December 20, 2018

Shenzhen Well.D Medical Electronics Co., LTD.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K182165
Trade/Device Name: Color Doppler Ultrasound System
Model; mEye1 and mEye2
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: November 22, 2018
Received: December 3, 2018

Dear Diana Hong:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
Robert A. Ochs, Ph.D.
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)*
K182165

Device Name
Color Doppler Ultrasound System
Model: mEye1 and mEye2

Indications for Use *(Describe)*
Diagnostic ultrasonic imaging for abdominal, pediatric, small organ, musculo-skeletal, cardiac, peripheral vascular, trans-vaginal and trans-rectal applications in B, M, PWD and Color Doppler modes.

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 Format

System: Color Doppler Ultrasound System

Transducer: 5C2AN convex array probe

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 (Track 1&3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N		N		N		THI
	Abdominal	N		N		N		THI
	Intra-operative(Specify)							
	Intra-operative(Neuro)							
	Laparoscopic							
	Pediatric	N		N		N		THI
	Small Organ(Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal (Conventional)	N		N		N		THI
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

Diagnostic Ultrasound Indications for Use Format

System: Color Doppler Ultrasound System

Transducer: 12L5AN linear array probe

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 (Track 1&3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative(Specify)							
	Intra-operative(Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ(Specify)	N		N		N		THI
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)	N		N		N		THI
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N		N		N		THI
	Other (Specify)							

510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K182165

1. Date of Preparation: 12/20/2018

2. Sponsor Identification

SHENZHEN WELL.D MEDICAL ELECTRONICS CO., LTD.
Well.d Park, Qinglan 3 Rd, National Biopharmaceutical Industrial Base, Pingshan New Area, Shenzhen, 518118, China.

Establishment Registration Number: 3008350665

Contact Person: Ning Bai
Position: Management Representative
Tel: +86-755-36900033
Fax: +86-755-36900033
Email: weld-200@163.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. Chengyu Wang (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 001-3609253199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Color Doppler Ultrasound System
Model: mEye1 and mEye2
Classification Name: Ultrasonic pulsed doppler imaging system
Classification: II
Product Code: IYN, IYO, and ITX
Regulation Number: 21 CFR 892.1550, 21 CFR 892.1560 and 21 CFR 892.1570
Review Panel: Radiology

Indications for Use:
Diagnostic ultrasonic imaging for abdominal, pediatric, small organ, musculo-skeletal, cardiac, peripheral vascular, trans-vaginal and trans-rectal applications in B, M, PWD and Color Doppler modes.

Device Description
The Color Doppler Ultrasound Systems are integrated preprogrammed color ultrasound imaging system, capable of producing a resolution intended for clinical diagnostic imaging applications. Their basic function is to acquire ultrasound signal and display the images in the imaging operation modes of B, M, PWD and Color Doppler.

5. Identification of Predicate Device

Predicate Device
510(k) Number: K113613
Product Name: Apogee 1200 Digital Color Doppler Ultrasound Imaging System

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1-2005+CORR.1:2006+CORR.2:2007+A1:2012, 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 basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests
- IEC 60601-2-37: 2007 Medical electrical equipment - Part2 -37 Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.
- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

- ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- NEMA UD 2-2004 (R2009) Acoustic output measurement standard for diagnostic ultrasound equipment

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 2 Substantially Equivalent Comparison

ITEM	Proposed Device	Predicate Device K113613
Product Code	IYN, IYO and ITX	IYN, IYO and ITX
Class	II	II
Indications for Use	Diagnostic ultrasonic imaging for abdominal, pediatric, small organ, musculo-skeletal, cardiac, peripheral vascular, trans-vaginal and trans-rectal applications in B, M, PWD and Color Doppler modes.	Diagnostic ultrasonic imaging for abdominal, pediatric, small organ, musculo-skeletal, cardiac, peripheral vascular, trans-vaginal and trans-rectal applications in B, M, PWD, CWD, Color Doppler and 3D imaging modes.
Configuration	Host and Probe	Host and Probe
Sterile	No	No
Single Use	No	No
Probe Type	Convex array: 3.5MHz Linear array: 7.5MHz	Convex array: 2.0-6.1 MHz Linear array: 4.0-15.0 MHz Phase array: 2.0-4.4 MHz
Operation Mode	B, M, PWD and Color Doppler modes	B, M, PWD, CWD, Color Doppler and 3D imaging modes
Applications	Abdominal, pediatric, small organ, musculo-skeletal, cardiac, peripheral vascular, trans-vaginal and trans-rectal	Abdominal, pediatric, small organ, musculo-skeletal, cardiac, peripheral vascular, trans-vaginal and trans-rectal
Screen Resolution	1024 x 768	1024 x 768
Power Supply	AC 100-240V, 50/60Hz DC 14.4V	100-240V, 50/60Hz
Electrical Safety	Complied with IEC 60601-1	Complied with IEC 60601-1
EMC	Complied with IEC 60601-1-2	Complied with IEC 60601-1-2
Performance	Complied with IEC 60601-2-37	Complied with IEC 60601-2-37

Software Level	Moderate level of concern	Moderate level of concern
Biocompatibility		
Cytotoxicity	Complied with ISO 10993-5	Complied with ISO 10993-5
Skin Irritation	Complied with ISO 10993-10	Complied with ISO 10993-10
Sensitization	Complied with ISO 10993-10	Complied with ISO 10993-10

The operation modes of the proposed device do not contain CWD and 3D imaging modes, which is different from that of predicate. There are only two types of probes in proposed device, which are less than that of predicate device. And it is not known whether the predicate device can be powered by battery or DC. However, the proposed device has been demonstrated that comply with requirements of electrical safety, EMC, performance and acoustic output. Therefore, the differences do not impact the safety and effectiveness.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate devices.