

K100079

Section 3 510(k) Summary

MAR -1 2010

As required by 807.97

The assigned 510(k) Number is _____

Sponsor	Shenzhen Well.D Medical Electronics Co., Ltd. 13/F & 12/F North, New Energy Bldg, Nanhai Ave, Nanshan District, Shenzhen 518054, China Mr. Ning Bai, General Manager <u>Tel: +86-755-26073352</u> Fax: +86-755-26073356 Email: <u>Weld-2000@163.com</u>
Submission Correspondent	Mr. Tarzan Wang / Ms. Diana Hong Shanghai Mid-Link Business Consulting Co., Ltd Sute 5D, No. 19, Lane 999, Zhongshan No.2 Road(S) Shanghai, 200030, China Tel: +86-21-64264467 Fax: +86-21-64264467 ext. 809 Email: <u>tarzan.wang@mid-link.net</u>
Preparing Date:	Sept. 28, 2009
Proposed Product	
Trade Name	Digital Ultrasound Scanner
Model	WED-3100
Product Code:	IYO & ITX
Regulation Number:	21 CFR 892.1560 & 21 CFR 892.1570
Device Class:	Class II
Submission Purpose:	New Device
Predicate Device:	EMP-2100 Full Digital Ultrasound Diagnostic Device K081873 Manufactured by: Shenzhen Emperor Electronic Technology Co., Ltd.
Device Description	This equipment is high resolution linear/convex ultrasound scanning diagnostic equipment. It adopts micro-computer control and digital scan converter (DSC), digital

beam-forming (DBF), real time dynamic aperture (RDA), real time dynamic receiving apodization, real time dynamic receiving focusing (DRF), Digital frequency scan (DFS), frame correlation technologies to endue its image with clarity, stability and high resolution.

Test Conclusion

Laboratory testing was conducted to validate and verify that the proposed devices met all design specifications, including electrical safety, EMC, specifications.

Intended Use/Indication for Use

WED-3100 Digital Ultrasound Scanner is intended for diagnostic ultrasound imaging analysis for abdomen, gynecology, obstetric, urology, small-parts.

The system is intended to use for the following type of studies: fetal, abdominal, pediatric, small organs, peripheral vascular, and musculo-skeletal (both conventional and superficial). The device is intended to adult, pregnant woman, pediatric and neonate.

The system is a prescription device intended to be used by or on the order of a physician or similar qualified health care professional. This device is not intended for home use.

Technology Characteristics

Table 3-1 WED-3100 basic technical specifications

Model	WED-3100
Monitor size	5 inch
Display mode	B, B+B, B+M, M, 4B
Image gray scale	256
Image storage	128
Cine loop	≥400 frame
Scan depth	80 mm~220 mm
Image flip	Up/down, left/right
Focus position	Adjustable
posture mark	40
Image Process	Histogram, Color encode, GAMA, Image Smoothen
Frame correlation	Adjustable

Measurement	Distance, circumference, area, volume, heart rate. GA,FW,EDD
Notation	Date, time, name, sex, age, hospital name、 Full screen words edit
output report	Measurement, Obstetric
Battery Continuous work	≥3Hours
Size	L(230mm)*W(120mm)*H(38mm)
Net weight	700g
Accuracy	Error ≤ ±10%
Measurement Range	Horizontal ≥ 1mm & Vertical ≥ 1mm

Table 3-2 Probe Technical Specification

Probe Mode	C1-11/50R/3.5MHz	L1-5/7.5MHz
Nominal Frequency	convex array probe	high-frequency linear array probe
Type		
Scan angle/width	70.4°	40mm
Number of Element	80	80
Size of Element	0.765mm x 16.3mm	0.5mm x 11mm
Spacing of Element	0.765mm	0.5mm
Size	62.4mm×16.30mm	47.00mm×11.00mm
Maximum number of active elements of single pulse	16	16
Scan Depth	80mm~220mm	40mm~90mm
Array dimensions	62.4mm x 16.3mm	47.0mm x 11.0mm
Dead Zone (mm)	≤3	≤6
Detect Depth(mm)	≥80	≥140
Resolution (mm)	Lateral	≤1 (Depth≤60) ≤3 (depth≤80) ≤5 (80<depth≤130)
	Axial	≤1 (Depth≤80) ≤1 (depth≤80)
Geometric position precision	Horizontal	≤5 ≤7.5
	Vertical	≤5 ≤5

Table 3-3 Transducer List

Transducer Model	Type	Frequency	Track
C1-11	Convex Array	3.5MHz	1
L1-5	Linear	7.5MHz	1

Effectiveness and Safety Considerations

Effectiveness:

Clinical Measurement Effectiveness Test was conducted on the subject device to evaluate its measurement accuracy.

