Wuhan Zoncare Bio-medical Electronics Co., Ltd.
℅ Long Yang, COO
Shenzhen Hlongmed Biotech Co., Ltd.
1002, 10th Floor, Zhongxing Administrative Building
Zhongxing Industrial Zone, Chuangye Road, Nanshan
Shenzhen, Guangdong 518054
CHINA

July 10, 2019

Re: K183041
Trade/Device Name: Full Digital Colour Doppler Ultrasonic Diagnostic System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: May 31, 2019
Received: June 5, 2019

Dear Long Yang:

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

Section 10

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)*

K183041

Device Name

Full Digital Colour Doppler Ultrasound Diagnostic System

Indications for Use *(Describe)*

The ZONCARE-M5 Ultrasound system is intended for use by a qualified physician or allied health professional for ultrasound evaluations. Specific clinical applications include:

Abdominal
Gynecology(including endovaginal)
Obstetric
Cardiac
Small parts(Breast,Testes,Thyroid,etc.)
Urology
Musculoskeletal
Peripheral vascular

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.

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Diagnostic Ultrasound Indications for Use Form

Full Digital Color Doppler Ultrasonic Diagnostic System

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

Clinical Application		Mode of Operation						
General (Track1 Only)	Specific (Track 1&3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & other	Fetal/Obstetrics	N		N		N	N	
	Abdominal	N		N	N	N	N	
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ(Specify)*	N		N		N	N	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N		N		N	N	
	Trans-vaginal	N		N		N	N	
	Trans-urethral							
	Musculo-skeletal (Conventional)	N		N		N	N	
	Musculo-skeletal (Superficial)	N		N		N	N	
	Intravascular							
	Other(Specify)**	N		N		N	N	
Cardiac	Adult Cardiac	N		N	N	N	N	
	Pediatric Cardiac							
	Intravascular(cardiac)							
	Trans-esoph.(cardiac)							
	Intra-cardiac							
Peripheral vascular	Peripheral vascular	N		N		N	N	
	Other(Specify)							

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

Additional comments: Combined mode: B+M

Note:* Small organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology

Diagnostic Ultrasound Indications for Use Form

ZONCARE-M5 with TL40 Transducer

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

Clinical Application		Mode of Operation						
General (Track1 Only)	Specific (Track 1&3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & other	Fetal/Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ(Specify)*	N		N		N	N	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal (Conventional)	N		N		N	N	
	Musculo-skeletal (Superficial)	N		N		N	N	
	Intravascular							
	Other(Specify)**							
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(cardiac)							
	Trans-esoph.(cardiac)							
	Intra-cardiac							
Peripheral vascular	Peripheral vascular	N		N		N	N	
	Other(Specify)							

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

Additional comments: Combined mode: B+M

Note:* Small organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology

Diagnostic Ultrasound Indications for Use Form

ZONCARE-M5 with TC10 Transducer

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

Clinical Application		Mode of Operation						
General (Track1 Only)	Specific (Track 1&3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & other	Fetal/Obstetrics	N		N		N	N	
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ(Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N		N		N	N	
	Trans-vaginal	N		N		N	N	
	Trans-urethral							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other(Specify)**							
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(cardiac)							
	Trans-esoph.(cardiac)							
	Intra-cardiac							
Peripheral vascular	Peripheral vascular							
	Other(Specify)							

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

Additional comments: Combined mode: B+M

Note:* Small organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology

Diagnostic Ultrasound Indications for Use Form

ZONCARE-M5 with TC50 Transducer

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

Clinical Application		Mode of Operation						
General (Track1 Only)	Specific (Track 1&3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & other	Fetal/Obstetrics	N		N		N	N	
	Abdominal	N		N		N	N	
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ(Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other(Specify)**	N		N		N	N	
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(cardiac)							
	Trans-esoph.(cardiac)							
	Intra-cardiac							
Peripheral vascular	Peripheral vascular							
	Other(Specify)							

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

Additional comments: Combined mode: B+M

Note:* Small organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology

Diagnostic Ultrasound Indications for Use Form

ZONCARE-M5 with TP16 Transducer

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

Clinical Application		Mode of Operation						
General (Track1 Only)	Specific (Track 1&3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & other	Fetal/Obstetrics							
	Abdominal	N		N	N	N	N	
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ(Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other(Specify)**							
Cardiac	Adult Cardiac	N		N	N	N	N	
	Pediatric Cardiac							
	Intravascular(cardiac)							
	Trans-esoph.(cardiac)							
	Intra-cardiac							
Peripheral vascular	Peripheral vascular							
	Other(Specify)							

