



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

SONOSCAPE MEDICAL CORP.

April 4, 2016

% Ms. Toki Wu

Regulatory Affairs Manager

4/f, 5/f, 8/f, 9/f & 10/f, Yizhe Building, Yuquan Road, Nanshan

Shenzhen, GuangDong 518051

CHINA

Re: K160258

Trade/Device Name: X5 Digital Color Doppler Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX

Dated: January 22, 2016

Received: February 1, 2016

Dear Ms. Wu:

This letter corrects our substantially equivalent letter of April 1, 2016. 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 black ink, appearing to read "Robert Ochs", is written over a faint, light-colored watermark of the FDA logo.

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

## Indications for Use

510(k) Number (if known)

Device Name

X5 Digital Color Doppler Ultrasound System

Indications for Use (Describe)

The SonoScape X5 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), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Cerebral 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 Form

System: SonoScape X5  
 Diagnostic Ultrasound Pulsed Echo System  
 Diagnostic Ultrasound Pulsed Doppler Imaging System

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 (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1	Notes 2
	Abdominal	N	N	N		N	N	Note 1	Notes 2
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Notes 2
	Small Organ (specify)	N	N	N		N	N	Note 1	Notes 2,6
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Notes 2
	Adult Cephalic	N	N	N	N	N	N	Note 1	Notes 2
	Trans-rectal	N	N	N		N	N	Note 1	Notes 2
	Trans-vaginal	N	N	N		N	N	Note 1	Notes 2
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Notes 2
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Notes 2
Other (Urology)	N	N	N		N	N	Note 1	Notes 2	
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	Notes 2
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Other (specify)									
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Notes 2
	Cerebral vascular			N					

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI                      Note 4: 3D                      Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Note 7: Elastography

### Diagnostic Ultrasound Indications for Use Form

Transducer: 3C-A Curved Array

Diagnostic Ultrasound 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 (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1	Notes 2
	Abdominal	N	N	N		N	N	Note 1	Notes 2
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	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
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Other (specify)									
Peripheral Vessel	Peripheral vessel								
	Cerebral vascular								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

Transducer: C613 Micro-curved Array

Diagnostic Ultrasound 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 (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	Note 1	Notes 2
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Notes 2
	Small Organ (specify)								
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Notes 2
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Other (Ob/GYN)									
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Other (specify)									
Peripheral Vessel	Peripheral vessel								
	Cerebral vascular								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Note 7: Elastography

### Diagnostic Ultrasound Indications for Use Form

Transducer: 3P-A Phased Array

Diagnostic Ultrasound 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 (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	Note 1	Notes 2
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Notes 2
	Adult Cephalic	N	N	N	N	N	N	Note 1	Notes 2
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
Intravascular									
Other (Ob/GYN)									
Other (Urology)									
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	Notes 2
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Cerebral vascular								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

Transducer: 7P-B Phased Array

Diagnostic Ultrasound 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 (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Notes 2
	Small Organ (specify)								
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Notes 2
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Other (Ob/GYN)									
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Other (specify)									
Peripheral Vessel	Peripheral vessel								
	Cerebral vascular								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

Transducer: L741 Linear Array

Diagnostic Ultrasound 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 (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	N	N	N		N	N	Note 1	Notes 2,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Notes 2
	Intravascular								
Other (Ob/GYN)									
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Other (specify)									
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Notes 2
	Cerebral vascular								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Note 7: Elastography

### Diagnostic Ultrasound Indications for Use Form

Transducer: 6V1 Micro-curved Array

Diagnostic Ultrasound 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 (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	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		N	N	N		N	N	Note 1	Notes 2
	Trans-vaginal		N	N	N		N	N	Note 1	Notes 2
	Trans-urethral									
	Trans-esoph.(non-Card)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Intravascular										
Other (Ob/GYN)										
Other (Urology)		N	N	N		N	N	Note 1	Notes 2	
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Intravascular(Cardiac)									
	Trans-esoph.(Cardiac)									
	Intra-cardiac									
Other (specify)										
Peripheral Vessel	Peripheral vessel									
	Cerebral vascular									

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

Transducer: EC9-5 Micro-curved Array

Diagnostic Ultrasound 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 (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	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		N	N	N		N	N	Note 1	Notes 2
	Trans-vaginal		N	N	N		N	N	Note 1	Notes 2
	Trans-urethral									
	Trans-esoph.(non-Card)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Intravascular										
Other (Ob/GYN)										
Other (Urology)		N	N	N		N	N	Note 1	Notes 2	
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Intravascular(Cardiac)									
	Trans-esoph.(Cardiac)									
	Intra-cardiac									
Other (specify)										
Peripheral Vessel	Peripheral vessel									
	Cerebral vascular									

