Mianyang Meike Electronic Equipment Co., Ltd. July 29, 2021
Wenjun Zhao
General Manger
No.63, Yinping Road, Longmen Town, Fucheng District
Mianyang, Sichuan, 621000
CHINA

Re: K210591
Trade/Device Name: Palm Bladder Scanner - PBSV7.1
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO,IYX

Dear Wenjun Zhao:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 9, 2021. Specifically, FDA is updating this SE Letter because of a clerical error in the 510(k) Summary as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jessica Lamb, Office of *in vitro* Diagnostics and Radiological Health, 301-796-6167, **jessica.lamb@fda.hhs.gov**.

Sincerely,

Michael D. O'Hara For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Mianyang Meike Electronic Equipment Co., Ltd.
Wenjun Zhao
General Manger
No.63, Yinping Road, Longmen Town, Fucheng District
Mianyang, Sichuan, 621000
CHINA

June 9, 2021

Re: K210591
Trade/Device Name: Palm Bladder Scanner - PBSV7.1
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: April 20, 2021
Received: May 10, 2021

Dear Wenjun Zhao:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210591

Device Name
Palm Bladder Scanner - PBSV7.1

Indications for Use *(Describe)*
Palm Bladder Scanner - PBSV7.1 is intended to project ultrasound energy through the lower abdomen of the nonpregnant patient to obtain an image of the bladder and uses that image to calculate the bladder volume non-invasively. It is contraindicated for fetal use and for use on pregnant patients. And it should not be used by those who are allergic to coupling agent and who have abdomen wound and skin disease.

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."

007_510(k) Summary
(As required by 21 CFR 807.92(a))

1.0 Submitter Information

Company:	Mianyang Meike Electronic Equipment Co., Ltd.
Address	No.63, Yinping Road, Longmen Town, Fucheng District, Mianyang, Sichuan, 621000, CHINA
Phone:	086-13308119236
Contact	Wenjun Zhao
Title:	General Manager

· Date: April. 26, 2021

2.0 Device Information

Trade/Device Name:	Palm Bladder Scanner - PBSV7.1
Model:	PBSV7.1
Common Name:	Diagnostic Ultrasound System with Accessories
Regulation Description:	Ultrasonic pulsed echo imaging system; Transducer, Ultrasonic, Diagnostic
Device:	System, Imaging, Pulsed Echo, Ultrasonic; Diagnostic ultrasonic transducer
Review Panel:	Radiology
Product Code:	IYO, ITX
Submission Type:	Special 510(k)
Regulation Number:	CFR 892.1560, CFR 892.1570
Device Class:	Class II

3.0 Predicate Device Information

Trade/Device Name:	Palm Bladder Scanner - PBSV5.1
510k Number:	K191307
Submitter:	Mianyang Meike Electronic Equipment Co., Ltd.

4.0 Device Description

Palm Bladder Scanner - PBSV7.1 is a medical device with high performance combined with modern B-mode ultrasound technology and computer technology. The PBSV7.1 is composed of data processing host, 3D ultrasonic probe and application software. The 3D ultrasonic probe will transmit the collected data to the host, which will process the received data into ultrasonic images and bladder volume data. Images and data will be transmitted to the running application software on the Android system PC tablet through the USB interface.

5.0 Indications for Use

Palm Bladder Scanner - PBSV7.1 is intended to project ultrasound energy through the lower abdomen of the nonpregnant patient to obtain an image of the bladder and uses that image to calculate the bladder volume

non-invasively. It is contraindicated for fetal use and for use on pregnant patients. And it should not be used by those who are allergic to coupling agent and who have abdomen wound and skin disease.

