MEDA Co., Ltd.
% Kai Chen
President
Meditech International, Inc.
(United States Designated Agent of MEDA Co., Ltd)
13505 Broadfield Drive
POTOMAC MD 20854

May 6, 2019

Re: K182460
Trade/Device Name: MD-6000P Bladder Scanner
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: April 8, 2019
Received: April 10, 2019

Dear Kai 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. 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

Thalia T. Mills, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182460

Device Name
MD-6000P Bladder Scanner

Indications for Use *(Describe)*
MD-6000P Bladder Scanner is intended to measure the urine volume in human bladder.
The device is intended to be used in medical and nursing care institutions. It should be operated by trained professionals.
The device is not intended for use on pregnant women. It cannot be used on wounded skin.

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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"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: MD-6000P Bladder Scanner

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							
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)	**P**						
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

Name: MEDA Co., Ltd.
Address: F2C, F3D, F4C, F5, F6C, Building C2, Xinmao Science Skill Park, Huayuan Industry Development Area, Tianjin 300384, P. R. China
Phone: +86-22-83713808
Fax: +86-22-83713880

Contact person: **KAI CHEN**
Medtech International, Inc. and
United States Designated Agent of MEDA Co., Ltd.
Address: 13505 Broadfield Drive, Potomac, MD 20854
Tel: 240 888 4001
Fax: 301 251 2881
Email: Drkaichen@gmail.com

Date Prepared: August 15, 2018

2. Device Information

Trade Name/Common Name: MD-6000P Bladder Scanner

Classification Name: Ultrasonic Pulsed Echo Imaging System (IYO)
Diagnostic Ultrasound Transducer (ITX)

Regulatory Class: Class II

Regulation Number: 892.1560; 892.1570

Product Code: IYO; ITX

3. Predicate Devices

Manufacturer: MEDA CO., LTD

Device Name: MD-6000 Bladder Scanner

510(k) Number: **K113304**

4. Device Description

MD-6000P Bladder Scanner is a hand-held device which utilizes ultrasonic distance measuring principle to calculate urine volume in the bladder.

The device takes mechanical sector scan by 2.5MHz ultrasonic waves and recognizes the reflected waves of the front and back walls of bladder to get the area of bladder section; then it makes 12 scans at an interval of 15° and calculates the urine volume in human bladder with volume integral algorithm.

5. Indications for Use

MD-6000P Bladder Scanner is intended to measure the urine volume in human bladder.

The device is intended to be used in medical and nursing care institutions. It should be operated by trained professionals.

The device is not intended for use on pregnant women. It cannot be used on wounded skin.

6. Comparison of Technological Characteristics

The subject and the predicate devices are based on the following same technological elements:

- Intended use: measure the urine volume in human bladder
- Mode of operation: B-mode
- Transducer type: mechanical sector probe
- Nominal ultrasound frequency: 2.5MHz
- Total number of elements: Single element
- Volume display resolution: 1ml
- Number of sections in one calculation: 12 sections with an interval of 15 °
- Pre-scan function
- Standards of safety, EMC, biocompatibility: AAMI/ANSI ES60601-1, IEC60601-2-37, UD2-2004 and FDA Guide for Track 1, IEC60601-1-2, ISO10993-5, ISO10993-10

The differences of MD-6000P Bladder Scanner and its predicate device:

Model / Item	**Subject Device** **MD-6000P Bladder Scanner**	**Predicate Device** **MD-6000 Bladder Scanner**
Display screen	1.3” OLED	6.4” True Color TFT LCD
Accuracy	±15% or ±15ml (take the maximum value)	±15%
Appearance	Hand-held	Portable
Measuring Range	20ml - 999ml	20ml - 999ml
Printing	External printer	Built-in printer
Pre-scan	Mark on the screen	Image on the screen

While there are some differences between the MD-6000P Bladder Scanner and its predicate device, they do not affect the safety or effectiveness.

7. Brief Discussion of Non-clinical Tests

Safety and EMC:

The safety and EMC testing were conducted on the MD-6000P and the testing results comply with the requirements of the following standards:

AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for

Safety, 005/(R)2012 And A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-2-37 Edition 2.1 2015 Medical electrical equipment–Part 2-37: Particular requirement for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

IEC 60601-1-2: 2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Acoustic output parameters:

The acoustic output parameters comply with the requirements of:

NEMA UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3, and

FDA Guidance document "Information for Manufactures Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued in September 2008

Biocompatibility:

The biocompatibility evaluation has been conducted according to ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. Tests for in vitro cytotoxicity, skin sensitization and irritation were conducted on the patient-contacting materials according to the requirements of:

ISO 10993-5:2009 Third Edition Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-10: 2010 Third Edition Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

FCC Certification:

Tests were conducted on the wireless part of MD-6000P and it complies with the requirements of FCC, CFR, Title 47 – Telecommunications, Chapter I - Federal Communications Commission, Subchapter A – General:

- Subpart J of Part 2 – Frequency Allocations and Radio Treaty Matters; General Rules and Regulations
- Subpart C of Part 15 – Radiofrequency Devices
- Part 18 – Industrial, Scientific, and Medical Equipment

Bench Testing:

Measurement accuracy of ±15% or ±15ml within the measurement range of 20-999ml

For the measurement range of 100-999ml, use MD-6000P Bladder Scanner to make scan on the phantom and compare the measurement value and the nominal value, the measurement accuracy met the requirements of ±15%.

For the measurement range of 20-100ml, use MD-6000P Bladder Scanner to make scan on the test object of water sac with known volume, the measurement accuracy met the requirements of ±15ml.

Software:

The software of MD-6000P has passed verification and validation according to the FDA guidance:

“Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” issued on May 11, 2005.

Clinical Testing:

The MD-6000P Bladder Scanner, subject of this submission, did not require clinical studies to support the determination of substantial equivalence.

8. Conclusions

The results of non-clinical tests demonstrate that the MD-6000P Bladder Scanner is substantially equivalent in safety and effectiveness to the legally marketed predicate device.