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

Transducer: PWD2.0

Diagnostic Ultrasound 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 (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic			N					
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Other (Ob/GYN)									
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Other (specify)									
Peripheral Vessel	Peripheral vessel								
	Cerebral vascular			N					

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Note 7: Elastography

## 510(k) Summary

### 1. Submitter [21 CFR807.92 (a) (1)]

Submitter: SONOSCAPE MEDICAL CORP.  
 Address: 4/f, 5/f, 8/f, 9/f & 10/f, Yizhe Building, Yuquan Road,  
 Nanshan, Shenzhen 518051, Guangdong, China  
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 Email: ra@sonoscape.net  
 Date Prepared March 30, 2016

### 2. Device [21 CFR807.92 (a) (2)]

Trade Name: X5 Digital Color Doppler Ultrasound System  
 Common Name: Diagnostic Ultrasound System and Transducers

Classification Regulatory:

	<u>FR Number</u>	<u>Product Code</u>
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

Classification Panel: Radiology

Device Class: II

### 3. Predicate Device(s) [21 CFR 807.92(a) (3)]

The identified predicate device within this submission is as follows:

SonoScape S8 Exp Portable Digital Color Doppler Ultrasound System K152164

### 4. Device Description [21 CFR 807.92(a) (4)]

This SonoScape X5 Digital Color Doppler Ultrasound System is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The X5 system utilizes the ultrasound echo characteristics, transmits ultrasonic energy into patient body, sweeps in a certain direction, processes the signals according to the

delay time and the echo strength, and images the organs by using the electronic circuits and backend controller to process, then analyzes the distance and the status of organs; and at the same time, this system utilizes Doppler and autocorrelation technology to image the blood flow and add the color-coding information to the grayscale image of B mode, then displays the image in real time. The probes provided with this system are electrical-acoustical and acoustical-electrical transducers. The probes firstly convert the electric excitation signal to the acoustic signal and transmit the signal into the patient body, then converts the echo signals from the patient body to electric signal. The echo signal is processed and converted by DSC to image signal to output to the LCD display. This system is a Track 3 device that employs a wide array of probes that include linear array, convex array and phased array.

This system consists of keyboard control panel, power supply module, color LCD monitor and optional probes.

This system is a portable, general purpose, software controlled, color diagnostic ultrasound system. Its basic function is to acquire ultrasound data and to display the image in B-Mode (including Tissue Harmonic Image), M-Mode, Color-Flow Doppler, Pulsed Wave Doppler, Continued Wave Doppler and Power Doppler, or the combination of these modes.

#### **5. Intended Use [21 CFR 807.92(a) (5)]**

The SonoScape X5 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), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Cerebral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

#### **6. Comparison with the Predicate device [21 CFR 807.92(a) (6)]**

X5 Digital Color Doppler Ultrasound System is comparable with and substantially equivalent to the predicate device:

SonoScape S8 Exp Portable Digital Color Doppler Ultrasound System K152164

##### ***Intended Use Comparison:***

Compared with the predicate device SonoScape S8 Exp (K152164), the Subject Device X5 has the same intended use.

**Table 1 Intended Use Comparison**

ID	Comparison Items	Subject Device SonoScape X5	Predicate Device SonoScape S8 Exp (K152164)
1	<b>Intended Use</b>	The device 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), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Cerebral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.	The device 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), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Cerebral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), Trans-esoph.(Cardiac), Laparoscopic, OB/Gyn and Urology.

*Note: According to Section D in the "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], issued on: July 28, 2014", the indications for use of the new device fall within the intended use of the predicate device, the two devices have the same intended use.*

**Regulation and Safety Standards Comparison:**

Subject device X5 has the same classification as the predicate device. And subject device X5 is designed in compliance with the FDA recognized safety standards, which are the same as the predicate device.

