Guangzhou Sonostar Technologies Co., Ltd. February 28, 2018
% Ms. Helen Nan
General Manager
Wenzhou Cytech Information Service Co., Ltd.
Room302, NO.21 Building, Kaiyu Garden, Xishan South Road
Wenzhou, Zhejiang 325000
CHINA

Re: K172750
Trade/Device Name: Wireless Probe Type Ultrasound Scanner (Model: UProbe-C; UProbe-L; BProbe)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: February 7, 2018
Received: February 7, 2018

Dear Ms. Nan:

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)*
K172750

Device Name
Wireless Probe Type Ultrasound Scanner (Model: UProbe-C; U-Probe-L; BProbe)

Indications for Use *(Describe)*
The Wireless Probe Type Ultrasound Scanner (Model: UProbe-C) (frequency: 3.5Hz, module: convex) is intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including obstetrics (OB), gynecology (GY) and general (abdominal) imaging.

The Wireless Probe Type Ultrasound Scanner (Model: UProbe-L) (frequency: 7.5Hz, module: linear) is intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including small organ and peripheral vessel imaging.

The Wireless Probe Type Ultrasound Scanner (Model: BProbe) is intended to project ultrasound energy through the lower abdomen of the nonpregnant patient to obtain an image of the bladder and uses that image to calculate the bladder volume non-invasively. It is contraindicated for fetal use and for use on pregnant patients. And it should not be used by those who are allergic to coupling agent and who have abdomen wound and skin disease.

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.

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Diagnostic Ultrasound Indications For Use Format

System: __Wireless Probe Type Ultrasound Scanner (Model: UProbe-C)_____

Transducer: __3.5MHz, Convex_____

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* (PDI)
Ophthalmic	Ophthalmic							
Fetal Imaging &Other	Fetal	N					N - Note 1	
	Abdominal	N					N - Note 1	
	Intra-operative (Specify)							
	Intra-Operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (Gynecology)	N					N - Note 1	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-epoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Specify)							

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

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Note 1: B and M Combined

Diagnostic Ultrasound Indications For Use Format

System: __Wireless Probe Type Ultrasound Scanner (Model: UProbe-L)_____

Transducer: __7.5MHz, Linear_____

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* (PDI)
Ophthalmic	Ophthalmic							
Fetal Imaging &Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-Operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid)	N					N - Note 1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-epoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel	N					N - Note 1	
	Other (Specify)							

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

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Note 1: B and M Combined

Diagnostic Ultrasound Indications For Use Format

System: __Wireless Probe Type Ultrasound Scanner (Model: BProbe)_____

Transducer: __3.5MHz_____

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* (PDI)
Ophthalmic	Ophthalmic							
Fetal Imaging &Other	Fetal							
	Abdominal	N						
	Intra-operative (Specify)							
	Intra-Operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (Gynecology)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-epoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Bladder)	N						

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

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

007_510(k) Summary

(As required by 21 CFR 807.92(a))

7.1 Submitter Information

· Company: Guangzhou Sonostar Technologies Co., Ltd.

· Address: 504#, C Building, #27 Yayingshi Road, Science Town, Guangzhou, Guangdong, 510665, P.R.China

· Phone: 086-20-32382095

· Fax: 086-20-62614030

· Contact: Weizhong Cai, General Manager

· Date: June 01, 2017

7.2 Device Information

· Trade/Device Name: Wireless Probe Type Ultrasound Scanner (Model: UProbe-C; UProbe-L; BProbe)

· Common Name: Diagnostic Ultrasound System and Transducer

· Classification: 1) Device: System, Imaging, Pulsed Echo, Ultrasonic

Regulation Description: Ultrasonic pulsed echo imaging system

Review Panel: Radiology

Product Code: IYO

Regulation Number: 21 CFR 892.1560

Device Class: 2

2) Device: Transducer, Ultrasonic, Diagnostic

Regulation Description: Diagnostic ultrasonic transducer

Review Panel: Radiology

Product Code: ITX

Regulation Number: 21 CFR 892.1570

Device Class: 2

7.3 Predicate Device Information

Predicate Device 1:

SONON Ultrasound Imaging System (Model: SONON 300C)

submitted by HEALCERION Co., Ltd.

510K Number: K151339

Predicate Device 2:

Penrith Elettra Ultrasound System

submitted by Penrith Corporation

510K Number: K100598

Predicate Device 3:

Palm Bladder Scanner - PBSV4.1

submitted by Mianyang Meike Electronic Equipment Co., Ltd.

