Mianyang Meike Electronic Equipment Co., Ltd. June 5, 2019
℅ Ms. Helen Nan
General Manager
Wenzhou Cytech Information Service Co., Ltd.
Room 302, Building 3, Hangqian Mansion, Hangqian Street
Lucheng District
Wenzhou, Zhejiang 325000
CHINA

Re: K191307
Trade/Device Name: Palm Bladder Scanner - PBSV5.1
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: April 1, 2019
Received: May 14, 2019

Dear Ms. Nan:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191307

Device Name
Palm Bladder Scanner - PBSV5.1

Indications for Use *(Describe)*

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.

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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007_510(k) Summary K191307

(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, General Manager

· Date: Apr 1, 2019

2.0 Device Information

· Trade/Device Name: Palm Bladder Scanner - PBSV5.1

· Model: PBSV5.1

· Common Name: Diagnostic Ultrasound System with Accessories

· Classification:

Device: Ultrasonic Pulsed Echo Imaging System
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: 2

3.0 Predicate Device Information

Palm Bladder Scanner - PBSV4.1 [510K Number:K130229; submitted by Mianyang Meike Electronic Equipment Co., Ltd.]

4.0 Device Description

Palm Bladder Scanner - PBSV5.1 is a medical device with high performance combined with modern B-mode ultrasound technology and computer technology. The device consists of host and probe, it can speedily complete the detection of bladder area through scan of probe connected with the device, and transmit B ultrasound echo signal detected to embedded computer system after processing before computer identifies the edge of image and volume calculation, realizes the measurement of bladder volume, displays and prints out the relative information through LED/built-in printer.

5.0 Indications for Use

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.

6.0 Comparison of Technological Characteristics with the Predicate Device

Palm Bladder Scanner - PBSV5.1 is substantially equivalent to the predicate device, Palm Bladder Scanner - PBSV4.1 cleared by the FDA in K130229. Palm Bladder Scanner - PBSV5.1 claims substantial equivalence because the proposed device has the same intended use, scope of application and operation compared with the predicate device. Meanwhile, PBSV5.1 also use the same ultrasound-based science technology and is the basic same in the technical characteristics, as well as the physical and operation. Both bladder scanner PBSV5.1 and PBSV4.1 use the piezoelectric ceramic wafers as the sensors to obtain B-type grayscale ultrasound images to achieve the intended use, and the material used in the product structure are

also identical.Both bladder scanner PBSV5.1 and PBSV4.1 are portable devices, and can be used to measure the urine volume in the bladder.

A brief summary of the similarities and differences between Palm Bladder Scanner - PBSV5.1 and Palm Bladder Scanner - PBSV4.1 (K130229) is included below:

Similarities

Both Palm Bladder Scanner - PBSV5.1 and Palm Bladder Scanner - PBSV4.1 have the same basic science & technology and all technical features. All technical features are as follows:

1)Both two devices use the piezoelectric ceramic wafers as transducers to obtain the ultrasound images of patient's bladder.

2)Both two devices can obtain and process the B-type grayscale images of patient’s bladder.

3)Both two devices can obtain the boundaries of the patient's bladder image through the same software algorithm.

4)Both two devices require the patient to be in a supine position.

5)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.

6)Both two devices use the probe to scan and display the 12/24 B-mode ultrasound image of the patient's bladder

7)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.

Differences

Compared with the predicate device, Palm Bladder Scanner - PBSV5.1 uses the new housing, replace the original ultrasonic transceiver part with an

analog circuit into a digital circuit, optimizes the software UI interface and change the battery.

The summary of the differences between Palm Bladder Scanner - PBSV5.1 and Palm Bladder Scanner - PBSV4.1 are listed in the following table.

Modification	Discussion
Housing	PBSV5.1 uses the same material as PBSV4.1, and the housing of PBSV5.1 was industrially designed for a better ergonomic interaction experience. The updated housing meets the mechanical strength requirements of 15.3 of IEC 60601-1.
Digital Circuit	In the circuit board, the ultrasonic transmitting and receiving part is replaced by an analog circuit to a digital circuit, which improves the signal-to-noise ratio of the ultrasonic signal and the image quality. The barcode scanning module has been added to input the patient information for the operator. The new circuit board meets the relevant requirements of IEC60601-1 and IEC60601-1-2.
Software	Under the premise of not changing the user operation, we have optimized the interface UI. At the same time,this device have been added the barcode scanning function and the operation mode of expert and simple. The design and development of software meets the requirement of IEC62304
Battery	The customized 7.4V lithium battery pack is changed to 4 standard 18650 lithium battery pack synthesis 7.4V to provide the power for the equipment.

The differences noted between Palm Bladder Scanner - PBSV5.1 and the predicate device, Palm Bladder Scanner - PBSV4.1 (K130229), do not present any new or different questions related to safety and effectiveness.

7.0 Discussion of Tests Performed

7.1 Clinical Tests

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

7.2 Non-Clinical Tests

The function and performance of Palm Bladder Scanner - PBSV5.1 has been evaluated through non-clinical design verification and validation testing. All necessary testing was conducted on the proposed Palm Bladder Scanner - PBSV5.1 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 - PBSV5.1 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:

Modification	Test Performed	Type of Testing
Housing	This device have been tested all electrical safety and basic performance by	AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated

	China Testing and Testing Group Co., Ltd.	Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (Iec 60601-1:2005, Mod). (General II (ES/EMC))
Digital Circuit	This device have been tested all electrical safety, basic performance and Ultrasonic sound output by China Testing and Testing Group Co., Ltd.	AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (Iec 60601-1:2005, Mod). (General II (ES/EMC))； AAMI / ANSI / 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. (General II (ES/EMC)); IEC 60601-2-37 Edition 2.1 2015, Medical Electrical Equipment -

		Part 2-37: Particular Requirements For The Basic Safety And Essential Performance Of Ultrasonic Medical Diagnostic And Monitoring Equipment. (Radiology); NEMA UD 2-2004 (R2009), Acoustic Output Measurement Standard For Diagnostic Ultrasound Equipment Revision 3. (Radiology); NEMA UD 3:2004 Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment; Acoustic output testing as per the guideline "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" dated September 9, 2008
Software	The development of software have been controlled according	ISO13485 Third edition 2016-03-01 Medical devices - Quality management systems -

	to the requirements of the software control procedures, and the software have been verified and validated.	Requirements for regulatory purposes:7.3 Design and Development; IEC62304 Medical Device Software - Software Life Cycle Processes
Battery	According to the requirements of IEC62133, the battery have been tested all items by China Testing and Testing Group Co., Ltd.	IEC 62133 Edition 2.0 2012-12, 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

8.0 Conclusion:

First, the subject device - Palm Bladder Scanner - PBSV5.1 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 - PBSV5.1 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 - PBSV5.1 is substantially equivalent to the predicate device - Palm Bladder Scanner - PBSV4.1 (K130229).