**Table 2 Regulation and Safety Standards Comparison**

ID	Comparison Items	Subject Device SonoScape X5	Predicate Device SonoScape S8 Exp (K152164)	Remark
2	<b>Classification Name</b>	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasound Transducer	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasound Transducer	<b>Same</b>
3	<b>Product Code</b>	90-IYN/90-IYO/90-ITX	90-IYN/90-IYO/90-ITX	<b>Same</b>
4	<b>Regulation Number</b>	892.1550/892.1560/892.1570	892.1550/892.1560/892.1570	<b>Same</b>
5	<b>Panel</b>	Radiology	Radiology	<b>Same</b>
6	<b>Class</b>	II	II	<b>Same</b>
7	<b>Acoustic Track</b>	TRACK 3	TRACK 3	<b>Same</b>
8	<b>Electrical Safety</b>	IEC 60601-1	IEC 60601-1	<b>Same</b>

ID	Comparison Items	Subject Device SonoScape X5	Predicate Device SonoScape S8 Exp (K152164)	Remark
	<b>EMC</b>	IEC 60601-1-2	IEC 60601-1-2	<b>Same</b>
	<b>Performance</b>	IEC 60601-2-37	IEC 60601-2-37	<b>Same</b>
	<b>Biocompatibility</b>	ISO 10993-5, ISO 10993-10	ISO 10993-5, ISO 10993-10	<b>Same</b>
	<b>Acoustic Output Display</b>	AIUM/NEMA UD3-2004 (R2009)	AIUM/NEMA UD3-2004 (R2009)	<b>Same</b>
	<b>Acoustic Output Measurement</b>	AIUM/NEMA UD2-2004 (R2009)	AIUM/NEMA UD2-2004 (R2009)	<b>Same</b>

**Acoustic Output Levels Comparison:**

The acoustic output levels of the subject device X5 are below the limits of FDA, which are the same as the predicate device SonoScape S8 Exp (K152164).

**Table 3 Acoustic Output Levels Comparison**

ID	Comparison Items	Subject Device SonoScape X5	Predicate Device SonoScape S8 Exp (K152164)	Remark
9	<b>Acoustic Output</b>	Derated $I_{SPTA}$ : 720mW/cm <sup>2</sup> maximum. TIS/TIB/TIC: 6.0 maximum, MI: 1.9 maximum, Derated $I_{SPPA}$ : 190W/cm <sup>2</sup> maximum	Derated $I_{SPTA}$ : 720mW/cm <sup>2</sup> maximum. TIS/TIB/TIC: 6.0 maximum, MI: 1.9 maximum, Derated $I_{SPPA}$ : 190W/cm <sup>2</sup> maximum	<b>Same</b>

**Probes Comparison:**

Subject device X5 has the similar probes as the predicate device SonoScape S8 Exp (K152164).

**Table 4 Probes Comparison**

ID	Comparison Items	Subject Device SonoScape X5	Predicate Device SonoScape S8 Exp (K152164)	Remark
10	<b>Probes</b>	3C-A Curved Array	C322 Micro-curved Array C344 Curved Array C353 Curved Array C542 Curved Array 3C-A Curved Array	<b>SE</b> Analysis 1 Analysis 2
		C613 Micro-curved Array	VC6-2 Curved Array C613 Micro-curved Array	
		3P-A Phased Array 7P-B Phased Array	2P1 Phased Array 2P2 Phased Array 3P1 Phased Array	

			5P1 Phased Array 5P2 Phased Array 8P1 Phased Array 4P-A Phased Array	
		L741 Linear Array	L741 Linear Array L742 Linear Array L743 Linear Array L752 Linear Array 10L1 Linear Array 10I2 Linear Array	
		6V1 Micro-curved Array EC9-5 Micro-curved Array	6V1 Micro-curved Array 6V3 Micro-curved Array EC9-5 Micro-curved Array BCC9-5 Micro-curved Array BCL10-5 Biplane (Curved + Linear Array)	
		PWD2.0 TCD	MPTEE Phased Array (Multi-plane) MPTEE mini Phased Array (Multi-plane) LAP7 Linear Array CWD2.0 CW CWD5.0 CW PWD2.0 TCD	

**SE Analysis 1:**

Compared with the predicate device, most of the probes (3C-A, C613, L741, 6V1, EC9-5, PWD2.0) are the same as them cleared with predicate device SonoScape S8 Exp (K152164). Most of these probes with X5 system have wider frequency range, which is redefined based on the frequency range of excitation pulse of the X5 system.

**SE Analysis 2:**

Compared with the predicate device, there are two new probes (3P-A and 7P-B), which are similar with the probe 2P1 and 5P1 respectively cleared with predicate device SonoScape S8 Exp (K152164). The clinical application is the same, the performance or frequency is similar, and the difference of these doesn't affect the safety, effectiveness and clinical use.

