization technology. SonoBeam is an improved version of Q-beam as a multi-beam blood flow high frame rate function which is based on traditional dual beamformer principle. Compared with Q-beam, SonoBeam multi-beamformer can improve the processing speed, and then increase the frame rate of image display and reduce noise. But both of them can improve image quality. so the SE is not affected.

9. Substantially Equivalent 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 XBit Series Digital Color Doppler Ultrasound System is substantially equivalent to the predicate devices with regard to safety and effectiveness.