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

February 26, 2021

Re: K201968
Trade/Device Name: SonoEye P3/ SonoEye V3/ Sono Eye G3 Digital Color Doppler Palm 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: January 13, 2021
Received: January 27, 2021

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 (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 and Part 809); 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)*
K201968

Device Name
SonoEye P3/ SonoEye V3/ SonoEye G3 Digital Color Doppler Palm Ultrasound System

Indications for Use *(Describe)*
The Digital Color Doppler Palm Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), B/M, CFM, Combined (B+CFM), Pulsed Wave and Fusion Harmonic Imaging modes. It is indicated for Abdominal, Neonatal Cephalic, Adult Cephalic, Cardiac Adult, Cardiac Pediatric.
The Digital Color Doppler Palm Ultrasound System is intended for use in environments where healthcare is provided by healthcare professionals.

Type of Use *(Select one or both, as applicable)*

[X] 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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K201968

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.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: July 3, 2020

2. **Device :**

Trade Name: SonoEye P3/ SonoEye V3/ SonoEye G3 Digital Color Doppler Palm 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	Lumify Diagnostic Ultrasound System	IYN,IYO,ITX	K192226
2.Reference device	Clarius Ultrasound System	IYN,ITX,IYO	K192107
3.Reference device	TE7 Diagnostic Ultrasound System	IYN,ITX,IYO	K 160381

4. **Device Description:**

The SonoEye P3/ SonoEye V3/ SonoEye G3 Digital Color Doppler Palm Ultrasound System is a mobile, general purpose, softwarecontrolled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data in various modes of operation. The SonoEye P3/ SonoEye V3/ SonoEye G3 Digital Color Doppler Palm

Ultrasound System is a portable system facilitating point of care ultrasound applications. The SonoEye P3 Series Digital Color Doppler Palm Ultrasound System includes:

• A commercial off-the-shelf (COTS) Android mobile device
• CHISON Ultrasound software is running as an app (Android) on the COTS device
• The SonoEye P3, SonoEye V3, SonoEye G3 Phase array USB transducer

5. **The requirement of commercial off-the-shelf (COTS) devices**

All models need to comply with IEC55032, IEC60950-1, among which we have selected typical models to do verification testing with SonoEye on ANSI/AAMI ES60601-1 and IEC60601-1-2, such as Samsung Galaxy A70s or Huawei MatePad Pro.

- Electrical Safety

The transducer and software, along with a representative device, have been verified as compliant with IEC 60601-1. The transducers meet Type BF isolated applied part requirements. When the transducer and software are used in conjunction with a device(COTS devices) compliant with IEC 60950‑1, the system meets IEC 60601-1 requirements for Class II equipment.

- Electromagnetic Compatibility

The transducer and representative Android device are classified as Group 1, Class A equipment in accordance with international standard CISPR 11 for radiated and conducted electromagnetic disturbances. When the transducer and software are used in conjunction with a device(COTS devices) compliant with IEC 55032, the system meets IEC 60601‑1-2 requirements for Group1,Class A equipment.

- Android devices' output current and voltage

The representative Android devices' output current is 1.5A and voltage is 5V. A COTS device connected to our transducer and system should meet the current and voltage range, the output current is greater than or equal to 1.5A, and the output voltage is 5V±5%.

- Full compliance with USB 2.0 standard

The representative Android devices are full compliance with USB 2.0 standard. A COTS device connected to our transducer and system should meet the standard.

- Representative Android devices

Representative Android devices are Samsung Galaxy A70s and Huawei MatePad Pro.The configuration is as follows.

Samsung Galaxy A70s：
•CPU frequency 2.0GHz (big quad core), 1.7GHz (small quad core), Octa-core
•RAM capacity 8GB
•ROM capacity 128GB
•Main screen resolution 2400x1080 pixels
•WLAN function Dual-band WIFI, IEEE 802.11 a/b/g/n/ac (support 2.4G and 5GHz)
•Operating System: Android 9
•Support Bluetooth 5.0

•Huawei MatePad Pro：
•CPU frequency 2 x Cortex-A76 Based 2.86 GHz+ 2 x Cortex-A76 Based 2.09 GHz+ 4 x Cortex-A55 1.86 GHz, Octa-core
•RAM capacity 8GB
•ROM capacity 128GB
•Main screen resolution 2560x1600 pixels
•WiFi function supports dual frequency (2.4GHz+5GHz)
•Bluetooth function supports Bluetooth 5.1 module
•Operating System: Android 9

6. Indications for Use:

The Digital Color Doppler Palm Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), B/M,CFM,Combined (B+CFM), Pulsed Wave and Fusion Harmonic Imaging modes. It is indicated for Abdominal, Neonatal Cephalic, Adult Cephalic, Cardiac Adult, Cardiac Pediatric.