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

Additional comments: Combined mode: B+M

Note:* Small organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology

ZONCARE中旗

Section 9

510(k) Summary

(as required by 807.92(c))

The assigned 510(K) number is: K183041

Date of Summary: 2019.5.31

1. Submitter information

Manufacturer Name: Wuhan Zoncare Bio-medical Electronics Co., Ltd

Address:Zoncare Building,#380,High-tech 2ND Road,Eastlake high-tech district ,Wuhan, Hubei , China

Contact Person and Title: Chenglin Tian/Manager of Medical Regulation

Tel: (86)-27-86637765

Fax: (86)-27-87174399

Email: fda_ce@zoncae.cn

2. Contact person

2.1 Primary Contact Person

Long Yang (COO)

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Tel: 0086-755-86664986

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2.2 Secondary Contact Person

Chenglin Tian/Manager of Medical Regulation

Wuhan Zoncare Bio-medical Electronics Co., Ltd

Zoncare Building, #380, High-tech 2ND Road, Eastlake high-tech district ,Wuhan, Hubei , China

Tel: (86)-27-86637765

3. Device information

Device name: Full Digital Colour Doppler Ultrasonic Diagnostic System

Model:ZONCARE-M5

Common Name:Diagnostic Ultrasound System with Accessories

Classification Name and Product Code:

21 CFR 892.1550 System, Imaging, Pulsed Doppler, Ultrasonic

Product code: IYN

21 CFR 892.1560 Ultrasonic, Pulsed echo, Imaging

Product code: IYO

21 CFR 892.1570 Transducer, Ultrasonic, Diagnostic

Product code: ITX

Regulatory Class: class II

4. Predicate device information

Manufacturer:Edan Instruments, Inc.

Address:3/F-B, Nanshan Medical Equipments Park, Nanhai Rd 1019#, Shekou,

Nanshan Shenzhen, 518067 P.R. China

Device name:Acclarix Diagnostic Ultrasound System

510(k)number:k150999

5. Indications for Use

The ZONCARE-M5 Ultrasound system is intended for use by a qualified physician or

allied health professional for ultrasound evaluations. Specific clinical applications include:

Abdominal

Gynecology (including endovaginal)

Obstetric

Cardiac

Small parts(Breast, Testes, Thyroid, etc.)

Urology

Musculoskeletal

Peripheral vascular

6. Device Description

The ZONCARE-M5 Ultrasound system consists of a main system along with associated transducers.

The system circuitry generates an electronic voltage pulse, which is transmitted to the transducer. In the transducer, a piezo electric array converts the electronic pulse into an ultrasonic pressure wave. When coupled to the body, the pressure wave transmits through body tissues. The waves are then reflected within the body and detected by the transducer, which then converts back to an electrical signal. The ZONCARE-M5 system then analyzes the returned signal to generate an image or conduct Doppler processing.

The ZONCARE-M5 system gives the operator the ability to measure anatomical structures, and offers analysis packages that provide information used by competent health care professionals to make a diagnosis.

The system provides hardware buttons for the User Interface.

7. Comparison to Predicate Devices

Wuhan Zoncare Bio-medical Electronics Co., Ltd believes the ZONCARE-M5 Ultrasound System described in this submission is substantially equivalent to the

predicate device as follow:

Acclarix AX8 Diagnostic Ultrasound System(k150999)

The following table shows similarities and differences between our device and the predicate devices.

Item	**Proposed Device**	**Predicate Device**
Trade name	Full Digital Colour Doppler Ultrasound Diagnostic System	Acclarix Diagnostic Ultrasound System
Model	ZONCARE-M5	AX8
510k submitter	Wuhan Zoncare Bio-medical Electronics Co.,Ltd.	Edan Instruments,Inc
510K Number	/	K150999
Intended use	Diagnostic ultrasound imaging or fluid flow analysis of the human body	Diagnostic ultrasound imaging or fluid flow analysis of the human body
Indication for use	The ZONCARE-M5 Ultrasound system is intended for use by a qualified physician or allied health professional for ultrasound evaluations. Specific clinical applications include: Abdominal Gynecology (including endovaginal) Obstetric Cardiac Small parts(Breast, Testes,Thyroid, etc.)	The Edan Acclarix AX8 Ultrasound system is intended for use by a qualified physician or allied health professional for ultrasound evaluations. Specific clinical applications include: Abdominal Gynecology(including endovaginal) Obstetric Cardiac Small parts (Breast, Testes,Thyroid, etc.)

