July 1, 2022

Suzhou Peaksonic Medical Technology Co., Ltd.
Calvin Ma
GM
2A, West Side of Building G4, Kunshan Hi-Tech Medical Device
Industrial Park Qiandeng, Kunshan
Suzhou, Jiangsu 215341
CHINA

Re: K213488
Trade/Device Name: Bladder Scanner, Model Name:M5
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: May 5, 2022
Received: May 19, 2022

Dear Calvin Ma:

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

Michael D. O'Hara, Ph.D.
Deputy Director
DHT 8C: Division of Radiological Imaging
and Radiation Therapy
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)*
K213488

Device Name
Bladder Scanner, Model Name:M5

Indications for Use *(Describe)*
The Bladder Scanner (Model Name:M5) is intended to project ultrasound energy through the lower abdomen of the non-pregnant 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.
Mode of operation: B-mode.
Intended user population:Trained and qualified healthcare professionals.
Intended use environment:Professional health care facilities.

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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K213488

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: June 29,2022

1. Submitter's Information

The submitter of this pre-market notification is:

Name:	SUZHOU PEAKSONIC MEDICAL TECHNOLOGY CO., LTD.
Address:	2A, West Side of Building G4, Kunshan Hi-Tech Medical Device Industrial Park Qiandeng, Kunshan, Suzhou, Jiangsu 215341 China
Contact person:	Calvin Ma
Title:	GM
E-mail:	service@peaksonic.com.cn
Tel:	86-512-36693388

2. Device Identification

510(K) number:	K213488
Trade/Device Name:	Bladder Scanner
Models:	M5
Common name:	System, Imaging, Pulsed Echo, Ultrasonic Transducer, Ultrasonic, Diagnostic
Regulation Number:	21 CFR 892.1560 21 CFR 892.1570
Regulation Name:	Ultrasonic pulsed echo imaging system Diagnostic ultrasonic transducer
Regulation Class:	Class II
Panel:	Radiology
Product Code:	IYO,ITX

3. Predicate Device

510(K) number:	K172750
Device Name:	Wireless Probe Type Ultrasound Scanner (Model: BProbe)
Manufacturer:	Guangzhou Sonostar Technologies Co., Ltd.
Common name	System, Imaging, Pulsed Echo, Ultrasonic Transducer, Ultrasonic, Diagnostic
Regulation Number:	21 CFR 892.1560 21 CFR 892.1570
Regulation Name:	Ultrasonic pulsed echo imaging system

	Diagnostic ultrasonic transducer
Regulation Class:	Class II
Panel:	Radiology
Product Code:	IYO,ITX

4. Device Description

The Bladder Scanner (model:M5) designed and manufactured by SUZHOU PEAKSONIC MEDICAL TECHNOLOGY CO., LTD. is a kind of B mode noninvasive bladder volume measurement and bladder wall thickness measurement based on ultrasonic imaging and measurement principle.

The Bladder Scanner (model:M5) is composed of main device, probe, trolley and upper computer software. The main device and probe measure bladder volume and bladder wall thickness, and they can transmit the patient information and measurement result to upper computer running upper computer software by WIFI or USB to manage and process patient's data, and the main device include print function.

The Bladder Scanner (model:M5) has the following characteristics:

•There are three operation modes for bladder volume measurement: Expert mode, simple mode and intelligent mode. In expert mode, real-time two-dimensional B-ultrasound image is displayed. The operator can judge whether the measurement position and measurement result are correct according to the displayed bladder section image. In the simple mode, there is no real-time two-dimensional scanning image, and the operator is guided by the instrument to move the probe to find the correct position for measurement. In the intelligent mode, in the pre scanning stage, only the real-time projection position map of the bladder scanning surface appears. Before the scanning, the position of the bladder is accurately located, and the positioning is carried out before scanning.

•The instrument is non-invasive and comfortable for patients when measuring bladder volume. When the user releases the scan key, it can obtain multiple two-dimensional plane ultrasound images in the body within a few seconds. The complex image processing technology is used to restore the three-dimensional image, and the complex algorithm is used to calculate the bladder volume and display the results.

• Two-dimensional plane scanning was used, and two-dimensional B-ultrasound images were displayed on the screen. After locating the position of bladder wall, the image was frozen by pressing the button on the probe. The corresponding image processing was used to separate the information of bladder wall from the image and calculate the thickness of bladder wall.

•The bladder volume measurement can print two orthogonal images + projection, patient information and volume value; bladder wall thickness measurement can print a B-ultrasound image, patient information and wall thickness value.

•Touch screen keyboard operation is adopted

•Multi language choice

•Information management, storage, printing, deletion and uploading.

•The probe is equipped with a display screen to guide the user to move the probe

•The instrument is composed of injection molding shell host, probe and trolley

•The display adopts 10.1 inch LCD (1280 * 800) pixels

•Power supply mode: AC power supply or battery power supply.

5. Indication for use

The Bladder Scanner (Model Name:M5) is intended to project ultrasound energy through the lower abdomen of the non-pregnant 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.

Mode of operation: B-mode.

Intended user population: Trained and qualified healthcare professionals.

Intended use environment: Professional health care facilities.

