Xuzhou Kaixin Electronic Instrument Co., Ltd.
% Long Yang, COO
Shenzhen Hlongmed Biotech Co., Ltd.
1201, Haosheng Business Center, 4096 Dongbin Road, Nanshan
Shenzhen, P.R.C
Shenzhen, Guangdong 518054
CHINA

July 7, 2023

Re: K223448
Trade/Device Name: Bladder Scanner Model: BVT02
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: June 7, 2023
Received: June 7, 2023

Dear Long Yang:

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,

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)*

K223448

Device Name
Bladder Scanner, Model BVT02

Indications for Use *(Describe)*

The BVT02 Bladder Scanner is B-mode pulsed-echo ultrasound device. It is intended as a portable device. The BVT02 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 BVT02 Bladder Scanner is intended to be used only by qualified medical 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.

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: BVT02 Bladder Scanner

Transducer: 2.5S120M2

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal(Superficial)							
	Intravascular							
	Other(Bladder)	N						
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

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

510(k) Summary

(as required by 807.92(c))

The assigned 510(K) number is: K223448

Date of Summary: 2023-07-06

1. Submitter information

Manufacturer Name: Xuzhou Kaixin Electronic Instrument Co., Ltd.

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2. Contact person

2.1 Primary Contact Person

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E-mail: xingkexin@126.com

3. Device Information

Trade/Device Name	Bladder Scanner
Model	BVT02
Common Name	Diagnostic Ultrasound System with Accessories
Classification Name	Ultrasonic Pulsed Echo Imaging System(IYO)/ Diagnostic Ultrasound Transducer(ITX)
Regulatory Class	Class II
Classification regulation	21CFR 892.1560 / 21CFR 892.1570
Review Panel	Radiology
Regulation Medical Specialty	Radiology
Product Code	IYO/ITX

4. Predicate Device

510(k) number	K131227
Device name	PadScan HD series Bladder Scanner
Sponsor	Caresono Technology Co., Ltd
Product Code	IYO/ITX

5. Intended Use

The BVT02 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 BVT02 Bladder Scanner is intended to be used only by qualified medical professionals.

6. Indications for Use

The BVT02 Bladder Scanner is B-mode pulsed-echo ultrasound device. It is intended as a portable device. The BVT02 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 BVT02 Bladder Scanner is intended to be used only by qualified medical professionals. Intended use environment: Professional health care

facilities.

7. Device Description

The BVT02 Bladder Scanner manufactured by Xuzhou Kaixin Electronic Instrument Co., Ltd. provides real‐time ultrasound imaging and measuring, and also provides non‐invasive volume measurement of the bladder. During image scanning, multiple 2D plane ultrasonic images are acquired in several seconds.

It features:

- Expert operating mode and Lite operating mode.
- Portable.
- Combined power supply with AC adapter and a battery.

8. Contraindications

Do not use the BVT02 Bladder Scanner on following case:

a) Fetal use or pregnant patients.

b) Patients with ascites.

c) Patients with open or damaged skin.

d) Wounds in the suprapubic region.

9. Comparison to Predicate Device

Xuzhou Kaixin Electronic Instrument Co., Ltd. believes the BVT02 Bladder Scanner described in this submission is substantially equivalent to the predicate devices as follows:

PadScan HD series Bladder Scanner (K131227)

The ultrasound power transmitted from the device is not user adjustable, and BVT02 Bladder Scanner is Track 1 System and meets the FDA's pre-amendment acoustic output limits, so as the predicate devices(PadScan HD 5, PadScan HD 3) are. Although there are some differences such as System Characteristics, Display, Patient Contacting Material, Range and Power, there is no significant differences in technological characteristics that affecting the safety and efficiently. These are evaluated by safety test and acoustic output test.

Table 6 Comparison to the predicate

(PadScan HD 5, PadScan HD 3)

Item	Element Of Comparison	Proposed Device	Predicate Device-K131227
1	Trade Name	Bladder Scanner	PadScan HD series Bladder Scanner
2	Model	BVT02	PadScan HD 5, PadScan HD 3
3	510k submitter	Xuzhou Kaixin Electronic Instrument Co., Ltd.	Caresono Technology Co., Ltd.
4	510(K) Number	K223448	K131227
5	Classifications Name & Citations	21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (Product code: IYO)	21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (Product code: IYO)
		21 CFR 892.1570 Diagnostic Ultrasonic Transducer (Product code: ITX)	21 CFR 892.1570 Diagnostic Ultrasonic Transducer (Product code: ITX)
6	Intended Use	The BVT02 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 non-invasively. The BVT02 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.
7	Indications for Use	The BVT02 Bladder Scanner is B-mode pulsed-echo ultrasound device. It is intended as a portable device. The BVT02 Bladder Scanner projects ultrasound energy through the lower abdomen of the patient to obtain	The PadScan HD series Bladder Scanner is B-mode pulsed-echo ultrasound device. It intended as a portable battery-operated device. The PadScan HD series Bladder Scanner projects ultrasound energy through the

