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

February 26, 2021

Re: K201316
Trade/Device Name: Bladder Scanner (Model: M3, M3-HD, M4, M4-HD)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: January 1, 2021
Received: January 25, 2021

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

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)*

K201316

Device Name
Bladder Scanner (Model:M3, M3-HD, M4, M4-HD)

Indications for Use *(Describe)*

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.

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."

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: January 1, 2021 K201316

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 Town, Kunshan Suzhou, JIANGSU, 215341, CHINA
Contact person:	Calvin Ma
Title:	General manager
E-mail:	service@peaksonic.com.cn
Tel:	+86- 512-36693388

2. Device Identification

Trade/Device Name:	Bladder Scanner
Models:	M3, M3-HD, M4, M4-HD
Regulation Number:	21 CFR 892.1560 21 CFR 892.1570
Common Name:	Ultrasonic, Pulsed echo, Imaging Transducer, Ultrasonic, Diagnostic
Regulation Class:	Class II
Product Code:	IYO, ITX

3. Predicate Device

510(K) number:	K190769
Device Name:	Bladder Scanner (Models:M2, M2-W, M1, M1-W)
Manufacturer:	Suzhou Lischka Medtech Co., Ltd.
Regulation Number:	21 CFR 892.1560 21 CFR 892.1570
Common Name:	Ultrasonic, Pulsed echo, Imaging Transducer, Ultrasonic, Diagnostic
Regulation Class:	Class II
Product Code:	IYO, ITX

4. Device Description

The M Series Bladder Scanner is a handheld battery-operated device, which is developed by SUZHOU PEAKSONIC MEDICAL TECHNOLOGY CO., LTD., and manufactured by Suzhou Lischka Medtech Co., Ltd., it provides non-invasive bladder volume measurement utilizing real-time ultrasound imaging. The device consists of the main unit, 3D probe (M4, M4-HD)/2D probe (M3, M3-HD), Data processing and storage modules, APP software, battery and Charger.

It features:

- M3 and M3-HD has two Operation Modes: Expert Mode and Easy Mode, M4 and M4-HD has three Operation Modes: Expert Mode, Easy Mode and intelligence mode
- Non-invasive, comfortable, correct, reliable, fast and simple operation. When the operator releases the button on the probe, multiple 2D plane ultrasound images are acquired in a few seconds. The equipment adopts sophisticated image processing techniques to restore the stereo image, and adopts a sophisticated algorithm to measure bladder volume and displays the measurement results on the screen.
- Use touch screen keyboard operation on tablet computer (or mobile phone)
- Multilingual choice
- Bluetooth Wireless Printing Report
- Volume preset reminder
- Information management, storage and printing
- Wifi wireless bidirectional transmission
- Leak-proof management of patient information: information is stored and transmitted after encryption, and the patient information can be viewed and uploaded only after password landing.
- The instrument consists of a handheld wireless scanner and a tablet computer (or mobile phone)
- Built-in battery power supply

The difference between these models is that the model of the probe is different. M4, M4-HD is 3D probe .M3, M3-HD is 2D probe. M3-HD, M4-HD will be operated by tablet computer, M3, M4 will be operated by smart mobile phone.

5. Indication for use

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.

6. Comparison to Predicate Device

Comparison to the predicate devices, the subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate device as summarized in the following table:

SE Comparisons	Predicate device	Subject device	Comments
Manufacturer/K#	Suzhou Lischka Medtech Co., Ltd./ K190769	SUZHOU PEAKSONIC MEDICAL TECHNOLOGY CO., LTD.	/
Trade name and model	Bladder Scanner (Models: M2, M2-W, M1, M1-W)	Bladder Scanner (Models: M3, M3-HD, M4, M4-HD)	/
Classifications name and Regulation Name	Regulation Number: 21 CFR 892.1560 21 CFR 892.1570 Regulation Name: Ultrasonic, Pulsed echo, Imaging Transducer, Ultrasonic, Diagnostic Product Code: IYO, ITX	Regulation Number: 21 CFR 892.1560 21 CFR 892.1570 Regulation Name: Ultrasonic, Pulsed echo, Imaging Transducer, Ultrasonic, Diagnostic Product Code: IYO, ITX	Same
Indication for use	The Bladder Scanner (Models: M2, M2-W, M1, M1-W) 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 Bladder Scanner is intended to be used only by qualified medical professionals.	The Bladder Scanner (Models: M3, M3-HD, M4, M4-HD) 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 Bladder Scanner is intended to be used only by qualified medical professionals.	Same
Contraindications	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	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	Same

