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

October 27, 2017

Re: K171926
Trade/Device Name: C5 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: May 1, 2017
Received: August 14, 2017

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.

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 (DICE) 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 (DICE) 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171926

Device Name
C5 Diagnostic Ultrasound System

Indications for Use *(Describe)*
C5 Diagnostic Ultrasound System is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

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: __C5 Diagnostic Ultrasound System____
Transducer: _____
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	N - Note 1 N - Note 2 N - Note 3	N
	Abdominal	N				N		N
	Intra-operative (Specify)							
	Intra-Operative (Neuro)							
	Laparoscopic							
	Pediatric	N				N	N - Note 1	N
	Small Organ (breast, testes, thyroid)	N				N	N - Note 1	N
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	N				N	N - Note 1	N
	Trans-urethral							
	Trans-esoph. (non-Card)							
	Musculo-skeletal **(Conventional)**	N						N
	Musculo-skeletal **(Superficial)**	N						N
	Intravascular							
	Other (OB/Gyn)	N	N	N		N	N - Note 1 N - Note 2 N - Note 3	N
	Other (Urology)	N				N	N - Note 1	N
Cardiac	Cardiac Adult	N	N	N		N	N - Note 3 N - Note 1 N - Note 2	N
	Cardiac Pediatric	N	N	N		N	N - Note 3 N - Note 1 N - Note 2	N
	Intravascular (Cardiac)							
	Trans-epoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel	N		N		N	N - Note 1 N - Note 2	N
	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 Color Doppler Combined;
Note 2: B, Color Doppler and PWD Combined;
Note 3: B and M Combined

Diagnostic Ultrasound Indications For Use Format

System: __C5 Diagnostic Ultrasound System____
Transducer: __Convex Array Transducer (3C6C)____
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	N		N	N - Note 1 N - Note 2 N - Note 3	N
	Abdominal	N				N	N - Note 1	N
	Intra-operative (Specify)							
	Intra-Operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, testes, thyroid)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (OB/Gyn)	N	N	N		N	N - Note 1 N - Note 2 N - Note 3	N
	Other (Urology)	N				N	N - Note 1	N
Cardiac	Cardiac Adult	N	N	N		N	N - Note 3 N - Note 1 N - Note 2	N
	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 Color Doppler Combined;
Note 2: B, Color Doppler and PWD Combined;
Note 3: B and M Combined

Diagnostic Ultrasound Indications For Use Format

System: __C5 Diagnostic Ultrasound System____
Transducer: __Linear Array Transducer (7L4C)_____
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	N				N	N - Note 1	N
	Small Organ (breast, testes, thyroid)	N				N	N - Note 1	N
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card)							
	Musculo-skeletal **(Conventional)**	N						
	Musculo-skeletal **(Superficial)**	N						
	Intravascular							
	Other (OB/Gyn)							
	Other (Urology)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-epoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel	N				N	N - Note 1	N
	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 Color Doppler Combined;
Note 2: B, Color Doppler and PWD Combined;
Note 3: B and M Combined

Diagnostic Ultrasound Indications For Use Format

System: __C5 Diagnostic Ultrasound System____
Transducer: __Trans-vaginal Transducer (6E1C)____
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	N		N	N - Note 3 N - Note 1 N - Note 2	N
	Abdominal							
	Intra-operative (Specify)							
	Intra-Operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, testes, thyroid)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	N				N	N - Note 1	N
	Trans-urethral							
	Trans-esoph. (non-Card)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (OB/Gyn)	N	N	N		N	N - Note 1 N - Note 2 N - Note 3	N
	Other (Urology)	N				N	N - Note 1	N
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 Color Doppler Combined;
Note 2: B, Color Doppler and PWD Combined;
Note 3: B and M Combined

Diagnostic Ultrasound Indications For Use Format

System: __C5 Diagnostic Ultrasound System_____
Transducer: __Micro-Convex Array Transducer (6C15C)___
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				N	N - Note 1	N
	Intra-operative (Specify)							
	Intra-Operative (Neuro)							
	Laparoscopic							
	Pediatric	N		N		N	N - Note 1 N - Note 2	N
	Small Organ (breast, testes, thyroid)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (OB/Gyn)	N	N	N		N	N - Note 1 N - Note 2 N - Note 3	N
	Other (Urology)	N				N	N - Note 1	N
Cardiac	Cardiac Adult	N	N	N		N	N - Note 3 N - Note 1 N - Note 2	N
	Cardiac Pediatric	N	N	N		N	N - Note 3 N - Note 1 N - Note 2	N
	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 Color Doppler Combined;
Note 2: B, Color Doppler and PWD Combined;
Note 3: B and M Combined

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: May 01, 2017

7.2 Device Information

· Trade/Device Name: Diagnostic Ultrasound System

· Model: C5

· Common Name: Diagnostic Ultrasound System and Transducer

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

Regulation Description: Ultrasonic pulsed doppler imaging system

Review Panel: Radiology

Product Code: IYN

Submission Type: 510(k)

Regulation Number: 21 CFR 892.1550

Device Class: 2

2) 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

3) 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

S12 Digital Color Doppler Ultrasound System

submitted by SonoScape Company Limited

510K Number: K142474

7.4 Device Description

The C5 Diagnostic Ultrasound System is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The basic principle is that system transmits ultrasonic energy into patient body and implements post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body.