6.0 Comparison of Technological Characteristics with the Predicate Device

Table 1 - Comparison table of the Subject device and Predicate device

Device Feature	Palm Bladder Scanner - PBSV7.1	Palm Bladder Scanner - PBSV5.1
510k number	K210591	K191370
Classification	CFR 892.1560, CFR 892.1570	
Product code	IYO, ITX	
Common name	Diagnostic Ultrasound System with Accessories	
Use	Prescription Use	
Indication for use	Palm Bladder Scanner - PBSV7.1 is intended to project ultrasound energy through the lower abdomen of the nonpregnant patient to obtain an image of the bladder and uses that image to calculate the bladder volume non-invasively. It is contraindicated for fetal use and for use on pregnant patients. And it should not be used by those who are allergic to coupling agent and who have abdomen wound and skin disease.	Palm Bladder Scanner - PBSV5.1 is intended to project ultrasound energy through the lower abdomen of the nonpregnant patient to obtain an image of the bladder and uses that image to calculate the bladder volume non-invasively. It is contraindicated for fetal use and for use on pregnant patients. And it should not be used by those who are allergic to coupling agent and who have abdomen wound and skin disease.
Display Mode	B	B
Frequency	3.5MHz	2.6MHZ
Scan Type	Convergent	Mechanical Sector Scan
Display Screen	Universal Tablet Computer (Non-medical Device)	8.4"TFT Color LCD
Power Supply	Internal Battery (four 18650 lithium batteries)	Internal Battery (four 18650 lithium batteries)
Battery Control	Capacity Instruction for Lower Power	Capacity Instruction and Alarm for Lower Power
Printer	Request Android system	Self-built printer for

	print	printing micro characters, graphic and image
Patient Case Record	⩽10000 Pieces	100 Pieces
Maximum Measurement	2000ml	999ml
Accuracy	±5%（⩾100mL）/ ±5mL（0~100mL）	±15%,±15 ml
Dead Zone	≤3mm	8mm
Language of Interface	English & Chinese	English

A brief summary of the similarities and differences between Palm Bladder Scanner - PBSV7.1 and Palm Bladder Scanner - PBSV5.1 (K191307) is included below:

Similarities

Both Palm Bladder Scanner - PBSV7.1 and Palm Bladder Scanner - PBSV5.1 have the same basic science & technology and all technical features. All technical features are as follows:

- Both two devices use the piezoelectric ceramic wafers as transducers to obtain the ultrasound images of patient's bladder.
- Both two devices can obtain and process the B-type grayscale images of patient's bladder.
- Both two devices can obtain the boundaries of the patient's bladder image through the same software algorithm.
- Both two devices require the patient to be in a supine position.
- Both two devices require an ultrasonic coupling agent to be placed between the probe sound-permeable window and the patient's skin surface for use as an ultrasound conductive medium.
- Both two devices use the probe to scan and display the 12/24 B-mode ultrasound image of the patient's bladder
- Both two devices use the same technology to achieve 3D image reconstruction, and use the same algorithm to calculate the volume of the reconstructed 3D image.
- Both two devices use the same material of probe and host.

Differences

The summary of the differences between Palm Bladder Scanner - PBSV7.1 and Palm Bladder Scanner - PBSV5.1 are listed in the following:

- **Transducer Frequency**

  2.6 MHz for PBSV5.1 and 3.5 MHz for PBSV7.1.
- **Scan type**

The scan type of the PBSV5.1 is mechanical sector scan and the PBSV7.1 uses convergent scan.

- **Display screen**

  PBSV7.1 uses Android off-the-shelf tablet as the display screen, the PBSV5.1 uses built-in 8.4"TFT Color LCD screen.

- **Printer**

  The PBSV5.1 has a printer as part of the device. The PBSV7.1 can print to a wireless printer available as an accessory through the off-the-shelf tablet.

- **Performance**

  The performance of the PBSV7.1 has been greatly improved.

  • Memory capacity of the patient case record has expanded from up to 100 pieces (PBSV5.1) to 10000 pieces (PBSV7.1).

  • Maximum Measurement can reach to 2000ml (PBSV7.1) instead of the 999ml (PBSV5.1).

  •Accuracy are improved. In PBSV5.1, there's a 15%/15ml margin of error, the PBSV7.1 managed to reduce the error to 5%/5ml. The area of dead zone reduces from 8mm to less than 3mm.

  • There are more language options in the PBSV7.1- Chinese and English while the PBSV5.1 can only be operated in English.