6. Technological Characteristics Comparison

Compared to the predicate device, the subject device has the same intended use, similar product design, and similar performance as the predicate device, the summarized comparison information is listed in the following table:

SE Comparisons	Proposed Devices Bladder Scanner (model:M5) K213488	Predicate Device K172750	Similarities/ Differences
Classification	Class II IYO, ITX	Class II IYO, ITX	Same
Indication for use	It is intended to project ultrasound energy through the lower abdomen of the non-pregnant 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	It is intended to project ultrasound energy through the lower abdomen of the non-pregnant 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.	Same

	and skin disease. Mode of operation: B-mode. Intended user population: Trained and qualified healthcare professionals. Intended use environment: Professional health care facilities.		
Patient Population	Adults and Pediatrics	Adults and Pediatrics	Same
Acoustic output level	Track 1	Track 3	Different Note 9
Modes of operation	B	B	Same
Number of elements	1	1	Same
Transducer Resonant Frequency	2.5 MHz Mechanical Sector Scan	3.5MHz Mechanical Sector Scan	Different Note 2
Sector Angle	120°	/	Different Note 1
Penetration Depth	190mm	≥150mm	Different Note 1
Volume measurement range	10-999ml	10-999ml	Same
Volume measurement accuracy	±7%, ±7ml	±10%	Different Note 3
Acoustic Output	Maximum MI:0.8 Maximum TIS:0.06	Maximum MI:0.47 Maximum TIS:0.037	Different Note 3
Anatomical Sites	Abdomen	Abdomen	Same
Display	Main device:10.1" TFT-LCD	IPAD or IPHONE	Different Note 4
Probe Connection to Display	Wired	Wireless	Different Note 5
Main device connects to PC	USB or WIFI	/	Different Note 6
Power	AC/DC Adapter: Input: AC100-240V, 50/60Hz,	DC3.8V 4200mA	Different Note 7

	Output: DC13.5V Battery: Li-ion rechargeable	lithium battery	
operating system	Android Upper computer software operates on windows PC	IPAD or IPHONE	Different Note 8
Patient-Contacting Materials	Evaluated according to ISO 10993-5 and ISO 10993-10	Evaluated according to ISO 10993-5 and ISO 10993-10	Same
Electrical Safety	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	Same
EMC	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	Same
Performance Safety	Evaluated according to IEC 62359:2017 and IEC 60601-2-37	Evaluated according to IEC 60601-2-37	Different Note 9
FCC Radio Frequency Testing	Tested to FCC requirements and found to comply with the requirements of FCC CFR Title 47 Part 15 Subpart C Section 15.247.	Tested to FCC requirements and found to comply with the requirements of FCC CFR Title 47 Part 15 Subpart C Section 15.247.	Same

Note 1: The subject device Bladder Scanner (model:M5) boasts similar technological characteristics with the predicate device K172750, for example, they have the same mode of operation, transducer type (i.e.Mechanical Sector Scan), target population and anatomical sites. Though they differ in transducer specification, range of measurement, accuracy, operation condition and screen display, such slight difference will not affect the core usage of the Bladder Scanner (model:M5), thus will not affecting the substantial equivalence between the two devices.

Note 2: Generally, the frequency of Diagnostic ultrasound is 2-10MHz, subject device's frequency is 2.5MHz, so it is able to measure bladder volume accurately.

Note 3: There are slight difference in measurement range, measurement accuracy, and acoustic output, the subject device has wider measurement range and more accurate measurement accuracy, the measurement range and accuracy were verified. The Acoustic Output is evaluated according to IEC 62359:2017.

Note 4: The display of main device is 10.1" TFT-LCD touch screen, doctor can read and operate easily.

Note 5: The probe of subject device connecting to main device by wire while the connection of probe of predicate device are wireless, obviously, the risk of subject is lower than predicate device.

Note 6: The subject device can transmit patient's data to upper computer by WIFI, its safety has

been further ensured by FCC requirements, which will not bring new concerns to the subject device's safety and effectiveness

Note 7: The voltage and capacity of battery and output of adaptor are different from predicate device, we evaluated their safety in accordance with IEC 60601-1, test results showed no safety risk.

Note 8: There are some differences in design ideas. The subject device includes two software, one only runs on main device of subject device, the operation system of main device is android, another can run on upper computer, its operation system is windows. All of software are verified and validated, no residual risk.

Note 9: The subject device Bladder Scanner (model:M5) follows Track 1 of FDA ultrasound submission, and the predicate device follows Track 3, but this difference does not raise issues in safety.

To sum up, all the differences don't affect the safety and effectiveness which is concluded after all the required testing, so it is reasonable to conclude that subject device Bladder Scanner (model:M5) is substantial equivalent with predicate device.

8. Performance Data

Clinical test:

Clinical testing is not required.

Non-clinical data

The subject device Bladder Scanner (model:M5) evaluated:

Safety and Performance:

IEC 60601-1:2012 Medical electrical equipment -Part 1: General requirements for basic safety and essential performance

IEC 62359:2017 Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields

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

EMC:

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

Biocompatibility:

1. ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro
2. ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

RF:

1. FCC CFR Title 47 Part 15 Subpart C Section 15.247: Frequency Hopping, Direct Spread Spectrum and Hybrid Systems that are in operation with the bands of 902-928 MHz, 2400-2483.5 MHz, and 5725-5850 MHz

Software verification&validation:

1. Guidance for the Content of Premarket Submissions for Software Contained in Medical Device

Performance verification

1. Internal verification protocol

9. Conclusion

The conclusion drawn from the nonclinical tests demonstrate that the subject device in 510(K) submission K213488, Bladder Scanner (Model Name:M5), is as safe, as effective, and performs as well as or better than the predicate device, Wireless Probe Type Ultrasound Scanner (Model: BProbe), cleared under K172750.