This system is a Track 3 device that employs a series of probes that include linear array (frequency: 7.5 MHz), convex array (frequency: 3.5 MHz), trans-vaginal (also belong to the category of “linear array”) (frequency: 6.5 MHz), micro-convex array (frequency: 5.0 MHz). This system consists of a mobile console with keyboard control panel, power supply module, color LCD monitor and optional probes.

This system is a mobile, general purpose, software controlled, color diagnostic ultrasound system. Its basic function is to acquire ultrasound data and to display the image in B-Mode , M-Mode, Color-Flow Doppler, Pulsed Wave Doppler and Power Doppler, or the combination of these modes (i.e. “B-Mode + Color-Flow Doppler”, “B-Mode + Color-Flow Doppler + Pulsed Wave Doppler” and “B-Mode + M-Mode”).

7.5 Indications for Use

C5 Diagnostic Ultrasound System is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

7.6 Comparison of Technological Characteristics with the Predicate Device

7.6.1 Comparison Table of Technological Characteristic with the Predicate Device

Comparison Items	Subject Device: Diagnostic Ultrasound System (Model: C5)	Predicate Device: S12 Digital Color Doppler Ultrasound System (K142474)
Classification & Intended Use		
Classification	Product Codes: IYN & IYO & ITX Class: 2	Product Codes: IYN & IYO & ITX Class: 2
Intended Use	A general-purpose ultrasonic imaging	A general-purpose ultrasonic imaging

	instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.	instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.
Technological Characteristics		
Design	Based on an embedded Linux Operating System	Based on an embedded Linux Operating System
	Autocorrelation for color processing and FFT for pulse.	Autocorrelation for color processing and FFT for pulse and CW Doppler processing.
	Supporting Linear probes (7.5MHz & 6.5 MHz) and Convex array probes (3.5MHz & 5.0MHz)	Supporting Linear, Curve linear and Phase array probes from 2 to 15MHz

	Cine play back capability	Cine play back capability
	Image file archive	Image file archive
	Software upgrade with USB flash drive	Software upgrade with USB flash drive
	Digital Scan Converter 1024×768	Digital Scan Converter 800×600
	With full keyboard panel	With full keyboard panel
Operation Controls	TGC 8 slider	TGC 8 slider
	Depth Range: 3.6 to 35.1cm	Depth Range: 3 to 24.8cm
	B Dynamic range control: 30-165dB	B Dynamic range control: 20-280dB
	Gray Scale Control: 0,1,2,3,4,5,6,7 8,9,10,11,12,13,14(14 Optional)	Gray Scale Control: 1,2,3,4,5,6,7 (7 Optional)
	Focal Number: adjustable, max 4	Focal Number: adjustable, max 12
	B persistance: 0-95%	B persistance: 0-95%
	PW sweeping speed 0,1,2,3,4 sec over display	PW sweeping speed 2,4,6,8 sec over display
	PW Wall filter setting: 0 to 3	PW Wall filter setting: 35 to 750
	PW sample volume: 0 to 7mm	PW sample volume: 0.7 to 21mm

	PW angle correction: adjustable, 0 to 85 degree	PW angle correction: adjustable, 0 to 72 degree
	Spectrum baseline: adjustable	Spectrum baseline: adjustable, such as shift and invert
	Color ROI setting: trackball to control size and position	Color ROI setting: trackball and set key to control size and position
	Color Wall Filter settings: 0 to 7	Color Wall Filter settings: 35 to 750
	Zoom adjustable	Zoom adjustable
	Freeze control: Toggling freeze key	Freeze control: Toggling freeze key
	Cine control: play/stop, loop speed, the start, the end, Frame by Frame	Cine control: play/stop, loop speed, the start, the end, Frame by Frame
Operation Mode	B, M, PW, Color, PDI, Compound Imaging (i.e. B+Color, B+Color+PW, B+M).	B, M, PW, CW, CFM, DPI, TDI, Tissue Harmonic Image, Color M Mode, PIH, Compound Imaging, 3D/4D Mode Panoramic Imaging, Trapezoid Imaging.
Display Modes	**B, PDI:** Single, Dual,	**B, CFM, DPI, TDI,**

