DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 6, 2017

CHISON MEDICAL IMAGING CO., LTD.
Mr. QIFEI LIU
REGULATORY AFFAIRS MANAGER
NO.228, CHANGJIANG EAST ROAD, BLOCK 51 AND 53, PHASE 5 INDUSTRIAL PARK,
SHUOFANG, New District, WUXI 214142
CHINA

Re: K170870
Trade/Device Name: Site~rite Halcyon Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed Doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: May 25, 2017
Received: May 30, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K1708070

Device Name
Site~Rite Halcyon Diagnostic Ultrasound System

Indications for Use *(Describe)*
The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified clinician for evaluation of Fetal/OB, Abdominal (GYN & Urology), Pediatric, Small Organ (breast, testes, thyroid), Cardiac (Adult & Pediatric), Peripheral Vascular, Vascular Access, Musculo-skeletal Conventional & Superficial.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Diagnostic Ultrasound Indications For Use

System: Site~Rite Halcyon Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	3,4
	Abdominal	N	N	N		N	N	N	3,4
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	3,4
	Small Organ[1] (Specify)	N	N	N		N	N	N	3,4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	3,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	3,4
	Other (Urology)	N	N	N		N	N	N	3,4
	Other (OB/GYN)	N	N	N		N	N	N	3,4
Cardiac	Cardiac Adult	N	N	N		N	N	N	3,4
	Cardiac Pediatric	N	N	N		N	N	N	3,4
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	3,4
Other	Vascular Access	N	N	N		N	N	N	3,4

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note : 1. Combined modes are B/M, B/CFM , B/PW ,B/CFM/PW
2. Small Organ: thyroid, testes, breast
3. Includes guidance of biopsy (2D)
4. Tissue Harmonic Imaging

Prescription Use ___×___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health

510(k) _____

System: Site~Rite Halcyon Diagnostic Ultrasound System
Transducer: C3

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	3,4
	Abdominal	N	N	N		N	N	N	3,4
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Other (Urology)	N	N	N		N	N	N	3,4
	Other (OB/GYN)	N	N	N		N	N	N	3,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
Peripheral Vessel	Peripheral vessel								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note : 1. Combined modes are B/M, B/CFM , B/PW, B/CFM/PW
2. Small Organ: thyroid, testes, breast
3. Includes guidance of biopsy (2D)
4. Tissue Harmonic Imaging

Prescription Use ___×___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k) _____

System: Site~Rite Halcyon Diagnostic Ultrasound System
Transducer: L7SVA

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	3,4
	Small Organ[1] (Specify)	N	N	N		N	N	N	3,4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	3,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	3,4
	Other (Urology)								
	Other (OB/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N	3,4
Other	Vascular Access	N	N	N		N	N	N	3,4

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note : 1. Combined modes are B/M, B/CFM , B/PW ,B/CFM/PW
2. Small Organ: thyroid, testes, breast
3. Includes guidance of biopsy (2D)
4. Tissue Harmonic Imaging

Prescription Use ___×___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health

Office of In Vitro Diagnostic and Radiological Health
510(k) _____

System: Site~Rite Halcyon Diagnostic Ultrasound System
Transducer: P3

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes	Other
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	N	3,4
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Other (Urology)								
	Other (OB/GYN)								
Cardiac	Cardiac Adult	N	N	N		N	N	N	3,4
	Cardiac Pediatric	N	N	N		N	N	N	3,4
Peripheral Vessel	Peripheral vessel								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note : 1. Combined modes are B/M, B/CFM , B/PW ,B/CFM/PW
2. Small Organ: thyroid, testes, breast
3. Includes guidance of biopsy (2D)
4. Tissue Harmonic Imaging

Prescription Use ___×___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k) _____

510(k) Summary

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

1. Submitter:

Submitter: Chison Medical Imaging Co., Ltd.
Address: No.228, ChangJiang East Road,Block 51 and 53,
Phase 5 Industrial Park, ShuoFang, New District,
Wuxi 214142, China
No.9 Xin Hui Huan Road, New District ,WuXi P.R.China
Contact: Mr. Liu Qifei
Tel: +86-510-85310019
Fax: +86-510-85310021
Date Prepared:June 15, 2016

2. Device :

Trade Name: Site~Rite Halcyon Diagnostic Ultrasound System

Common Name: Diagnostic Ultrasound System with Accessories

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):

SonoTouch Series Diagnostic Ultrasound Systems
510(k) Number: K121867

4. Device Description:

The Site~Rite Halcyon device is a compact and extremely portable ultrasound system consisting of a hand-carried console with the ability to dock it with a Docking station or mobile Docking cart.The primary means of control is graphical user interface implemented by a touch sensitive screen over the color LED display providing additional command input and keyboard entry. It utilizes interchangeable electronic-array transducers operating B-Mode (including Tissue Harmonic Imaging), M-Mode, Pulsed (PW) Doppler Mode, Color Doppler Mode, or a combination of these modes. with digital acquisition, processing and display capability operating under a Linux OS. Powered by an integrated battery in the docking station , the Site~Rite Halcyon is used primarily where portability, size and convenience are essential.