Safety:

The subject device meet the following Electrical Safety Standards and Biocompatibility Standards.

IEC 60601-1: 1988 Amendment 1, 1991-11 Amendment 2 1995, Medical Electrical Equipment – Part 1: General Requirements for safety.

IEC 60601-1-2: 2001, Medical Electrical Equipment – Part 1-2: General Requirements for safety – Collateral Standard: Electromagnetic Compatibility –Requirements and Tests

IEC 60601-2-37:2004, 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.

ISO 10993 -5: 1999, Biological Evaluation of Medical Devices – Part 5: Test for in vitro cytotoxicity

ISO 10993-10: 2002, Biological Evaluation of Medical Devices – Part 10: Tests for irritation and delayed-type hypersensitivity

ISO 10993-12: 1999, Biological Evaluation of Medical Devices – Part 12: Sample preparation and reference materials.

SE Analysis

The subject device has same classification information, same intended use, same indication for use, similar product design, similar specification, same safety elements, similar label and labeling, same software specification as predicate device.

The differences are included as followings:

The device and predicate device have difference in performance specification, such as scan/angle/width, maximum number of elements for a single pulse, frequency, number of element, size of element, spacing of element, array dimensions, detect depth and resolution. But the propose device have tested for clinical measurement accuracy, so these difference can prove the effectiveness of propose device.

The device and predicate device have difference in label and labeling, but all of the label and labeling meet the requirements of FDA.

The proposed device has tested according with the safety standard IEC 60601-1, IEC60601-1-2 for the safety.

The proposed device has tested according with the clinical measurement accuracy report, UD2 Acoustic Output report for the effectiveness.

The proposed device has tested according with the ISO 10993 series standard for the Biocompatibility performance.

Therefore, the differences above 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.

No new technology is applied in the subject device. Most of the main aspects on effectiveness and safety between the subject device and predicate device are same. The differences are slight so that no substantial influence on the effectiveness and safety.

SE Determination

The proposed device, Digital Ultrasonic Diagnostic Scanner/WED 3100, is substantially equivalent (SE) to the predicate device EMP-2100 Full Digital Ultrasound Diagnostic Device (K081873).



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

MAR - 1 2010

Shenzhen Well.D Medical Electronics Co., Ltd.
% Mr. Marc M. Mouser
Program Manager & FDA Office Coordinator
Underwriters Laboratories, Inc.
2600 N.W. Lake Road
CAMAS WA 98607-8542

Re: K100079

Trade/Device Name: Digital Ultrasound Diagnostic Scanner, WED-3100
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: February 5, 2010
Received: February 16, 2010

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the Digital Ultrasound Diagnostic Scanner, WED-3100, as described in your premarket notification:

Transducer Model Number

L1-5
C1-11

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device

can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

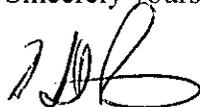
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,



Donald St. Pierre
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indication for Use

510(k) Number (if known): K100079

Device Name: WED-3100 Digital Ultrasound Scanner

Indications for Use:

WED-3100 Digital Ultrasound Scanner is intended for diagnostic ultrasound imaging analysis for abdomen, gynecology, obstetric, urology and small-parts.

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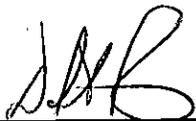
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of ~~Device Evaluation (ODE)~~
(OIDD)



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Division of Radiological Devices

Office of *In Vitro* Diagnostic Device Evaluation and Safety

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

Note 1: B+B mode, 4B mode

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

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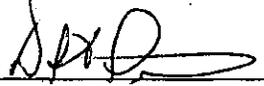
K100079

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

Note 1: B+B mode, 4B mode

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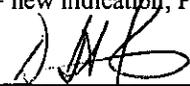
510(k) Number K160079

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	PWD	CWD	Color Doppler	Combined (BM)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
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	Trans-urethral							
	Trans-esoph. (non-Card.)							
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	Intravascular (Cardiac)							
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	Intra-cardiac							
Other (Specify)								
Peripheral	Peripheral vessel	N	N				N	Note 1
Vessel	Other (Specify)							

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