Avantsonic Technology Co., Ltd.
Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd
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Chongquing 401133
China

December 29, 2023

Re: K230986
Trade/Device Name: Bladder Scanner
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: November 23, 2023
Received: November 24, 2023

Dear Ray Wang:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

Julie Sullivan -S

Julie Sullivan, Ph.D.
Director
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

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)*
K230986

Device Name
Bladder Scanner

Indications for Use *(Describe)*
The Bladder Scanner is B-mode pulsed-echo ultrasound device adopts a 3D mechanical fan scanning probe for the ultrasonic scanning for bladder and measures the bladder volume from the abdominal surface utilizing the principles of ultrasonic imaging. The Bladder Scanner is intended to be used only in hospital and by qualified medical professionals.

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.

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The assigned 510(k) Number: K230986

510(k) Summary

This 510(k) Summary of 510(k) substantial equivalence information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Date of Preparation: 2023/12/27

2. Sponsor Identification

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Bladder Scanner
Common Name: Diagnostic Ultrasound System with Accessories

Regulatory Information
Classification Name: Ultrasonic Pulsed Echo Imaging System(IYO) ,
Diagnostic Ultrasound Transducer (ITX)
Classification: II
Product Code: IYO, ITX
Regulation Number: 21 CFR 892.1560, 21 CFR 892.1570
Review Panel: Radiology

Indication for use Statement:

The Bladder Scanner is B-mode pulsed-echo ultrasound device adopts a 3D mechanical fan scanning probe for the ultrasonic scanning for bladder and measures the bladder volume from the abdominal surface utilizing the principles of ultrasonic imaging. The Bladder Scanner is intended to be used only in hospital and by qualified medical professionals.

Device Description:
The Bladder Scanner (Model: AS-2) is a hand-held battery-operated device, it provides non-invasive bladder volume measurement utilizing real-time ultrasound imaging. The proposed device consists of the main unit (include 3D probe), battery power adapter and USB charging cable.

The device features：

- The measurement of bladder capacity includes two operation modes: Pre-scanning and Scanning;
- There are two ways to enter the scanning stage in the pre-scanning stage: first, when the probe is in the center of bladder for about 5 seconds, the device automatically enters the scanning mode; Second, during the pre-scanning process, the user can click the scanning button again to force the device to enter the scanning mode.
- Non-invasive operation.
- Volume setting
- Built-in battery power supply
- The ultrasonic signal is continuously transmitted at a frequency of 2.5 MHz.

5. Identification of Predicate Device(s)

Predicate Device:
510(k) Number: K201316
Product Name: Bladder Scanner
Manufacturer: Suzhou Peaksonic Medical Technology Co., Ltd.

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- 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.
- IEC 60601-1:2012, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014, Medical Electrical Equipment-Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility-Requirements And Tests
- 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;
- IEC 62359 Edition 2.1 2017-09 Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields
- IEC 62133-2 Edition1.0 2017-02 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 - Part 2: Lithium systems

The Bladder Scanner volume measurement range is: 0 ml～999 ml;
The Bladder Scanner volume measurement accuracy is：
≤ ±10 ml (measured volume＜100ml)，≤ ±7.5% (measured volume ≥100ml).
Conducted the Bladder Scanner volume measurement accuracy test for the measurement range 0 ml～999 ml, the measurement accuracy met the requirements.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