5. Indications for Use:

The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified clinician for evaluation of Fetal/OB, Abdominal (GYN & Urology), Pediatric, Small Organ (breast, testes, thyroid), Cardiac (Adult & Pediatric), Peripheral Vascular, Vascular Access, Musculo-skeletal Conventional & Superficial

6. Summary of Non-Clinical Tests:

The Site~Rite Halcyon Diagnostic 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.

lEC 60601-1: 2005 Medical Electrical Equipment - Part 1: General Requirements for Safety

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

lEC 60601-2-37: 2007 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.

NEMA UD 2-2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Version 3.

NEMA UD3: 2004 Standards for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

7. Clinical Test:

No clinical testing was required.

8. Comparison to Predicate Device:

Table 1 Substantial Equivalence Comparison

	Predicate Device	Submission Device	Remark
Product Name	**SonoTouch Series Diagnostic Ultrasound Systems**	**Site~Rite Halcyon Diagnostic Ultrasound System**	
Indications for Use	Fetal/OB; Abdominal (GYN & Urology); Pediatric;	Fetal/OB; Abdominal (GYN & Urology); Pediatric;	SE Analysis 1

	Small Omgan(breast, testes, thyroid); Cardiac (adult & pediatric); Peripheral Vascular; Musculo-skeletal Conventional & Superficial; Transrectal; Transvaginal.	Small Omgan(breast, testes, thyroid); Cardiac (adult & pediatric); Peripheral Vascular; Vascular Access; Musculo-skeletal Conventional & Superficial.	
Design	Based on an embedded Linux operating system. Autocorrelation for color processing and FFT for pulse Supporting Linear, Curve , and Phase array probes . Cine play back capability Image file archive	Based on an embedded Linux operating system. Autocorrelation for color processing and FFT for pulse Supporting Linear, Curve , and Phase array probes . Cine play back capability Image file archive	Same
Operation Controls	**B-Mode** B/M Acoustic Output: 0-10, 1 step	**B-Mode** B/M Acoustic Output: 0-10, 1 step	Same
	Focus Number: 4 steps	Focus Number: 4 steps	Same
	High Density: 0, 1	High Density: 0, 1	Same
	Frame Average: 0-7 steps	Frame Average: 0-7 steps	Same
	Edge Enhance: 0-7steps	Edge Enhance: 0-7steps	Same
	B Color Map: 0-31steps	B Color Map: 0-31steps	Same
	Gain: 0 – 255 steps	Gain: 0 – 255 steps	Same
	Dynamic Range: 30 – 90dB	Dynamic Range: 30 – 90dB	Same
	THI: on/off	THI: on/off	Same
	Depth: 1.5 – 24.6 cm	Depth: 1.5 – 24.6 cm	Same
	Color Flow Mode CF/PDI Focus Depth	**Color Flow Mode** CF/PDI Focus Depth	Same
	Frame Average: 0-7 steps	Frame Average: 0-7 steps	Same
	PRF: 0-15 steps	PRF: 0-15 steps	Same
	Gain: 0 – 255 steps	Gain: 0 – 255 steps	Same
	Wall Filter: 0-3 steps	Wall Filter: 0-3 steps	Same
	Angle:20,0,-20	Angle:20,0,-20	Same
	CF/PDI Focal Number: 1	CF/PDI Focal Number: 1	Same
	Color Map: 0-8 steps	Color Map: 0-8 steps	Same
	Color Threshold: 0-15 steps	Color Threshold: 0-15 steps	Same
	M-Mode Sweep Speed: 4 steps	**M-Mode** Sweep Speed: 4 steps	Same
	M Color: 4 types	M Color: 4 types	Same
	M Gain: 0 – 255 steps	M Gain: 0 – 255 steps	Same
	PW-Mode Doppler Gain:0~255	**PW-Mode** Doppler Gain:0~255	Same
	PRF:0~15	PRF:0~15	Same
	Wall Filter:0~3	Wall Filter:0~3	Same
	Volume:0~15	Volume:0~15	Same
	Pixel Ratio(0~7)	Pixel Ratio(0~7)	Same
	Doppler Dynamic(0~7)	Doppler Dynamic(0~7)	Same
	Enhance(0~3)	Enhance(0~3)	Same

