



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Caresono Technology Co., Ltd.  
% Mr. Long Yang, COO  
Shenzhen Hlongmed Biotech Company  
R15-08, East Building, Yihai Plaza, Chuangye Road  
Nanshan District  
Shenzhen, Guangdong 518054  
CHINA

April 8, 2016

Re: K153581  
Trade/Device Name: Bladder Scanner  
Regulation Number: 21 CFR 892.1560  
Regulation Name: Ultrasonic pulsed echo imaging system  
Regulatory Class: II  
Product Code: IYO, ITX  
Dated: March 15, 2016  
Received: March 25, 2016

Dear Mr. 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. 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. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style. Behind the signature, there is a faint, large watermark of the letters "FDA" in a light blue color.

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

Section 5

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

**Indications for Use**

510(k) Number (if known)  
K153581

Device Name  
Bladder Scanner

Indications for Use (Describe)

The Bladder Scanner(model: PadScan HD2) is B-mode pulsed-echo ultrasound device. It intended as a handheld battery-operated device. The PadScan HD2 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 HD2 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 HD2 Bladder Scanner

Transducer: N3

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: K153581

Date of Summary: April 8, 2016

**1. Submitter information**

Manufacturer Name: Caresono Technology Co., Ltd.

Address: 4th Floor, No.11 Building Initiating Zone Instruments and Meters Industry Base, Near Port Industry Zone, Dandong, Liaoning, CHINA 118009

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**2. Contact person**

**2.1 Primary Contact Person**

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**2.2 Secondary Contact Person**

Yuzhong Ma (Management Representative)

Caresono Technology Co., Ltd.

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Tel: 0086-415-6123779

### 3. Device Information

Trade/Device Name	Bladder Scanner
Model	PadScan HD2
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 Bladder Scanner (model: PadScan HD2) 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 HD2 Bladder Scanner is intended to be used only by qualified medical professionals.

### 6. Indications for Use

The Bladder Scanner (model: PadScan HD2) is B-mode pulsed-echo ultrasound device. It intended as a handheld battery-operated device. The PadScan HD2 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 HD2 Bladder Scanner is intended to be used only by qualified medical professionals.

### 7. Device Description

The PadScan HD2 Bladder Scanner manufactured by Caresono Technology Co., Ltd. provides real-time ultrasound imaging and measuring, and also provides non-invasive volume measurement of the bladder. It is a handheld bladder scanner; the main unit and the probe are all-in-one.

It features:

- Expert operating mode and Easy operating mode
- Non-invasive, comfortable, correct, reliable, fast and simple operation
- SD card storage
- Voice recording function
- Urine volume setting and alarm setting
- Multi-language selection
- Injection molded shell, the main unit and the probe are all-in-one, 2.5-inch LCD screen(240x320pixels)
- Power supply with built-in battery.

## **8. Contraindications**

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

## **9. Comparison to Predicate Device**

Caresono Technology Co., Ltd believes the PadScan HD2 Bladder Scanner described in this submission is substantially equivalent to the predicate device as follows:

PadScan HD series Bladder Scanner (K131227)

The ultrasound power transmitted from the device is not user adjustable, and PadScan HD2 Bladder Scanner is Track 1 System and meets the FDA's pre-amendment acoustic output limits, So as the predicate devices are. Although there are some differences such as resonant frequency, power source and size of display screen, appearance, 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 6-1 Comparison to the predicate**

<b>Items</b>	<b>Proposed Device</b>	<b>Predicate Device-K131227</b>
Trade Name	Bladder Scanner	PadScan HD series Bladder Scanner
Model	PadScan HD 2	PadScan HD 5, PadScan HD 3
510k submitter	Caresono Technology Co., Ltd.	Caresono Technology Co., Ltd.
510(K) Number	-----	K131227
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)
Intended Use	The Bladder Scanner (model: PadScan HD2) 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 HD2 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.
Indications for Use	The Bladder Scanner (model: PadScan HD2) is B-mode pulsed-echo ultrasound device. It intended as a handheld battery-operated device. The PadScan HD2 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 HD2 Bladder Scanner is intended to be	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 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

	used only by qualified medical professionals.	qualified medical professionals.
Contraindications	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	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
Modes of operation	B mode	B mode
System Characteristics	a) handheld, the main unit and the probe are all-in-one b) LCD Display c) Power source: Battery	a) Portable b) LCD Display c) Thermal Printer d) Power source: Battery or AD-DC adapter
Display	PadScan HD2: 2.5" TFT-LCD	PadScan HD5: 8" TFT-LCD PadScan HD3: 7" TFT-LCD
Controls for Change of acoustic output during scan	No	No
Transducer Type	Mechanical Sector Probe	Mechanical Sector Probe
Measurement localization	Abdomen	Abdomen
Transducer Resonant Frequency	3.5 MHz	2.5 MHz
Number of elements	1	1
Sector Angle	120 degree	120 degrees
No. of Scan Planes	1	12
FDA Limits	Track 1	Track 1
Product Safety	AAMI / ANSI	IEC 60601-1:2005 +CORR.1(2006)

Certification	ES60601-1:2005/(R)2012 And A1:2012,, C1:2009/(R)2012 And A2:2010/(R)2012	+CORR.2(2007)
	IEC 60601-2-37:2007	IEC 60601-2-37:2007
EMC Compliance	IEC 60601-1-2:2007	IEC 60601-1-2:2007
Patient Contacting Material	PC(Skin Contact)	Plastic, PE (Skin Contact)
Range	Bladder volume range: 0-999ml Accuracy: $\pm 15\%$ , $\pm 15\text{ml}$	Bladder volume range: 0-999ml Accuracy: $\pm 15\%$ , $\pm 15\text{ml}$
Classification of protection against electric shock	Class II equipment Type B equipment	Class II equipment Type B equipment
Real-time scanning	Yes (Pre-scan)	Yes (Pre-scan)
PC Data Upload	Using SD card	Using USB flash disk
Power	Battery Charger: input: 100-240Va.c., 50/60Hz Output: 8.4Vd.c Battery: Li-ion rechargeable	AC/DC Adapter: Input: AC100-240V, 50/60Hz, Output: DC14V $\pm$ 0.5V Battery: Li-ion rechargeable

Caresono Technology Co., Ltd. believes that the PadScan HD2 Bladder Scanner is substantially equivalent to the PadScan HD2 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 ES 60601-1:2005 and IEC 60601-2-37:2007.

### 10.2 EMC

Electromagnetic Compatibility data demonstrates that the device is in compliance with IEC 60601-1-2:2007.

### **10.3 Performance-Bench Testing**

1) The PadScan HD2 Bladder Scanner had been tested as Track 1 device per the FDA Guidance document “Information for Manufactures Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers” issued in September 2008. The acoustic output is measured and calculated per NEMA UD 2:2004 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.

2) The PadScan HD2 Bladder Scanner had been tested volume accuracy per the FDA Guidance document “Information for Manufactures Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers” issued in September 2008. 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 PadScan HD2 Bladder Scanner was evaluated with safety (ES 60601-1:2005 and IEC 60601-2-37:2007), EMC (IEC 60601-1-2:2007), Biocompatibility (ISO 10993-5:2009, ISO10993-10:2010), Acoustic Output (NEMA UD2:2004) and volume accuracy. The conclusions drawn from testing of the PadScan HD2 Bladder Scanner demonstrate that the device is as safe and effective as the legally marketed predicate device.