	Quad **M:** V1/3, V1/2(Dual), V2/3, H1/2, H1/4, 01/4 **PW:** V1/3, V1/2(Dual), V2/3, H1/2, H1/4, 01/4	**4D:** Single, Dual, Quad **B+CFM, B+DPI,** **B+TDI:** Dual Live **B/M, CFM/M, TDI/M,** **Steer M:** V1/3, V1/2(Dual), V2/3, H1/2, H1/4, 01/4 **PW, CW:** V1/3, V1/2(Dual), V2/3, H1/2, H1/4, 01/4
Measurement Items	**B, PDI, Color Doppler:** Distance, Area, Circumference, Volume, Area Ratio, Distance Ratio, Angle, Abdomen, Kidney, Gynecology, Uterus, Ovary, Follicles, Obstetrics, AFI, Fetal Cardiology, Small Parts, Urology, Pediatric **M:** Distance, Time, Heart Rate, Slope Rate, Fetal Cardiology **PW:** Flow Speed Ratio, Speed, Time, Heart Rate, Acceleration, Spectral Trace,	**B, CFM, DPI, TDI:** Area Ratio, Angle, Volume, Volume L×W×H, Doppler Area, Vascular, Small Part, Ortho, OB/GYN, Cardiac, URO, VHE; **M:** Distance, Time, Slope, HR, Left Ventricle, Mitral Valve, Aortic Valve; **PW/CW:** Flow Velocity, Acceleration, Time, Trace, Auto Trace, HR, Vascular, OB/GYN, Cardiac, VE

	Obstetrics, Vascular	
Cine Loop	Automatic review/manual review	Automatic review/manual review
	Review speed can be adjusted	Review speed can be adjusted
Operating Condition	Temperature:5~+40℃	Temperature: 10~40℃
	Relative humidity: 25~80%	Relative humidity: 30~75%
	Air pressure: 700hPa~1060hPa	Air pressure: 700hPa~1060hPa
Storage Condition	Temperature: -20~+55℃	Temperature: -20~55℃
	Relative humidity: 25~93%	Relative humidity: 20~90%
	Air pressure: 700hPa~1060hPa	Air pressure: 700hPa~1060hPa
Power Supply	Voltage: 100-240V AC	Voltage: 100-240V AC
	Frequency: 50/60 Hz	Frequency: 50/60 Hz
	Power Consumption: 100-240V AC, 2.4-1A	Power Consumption: 100-240V AC, 2.7-1.1A
Screen Size	15 inch LCD monitor	15 inch LCD monitor
Safety & Effectiveness		
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
Bio-compatibility	Evaluated according to	Evaluated according to

	ISO 10993-5 & ISO 10993-10	ISO 10993-5 & ISO 10993-10
Performance Safety	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37

7.6.2 Brief Summary

First, the subject device enjoys identical classification and similar intended use with the predicate device, which forms the foundation of substantial equivalence between the two devices. Though their intended use are not identical, the intended use of subject device is covered by that of predicate device which has a larger usage scope, thus will not affecting the substantial equivalence comparison between the two devices.

Secondly, the subject device boasts similar technological characteristics with the predicate device: 1) they have identical cine loop setting and screen size; 2) though their operation mode, display modes and measurement items are not identical, the operation mode, display modes and measurement items of subject device are covered by those of predicate device; 3) they share similar design which is almost the same, and the slight difference in digital scan converter will not affect the core usage of devices, thus will not affecting their substantial equivalence comparison; 4) though they are not identical in operating condition and storage condition, their slight difference in operating condition and storage condition will not affect the core usage of subject device as long as users operate according to instruction, thus will not influencing the substantial equivalence comparison between them; 5) although their power supply are slightly different, the electrical safety and EMC of subject device have been tested according to FDA recognized standards - IEC 60601-1 and IEC 60601-1-2, thus will not bringing in new safety concerns; 6) though the two devices are quite different in operation controls, the basic safety and essential performance of subject device has

been evaluated according to FDA recognized standard - IEC 60601-2-37, thus will not bringing new safety and effectiveness concerns. All of the above facts further support that the two devices are substantially equivalent.

Last but not least, the safety and effectiveness of subject device have been tests according to the same FDA recongized standards as the predicate device - IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37, ISO 10993-5 and ISO 10993-10, the result of which displays that subject device fully meets the standards requirement, that subject device will be as safe and effective for usage as the predicate device.

Accordingly, it is reasonable to conclude that two devices are substantially equivalent.

7.7 Discussion of Tests Performed

7.7.1 Clinical Tests

Clinical testing was not performed for C5 Diagnostic Ultrasound System 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 ISO 10993-5 and ISO 10993-10;

2) Electrical Safety according to AAMI / ANSI ES60601-1;

3) Electromagnetic Compatibility according to IEC 60601-1-2;

4) Performance Safety and Effectiveness according to IEC 60601-2-37.

7.8 Conclusion

From the above analysis, it is reasonable for us to conclude that the subject device - C5 Diagnostic Ultrasound System is substantially equivalent to the predicate device - S12 Digital Color Doppler Ultrasound System (K142474).