



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

MEDA CO.,LTD.
% Mr. Kai Chen
President
Medtech International, Inc.
13505 Broadfield Drive
POTOMAC MD 20854

November 17, 2015

Re: K152318
Trade/Device Name: MD-2300S Ultrasonic A/B Scanner for Ophthalmology
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: October 26, 2015
Received: November 2, 2015

Dear Mr. Chen:

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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style and is positioned above the printed name and title.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152318

Device Name

MD-2300S Ultrasonic A/B Scanner for Ophthalmology

Indications for Use (Describe)

MD-2300S Ultrasonic A/B Scanner for Ophthalmology is intended for ophthalmological ultrasonic diagnosis and AL biometric measurement.

The 10MHz B-Probe applies to normal ophthalmological ultrasonic diagnosis; and the 20MHz B-Probe is suitable for observing the details of intraocular and retina structure.

The device should be operated by trained medical staff.

Patients with eyelid trauma and severe eye infection are prohibited from using B-Scan; and patients with keratitis and cornea trauma are prohibited from using A-Biometric scan.

The A-biometric scan should be used cautiously on patients without independent behavior abilities or who are highly sensitive to contacting measurements, whose ineffective cooperation may result in inaccurate measurements.

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.

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510(k) Submission of MEDA. CO., LTD

Indications for Use Statement

MD-2300S Ultrasonic A/B Scanner for Ophthalmology

Diagnostic Ultrasound Indications for Use Format

System: MD-2300S Ultrasonic A/B Scanner for Ophthalmology

Transducer: 10MHz B-Probe (Prb2100B/10)

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

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

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

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

510(k) Submission of MEDA. CO., LTD

Indications for Use Statement

MD-2300S Ultrasonic A/B Scanner for Ophthalmology

System: MD-2300S Ultrasonic A/B Scanner for Ophthalmology

Transducer: 20MHz B-Probe (Prb2100B/20)

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

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

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

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

510(k) Submission of MEDA. CO., LTD

Indications for Use Statement

MD-2300S Ultrasonic A/B Scanner for Ophthalmology

System: MD-2300S Ultrasonic A/B Scanner for Ophthalmology

Transducer: Prb1000A/10-C A-Probe

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

Clinical Application		Mode of Operation						
General (Track1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (A-mode)
Ophthalmic	Ophthalmic							P
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
Intravascular								
Other (Bladder)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

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

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

510(k) SUMMARY

1. Submitter Information

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Date Prepared: August 5, 2015

2. Device Information

Trade Name/Common Name: MD-2300S Ultrasonic A/B Scanner for Ophthalmology

Classification Name: Ultrasonic Pulsed Echo Imaging System
Diagnostic Ultrasound Transducer

Regulation Number: 892.1560; 892.1570

Product Code: IYO; ITX

3. Predicate Devices

1) For B-mode and IOL Calculation (for the cases that patients have undergone refractive surgery)

Manufacturer: Quantel Medical Inc.

Trade Name: "Aviso" Ophthalmic Ultrasound System

Common Name: Ophthalmic A and B scan ultrasound System

510(k) Number: **K051851**

Although "Aviso" Ophthalmic Ultrasound System has A-mode, it is "STD-A" A-scan 8MHz which is different from the A-mode of MD-2300S. So, for A-mode, we selected the following product produced by our company:

2) For A-mode and IOL Calculation (for the cases that patients have not undergone refractive surgery)

Manufacturer: MEDA CO., LTD

Device Name: MD-1000A Ultrasonic Biometer for Ophthalmology

510(k) Number: **K121243**

4. Device Description

MD-2300S Ultrasonic A/B Scanner for Ophthalmology is an ultrasonic imaging instrument specialized in ophthalmological diagnosis. It consists of a main unit, a power adaptor, a 10MHz B-Scan probe, a 20MHz B-Probe, a 10MHz A-Probe, a footswitch, a keyboard and a mouse.

MD-2300S includes two most popular operation modes for ophthalmological clinical diagnosis: B-mode ultrasonic section imaging and A-mode axial biometric parameter measurement.

The 10MHz B-Probe applies to normal ophthalmological ultrasonic diagnosis; and the 20MHz B-Probe is suitable for observing the details of intraocular and retina structure.

The part of B-mode uses 10MHz and 20MHz mechanical sector-scan probes for scanning. It acquires echo signal through ultrasonic pulse transmitting and receiving circuits; and converts it into digital information to save in FIFO; the data information of each echo line is transmitted to the embedded board through USB port. The application software running on Windows XPE platform realizes real time display, saving and case report generation for images of eye tissue.