	Urology Musculoskeletal Peripheral vascular	Urology Musculoskeletal Peripheral vascular Intra-operative.
Installation and use	Portable(laptop)Mobile Equipment	Portable(laptop)Mobile Equipment
Safety standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37, ISO 10993-1,-5,-10,-12 NEMA UD2 NEMA UD3	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37, ISO 10993-1,-5,-10,-12 AIUM,NEMA UD2,UD3
Patient contact materials	Complies with ISO 10993	Complies with ISO 10993
General Imaging mode	B-Mode,M-Mode,Color,PDI,PW, CW	B-Mode,M-Mode,Color,PDI/DPDI, PW,CW
Measurements	B-Mode:Distance,Circ/Area,Angle, Volume,Stenosis M-Mode:Distance, Time,Slope and Heart Rate D-Mode:Velocity, RI,Time, PI, Heart Rate,Auto Trace PG,S/D, ΔV,Acceleration,PHT, VTI	B-Mode:Distance,Circ/Area,Angle, Volume,Stenosis M-Mode:Distance, Time,Slope and Heart Rate D-Mode:Velocity,RI,Time, PI, Heart Rate, Auto Trace PG,S/D, ΔV,Acceleration,PHT, VTI
Principle of Operation	Applying high voltage burst to the Piezoelectric material in the	Applying high voltage burst to the Piezoelectric material in the

	transducer and detect reflected echo to construct diagnostic image	transducer and detect reflected echo to construct diagnostic image
Acoustic output	Track 3: MI, TIS, TIC,TIB (TI Range 0-6.0) Derated I_{SPTA}: 720W/cm2 maximum,Mechanic Index ≤1.9 maximum or Derated I_{SPPA} 190 W/cm^2 max	Track 3: MI, TIS, TIC,TIB (TI Range 0-6.0) Derated I_{SPTA}: 720W/cm2 maximum,Mechanic Index≤1.9 maximum or Derated I_{SPPA} 190 W/cm^2 max
Transducer Types	Convex Array Linear Array Phased Array	Convex Array Linear Array Phased Array Micro Convex Array
Transducer Frequency	2.0-12.0MHz	2.5-15.0MHz
Display	Primary Screen:12.1inch(1024*768)	Primary Screen:15 inch(1920x1080)
Dimensions/ Weight	370mm(W)*470mm(L)*380mm(H) Weight:nearly 9kg (with Rechargeable battery, without power adaptor or transducers)	407mm(W)*388mm(L)*77mm(H) Weight: ≤9.1kg(with Rechargeable battery, without power adaptor or transducers)
Power Supply	100-240V 50/60Hz	100-240V 50/60Hz
Rechargeable battery	Yes	Yes

The subject device has same intended use, similar product design, same performance effectiveness, and performance safety as the predicate device.

The differences between the subject device and predicate device do not affect the basic design principle, usage, effectiveness and safety of the subject device. And no question is

raised regarding to effectiveness and safety.

8. Effectiveness and Safety Considerations

Clinical test:

Clinical testing is not required

Non-clinical test:

The ZONCARE-M5 Ultrasound System complies with

(1)AAMI/ANSI ES60601-1 Electrical Safety

(2) IEC 60601-1-2 Electromagnetic Compatibility

(3) Acoustic output testing as per the guideline “Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers” dated September 9, 2008.

The following biocompatibility standards are conducted on the subject device:

(1) ISO 10993-1, ISO 10993-5 and ISO 10993-10

The tests were selected to show substantial equivalence between the subject device and the predicate.

9. Substantial Equivalence Conclusion

Verification and validation testing has been conducted on the ZONCARE-M5 Ultrasound System.This premarket notification submission demonstrates that ZONCARE-M5 Ultrasound System is substantially equivalent to the predicate devices.