



September 24, 2026

MEDA Co., Ltd.
Linda Zhang
RA
F2C, F3D, F4C, F5, F6C, Building C2,
Xinmao Science Skill Park, Huayuan Industry Development Area
Tianjin, 300384
China

Re: K260313
Trade/Device Name: MD-6000S Bladder Scanner
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: August 25, 2026
Received: August 25, 2026

Dear Linda Zhang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

MARJAN NABILI -S for

Yanna Kang, Ph.D.

Assistant Director

Mammography and Ultrasound Team

DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices

OHT8: Office of Radiological Health

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K260313

?

Please provide the device trade name(s).

?

MD-6000S Bladder Scanner

Please provide your Indications for Use below.

?

MD-6000S Bladder Scanner is a B-mode pulsed-echo ultrasound device. It is intended to measure the volume of bladder. The device is intended to be used in medical and nursing care institutions. It should be used by appropriately trained and qualified healthcare professionals.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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510(k) SUMMARY

1. Submitter Information

510(k) owner's name: **MEDA Co., Ltd.**

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Date Prepared: September 24, 2026

2. Device Information

Trade Name/Common Name: MD-6000S 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

Device Name: CUBEScan™ BioCon-1100

510(k) Number: **K200548**

Manufacturer: Mcube Technology Co., Ltd.

4. Device Description

MD-6000S Bladder Scanner is intended to measure the volume of bladder.

The device consists of a Main Unit and a 2.5 MHz 3D probe; the Main Unit is equipped with a color LCD touchscreen, a rechargeable Li-ion battery and a dock which integrates a thermal printer and AC power supply. Its software system is MD60SBLD V1.0.

5. Indications for Use

MD-6000S Bladder Scanner is a B-mode pulsed-echo ultrasound device.

It is intended to measure the volume of bladder.

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

6. Comparison of Technological Characteristics

The CUBEScan BioCon-1100 is a B-mode pulsed-echo ultrasound device. The BioCon-1100 projects ultrasonic energy through the lower abdomen of a patient to obtain images of the bladder to calculate the urine volume non-invasively. The BioCon-1100 is intended to be used by a qualified medical professional in hospitals and other healthcare facilities to non-invasively measure the urine volume in the bladder. Contraindications for the BioCon-1100 are fetal use and use on pregnant patients.

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

Model Item	Subject Device MD-6000S Bladder Scanner	Predicate Device CUBEScan™ BioCon-1100
Display	10.1 inch	10.1 inch
Volume Range	0-999mL	0-999mL
Accuracy	± 7.5% or ± 7.5mL, whichever is greater (based on phantom)	± 7.5mL (0-99mL) ± 7.5% (100-999mL)
Probe Mode	B-Mode scan image; 3D-Mechanical Sector Scan	B-Mode scan image; 3D-Mechanical Sector Scan
Probe Scan Angel	120°	120°
Printer	Built in Thermal Printer	Built in Thermal Printer

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

Model	Subject Device MD-6000S Bladder Scanner	Predicate Device CUBEScan™ BioCon-1100
Probe frequency	2.5MHz	Dual frequency (2.8 MHz, 3.7MHz)
OS	Android	Linux
Power Supply	Power supply cord	Power adaptor

As it can be seen from the above tables, both MD6000S and CUBEScan BioCon-1100 are B-mode pulsed-echo portable ultrasound devices, and have the same intended use.

The MD-6000S has similar performance characteristics, controls and indicators, and specifications as its equivalent device. It incorporates the same operational principles and technology as the BioCon-1100.

The primary difference between the products is that:

- 1) MD-6000S uses a 2.5MHz ultrasound transducer and BioCon-1100 uses Dual frequency (2.8 MHz, 3.7MHz) ultrasound transducer.
- 2) The MD-6000S runs on Android, while the BioCon-1100 runs on Linux.
- 3) The MD-6000S is powered by an internal switching power supply connected via a power cord, whereas the BioCon-1100 is powered by an external adapter.

Although there are some differences between the MD-6000S and BioCon-1100, they have no substantial impact on the intended use, safety and effectiveness of the device.

7. Brief Discussion of Non-clinical Tests

The device has been verified to meet the following requirements, with all verifications passed:

Safety and EMC:

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

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2: 2020 and AAMI ES60601-1:2005, AAMI ES60601-1:2005/ AMD1:2012, AAMI ES 60601-1:2005/ AMD2:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013, IEC 60601-1-6:2010/AMD2:2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance-Collateral standard: Usability for use in conjunction with IEC 62366-1:2015, IEC 62366-1:2015/AMD1:2020 Medical devices - Part 1: Application of usability engineering to medical devices

IEC 60601-2-37: 2024 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/AMD1: 2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC TR 60601-4-2: 2016 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

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 *Marketing Clearance of Diagnostic Ultrasound Systems and Transducers* issued on February 21, 2023

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 skin irritation were conducted on the patient-contacting materials according to the requirements of:

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

ISO 10993-10: 2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization

ISO 10993-23: 2021 Biological evaluation of medical devices - Part 10: Tests for irritation

Bench Testing:

Measurement accuracy of $\pm 7.5\%$ or ± 7.5 mL within the measurement range of 0 mL – 999 mL

For the measurement range of 100 mL – 999 mL, use MD-6000S Bladder Scanner to make scan on the phantom and compare the measurement value and the nominal value, the measurement accuracy met the requirements of $\pm 7.5\%$.

For the measurement range of 0 mL – 99 mL, use MD-6000S Bladder Scanner to make scan on the phantom and compare the measurement value and the nominal value, the measurement accuracy met the requirements of $\pm 7.5\text{mL}$.

Clinical Validation Study:

Two clinical studies were conducted to evaluate the accuracy of the MD-6000S Bladder Scanner in measuring bladder volume — one enrolling pediatric and adult volunteers, and a second focused on individuals with high BMI. The studies assessed measurement accuracy across different bladder volume ranges and BMI levels, using Bland-Altman statistics and 95% limits of agreement as the analytical framework. Accuracy requirements were pre-defined and applied consistently across both studies. Based on statistical analysis of test data, good agreement is confirmed between MD-6000S measurements and voided-urine-volume reference values.

8. Conclusions

The results of non-clinical tests as well as the software and essential performance verification and validation demonstrate that the MD-6000S Bladder Scanner is substantially equivalent in safety, effectiveness and performance to the legally marketed predicate device.