Modes of operation	B mode	B mode	Same
System Characteristics and structure	Portable, LCD Display, Thermal Printer, Power source: Battery	Portable, Smartphone or tablet computer display, Thermal Printer, Power source: Battery	Different, The design of predicate device is built-in software and ultrasound image and data is displayed on the device's display. Subject device has no display itself and ultrasound image and data is displayed on the smartphone and tablet computer through APP software. The principles, algorithms, and probes of both devices are the same. The subject device has performed software verification according to the FDA guidance and IEC 62304, the difference does not affect the safety and performance.
Display	M2: 2.4" TFT-LCD M1: 2.4" TFT-LCD	M3-HD, M4-HD will be provided customer with a Samsung SM-T590 10.5 inch. The display of M3, M4 will be according to the customer's smart mobile phone specifications	Different, The size and specification of the display is different and does not affect product safety and performance.
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
Transducer Resonant Frequency	2.5Mhz	2.5Mhz	Same
Number of elements	1	1	Same
Sector Angle	120°	120°	Same
Number of Scan Planes	M2, M2-W:12 , M1, M1-W:1	M4, M4-HD:12 , M3, M3-HD:1	Same

Patient Contacting Material	PC (skin contact)	PC (skin contact)	Same
Volume measurement range	0ml-999ml	0ml-999ml	Same
Volume measurement accuracy	M2/M2-W: ±7%, ±7ml; M1/M1-W: ±14%, ±14ml	M4/M4-HD: under 100 mL: ±7mL; 100 to 999 mL: ±7%, M3/M3-HD: under 100 mL: ±14mL; 100 to 999 mL: ±14%	Same
Classification of protection against electric shock	Class II equipment	Class II equipment	Same
Applied part type	B type	B type	Same
Real-time scanning	Yes (Pre-scan)	Yes (Pre-scan)	Same
PC Data Upload	USB connection	USB connection	Same
Power	Lithium battery: URR18650ZY-2600 mAh(SNLB-435) 7.4Vd.c. 2600mAh Charger: HXY-084V1500A-UL AC100-240Va	Lithium battery: NCA653864SA-2400 mAh (PC015-2S1P) 7.4Vd.c. 2400mAh Charger: HXY-084V1500A-UL AC100-240Va	Different, The lithium battery used in the predicate device and subject device is different. The lithium battery has been performed safety test according to the IEC62133, and the subject device has been performed safety test according to the IEC 60601-1, so the difference in lithium battery specifications will not raise new safety and performance risks.
WIFI	M1, M2 does not contain WIFI connection. M1-W, M2-W contain WIFI connection	WIFI connection.	Same
Bluetooth	Connect to the printer using Bluetooth to print a test image.	Connect to the printer using Bluetooth to print a test image.	Same
Safety and EMC Standards compliance	ES60601-1:2005+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

All the differences don't affect the safety and effectiveness which is concluded after all the required testing, so no safety and effectiveness issues relating to the system come into conclusion.

7. Performance Data

Clinical test:

Clinical testing is not required.

Non-clinical data

The M3,M3-HD,M4,M4-HD Bladder Scanner comply with:

Safety:

1. ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
2. IEC 60601-1-2 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests

Performance:

3. IEC 60601-2-37 Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
4. NEMA UD 2 Standard for real-time display of thermal and mechanical acoustic output indies on diagnostic ultrasound equipment.
5. Acoustic output testing as per the guideline "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" dated September 9, 2008.

WIFI and Bluetooth connection:

6. FCC CFR TITLE 47 PART 15 SUBPART C SECTION 15.247

The tests were selected to show substantial equivalence between the subject device and the predicate.

8. Conclusion

The M3,M3-HD,M4,M4-HD Bladder Scanner was evaluated with safety, EMC and Acoustic Output. The conclusions drawn from testing of the M3,M3-HD,M4,M4-HD Bladder Scanner demonstrate that the device is as safe and effective as the legally marketed predicate devices(K190769).