Item	Proposed Device	Predicate Device K201316	Remark
Device name	Bladder Scanner	Bladder Scanner	/
Model	AS-2	M3-HD, M4-HD	/
Classification Regulation	21 CFR 892.1560 21 CFR 892.1570	21 CFR 892.1560 21 CFR 892.1570	SAME
Classification	II	II	SAME
Product Code	IYO, ITX	IYO, ITX	SAME
Regulation Name	Ultrasonic Pulsed Echo Imaging System(IYO) Diagnostic Ultrasound Transducer (ITX)	Ultrasonic Pulsed Echo Imaging System(IYO) Diagnostic Ultrasonic Transducer (ITX)	SAME
Indications for use	The Bladder Scanner is B-mode pulsed-echo ultrasound device adopts a 3D mechanical fan scanning probe for the ultrasonic scanning for bladder and measures the bladder volume from the abdominal surface utilizing the principles of ultrasonic imaging. The Bladder Scanner is intended to be used only by qualified medical professionals.	The Bladder Scanner (Models: M3, M3-HD, M4, M4-HD) is B-mode pulsed-echo ultrasound device. It intended as a handheld battery-operated device. The M3, M3-HD, M4, M4-HD Bladder Scanner projects ultrasound energy through the lower abdomen of the patient to obtain images of the bladder which is used to calculate bladder Volume noninvasively. The M3, M3-HD, M4, M4-HD Bladder Scanner is intended to be used only by qualified medical professionals.	SAME
Contraindications	Do not carry out any inspection or exploration on any wounds to prevent cross-infection and disease aggravation. This equipment is not applicable to the bladder scanning of the pregnant and fetuses, patients with surgical scars or scars on the abdomen (for this will affect the measurement accuracy), patients with ascites, and patients with bladder catheters (for this will affect the measurement accuracy).	Do not use the Bladder Scanner on following cases: a) Fetal use or pregnant patients b) Patients with ascites c) Patients with open or damaged skin. d) Wounds in the suprapubic region	Difference (1)
System Characteristics and structure	Portable, Power source: Battery	Portable, Tablet computer display, Thermal Printer, Power source: Battery	SAME
Display screen	1.54 inch, 240*240, high-resolution IPS	M3-HD, M4-HD will be provided	Difference

	display.	customer with a Samsung SM-T590 10.5 inch	(2)
Controls for Change of acoustic output during scan	No	No	SAME
Transducer type	Mechanical Sector Probe	Mechanical Sector Probe	SAME
Measurement place	Abdomen	Abdomen	SAME
Nominal ultrasound frequency	2.5 MHz	2.5Mhz	SAME
Number of elements	1	1	SAME
Sector Angle	120°	120°	SAME
Number of Scan Planes	12	M4-HD:12 , M3-HD:1	SAME with M4-HD model
Volume measurement range	0 ml～999 ml	0ml-999ml	SAME
Volume measurement accuracy	≤ ±10 ml (measured volume＜100ml) ≤ ±7.5% (measured volume ≥100ml)	M4-HD： under 100 mL: ±7mL; 100 to 999 mL: ±7%, M3-HD： under 100 mL: ±14mL; 100 to 999 mL: ±14%	Difference (3)
Classification of protection against electric shock, Applied part type	Class II equipment, B type	Class II equipment , B type	SAME
Real-time scanning	Yes (Pre-scan)	Yes (Pre-scan)	SAME
PC Data Upload	No	USB connection	Difference (5)
Power	Lithium battery: PA-1S2P35R3-2T 3.6 V 7000 mAh Charger: 100~ 240V～, 50 -60Hz 0.4A	Lithium battery: NCA653864SA-2400 mAh (PC015-2S1P) 7.4Vd.c. 2400mAh Charger: HXY- 084V1500A-UL AC100-240Va	Difference (4)
WIFI	No	WIFI connection.	Difference (5)

Bluetooth	No	Connect to the printer using Bluetooth to print a test image.	Difference (5)
Patient contact material	Polyethylene (PE), skin contact	Polycarbonate (PC), skin contact	Difference (6)
Biocompatibility	ISO 10993-5 &ISO 10993-10	Unknown	
Safety and EMC Standards compliance	IEC 60601- 1:2005+A1:2012 IEC 60601-1-2:2014 IEC 60601-2-37:2015	ES60601- 1:2005+A1:2012 IEC 60601-1-2:2014 IEC 60601-2-37:2015	SAME
FDA limit	Track 1	Track 1	SAME

Analysis：

Difference (1)

The contraindications of proposed device have covered that of the predicate device，the difference would not affect the safety and effectiveness of the proposed device.

Difference (2)

The proposed device and the predicate device have different display screen size and specification design, the difference would not affect the safety and effectiveness of the proposed device.

Difference (3)

The volume measurement accuracy of proposed device is between that of the two models of the predicate device，the difference would not affect the safety and effectiveness of the proposed device.

Difference (4)

There is difference on the battery voltage, but the design of proposed device comply with electrical safety standard IEC 60601-1, and its Li-ion battery comply with the battery safety standard IEC 62133, so the voltage difference would not affect its safety and effectiveness.

Difference (5)

The proposed device does not data transmission function, such as WiFi, USB and Bluetooth, the difference would not affect the safety and effectiveness of the proposed device.

Difference (6)

The proposed device and the predicate device have different patient contact materials, but the patient contact materials of proposed device meet the ISO10993 standards, the difference would not affect its safety and effectiveness.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.