The Digital Color Doppler Palm Ultrasound System is intended for use in environments where healthcare is provided by healthcare professionals.

7. Summary of Non-Clinical Tests:

The Digital Color Doppler Palm 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.

The product fulfils the requirement of:

ANSI/AAMI ES60601-1:2005Medical Electrical Equipment - Part 1: General Requirements for Safety.

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: 2007 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.

ISO 10993-1:2009 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)

8. 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.

9. Comparison to Predicate Device:

Table 1 Substantial Equivalence Comparison

Items	Main predicate device	Reference device	Reference device	Submission Device	Remark
	Lumify Diagnostic Ultrasound System	Clarius Ultrasound System	TE7 Diagnostic Ultrasound System	Digital Color Doppler Palm Ultrasound System	
Indications for Use	Fetal/Obstetric, Abdominal, Pediatric, Cephalic, Urology, Gynecological, Cardiac Fetal Echo, Small Organ, Musculoskeletal, Peripheral Vessel, Carotid, Cardiac.	ophthalmic, fetal, abdominal, intraoperative (non-neurological), pediatric, small organ, cephalic (adult), trans-rectal, transvaginal, musculo-skeletal (conventional, superficial), urology, gynecology, cardiac (adult, pediatric), peripheral vessel, carotid, and procedural guidance of needles into the body.	fetal, abdominal, intra-operative(abdominal, thoracic, and vascular), pediatrics, small organ(breast, thyroid, testes), neonatal and adult cephalic, trans-esoph.(Cardiac), trans-vaginal, musculo-skeletal(conventional, superficial), urology, peripheral vessel, adult and pediatric cardiac, ophthalmic exams	Abdominal, Neonatal Cephalic, Adult Cephalic, Cardiac Adult, Cardiac, Pediatric	Same

Items	Main predicate device	Reference device	Reference device	Submission Device	Remark
	Lumify Diagnostic Ultrasound System	Clarius Ultrasound System	TE7 Diagnostic Ultrasound System	Digital Color Doppler Palm Ultrasound System	
Design	Autocorrelation for color processing and FFT for pulse 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 Doppler processing. Supporting Linear, Phase array, Micro convex array, Endocavity probe and Volume probes. Cine play back capability Image file archive	Autocorrelation for color processing and FFT for pulse Doppler processing. Supporting Linear, convex and phased array. Cine play back capability Image file archive	Autocorrelation for color processing and FFT for pulse Doppler processing. Supporting Phased probe. Cine play back capability Image file archive	Same
Operating Controls	TGC	TGC	TGC	STC	Same
	Depth Range: 0.003 to >30 cm	Depth Range: 5.0 to 10.0cm (Depth depend on probe type)	Depth depend on probe type	Depth Range: 1.0 to 22cm	SE Analysis 1
	256 shades of gray	256 in B-Mode	30-240 in B mode	256 shades of gray	Same
	Gain	Gain	Gain	Gain:0-255,1/step	Same
	Focus	Focus	Focus	Focus: adjustable	Same
	Color box size/position can be adjust	ROI adjust	ROI adjust	ROI size/position: adjustable	Same
	N/A	Baseline	Baseline	Baseline	Same
	Cine control: drag scroll bar, press  or 	Tap the cine capture button to capture the cine as part of the exam.	Cine control	Cine control: step, play backward, play continuously	Same
	Freeze control: Toggling freeze key	Freeze control: Toggling freeze key	Freeze control: Toggling freeze key	Freeze control: Toggling freeze key	Same
Safety Compliance	ANSI/AAMI ES60601-1 IEC60601-1 IEC60601-2-37 IEC60601-1-2 ISO 10993-1	ANSI/AAMI ES60601-1 IEC60601-1 IEC 60601-2-37 IEC 60601-1-2 ISO 10993-1	ANSI/AAMI ES60601-1 IEC60601-1 IEC60601-2-37 IEC60601-1-2 ISO 10993-1	ANSI/AAMI ES60601-1 IEC60601-1 IEC60601-2-37 IEC60601-1-2 ISO 10993-1	Same