The part of A-mode uses 10MHz A-biometric probe for A-mode scanning. It acquires echo signal through ultrasonic pulse transmitting and receiving circuits; and converts it into digital information to save in FIFO; the data information of each echo line is transmitted to the embedded board through USB port. Based on the interface reflection of ultrasound wave in three different tissues of anterior chamber, lens and vitreous body, the application software running on Windows XPE platform measures the transmitting time of ultrasound wave in different tissues and then calculates distances of each segment according to the acoustic velocity of different tissues to get the axial length and generates case report of A-biometry automatically, thus provides parameters for intraocular lens implantation operation.

5. Indications for Use

MD-2300S Ultrasonic A/B Scanner for Ophthalmology is intended for ophthalmological ultrasonic diagnosis and AL biometric measurement.

The device should be operated by trained medical staff.

Patients with eyelid trauma and severe eye infection are prohibited from using B-Scan; and patients with keratitis and cornea trauma are prohibited from using A-Biometric scan.

The A-biometric scan should be used cautiously on patients without independent behavior abilities or who are highly sensitive to contacting measurements, whose ineffective cooperation may result in inaccurate measurements.

6. Technological characteristics

a) Safety

The electrical, mechanical, environmental safety testing were conducted according to standard IEC60601-1: 2005 + AM1: 2012 and IEC 60601-2-37: 2007.

The EMC testing was conducted in accordance with standard IEC 60601-1-2: 2007.

The safety standards performed by the MD-2300S are substantially equivalent to the predicate products.

b) Characteristics

B-mode:

1. Scanning method: mechanical sector scan
2. Display mode: B, B+A
3. Scanning Angle: 53°
Display depth adjustable range: 10MHz: 28mm~60mm; 20MHz: 19 mm~40mm
4. Variable delayed depth: 10MHz: 0 mm~15 mm; 20MHz: 0 mm~10mm
5. Adjustable Gain Scope: 1-105dB
6. TGC: -20dB~20dB dynamic range, manual sectional adjustment (6-section adjustable)
7. Grey Scale: 256 Levels
8. Frame Rate: 10 fps
9. Image saving: 100 images
10. Dynamic loop: 10s/100 images, loop or frame by frame playback
11. Image processing and Signal Post-processing: Frame-Averaging, Pseudo-Color Codes, and Gamma Correction
12. Axial Resolution
 - a) 10MHz Probe: No more than 0.1mm;
 - b) 20MHz Probe: No more than 0.08mm,
13. Lateral Resolution
 - a) 10MHz Probe: No more than 0.2mm;
 - b) 20MHz Probe: No more than 0.15mm.
14. Geometric Position Accuracy for Image Measurement
 - a) Horizontal: No more than 5%
 - b) Vertical: No more than 3%

A-mode:

1. AL Biometric Measuring Range: Axial Length (AL): 15mm-40mm;
2. AL Biometric Measuring Accuracy: No more than ± 0.05 mm.
3. Total gain: 98dB, users adjustable gain scope: 1~60dB
4. Measuring mode: 5 groups (Normal, Aphakic, Special, Cataract and manual measurement)
5. Measuring method: Immersion/Contact
6. IOL calculation: SRK-T, SRK-II, BINK-II, HOLLADAY, HOFFER-Q and HAIGIS
7. Support IOL calculation after refractive surgery, two groups of formulas can be calculated contrastively and displayed simultaneously.
8. Automatic measurement and 10 groups averaging and display standard deviation.
9. 8 groups of IOL constants can be stored.

For the A-mode part of MD-2300S, the main specifications and IOL calculation for cases that have not undergone refractive surgery are substantially equivalent with those of MD-1000A;

whereas, the IOL calculation for cases that have undergone refractive surgery is identical with that of the Aviso.

For the B-mode part of MD-2300S, the display depth, focus, scanning angle, adjustable gain and TGC are substantially equivalent with those of the Aviso.