Item	Element Of Comparison	Proposed Device	Predicate Device-K131227
		images of the bladder which is used to calculate bladder volume non-invasively. The BVT02 Bladder Scanner is intended to be used only by qualified medical professionals. Intended use environment: Professional health care facilities.	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.
8	Contraindications	Do not use the BVT02 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 PadScan HD series 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
9	Modes of operation	B mode	B mode
10	System Characteristics	a)Portable b)LCD Display c)Power source: Battery or AD-DC adapter	a) Portable b) LCD Display c) Thermal Printer d) Power source: Battery or AD-DC adapter
11	Display	3.5" TFT-LCD	PadScan HD5: 8" TFT-LCD PadScan HD3: 7" TFT-LCD
12	Controls for Change of acoustic output	No	No

Item	Element Of Comparison	Proposed Device	Predicate Device-K131227
	during scan		
13	Transducer Type	Mechanical Sector Probe	Mechanical Sector Probe
14	Measurement localization	Abdomen	Abdomen
15	Transducer Resonant Frequency	2.5 MHz	2.5 MHz
16	Number of elements	1	1
17	Sector Angle	120 degrees	120 degrees
18	No. of Scan Planes	12	12
19	FDA Limits	Track 1	Track 1
20	Product Safety Certification	AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012	IEC 60601-1:2005 +CORR.1(2006) +CORR.2(2007)
		IEC 60601-2-37:2015	IEC 60601-2-37:2007
21	EMC Compliance	IEC 60601-1-2:2014	IEC 60601-1-2:2007
22	Patient Contacting Material	Plastic, Medical PP (Skin Contact) Complies with ISO 10993	Plastic, PE (Skin Contact) Complies with ISO 10993
23	Range	Bladder volume range: 20-999ml Accuracy: ±15%, ±15ml	Bladder volume range: 0-999ml Accuracy: ±15%, ±15ml
24	Classification of protection against	Class II equipment Type B equipment	Class II equipment Type B equipment

Item	Element Of Comparison	Proposed Device	Predicate Device-K131227
	electric shock		
26	Real-time scanning	Yes (Pre-scan)	Yes (Pre-scan)
27	Scan time	< 5 seconds	< 5 seconds
27	PC Data Upload	Using USB flash disk	Using USB flash disk
28	Power	AC/DC Adapter: Input:AC100-240V, 50-60Hz Output: DC12.8V 3.0A Battery: Li-ion rechargeable	AC/DC Adapter: Input: AC100-240V, 50/60Hz, Output: DC14V±0.5V Battery: Li-ion rechargeable

Xuzhou Kaixin Electronic Instrument Co., Ltd. believes that the BVT02 Bladder Scanner is substantially equivalent to the PadScan HD series Bladder Scanner of Caresono Technology Co., Ltd.

10. Non-clinical Testing Summary

10.1 Safety

Electrical, mechanical, environmental safety and performance data demonstrates that the device is in compliance with ANSI/AAMI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 and IEC 60601-2-37:2007+AMD1:2015 CSV.

10.2 EMC

Electromagnetic Compatibility data demonstrates that the device is in compliance with IEC 60601-1-2:2014.

10.3 Performance-Bench Testing

1) The BVT02 Bladder Scanner had been tested as Track 1 device per the FDA Guidance document “Marketing Clearance of Diagnostic Ultrasound Systems and Transducers” issued in June 27, 2019. The acoustic output is measured and calculated per IEC 62359:2010+AMD1:2017 CSV.

2) The BVT02 Bladder Scanner had been tested volume accuracy per the FDA Guidance document "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued in June 27, 2019. All the test results comply with the pre-set acceptability criterion, which is the same as predicate device.

10.4 Biocompatibility

The biocompatibility testing conducted in according with standard Biocompatibility ISO 10993-5:2009 and ISO 10993-10:2010.

11. Substantial Equivalence Conclusion

The BVT02 Bladder Scanner was evaluated with safety (AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 and IEC 60601-2-37:2007+AMD1:2015 CSV), EMC (IEC 60601-1-2:2014), Biocompatibility (ISO 10993-5:2009, ISO10993-10:2010), Acoustic Output (IEC 62359:2010+AMD1:2017 CSV) and volume accuracy. The conclusions drawn from testing of the BVT02 Bladder Scanner demonstrate that the device is as safe and effective as the legally marketed predicate device.