510K Number: K130229

7.4 Device Description

The Wireless Probe Type Ultrasound Scanner (Model: UProbe-C; UProbe-L; BProbe) is a wireless ultrasound system that uses pulsed-echo technology to transmit ultrasound images via wireless communication to a mobile device that utilizes the iOS operating system.

The mobile device for use with the Wireless Probe Type Ultrasound Scanner (Model: UProbe-C; UProbe-L; BProbe) are those that utilizes the iOS operating system, i.e. all series of iPad or iPhone from Apple Inc.

The Wireless Probe Type Ultrasound Scanner is a portable, general-purpose, software-controlled, hand-held diagnostic ultrasound system that consists of (i) a commercial off-the-shelf iOS mobile device, (ii) the Wireless Probe Type Ultrasound Scanner software that runs as an app on the mobile device, (iii) the battery-operated, hand-held Wireless Probe Type Ultrasound

Scanner transducer that communicates wirelessly with iOS mobile devices, and (iv) the instructions for use manual, USB Cable for Charging, wrist wrap.

The Wireless Probe Type Ultrasound Scanner utilizes pulsed-echo technology to determine the depth and location of tissue interfaces, and to measure the duration of an acoustic pulse from the transmitter to the tissue interface and back to the receiver. Ultrasound waves are emitted from the transducer, propagate through tissues, and return to the transducer as reflected echoes. The returned echoes are then converted into electrical impulses by transducer crystals and further processed in order to form the ultrasound image presented on the screen.

The device components are not supplied sterile and do not require sterilization prior to use.

7.5 Indications for Use

The Wireless Probe Type Ultrasound Scanner (Model: UProbe-C) (frequency: 3.5Hz, module: convex) is intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including obstetrics (OB), gynecology (GY) and general (abdominal) imaging.

The Wireless Probe Type Ultrasound Scanner (Model: UProbe-L) (frequency: 7.5Hz, module: linear) is intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including small organ and peripheral vessel imaging.

The Wireless Probe Type Ultrasound Scanner (Model: BProbe) is intended to project ultrasound energy through the lower abdomen of the nonpregnant patient to obtain an image of the bladder and uses that image to calculate the bladder volume non-invasively. It is contraindicated for fetal use and for use on pregnant patients. And it should not be used by those who are allergic to coupling agent and who have abdomen wound and skin disease.

7.6 Comparison of Technological Characteristics with the Predicate Device

7.6.1 Comparison Table of Technological Characteristic with the Predicate Device for Model: UProbe-C

Comparison Items	Subject Device: Wireless Probe Type Ultrasound Scanner (Model: UProbe-C)	Predicate Device 1: SONON Ultrasound Imaging System (Model: SONON 300C) (K151339)
Classification & Intended Use		
Classification	IYO & ITX Class 2	IYO & ITX Class 2
Intended Use	Intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including obstetrics (OB), gynecology (GY)	Intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including obstetrics (OB), gynecology (GY)

	and general (abdominal) imaging.	and general (abdominal) imaging.
Technological Characteristics		
Environment of Use	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings
Acoustic Output Levels	Below Track 3 FDA limits in accordance with Sept. 2008 ultrasound systems guidance document	Below Track 3 FDA limits in accordance with Sept. 2008 ultrasound systems guidance document
Imaging Capacities	• pulsed-echo ultrasound • Mode B (2D) scan • Mode BM scan	• pulsed-echo ultrasound • Mode B (2D) scan
Patient Population	For use in all patients	For use in all patients
Anatomic Structures / Clinical applications	General clinical applications, including fetal\obstetrics, gynecology, abdominal	General clinical applications, including fetal\obstetrics, gynecology, abdominal
Users	Healthcare professionals	Healthcare professionals
Principle / Method of Operation	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the

	transducer and converted to electrical signals that are processed and displayed as images of anatomic structures.	transducer and converted to electrical signals that are processed and displayed as images of anatomic structures.
Image Display Unit	Mobile device (4 to 13 inches approximately)	Mobile device (4 to 10 inches approximately)
Probe Characteristics	Convex, 3.5 MHz frequency;	Convex, 3.5 MHz frequency
Probe Connection to Display	Wireless	Wireless
Off-the-shelf operating system	iOS	iOS / Android
Software	Run as an app on off-the-shelf mobile device	Run as an app on off-the-shelf mobile device
System Components	• Commercial off-the-shelf iOS mobile device, • Wireless Probe Type Ultrasound Scanner software that runs as an app on the mobile device, • Wireless Probe Type Ultrasound Scanner battery-operated,	• Commercial off-the-shelf iOS or Android mobile device, • SONON Ultrasound Imaging System software that runs as an app on the mobile device, • SONON Ultrasound Imaging System battery-operated,