*Note: detailed description information about the new probe (including the engineering drawing) and the further comparison can be found in **Substantial Equivalence Comparison** of this submission.*

**Technical Characteristics Comparison:**

Compared with the predicate device SonoScape S8 Exp (K152164), the Subject Device X5 has the similar technical characteristics, including Design, Operation Controls, Display Modes, Operation Modes, Measurement Items, Cine Loop, Operating and Storage Condition. And the differences will not raise new risk and different questions of safety and effectiveness and considered Substantially Equivalent in safety and effectiveness. The detailed analysis is shown as the following (*shown in table 5*).

**Table 5 Technical Features Comparison**

ID	Comparison Items	Subject Device SonoScape X5	Predicate Device SonoScape S8 Exp (K152164)	Remark
11	Design	Based on an embedded Linux operating system.	Based on an embedded Linux operating system.	<b>Same</b>
		Autocorrelation for color processing and FFT for pulse and CW Doppler processing.	Autocorrelation for color processing and FFT for pulse and CW Doppler processing.	<b>Same</b>
		Supporting Linear, Curve and Phased Array probes	Supporting Linear, Curve and Phase array probes	<b>Same</b>
		Cine play back capability	Cine play back capability	<b>Same</b>
		Image file archive	Image file archive	<b>Same</b>
		Software upgraded with USB flash drive.	Software upgraded with USB flash drive.	<b>Same</b>
		Digital Scan Converter 1130*820	Digital Scan Converter 800x600	<b>SE</b> Analysis 3
12	Operation Controls	TGC 8 slider	TGC 8 slider	<b>Same</b>
		Depth Range: 1.5 to 40cm	Depth Range: 3 to 24.8cm	<b>SE</b> Analysis 4
		B Dynamic range control: 20-200	B Dynamic range control: 20-280dB	<b>SE</b> Analysis 4
		Gray map: 1-16	Gray Scale Control: 1,2,3,4,5, 6,7 (7 optional)	<b>SE</b> Analysis 4
		Focal Number: adjustable	Focal Number: adjustable	<b>Same</b>
		B persistence: Off, low, mid, high, max	B persistence: 0-95%	<b>SE</b> Analysis 4
		PW sweeping speed: min, slow, med, fast, max	PW sweeping speed 2,4,6,8 sec over display	<b>SE</b> Analysis 4
		PW Wall filter setting: min, low, mid, high, max	PW Wall filter setting: 35 to 750	<b>SE</b> Analysis 4
		PW sample volume:0.5 to 24mm	PW sample volume:0.7 to 21mm	<b>SE</b> Analysis 4
		PW angle correction: adjustable, -88 to 88 degree	PW angle correction: adjustable, 0 to 72 degree	<b>SE</b> Analysis 4

ID	Comparison Items	Subject Device SonoScape X5	Predicate Device SonoScape S8 Exp (K152164)	Remark
		Spectrum baseline: adjustable, such as shift and invert	Spectrum baseline: adjustable, such as shift and invert	<b>Same</b>
		Color ROI setting: trackball and set key to control size and position	Color ROI setting: trackball and set key to control size and position	<b>Same</b>
		Color Wall Filter settings: min, low, mid, high, max	Color Wall Filter settings: 35 to 750	<b>SE</b> Analysis 4
		Zoom adjustable	Zoom adjustable	<b>Same</b>
		Freeze control: Toggling freeze key	Freeze control: Toggling freeze key	<b>Same</b>
		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	<b>Same</b>
13	<b>Operation Mode</b>	B, M, PW, CW, CFM, PDI, THI, PHI, Compound Imaging	B, M, PW, CW, CFM, DPI, TDI, Tissue Harmonic Image, Color M Mode, PHI, Compound Imaging, 3D/4D Mode, Panoramic Imaging, Trapezoid Imaging, Elastography	<b>SE</b> Analysis 5
14	<b>Display Modes</b>	B,CFM, PDI, B+CFM, B+PDI, M, PW,CW: V1/2,V1/1,V2/1, H1/1,Full	B,CFM,DPI,TDI, 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	<b>SE</b> Analysis 5
15	<b>Measurement Items</b>	B, CFM, DPI: Distance, Area, Volume, Angle; M: Distance, Slope, %Sten(D), Ratio(D), Time, HR; CFM/PDI: Doppler Area, Color Flow, Flow Velocity; PW/CW: Velocity, Acceleration, Auto Trace, Time, HR, RI, PI, S/D	B, CFM, DPI, TDI: Distance, Area, Volume, Angle, Doppler Area, Color Flow, OB, SMP, GYN, Vascular, Abdomen, Cardiac, Urology, Pediatrics M: Distance, Slope, %Sten(D), Ratio(D), Time, HR, OB, SMP, Vascular, GYN, Abdomen, Cardiac, Urology PW/CW: Velocity, Acceleration, RI, PI, S/D, Auto Trace, Manual Trace, Time, HR, OB, SMP, Vascular, GYN, Abdomen, Cardiac, Urology	<b>SE</b> Analysis 5