	Angle(-70~+70 degrees)	Angle(-70~+70 degrees)	Same
	Color Map(0~8)	Color Map(0~8)	Same
	Sweep Speed: 4 steps	Sweep Speed: 4 steps	Same
	PW Angle Steer: -20°—20°	PW Angle Steer: -20°—20°	Same
Safety Standards Compliance	IEC60601-1 IEC60601-1-2 IEC60601-2-37 ISO 10993-1 ISO 10993-5 ISO 10993-10 AIUM/ NEMA UD2 AIUM/ NEMA UD3	IEC60601-1 IEC60601-1-2 IEC60601-2-37 ISO 10993-1 ISO 10993-5 ISO 10993-10 AIUM/ NEMA UD2 AIUM/ NEMA UD3	Same
Operation Mode	B, THI,B/M, M, CFM, PW,PDI,DPD, Trapezoidal image,Compound Imaging	B, THI,B/M, M, CFM, PW,PDI,DPD, Trapezoidal image,Compound Imaging	Same
Display Modes	B, 2B,4B, B/M ,M, B+PW, B+CFM, B+PDI/DPD, B+CFM+PW,B+ PDI/DPD+PW	B, 2B,4B, B/M ,M, B+PW, B+CFM, B+PDI/DPD, B+CFM+PW,B+ PDI/DPD+PW	Same
Display Annotations	Logo; Hospital Name; Exam date;Exam time; Acoustic Power ;Mechanical index;Tissue thermal indes; patient name and ID; Image Preview ; Gray/Color Bar ; Cine Gauge ; Measurement Summary Window; Measurement results window;Probe Type ;Imaging Parameters by Mode ; focal position; Body Pattern;Image Management Menu; Image Palette ; System Messages ; Menu indication ;Status;Battery status ; Biopsy Guide Line and Zone ;Heart Rate ;TGC curve display; Imaging parameters displayed on the screen	Logo; Hospital Name; Exam date;Exam time; Acoustic Power ;Mechanical index;Tissue thermal indes; patient name and ID; Image Preview ; Gray/Color Bar ; Cine Gauge ; Measurement Summary Window; Measurement results window;Probe Type ;Imaging Parameters by Mode ; focal position; Body Pattern;Image Management Menu; Image Palette ; System Messages ; Menu indication ;Status;Battery status ; Biopsy Guide Line and Zone ;Heart Rate ;TGC curve display; Imaging parameters displayed on the screen	Same
Display Monitor	10”high-resolution color LCD monitor	10”high-resolution color LCD monitor	Same
Measurements	**2D mode:** Distance ,Area, Volume,Ratio,Strenosis, Histogram,Profile, Angle **M mode:** Distance,Time, Slope, Heart Rate,Velocity; **Doppler mode:** D Velocity ,Time ,Heart Rate,Acceleration ,D Trace,PS/ED , Volume Flow	**2D mode:** Distance ,Area, Volume,Ratio,Strenosis, Histogram,Profile, Angle **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 1ports	Convex Array, Phased Array, Linear Array 1ports	Same
Acoustic Output	Derated I_{SPTA}: 720mW/cm^2 maximum. TIS/TIB/TIC: 6.0 maximum, MI: 1.9 maximum, Derated I_{SPPA}: 190 W/cm^{2}maximum	Derated I_{SPTA}: 720mW/cm^2 maximum. TIS/TIB/TIC: 6.0 maximum, MI: 1.9 maximum, Derated I_{SPPA}: 190 W/cm^{2}maximum	Same
Power Supply	Voltage: 100-240V~ Frequenzy:50-60Hz Power Consumption:60VA Max.	Voltage: 100-240V~ Frequenzy:50-60Hz Power Consumption:60VA Max.	Same

Comparison Analysis

SE Analysis1:

Compared with the predicate device, the subject device has some differences in Indications for Use Items. But all of them for the subject device include the clinical basic items, and fall within these for the predicate device; all of them meet the clinical use and no new risk is raised.

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 Imaging Co., Ltd. concludes that the Site~Rite Halcyon Diagnostic Ultrasound System is substantially equivalent to the predicate devices with regard to safety and effectiveness.