DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 3, 2017

Sonoscape Medical Corp.
% 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: K163427
Trade/Device Name: X3 Exp/X3/X3 Pro/X1 Pro/X1 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: November 30, 2016
Received: December 6, 2016

Dear Ms. Wu:

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163427

Device Name

X3 Exp/X3/X3 Pro/X1 Pro/X1 Digital Color Doppler Ultrasound System

Indications for Use *(Describe)*

The SonoScape X3 Exp/X3/X3 Pro/X1 Pro/X1 Digital Color Doppler 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), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Cerebral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (pediatric 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 X3 Exp/X3/X3 Pro/X1 Pro/X1
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	P	P	P		P	P	Note 1	Notes 2
	Abdominal	P	P	P		P	P	Note 1	Notes 2
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Notes 2
	Small Organ (specify)	P	P	P		P	P	Note 1	Notes 2,6
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2
	Adult Cephalic	P	P	P	P	P	P	Note 1	Notes 2
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	Note 1	Notes 2
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Notes 2
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Notes 2
	Other (Urology)	P	P	P		P	P	Note 1	Notes 2
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1	Notes 2
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Notes 2
	Cerebral vascular			P					

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	P	P	P		P	P	Note 1	Notes 2
	Abdominal	P	P	P		P	P	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)	P	P	P		P	P	Note 1	Notes 2
	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	P	P	P		P	P	Note 1	Notes 2
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Notes 2
	Small Organ (specify)								
	Neonatal Cephalic	P	P	P	P	P	P	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	P	P	P	P	P	P	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	P	P	P		P	P	Note 1	Notes 2
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2
	Adult Cephalic	P	P	P	P	P	P	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	P	P	P	P	P	P	Note 1	Notes 2
	Cardiac Pediatric	P	P	P	P	P	P	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	P	P	P		P	P	Note 1	Notes 2
	Small Organ (specify)								
	Neonatal Cephalic	P	P	P	P	P	P	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	P	P	P	P	P	P	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)	P	P	P		P	P	Note 1	Notes 2,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	Note 1	Notes 2
	Musculo-skeletal (Superficial)	P	P	P		P	P	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	P	P	P		P	P	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	P	P	P		P	P	Note 1	Notes 2
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	P	P	P		P	P	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	P	P	P		P	P	Note 1	Notes 2
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	P	P	P		P	P	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			P					
	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			P					

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	December 23, 2016

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

Trade Name:	X3 Exp/X3/X3 Pro/X1 Pro/X1 Digital Color Doppler Ultrasound System
Common Name:	Diagnostic Ultrasound System and Transducers

Classification Regulatory:

	FR Number	Product Code
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 X5 Digital Color Doppler Ultrasound System K160258

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

This SonoScape X3 Exp/X3/X3 Pro/X1 Pro/X1 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 X3 Exp/X3/X3 Pro/X1 Pro/X1 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 X3 Exp/X3/X3 Pro/X1 Pro/X1 Digital Color Doppler 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), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Cerebral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (pediatric and adult), OB/Gyn and Urology.

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

X3 Exp/X3/X3 Pro/X1 Pro/X1 Digital Color Doppler Ultrasound System is comparable with and substantially equivalent to the predicate device:

SonoScape X5 Digital Color Doppler Ultrasound System K160258

Intended Use Comparison:

Compared with the predicate device SonoScape X5 (K160258), the Subject Device X3

Exp/X3/X3 Pro/X1 Pro/X1 has the same intended use.

Technical Characteristics Comparison:

Compared with the predicate device SonoScape X5 (K160258), the Subject Device X3 Exp/X3/X3 Pro/X1 Pro/X1 has the same technical characteristics, including Design, Operation Controls, Operation Mode, Display Modes, Measurement Items, Power Supply, Screen Size, Cine Loop, Operating and Storage Condition.

Compared with the predicate device SonoScape X5 (K160258), there are some hardware optimizations made to the Subject Device X3 Exp/X3/X3 Pro/X1 Pro/X1, including the modification of the video conversion chip in the display module which makes the display better, additional isolation to the IO docking station and other minor changes or optimizations on the circuit, which will not affect the safety and effectiveness of the Subject Device.

Probes Comparison:

Subject device X3 Exp/X3/X3 Pro/X1 Pro/X1 has the same probes as the predicate device SonoScape X5 (K160258).

Table 1 Probes Comparison

Subject device SonoScape X5	Predicate Device SonoScape X5 (K160258)	Remark
3C-A Curved Array	3C-A Curved Array	**Same**
C613 Micro-curved Array	C613 Micro-curved Array	
3P-A Phased Array 7P-B Phased Array	3P-A Phased Array 7P-B Phased Array	
L741 Linear Array	L741 Linear Array	
6V1 Micro-curved Array EC9-5 Micro-curved Array	6V1 Micro-curved Array EC9-5 Micro-curved Array	
PWD2.0 TCD	PWD2.0 TCD	

And, compared with predicate device, the subject device (X3 Exp/X3/X3 Pro/X1 Pro/X1) complies with the same regulation and safety standards and has the consistent acoustic output levels. Therefore they can be considered Substantially Equivalent 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 X3 Exp/X3/X3 Pro/X1 Pro/X1 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 X3 Exp/X3/X3 Pro/X1 Pro/X1 system met all design specifications and the X3 Exp/X3/X3 Pro/X1 Pro/X1 system conformed to applicable medical device standards.

The X3 Exp/X3/X3 Pro/X1 Pro/X1 system has been designed and manufactured to meet the following standards:

IEC 60601-1:2005+A1:2012, Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance [08/20/2012], including the US National Differences;

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 X3 Exp/X3/X3 Pro/X1 Pro/X1 Digital Color Doppler Ultrasound System is substantially equivalent to the predicate device with regard to safety and effectiveness.