	hand-held ultrasound diagnostic transducer that communicates wirelessly with iOS mobile devices	hand-held ultrasound diagnostic transducer that communicates wirelessly with iOS or Android mobile devices
Safety & Effectiveness		
Patient-Contacting Materials	Evaluated according to FDA recognized standards - ISO 10993-5 and ISO 10993-10	All materials with patient contact are biocompatible and can be disinfected
Electrical Safety	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1
EMC	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2
Performance Safety	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37

Brief Summary

First, the subject device (Model: UProbe-C) enjoys identical classification and intended use with the predicate device 1, which forms the foundation of their substantial equivalence.

Secondly, the subject device (Model: UProbe-C) boasts almost the same technological characteristics with the predicate device 1. And their slight differences in imaging capacities, image display unit and off-the-shelf operating system will not affect the core usage of the two devices, thus will not affecting the substantial equivalence comparison between the two devices. Such fact further supports that the two devices are substantial equivalent.

Last but not least, the safety and effectiveness of the subject device (Model: UProbe-C) have been evaluated according to the same FDA recognized standards as the predicate device 1, which ensures that the subject device will be safe and effective for usage as the predicate device, that the two devices are substantial equivalent.

As a result, it is reasonable to conclude that subject device (Model: UProbe-C) is substantial equivalent with predicate device 1.

7.6.2 Comparison Table of Technological Characteristic with the Predicate Device for Model: UProbe-L

Comparison Items	**Subject Device: Wireless Probe Type Ultrasound Scanner (Model: UProbe-L)**	**Predicate Device 1: SONON Ultrasound Imaging System (Model: SONON 300C) (K151339)**	**Predicate Device 2: Penrith Elettra Ultrasound System (K100598)**
Classification & Intended Use			
Classification	IYO & ITX Class 2	IYO & ITX Class 2	IYN & IYO & ITX - Class 2
Intended Use	Intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body	Intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body	Intended for diagnostic imaging or fluid flow analysis of the human body including: fetal, abdominal,

	for general clinical applications including small organ and peripheral vessel imaging.	for general clinical applications including obstetrics (OB), gynecology (GY) and general (abdominal) imaging.	intraoperative, intraoperative neurological, pediatric, small organ, neonatal, cephalic, cardiac, peripheral vessel, musculoskeletal (conventional), musculoskeletal (superficial).
Technological Characteristics			
Environment of Use	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings
Acoustic Output Levels	Below Track 3 FDA limits in accordance with Sept. 2008 ultrasound systems guidance document	Below Track 3 FDA limits in accordance with Sept. 2008 ultrasound systems guidance document	Below Track 3 FDA limits in accordance with Sept. 2008 ultrasound systems guidance document
Imaging Capacities	• pulsed-echo ultrasound • Mode B (2D) scan • Mode BM scan	• pulsed-echo ultrasound • Mode B (2D) scan	• pulsed-echo and Doppler ultrasound • Mode B (2D), Color, Amplitude

			Doppler
Patient Population	For use in all patients	For use in all patients	For use in all patients
Anatomic Structures / Clinical applications	General clinical applications, including small organ and peripheral vessel	General clinical applications, including fetal\obstetrics, gynecology, abdominal	General clinical applications, including fetal, abdominal, intraoperative, pediatric, small organ, cephalic, cardiac, peripheral vessel, and musculoskeletal
Users	Healthcare professionals	Healthcare professionals	Healthcare professionals
Principle / Method of Operation	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to

	the transducer and converted to electrical signals that are processed and displayed as images of anatomic structures.	the transducer and converted to electrical signals that are processed and displayed as images of anatomic structures.	the transducer and converted to electrical signals that are processed and displayed as images of anatomic structures.
Image Display Unit	Mobile device (4 to 13 inches approximately)	Mobile device (4 to 10 inches approximately)	Video display (unknown size)
Probe Characteristics	Linear, 7.5MHz frequency	Convex, 3.5MHz frequency	L8-3 linear, L12-5 linear, and C5-2 curvilinear
Probe Connection to Display	Wireless	Wireless	Wireless or wired
Off-the-shelf operating system	iOS	iOS / Android	Unknown
Software	Run as an app on off-the-shelf mobile device	Run as an app on off-the-shelf mobile device	Unknown
System Components	• Commercial off-the-shelf iOS mobile device, • Wireless Probe Type Ultrasound	• Commercial off-the-shelf iOS or Android mobile device, • SONON	• System console housing electronic circuitry • Video display