ID	Comparison Items	Subject Device SonoScape X5	Predicate Device SonoScape S8 Exp (K152164)	Remark
16	Power Supply	Voltage: 100-240V~	Voltage: 110-240 VAC	<b>SE</b> Analysis 6
		Frequency: 50/60Hz	Frequency: 50/60 Hz	<b>Same</b>
		Power Consumption: 100-240V~, 1.5-0.75A	Power Consumption: 110-240V AC, 2.7-1.2A	<b>SE</b> Analysis 6
17	Screen Size	15.6 inch LCD monitor	15 inch LCD monitor	<b>SE</b> Analysis 7

**SE Analysis 3:**

Design, compared with the predicate device, the subject device employs the almost same design and has some differences in Digital Scan Converter. But both of them comply with the requirements of IEC60601-1 and meet clinical requirements. Therefore they can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

**SE Analysis 4:**

Operation Controls, compared with the predicate device, the subject device employs the same operation controls design and has some differences in value range or setting. But both of them comply with the requirements of IEC60601-1 & IEC60601-2-37 and meet clinical requirements. Therefore they can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

**SE Analysis 5:**

Compared with the predicate device, the subject device has some differences in Operation Mode, Display Modes and Measurement Items. But all of them for the subject device include the clinical basic items, and fall within these for the predicate device; all of them meet the clinical use and no new risk is raised.

**SE Analysis 6:**

Power Supply, compared with the predicate device, the subject device employs the same power type and has some differences in voltage range and power consumption. But both of them comply with the requirements of IEC60601-1. Therefore they can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

**SE Analysis 7:**

Screen Size, compared with the predicate device, the subject device employs the same screen type and has some differences in screen size. But both of them comply with the

requirements of IEC60601-1 & IEC60601-1-2 and meet clinical requirements. Therefore they can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

Therefore the Subject Device X5 can be considered Substantially Equivalent to the Predicate Devices in safety and effectiveness, and no new risk is raised, so the SE is not affected.

#### **7. Non-Clinical Tests [21 CFR 807.92(b) (1)]**

The X5 Digital Color Doppler Ultrasound System has been evaluated for electrical, mechanical, thermal and electromagnetic compatibility safety, biocompatibility and acoustic output.

Laboratory tests (including Phantom tests) were conducted to verify that the X5 system met all design specifications and the X5 system conformed to applicable medical device standards.

The X5 system has been designed and manufactured to meet the following standards: IEC 60601-1:12005+A1:2012, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance [08/20/2012];

IEC 60601-1-2:2007, Medical Electrical Equipment -Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility-Requirements and tests [03/30/2007];

IEC 60601-2-37:2007, Medical Electrical Equipment-Part 2-37: Particular requirements for basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment [08/09/2007];

ISO 10993-5:2009, Biological Evaluation of Medical Devices, Part 5-Tests for in vitro cytotoxicity [06/01/2009];

ISO 10993-10:2010, Biological Evaluation of Medical Devices- Part 10: Tests for irritation and skin sensitization [08/01/2010];

AIUM/NEMA UD 2:2004 (R2009), Acoustic output measurement standard for diagnostic ultrasound equipment [08/21/2009]; and

AIUM/NEMA UD 3:2004 (R2009), Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment [08/13/2010].

#### **8. Clinical Test [21 CFR 807.92(b) (2)]**

No clinical testing was required.

**9. Substantially Equivalent Conclusions [21 CFR 807.92(b) (3)]**

In accordance with the 21 CFR Part 807 and based on the information provided in this premarket notification, SONOSCAPE MEDICAL CORP. concludes that X5 Digital Color Doppler Ultrasound System is substantially equivalent to the predicate device with regard to safety and effectiveness.