



January 29, 2019

Sonoscape Medical Corp.  
Toki Wu  
Regulatory Affairs Manager  
4/f, 5/f, 8/f, 9/f & 10/f  
Yizhe building, Yuquan road, Nanshan  
SHENZHEN, 518051 GUANGDONG  
CHINA

Re: K182648

Trade/Device Name: X5 Series Digital Color Doppler Ultrasound System  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic Pulsed Doppler Imaging System  
Regulatory Class: Class II  
Product Code: IYN  
Dated: December 14, 2018  
Received: December 27, 2018

Dear Toki 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



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)  
K182648

Device Name  
X5 Series Digital Color Doppler Ultrasound System

Indications for Use (Describe)

The 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), Trans-esoph.(Cardiac), 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: X5 Series Digital Color Doppler Ultrasound System  
 (including: X5 Exp, X5, X5 Pro, X6 Exp, X6, X6 Pro)  
 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 2,8
	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 2,6,7
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3
	Adult Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3
	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 2,3
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)	P	P	P	P	P	P	Note 1	Notes 2,3
	Intra-cardiac								
Other (specify)									
Peripheral Vessel	Peripheral vessel	P	P	P	N	P	P	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

Note 8: Contrast imaging

## 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 2,8
	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

Note 8: Contrast imaging

## Diagnostic Ultrasound Indications for Use Form

Transducer: C613 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

Note 8: Contrast imaging

## 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 2,3
	Adult Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3
	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 2,3
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3
	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

Note 8: Contrast imaging



## 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

Note 8: Contrast imaging



## 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 2,6,7
	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

Note 8: Contrast imaging

## 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

Note 8: Contrast imaging

## 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

Note 8: Contrast imaging

## Diagnostic Ultrasound Indications for Use Form

Transducer: C322 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	P	P	P		P	P	Note 1	Notes 2
	Abdominal	P	P	P		P	P	Note 1	Notes 2,8
	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
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

Note 8: Contrast imaging

**Diagnostic Ultrasound Indications for Use Form**

Transducer: C1-6 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 2,8
	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
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

Note 8: Contrast imaging

## Diagnostic Ultrasound Indications for Use Form

Transducer: VC6-2 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
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

Note 8: Contrast imaging





## Diagnostic Ultrasound Indications for Use Form

Transducer: S1-5 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 2,3
	Adult Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3
	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 2,3
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3
	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

Note 8: Contrast imaging

## Diagnostic Ultrasound Indications for Use Form

Transducer: L746 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

Note 8: Contrast imaging

## Diagnostic Ultrasound Indications for Use Form

Transducer: 10I2 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)									
	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

Note 8: Contrast imaging

## Diagnostic Ultrasound Indications for Use Form

Transducer: 9L-A 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 2,6,7
	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

Note 8: Contrast imaging

### Diagnostic Ultrasound Indications for Use Form

Transducer: 12L-B 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 2,6,7
	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  
 Note 8: Contrast imaging

## Diagnostic Ultrasound Indications for Use Form

Transducer: 6V3 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

Note 8: Contrast imaging

## Diagnostic Ultrasound Indications for Use Form

Transducer: 6V7 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

Note 8: Contrast imaging



## Diagnostic Ultrasound Indications for Use Form

Transducer: BCC9-5 Biplane (curved+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

Note 8: Contrast imaging

### Diagnostic Ultrasound Indications for Use Form

Transducer: MPTEE 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								
	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)									
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)	P	P	P	P	P	P	Note 1	Notes 2,3
	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

Note 8: Contrast imaging

## Diagnostic Ultrasound Indications for Use Form

Transducer: MPTEE mini 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								
	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)									
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)	P	P	P	P	P	P	Note 1	Notes 2,3
	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

Note 8: Contrast imaging

## Diagnostic Ultrasound Indications for Use Form

Transducer: 13L-A 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

Note 8: Contrast imaging

## Diagnostic Ultrasound Indications for Use Form

Transducer: 18L-A 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

Note 8: Contrast imaging

## Diagnostic Ultrasound Indications for Use Form

Transducer: 10L-I 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)								
	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

Note 8: Contrast imaging

## Diagnostic Ultrasound Indications for Use Form

Transducer: 6V3A 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									
	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)										
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

Note 8: Contrast imaging



## Diagnostic Ultrasound Indications for Use Form

Transducer: 12LT-A 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)								
	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

Note 8: Contrast imaging

## Diagnostic Ultrasound Indications for Use Form

Transducer: 12LI-A 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)								
	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

Note 8: Contrast imaging

## Diagnostic Ultrasound Indications for Use Form

Transducer: 6CI-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

Note 8: Contrast imaging

## Diagnostic Ultrasound Indications for Use Form

Transducer: 6CT-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
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

Note 8: Contrast imaging

## Diagnostic Ultrasound Indications for Use Form

Transducer: CWD2.0

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								
	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				
	Cardiac Pediatric				P				
	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

Note 8: Contrast imaging

## Diagnostic Ultrasound Indications for Use Form

Transducer: CWD5.0

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								
	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						N		
	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

Note 8: Contrast imaging

## Diagnostic Ultrasound Indications for Use Form

Transducer: C542 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  
 Note 8: Contrast imaging



## Diagnostic Ultrasound Indications for Use Form

Transducer: C361 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
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

Note 8: Contrast imaging

# 510(k) Summary

## K182648

### 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  
 Contact Person: Toki Wu  
 Tel: +86 755 26722890  
 Fax: +86 755 26722850  
 Email: ra@sonoscape.net  
 Date Prepared January 22, 2019

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

Trade Name: X5 Series Digital Color Doppler Ultrasound System  
 Model: X5/X5 Exp/X5 Pro/X6/X6 Exp/X6 Pro  
 Common Name: Diagnostic Ultrasound System and Transducers