	Scanner software that runs as an app on the mobile device, • Wireless Probe Type Ultrasound Scanner battery-operated, hand-held ultrasound diagnostic transducer that communicates wirelessly with iOS mobile devices	Ultrasound Imaging System software that runs as an app on the mobile device, • SONON Ultrasound Imaging System battery-operated, hand-held ultrasound diagnostic transducer that communicates wirelessly with iOS or Android mobile devices	• Power supply • User controls • Transducers (L8-3 linear, L12-5 linear, C5-2 curvilinear) that communicate wirelessly or via wire with system console
Safety & Effectiveness			
Patient-Contacting Materials	Evaluated according to FDA recognized standards - ISO 10993-5 and ISO 10993-10	All materials with patient contact are biocompatible and can be disinfected	All materials with patient contact are biocompatible
Electrical Safety	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	Unknown

EMC	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	Unknown
Performance Safety	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37	Unknown

Brief Summary

First, the subject device (Model: UProbe-L) enjoys similar classification and intended use with predicate device 2. The classification and intended use of the subject device (Model: UProbe-L) is covered by those of the predicate device 2 which has a broader usage scope, which forms the foundation of the substantial equivalence between the two devices.

Secondly, the subject device (Model: UProbe-L) boasts similar technological characteristics with predicate device 2. They have the same environment of use, acoustic output levels, patient population, users and principle/method of operation; they have similar anatomic structure, probe characteristics and probe connection to display, i.e. those 3 aspects of the subject device (Model: UProbe-L) is covered by those of the predicate device 2 which has a broader usage scope; they have similar imaging capacities, i.e. some imaging capacities of subject device (Model: UProbe-L) are covered by that of the predicate device 2, and the different imaging capacities of subject device (Model: UProbe-L) - Model BM Scan is commonly used, not newly developed imaging capacity, thus will not bringing new safety and effectiveness concerns to the substantial equivalence comparison between the two device; although the subject device (Model: UProbe-L) has different image display unit, off-the-shelf operating system, software and system components compared with the predicate device 2, such characteristics have already been adopted by

predicate device 1, not newly developed, which will bring no new safety and effectiveness concerns. All those facts further supports that the subject device (Model: UProbe-L) and predicate device 2 are substantially equivalent.

Last but not least, the safety and effectiveness of the subject device (Model: UProbe-L) have been further ensured by the following FDA recognized standards - ISO 10993-5 & ISO 10993-10, IEC 60601-1 & IEC 60601-1-2 and IEC 60601-2-37, which shows that the subject device will be safe and effective for usage as the device that has already been on the market.

As a result, it is reasonable to conclude that subject device (Model: UProbe-L) is substantial equivalent with predicate device 2.

7.6.3 Comparison Table of Technological Characteristic with the Predicate Device for Model: BProbe

Comparison Items	**Subject Device: Wireless Probe Type Ultrasound Scanner (Model: BProbe)**	**Predicate Device 3: Palm Bladder Scanner - PBSV4.1 (K130229)**
Classification & Intended Use		
Classification	IYO & ITX Class 2	IYO & ITX Class 2
Intended Use	Intended to project ultrasound energy through the lower abdomen of the nonpregnant patient to obtain an image of the	Intended to project ultrasound energy through the lower abdomen of the nonpregnant patient to obtain an image of the

		bladder and uses that image to calculate the bladder volume non-invasively.	bladder and uses that image to calculate the bladder volume non-invasively.
Technological Characteristics			
Mode of Operation		B	B
Transducer Characteristics	Type	3.5MHz Mechanical Sector Scan	2.6MHz Mechanical Sector Scan
	Time from 3D Scan Initiation to Result Display	4 seconds	4 seconds
	Penetration Depth	⩾150mm	⩾140mm
Range of Measurement		10-999ml	0-999ml
Accuracy		±10%	·±25% (60ml≤ volume ≤ 150ml) ·±15% (150ml≤ volume ≤ 999ml)
Power Supply		DC3.8V 4200mA lithium battery	7.4v Li Ion Rechargeable
Screen Display		IPAD or IPHONE	Color LCD
Probe Connection to Display		Wireless	Wired
Operation Condition		· Temperature: +5℃~+40℃	· Temperature: +5℃~+40℃

