AvantSonic Technology Co., Ltd.
% Mr. Kevin Wang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
22A, Haijing Square, No. 18, Taizi Road
Nanshan District, Shenzhen, 518067
CHINA

January 24, 2018

Re: K171528
Trade/Device Name: Bladder Scanner (model: PadScan DS3, PadScan Z3, PadScan Z5)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: December 18, 2017
Received: December 18, 2017

Dear Mr. 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 (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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K171528

Device Name
Bladder Scanner (model: PadScan DS3, PadScan Z3, PadScan Z5)

Indications for Use *(Describe)*
The Bladder Scanner (model: PadScan DS3, PadScan Z3, PadScan Z5) is B-mode pulsed-echo ultrasound device. It intended as a handheld battery-operated device. The 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 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.

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Diagnostic Ultrasound Indications for Use Form

System: PadScan DS3

Transducer: MP2A

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: PadScan Z3

Transducer: MP2

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: PadScan Z5

Transducer: MP2

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

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2017/05/08

1. Submission sponsor

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2. Submission correspondent

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Contact person: Kevin Wang
E-mail: kevin@chonconn.com
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3. Subject Device Information

Trade/Device Name	Bladder Scanner
Model	PadScan DS3, PadScan Z3, PadScan Z5
Common Name	Diagnostic Ultrasound System with Accessories
Regulatory Class	Class II
Classification	21CFR 892.1560/Ultrasonic Pulsed Echo Imaging System/IYO
	21CFR 892.1570/Diagnostic Ultrasound Transducer/ITX
Submission type	Traditional 510(K)

4. Predicate Device

510(K) number	K131227
Device Name	PadScan HD series Bladder Scanner
Manufacturer	Caresono Technology Co., Ltd
Product Code	IYO, ITX

5. Device Description

The PadScan Series manufactured by AvantSonic Technology Co., Ltd. provides non-invasive volume bladder measurement utilizing real-time ultrasound imaging and measurement. The equipment consists of the main unit, 3D probe, battery and adapter.

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
- Urine volume setting and alarm setting
- Multi-language selection
- Combined power supply with AC adapter and a built-in battery

The difference between these models is the size of the LCD screen and enclosure structure. PadScan DS3 is provided 7-inch LCD screen. PadScan Z3 is provided 7-inch LCD screen and LCD screen stand. PadScan Z5 is provided 8-inch LCD screen and LCD screen which has a handle.

6. Intended use

The Bladder Scanner (model: PadScan DS3, PadScan Z3, PadScan Z5) 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.

7. Indication for use

The Bladder Scanner (model: PadScan DS3, PadScan Z3, PadScan Z5) is B-mode pulsed-echo ultrasound device. It intended as a handheld battery-operated device. The 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 Bladder Scanner is intended to be used only by qualified medical professionals.

8. 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

9. 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

Table 1

SE Comparisons	PadScan DS3, PadScan Z3, PadScan Z5	PadScan HD series Bladder Scanner	Note
Manufacturer/K#	AvantSonic/Present application	Caresono/K131227	--

Intended Use	The PadScan 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.	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: 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 HD2 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	a) Portable b) LCD Display c) Thermal Printer d) Power source: Battery or AD-DC adapter	a) Portable b) LCD Display c) Thermal Printer d) Power source: Battery or AD-DC adapter	Same
Display	PadScan DS3: 7" TFT-LCD PadScan Z3: 7" TFT-LCD PadScan Z5: 8" TFT-LCD	PadScan HD3: 7" TFT-LCD PadScan HD5: 8" TFT-LCD	Same
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	12	12	Same
Patient Contacting Material	PE (skin contact)	PE (skin contact)	Same
Volume measurement range	0ml-999ml	0ml-999ml	Same
Volume measurement accuracy	±10%, ±10ml	±15%, ±15ml	Different
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, Bluetooth	SD card	Different
Power	AC/DC Adapter: Input: AC 100V-240V, 50/60Hz, Output: DC13.5V±0.5V Battery: Li-ion rechargeable	AC/DC Adapter: Input: AC100-240V, 50/60Hz, Output: DC14V±0.5V Battery: Li-ion rechargeable	Different
Standards compliance	IEC 60601-1:2005+A1:2012	IEC 60601-1:2005 +CORR.1(2006) +CORR.2(2007)	Different
	IEC 60601-1-2:2014	IEC 60601-1-2:2007	
	IEC 60601-2-37:2015	IEC 60601-2-37:2007	
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.

10. Performance Data

Clinical test:

Clinical testing is not required.

Non-clinical data

The PadScan DS3, PadScan Z3 and PadScan Z5 Bladder Scanner comply with:

(1) IEC 60601-1 Electrical Safety

(2) IEC 60601-1-2 Electromagnetic Compatibility

(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.

The following biocompatibility standards are conducted on the subject device:
(1) ISO 10993-1, ISO 10993-5 and ISO 10993-10

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

11. Conclusion

Based on the safety and performance testing and compliance with acceptable voluntary standards, we believe that the PadScan DS3, PadScan Z3 and PadScan Z5 Bladder Scanner are substantially equivalent to their predicate device in K131227 and does not raise any new safety and/or effectiveness issues.