Suzhou Lischka Medtech Co., Ltd.
℅ Shi Jing
R&D Manager
NO.999 Qujia Road, Qiandeng Town
Kunshan, Jiangsu 215341
CHINA

May 22, 2019

Re: K190769
Trade/Device Name: Bladder Scanner (Models: M2, M2-W, M1, M1-W)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: March 26, 2019
Received: March 26, 2019

Dear Shi Jing:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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)*

K190769

Device Name
Bladder Scanner（Models： M2, M2-W, M1, M1-W）

Indications for Use *(Describe)*

The Bladder Scanner (Models: M2, M2-W, M1, M1-W) is B-mode pulsed-echo ultrasound device. It intended as a handheld battery-operated device. The M2, M2-W, M1, M1-W 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 M2, M2-W, M1, M1-W 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.

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Diagnostic Ultrasound Indications for Use Form

System: M2

Transducer: H3D-1

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Bladder)	N						
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

System: M1
Transducer: HD2-1

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Bladder)	N						
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

510(K) Summary

K190769

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 10 March 2019

1. Submitter's Information

The submitter of this pre-market notification is:

Name:	Suzhou Lischka Medtech Co., Ltd.
Address:	2F,BuildingG4, Kunshan Hi-Tech Medical Device Industrial Park, NO.999 Qujia Road, Qiandeng Town, Kunshan City, Jiangsu Prov. 215341,China
Contact person:	Shi Jing
Title:	R&D manager
E-mail:	shi.jing@lischka.cn
Tel:	+86- 512-36692288-831

2. Device Identification

Trade/Device Name:	Bladder Scanner
Models:	M2, M2-W, M1, M1-W
Regulation Number:	21 CFR 892.1560 21 CFR 892.1570
Regulation Name:	Ultrasonic, Pulsed echo, Imaging Transducer, Ultrasonic, Diagnostic
Regulation Class:	Class II
Product Code:	IYO, ITX

3. Predicate Device

510(K) number:	K131227
Device Name:	PadScan HD series Bladder Scanner
Manufacturer:	Caresono Technology Co., Ltd
Regulation Number:	21 CFR 892.1560 21 CFR 892.1570
Regulation Name:	Ultrasonic, Pulsed echo, Imaging Transducer, Ultrasonic, Diagnostic
Regulation Class:	Class II
Product Code:	IYO, ITX

4. Device Description

The M Series Bladder Scanner manufactured by Suzhou Lischka Medtech Co., Ltd. provides non-invasive volume bladder measurement utilizing real-time ultrasound imaging and measurement. The equipment consists of the main unit, 3D probe (M2, M2-W)/2D probe (M1, M1-W), battery and Charger. It features:

- Two Operation Modes: Expert Mode and Easy Mode
- Non-invasive, comfortable, correct, reliable, fast and simple operation
- Printouts with ultrasound images and various parameters through PC software
- Touch screen keyboard operation
- Voice input and play functions
- Multi-language selection
- Information storage
- Information printing
- built-in battery

The difference between these models is that the model of the probe is different. M2, M2-W is 3D probe .M1,M1-W is 2D probe. M2-W, M1-W have WIFI connection function, M2, M1 do not have WIFI connection function.

5. Intended 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.

6. Indication for use

The Bladder Scanner (Models: M2, M2-W, M1, M1-W) is B-mode pulsed-echo ultrasound device. It intended as a handheld battery-operated device. The M2, M2-W, M1, M1-W 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 M2, M2-W, M1, M1-W Bladder Scanner is intended to be used only by qualified medical professionals.

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.