- **Software**

  Under the premise of not changing the user operation, we have optimized the interface UI. At the same time, PBSV7.1 have been removed the bar code scanning function and the gender switch function. The added functions are •Hospital information setting function •Batch data operation function •Data uploading •Exporting, backup and restoring function •User automatic logout function. The design and development of software meets the requirement of IEC62304.

The differences noted between Palm Bladder Scanner - PBSV7.1 and the predicate device, Palm Bladder Scanner - PBSV5.1 (K191307), do not present any new or different questions related to safety and effectiveness.

7.0 Compatibility Specifications for Universal PC Tablet

7.1 Universal PC Tablet Compatibility

Table 2 - List of Compatibility Specifications

Specification	Requirement
CPU:	Above 1.5GHz
RAM:	Above 3GB
Storage Memory:	Above 32GB
Screen:	Above 1920×1080 of Resolution

Network:	Wi-Fi, Bluetooth
USB Interface:	Type-C
OS Version:	On Android 8.0 and above
Print:	Support Wi-Fi Print
EMC and Electrical Safety:	Meet the standard of IEC60601-1 or IEC62368-1
Mobile Phone Capability:	Must approved by FCC

7.2 Warnings

Risks and safety accidents may be caused by irregular use or use of any tablet PC tablet that does not meet the specific requirements listed in the Compatibility Specifications Table for that may lead to abnormal operations of the application software or other issues.

The user must assume responsibility for assuring the performance of any tablet PC with the system other than listed in the Compatibility Specifications Table and using the tablet PC regularly.

8.0 Discussion of Tests Performed

8.1 Clinical Tests

Clinical testing was not performed for the subject device as part of the submission.

8.2 Non-Clinical Tests

The function and performance of Palm Bladder Scanner - PBSV7.1 has been evaluated through non-clinical design verification and validation testing. All necessary testing was conducted on the proposed Palm Bladder Scanner - PBSV7.1 to support a determination of substantial equivalence to the unmodified predicate device. Specifically, the impacts of the design changes presented with the subject device were evaluated through Design Control, and a number of required testing accordingly determined and subsequently performed. All necessary validation testing, including comprehensive software verification and validation, was performed, the results of which demonstrate that Palm Bladder Scanner - PBSV7.1 successfully meets design specification.

These testings confirm that the design changes presented with the subject device do not raise new questions of safety and effectiveness, the subject device meets design specifications, and that the subject and predicate devices are substantially equivalent:

Table 3 - Performance testing

Standard	Title
IEC 60601-1: 2005+ A1:2012	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD).

IEC 60601-2-37: 2007+ AMD1 2015	Medical Electrical Equipment - Part 2-37: Particular Requirements For The Basic Safety And Essential Performance Of Ultrasonic Medical Diagnostic And Monitoring Equipment.
IEC 60601-1-2: 2007+ AMD1 2015	Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests.
IEC 62133:2012	Secondary Cells And Batteries Containing Alkaline Or Other Non-Acid Electrolytes - Safety Requirements For Portable Sealed Secondary Cells, And For Batteries Made From Them, For Use In Portable Applications [Including: Corrigendum 1 (2013)].
IEC 62359: 2017	Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields.
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.

The conclusion from the testing is the device is safe and effective for it's intended use, and performs as well or better than the predicate devices.

9.0 Software

The software and firmware in the Palm Bladder Scanner - PBSV7.1 has been developed and verified according to IEC 62304:2006. The verification report, traceability, and risk analysis demonstrate the PBSV7.1 operates as intended and risks mitigated in firmware have been verified.

10.0 Conclusion

First, the subject device - Palm Bladder Scanner - PBSV7.1 enjoys the same intended use with the predicate device, which forms the foundation of their substantial equivalence.

Secondly, they share almost the same technological characteristics and the differences will not affect the core usage of the subject device, which further support their substantial equivalence.

Moreover, the safety and effectiveness of Palm Bladder Scanner - PBSV7.1 have been evaluated according to appropriate standards, which ensures that the new device will not bring new safety and effectiveness concerns, that the

subject device is substantial equivalent to the predicate device.

In a word, it is reasonable for us to conclude that the subject device - Palm Bladder Scanner - PBSV7.1 is substantially equivalent to the predicate device - Palm Bladder Scanner - PBSV5.1 (K191307).