The differences of MD-2300S and its predicate devices are as follows:

Item		Model	Subject Device	Predicate Device	
			MD-2300S	Aviso	MD-1000A
B-Scan	10MHz	Scanning angle	53°	50°	N/A
		Display depth	28mm to 60mm;	20 to 60 mm	
		Focus	20 to 26 mm	24 to 26 mm	
		Axial resolution	0.1 mm	0.2 mm	
		Lateral resolution	0.2 mm	0.6 mm	
	20MHz	Scanning angle	53°	50°	
		Display depth	19 mm to 40mm	—	
		Focus	20 to 26 mm	24 to 26 mm	
		Axial resolution	0.08 mm	0.1 mm	
		Lateral resolution	0.15 mm	0.25 mm	
	General features	Adjustable gain scope	1-105dB	20 to 110 dB	
		Time Gain Control	-20dB~20 dB	0 to 30 dB	
		Storage capacity	Unlimited storage capacity for still images and video sequences (up to 10 second duration)	Unlimited storage capacity for still images and video sequences (up to 40 second duration)	
		Image post-processing tools	Algorithmic & color image filters , calipers, areas, angles, markers, comments, magnify	Algorithmic & color image filters, calipers, areas, angles, markers, comments	
A-Scan	Probe	Total gain of receiver	98dB	N/A	100dB
		Adjustable gain scope	1-60dB	N/A	0-50dB
	Axial length measurements	Calculation of SD and AV	Automatic calculation of standard deviation and average total length (series of 10 measurements)	N/A	Automatic calculation of standard deviation and average total length (series of 8 measurements)
User interface touch screen size			12.1"	3.4" (W) x 4.5" (H)	6.4"
Power Adapter			FSP065-DHBM1(12V)	—	HES49-12040 12V/4A (UL E164433)
Foot Switch			MD-1000.FS-2	—	MD-1000.FS-1

From the above comparison, the axial resolution and lateral resolution of MD-2300S are better than those of the Aviso. In the field of storage capacity and image post-processing, MD-2300S provides the same function with those of the Aviso. MD-2300S added the function of “magnify”

in post-processing tools.

The MD-2300S, Aviso and MD-1000A use different power adapters and foot switches, and the screen size is different, but they all meet the requirements of IEC 60601-1.

While there are some differences between the MD-2300S and its predicate devices, they do not affect the safety or effectiveness.

7. Brief Discussion of Non-clinical Tests

The safety and EMC testing were conducted on the MD-2300S and the testing results comply with the requirements of IEC 60601-1 and IEC 60601-2-37 for safety and the IEC 60601-1-2 for EMC. The acoustic output parameters comply with the requirements of IEC 60601-2-37 and FDA Guidance on diagnostic ultrasound systems and transducers.

The biocompatibility evaluation has been made according to ISO 10993. Tests for in vitro cytotoxicity, skin sensitization and irritation were conducted on the patient-contacting materials, and they conform to the biocompatibility requirements.

The software and essential performance have passed verification and validation, and the results comply with the requirements.

8. Brief Discussion of Clinical Evaluation and Validation

The clinical literature retrieval was conducted and Clinical Evaluation Report was completed according to the requirements of 93/42/EEC MEDDEV. 2.7.1 Rev.3. It showed that MD-2300S conforms to the requirements of its intended use and no unacceptable risks were found.

As part of the product design validation, we have entrusted Tianjin Eye Hospital to make clinical effectiveness validation. Following is a summary of the details about the clinical validation study:

B-Mode: select randomly outpatients and inpatients that need to make B-mode ultrasonic examination, the selection of diseases should cover typical cases of ultrasonic diagnosis for ophthalmology. Use 10MHz B-Probe of MD-2300S to make ultrasonic inspection; if further details of intraocular and retina tissues need to be observed, use 20MHz B-Probe. Clinical doctors validate the intended use according to the image quality of B-Scan on orbit and intraocular tissues.

A-Mode: the expected user representatives use MD-2300S and ODM-2100 Ultrasonic A/B Scanner for Ophthalmology (K063433) which was already cleared to make axial length (AL) measurement on the same subject.

Select 50 eyes randomly from outpatients and inpatients that need to measure axial length (AL). The sex and age of patients are not restricted.

The statistical processing results for AL measuring data with Bland-Altman statistical method should have no obvious difference.

The validation results show:

B-Mode: the B-Scan image of MD-2300S can display the intraocular structure clearly and provide valuable reference base for clinical diagnosis. The image resolution as well as the

scanning scope, frame rate, gain adjustment, saving, image processing, cineloop, case management and other functions are able to satisfy the clinical demands.

A-Mode: the result of statistical processing for the AL measuring data showed that the measuring results of both products have good consistency.

The intended use of MD-2300S meets the clinical requirements and no new unacceptable risks were found.

9. Conclusions

The results of non-clinical tests as well as clinical evaluation and validation demonstrate that the MD-2300S Ultrasonic A/B Scanner for Ophthalmology is substantially equivalent in safety, effectiveness and performance to the legally marketed predicate devices.