7. 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	Bladder Scanner (Models: M2, M2-W, M1, M1-W)	PadScan HD series Bladder Scanner	Note
Manufacturer/K#	Suzhou Lischka /Present application	Caresono/K131227	--
Trade name and model	Bladder Scanner (Models: M2, M2-W, M1, M1-W)	PadScan HD series Bladder Scanner (Models: HD5, HD3)	
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
Intended 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 PadScan HD series 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 PadScan HD series Bladder Scanner is intended to be used only by qualified medical professionals.	Same
Contraindications	Do not use the Bladder Scanner on following cases:	Do not use the PadScan HD Bladder Scanner on following cases:	Same

	a) Fetal use or pregnant patients b) Patients with ascites c) Patients with open or damaged skin. d) Wounds in the suprapubic region	a) Fetal use or pregnant patients b) Patients with ascites c) Patients with open or damaged skin. d) Wounds in the suprapubic region	
Modes of operation	B mode	B mode	Same
System Characteristics	Portable LCD Display Thermal Printer Power source: Battery	Portable LCD Display Thermal Printer Power source: Battery or AC-DC adapter	Different, but both our device and predicate device met the requirements of IEC 60601-1, The difference does not affect the safety and performance.
Display	M2: 2.4" TFT-LCD M1: 2.4" TFT-LCD	PadScan HD2: 2.5" TFT-LCD PadScan HD5: 8" TFT-LCD	Different, The size 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	3.5Mhz or 2.5Mhz	2.5Mhz	Basically the same
Number of elements	1	1	Same
Sector Angle	120°	120°	Same
Number of Scan Planes	M2, M2-W-12 , M1, M1-W-1	PadScan HD5-12, PadScan HD2-1	Same

Patient Contacting Material	PE (skin contact)	PE (skin contact)	Same
Volume measurement range	0ml-999ml	0ml-999ml	Same
Volume measurement accuracy	M2/M2-W：±7%, ±7ml M1/M1-W：±14%, ±14ml	±15%, ±15ml	Different, Our products are more accurate than the predicate device, and performed the accurate test, the performance is better than the predicate device without additional risks.
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	Using USB flash disk	Different ，Compared to the predicate devices, the way of PC Data Upload is changed from SD card to USB connection Transmission. The difference does not affect the Intended Use, it will not raise safety and effectiveness issue.
Power	Lithium battery: URR18650ZY-2600 mAh(SNLB-435) 7.4Vd.c. 2600mAh Charger: HXY-084V1500A-UL AC100-240Va	AC/DC Adapter: Input: AC100-240V, 50/60Hz, Output: DC14V±0.5V Battery: Li-ion rechargeable	Different, all the electrical safety testing has been conducted according to IEC 60601-1: 2012, and results showed pass, therefore, difference between input power will not reduce the subject's safety and effectiveness. Please refer to *015_IEC60601-1 test report of M2,M2-W,M1,M1-W.*

WIFI	M1, M2 does not contain WIFI connection M1-W, M2-W contain WIFI connection	Do not contain WIFI connection.	Different, Compared with equivalent equipment, our products have added WIFI and bluetooth connection functions. We have tested according to FCC requirements (CFR 47 PART 15), which proves that our products meet the requirements for wireless signal function safety, and there is no unacceptable safety and performance.
Bluetooth	Connect to the printer using Bluetooth to print a test image	Do not contain Bluetooth connection.	
Standards compliance	IEC 60601-1:2005+A1:2012 IEC 60601-1-2:2014 IEC 60601-2-37:2015	IEC 60601-1:2005 +CORR.1(2006) +CORR.2(2007) IEC 60601-1-2:2007 IEC 60601-2-37:2007	Different, We verified the product with a newer version of the standard. Compliance with new standards does not reduce the subject's safety and effectiveness.
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.

8. Performance Data

Clinical test:

Clinical testing is not required.

Non-clinical data

The M2, M2-W, M1, M1-W 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.

Biocompatibility:

6. ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
7. ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
8. ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

WIFI and Bluetooth connection:

9. 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.

9. Conclusion

The M series Bladder Scanner was evaluated with safety, EMC, Biocompatibility and Acoustic Output.
The conclusions drawn from testing of the M series Bladder Scanner demonstrate that the device is as safe and effective as the legally marketed predicate devices.