Items	Main predicate device	Reference device	Reference device	Submission Device	Remark
	Lumify Diagnostic Ultrasound System	Clarius Ultrasound System	TE7 Diagnostic Ultrasound System	Digital Color Doppler Palm Ultrasound System	
Operation Mode	B mode	B mode	B mode	B mode	Same
	N/A	PW mode	Pulsed wave Doppler mode	PW mode	Same
	M mode	M mode	M mode	B/M mode	Same
	Color mode	Color Doppler Mode	Color mode	CFM mode	Same
	N/A	N/A	IQ	FHI	Same
	Gain	Gain	Gain	Gain	Same
	Depth	Depth	Depth	Depth	Same
	TGC	TGC	TGC	STC	Same
	N/A	Spatial Compound	Spatial Compound	Compound	Same
	Frequency	Frequency	Frequency	Frequency Scaling	Same
	Freeze	Freeze	Freeze	Freeze/Unfreeze	Same
	Zoom	Zoom	Zoom	Zoom	Same
	2D distance	2D distance	distance	B-distance	Same
	Circumference	Circumference	Circumference	B-Circumference	Same
	Area	Area	Area	B-Area	Same
	N/A	Volume	Volume	B-Volume	Same
	N/A	Distance	Distance	B/M-Distance	Same
	N/A	M-Time	Time	B/M-Time	Same
	N/A	M-HR	HR	B/M-HR	Same
	N/A	Velocity	Velocity	PW-Velocity	Same
	N/A	Time	Time	PW-Time	Same
	N/A	Vascular	Vascular	Vessel measure package	Same
	N/A	Small Organ	Abdomen	Abdomen measure package	Same
	N/A	N/A	Cardiology	Cardiac measure package	Same
	N/A	Report	Report	General report	Same
	N/A	N/A	Vascular Exam Report	Vessel report	Same
	N/A	N/A	Abdomen Exam Report	Abdomen report	Same
	N/A	N/A	Cardiac Exam Report	Cardiac report	Same
	Language follow system	N/A	Multi-language Interface	Multi-language Interface	Same
	Thumbnail	N/A	Thumbnail window	Clipboard	Same
	N/A	N/A	iTouch	Instant AIO	Same
	Biopsy Guide	Biopsy Guide	Biopsy Guide	Biopsy Guide	Same

Items	Main predicate device	Reference device	Reference device	Submission Device	Remark
	Lumify Diagnostic Ultrasound System	Clarius Ultrasound System	TE7 Diagnostic Ultrasound System	Digital Color Doppler Palm Ultrasound System	
	Line				
	Reacts Session Views	N/A	N/A	SonoRemote	Same
	N/A	N/A	iNeedle	SonoNeedle	Same
	N/A	NeedleEnhance	iNeedle	SuperNeedle	Same
	Save Loop	Save Cine	Save Clip	Save Cine	Same
	Save Image	Save Image	Save Image	Save Image	Same
	Playing Loops	Cine Loop	CineReview	Cine Loop	Same
	Annotation	Annotation	Annotation	Annotation	Same
	N/A	Bodymark	Bodymark	Bodymark	Same
	N/A	N/A	Arrow	Arrow Mark	Same
	Patient Database	Patient information	Patient information	Patient management	Same
	N/A	Angle/Baseline on PW	Angle/Baseline on PW	Voice/Angle/Baseline on PW	Same
	N/A	N/A	Physical key	Physical key	Same
	Setting	Setting	Setup	Setting	Same
	Patient Database	Patient information	Patient data management	Archives	Same
	Walkthrough	Quick Start Guide and Video Tutorials	Operation Note	Tutorials	Same
	Review	Review	Review	Easyview	Same
	N/A	Demo	iVision	Demo	Same
	About	N/A	System information	About	Same
	N/A	Adjust sample Gate location	Drag the SV gate to place the SV on the target	Adjust sample Gate location	Same
	N/A	Adjust size of sample Gate horizontal	Drag the SV gate to place the SV on the target	Adjust size of sample Gate horizontal	Same
	N/A	Adjust size of sample Gate vertical	Drag the SV gate to place the SV on the target	Adjust size of sample Gate vertical	Same
	N/A	Adjust PW sample gate	Drag the SV gate to place the SV on the target	Adjust PW sample gate	Same