		·Humidity Rate: 25%-80% · Atmospheric Pressure: 700hPa~1060hPa	·Humidity Rate: ≤70% · Atmospheric Pressure: 700hPa~1060hPa
Acoustic Output	Maximum MI	0.47	0.89
	Maximum TIS	0.037	0.98
Target Population		Adult and Children	Adult and Children
Anatomical Sites		Abdomen	Abdomen
Safety and Effectiveness			
Patient-Contacting Materials		Evaluated according to ISO 10993-5 and ISO 10993-10	Evaluated according to ISO 10993-5 and ISO 10993-10
Electrical Safety		Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1
EMC		Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2
Performance Safety		Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37
FCC Radio Frequency Testing		Tested to FCC requirements and found to comply with the requirements of FCC CFR Title 47 Part 15 Subpart C Section 15.247.	Not applicable.

First, the subject device (Model: BProbe) enjoys the same classification and intended use with the predicate device 3, which forms the foundation of the substantial equivalence between the two devices.

Secondly, the subject device (Model: BProbe) boasts similar technological characteristics with the predicate device 3, for example, they have the same mode of operation, transducer type (i.e.Mechanical Sector Scan), target population and anatomical sites. Though they differ in transducer specification, range of measurement, accuracy, operation condition and screen display, such slight difference will not affect the core usage of the subject device (Model: BProbe), thus will not affecting the substantial equivalence between the two devices. Although they do not have the same power supply and acoustic output index, such difference has been verified by FDA recognized standards - IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-37. And though they have different probe connection to display, the wireless connection adopted by the subject device (Model: BProbe) is not newly developed technology, it has already bee adopted by predicate device 1, and its safety has been further ensured by FCC requirements, which will not bring new concerns to the subject device's safety and effectiveness, thus will not affecting the substantial equivalence comparison between the two devices. All of those facts further supports that the two devices are substantial equivalent.

Last but not least, the safety and effectiveness of the subject device (Model: BProbe) have been further ensured by the following FDA recognized standards - ISO 10993-5 & ISO 10993-10, IEC 60601-1 & IEC 60601-1-2 and IEC 60601-2-37, and FCC requirements, which shows that the subject device will be as safe and effective for usage as the device that has already been on the market.

As a result, it is reasonable to conclude that subject device (Model: BProbe) is substantial equivalent with predicate device 3.

7.7 Discussion of Tests Performed

7.7.1 Clinical Test

Clinical testing was not performed for Wireless Probe Type Ultrasound Scanner (Model: UProbe-C; UProbe-L; BProbe) as part of the submission.

7.7.2 Non-Clinical Tests

The subject device was tested/analyzed according to the following standards in order to ensure its effectiveness and safety:

1) Biocompatibility according to AAMI / ANSI / ISO 10993-5:2009/(R)2014, Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity. (Biocompatibility) and AAMI / ANSI / ISO 10993-10:2010/(R)2014, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization. (Biocompatibility);

2) Electrical Safety according to AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012,, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (Iec 60601-1:2005, Mod). (General II (ES/EMC));

3) Electromagnetic Compatibility according to AAMI / ANSI / IEC 60601-1-2:2007/(R)2012, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests (Edition 3). (General II (ES/EMC));

4) Performance Safety and Effectiveness according to IEC 60601-2-37 Edition 2.0 2007, Medical Electrical Equipment - Part 2-37: Particular Requirements For The Basic Safety And Essential Performance Of Ultrasonic Medical Diagnostic And Monitoring Equipment. (Radiology);

5) FCC Radio Frequency Testing: The Wireless Probe Type Ultrasound Scanner was tested according to FCC requirements and found to comply with the requirements of FCC CFR Title 47 Part 15 Subpart C Section 15.247: Frequency Hopping, Direct Spread Spectrum and Hybrid Systems that are in operation with the bands of 902-928 MHz, 2400-2483.5 MHz, and 5725-5850 MHz.

7.8 Conclusion

From the above analysis, it is proper to conclude that the subject device (Model: UProbe-C; UProbe-L; BProbe) will be as safe and effective for usage as the listed predicate devices that have already been on the U.S. market.