Items	Main predicate device	Reference device	Reference device	Submission Device	Remark
	Lumify Diagnostic Ultrasound System	Clarius Ultrasound System	TE7 Diagnostic Ultrasound System	Digital Color Doppler Palm Ultrasound System	
Display Annotations	Logo; Hospital Name;Exam date;Exam time;Mechanical index;Thermal indes;Probe model;TGC Corve;Focus position;Imaging parameters; System status;Gray/Color bar	Logo Hospital Name(NA) Exam date; Exam time; End exam;MI; TI; TGC; Probe model; Imaging parameters; System status; Gray/Color bar	Probe model, acoustic output value, MI,TI, iNeedle, iTouch, frequency, TGC, System status, Depth, Gain	Logo; Hospital Name; Exam date; Exam time; Mechanical index; Thermal indes; Probe model; STC; Focus position; Imaging parameters; System status; Gray/Color bar	Same
Measurements	**2D mode:** Depth , Distance ,Area, Circumference	**B mode:** Depth, Distance, Area, Circumference **Doppler mode:** Volume, Velocity, Time **M mode:** Distance, Time, HR	**2D mode:** Depth, Distance, Area, Circumference **B/C mode:** Volume **Doppler mode:** Velocity, Time, **M mode:** Distance, Time, HR	**2D mode:** Depth, Distance, Area, Volume **Doppler mode:** D Velocity, Time, **B/M mode:** Distance, Time, HR	Same
Transducer Types & Connectors	Convex Array, Phased Array, Linear Array, USB interface	Micro convex array, Endocavity probe and Volume probes	Linear, convex and phased array.	Phased Array USB interface	Same
Users / Sites	Hospitals, clinics usage	Hospitals, clinics usage	Hospitals, clinics usage	Hospitals, clinics usage	Same
Acoustic Output	Track 3; Ispta.3 ≤ 720 mW/cm^2 MI ≤ 1.9 TI ≤ 6.0	Track 3 (ISPTA) of 720 mW/ cm^2 MI: 0.0 to 1.9, TI: This is continuously displayed over the range of 0.0 to maximum output, based on the scanner and application, in increments of	Track 3 Ispta.3 ≤ 720 mW/cm^2 MI ≤ 1.9	Track 3; Ispta.3 ⩽ 720 mW/cm^2 MI ⩽ 1.9 TI ⩽ 6.0	Same

Items	Main predicate device	Reference device	Reference device	Submission Device	Remark
	Lumify Diagnostic Ultrasound System	Clarius Ultrasound System	TE7 Diagnostic Ultrasound System	Digital Color Doppler Palm Ultrasound System	
		0.1			
Power Requirements	Power requirements: AC :100V-240V, Frequenzy:50-60Hz Operating temperature:5-40 ℃ ; relative humidity 15-95%; Barometric pressure:700 to 1060 hPa	Input: 12 VDC, 11.5 A Temperature: 0°C (50°F) to 40°C (113°F) Humidity: 15% to 95%s	Voltage: 100V-240V Temperature: 0°C (50°F) to 40°C (113°F) Humidity: 30% to 85%s Atmosphere pressure: 700 to 1060 hPa	Power requirements: DC 5V, Operating temperature:10-38 ℃ ; relative humidity 30-75%; Barometric pressure:700 to 1060 hPa	SE Analysis 2

Comparison Analysis

SE Analysis 1:

Operation Controls, compared with the predicate device, the subject device employs the same operation controls design and has some differences in value range. But both of them comply with the requirements of IEC60601-1 & 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:

Operation Controls, compared with the predicate device, the subject device employs the same operation controls design and has some differences in presenting voltage, humidity and temperature.

For voltage, the voltage of subject device is different with predicate device since hardware configuration is different. The subject device has passed the hardware test and complied with requirement of IEC60601-1 & IEC60601-2-37 and also meets clinical requirements

For temperature, compared with predicate device, the temperature of subject device is lower than it, but still in a normal range. The subject device has passed temperature test and complied with requirement of IEC60601-1 & IEC60601-2-37 and meet clinical requirements

For humidity, compared with predicate device, the humidity of subject device is in a normal range and complied with requirement of IEC60601-1 & 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.

10. 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 SonoEye P3/ SonoEye V3/ SonoEye G3 Digital Color Doppler Palm Ultrasound System is substantially equivalent to the predicate devices with regard to safety and effectiveness.