Classification Regulatory:

	<u>CFR Number</u>	<u>Product Code</u>
Ultrasonic Pulsed Doppler Imaging System (Primary)	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:

Type	Manufacturer	Device	510 (K) Number
Main predicate device	Sonoscape Medical Corp.	P10 Series Digital Color Doppler Ultrasound System	K173058
Reference Device	Sonoscape Medical Corp.	X5 Digital Color Doppler Ultrasound System	K160258
Reference Device	Philips Ultrasound, Inc.	EPIQ 5/EPIQ 7 Diagnostic Ultrasound System	K160807

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

This SonoScape X5 Series 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 Series 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 auto-correlation 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 (X5 Series Digital Color Doppler Ultrasound System) are additional models (X5 Exp, X5 Pro, X6, X6 Exp, X6 Pro), additional transducers (C1-6, 12L-B, 9L-A, 18L-A, 13L-A, L746, 10L-I, 10I2, 6V7, 6V3, 6V3A, C361, VC6-2, C542, C322, 12LT-A, 12LI-A, 6CT-A, 6CI-A, BCC9-5, S1-5, 2P1, CWD5.0, CWD2.0, MPTEE and MPTEE min probes), additional functions (Elastography, Contrast imaging) and updated intended use (Trans-esoph.(Cardiac)) to legally marketed SonoScape X5 (K160258).

Note: X5 Exp, X5, X5 Pro, X6 Exp, X6, X6 Pro models are considered as a serial products as they are the same except partial functions, including the same design, hardware, software, mechanic construction, power supply board, main board, specification and etc. The differences among them can be seen as the following table.

Table 1 Comparison table

Model	Configuration Description
X5 Exp	With full functions and configuration
X5	Does not support the velocity measurement compared with X5 Exp
X5 Pro	Does not support the slope ratio measurement compared with X5 Exp

X6 Exp	Does not support the time ratio measurement compared with X5 Exp
X6	Does not support the time ratio, slope ratio measurement compared with X5 Exp
X6 Pro	Does not support the time ratio, velocity measurement compared with X5 Exp
Note: The slope ratio, time ratio, velocity and velocity ratio measurement items mentioned above refer to those of the M-mode basic measurements for Urology.	

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

The 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), Trans-esoph.(Cardiac), OB/Gyn and Urology.

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

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

Type	Manufacturer	Device	510 (K) Number
Main predicate device	Sonoscape Medical Corp.	P10 Series Digital Color Doppler Ultrasound System	K173058
Reference Device	Sonoscape Medical Corp.	X5 Digital Color Doppler Ultrasound System	K160258
Reference Device	Philips Ultrasound, Inc.	EPIQ 5/EPIQ 7 Diagnostic Ultrasound System	K160807

X5 Series Digital Color Doppler Ultrasound System has the same intended uses, complies with the same regulation and safety standards, has the consistent acoustic output levels, has similar probes and has the same technical characteristics as the predicate device legally marketed P10 Series (K173058) , X5 (K160258) and EPIQ 5/EPIQ (K160807).

#### Intended Use Comparison:

Compared with the predicate device P10 Series (K173058), the Subject Device X5 Series has the same intended use.

**Table 2 Intended use Comparison**

Subject Device	Predicate Device	Remark
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<b>SonoScape X5/X5 Exp/X5 Pro/X6 /X6Exp/X6 Pro</b>	<b>Legally marketed SonoScape P10 Exp, P10, P10Pro, P11, M10, P9 (K173058)</b>	
The 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), Trans-esoph.(Cardiac), 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 (pediatric and adult), Trans-esoph.(Cardiac), Laparoscopic, OB/Gyn and Urology.	Same

Technical Characteristics Comparison:

Compared with the predicate device P10 Series (K173058), the Subject Device X5 Series 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.

Probes Comparison:

Subject device X5 Series has the similar probes as the predicate device SonoScape P10 Series (K173058).

**Table 3 a) Probes Comparison**

<b>Subject device SonoScape X5/X5 Exp/X5 Pro/X6/X6 Exp/X6 Pro</b>	<b>Predicate Device SonoScape P10 Exp, P10, P10Pro, P11, M10, P9 (K173058)</b>	<b>Remark</b>
C322 Micro-curved Array C361 Micro-curved Array 3C-A Curved Array	C322 Micro-curved Array C351 Micro-curved Array C361 Micro-curved Array	

C1-6 Curved Array 6CT-A Curved Array 6CI-A Curved Array	3C-A Curved Array C1-6 Curved Array 6CT-A Curved Array 6CI-A Curved Array	
VC6-2 Curved Array C613 curved Array C542 curved Array	VC6-2 Curved Array C613 curved Array C542 curved Array	
2P1 Phased Array S1-5 Phased Array 7P-B Phased Array 3P-A Phased Array	2P1 Phased Array S1-5 Phased Array 7P-B Phased Array 3P-A Phased Array	
L741 Linear Array L746 Linear Array 10I2 Linear Array 9L-A Linear Array 12L-B Linear Array 13L-A Linear Array 18L-A Linear Array 10L-I Linear Array 12LT-A Linear Array 12LI-A Linear Array	L742 Linear Array L741 Linear Array L746 Linear Array 10I2 Linear Array 9L-A Linear Array 12L-B Linear Array 13L-A Linear Array 18L-A Linear Array 10L-I Linear Array 12LT-A Linear Array 12LI-A Linear Array	
6V1 Micro-curved Array 6V3 Micro-curved Array 6V3A Micro-curved Array 6V7 Micro-curved Array EC9-5 Micro-curved Array BCC9-5 Micro-curved Array	6V1 Micro-curved Array 6V3 Micro-curved Array 6V3A Micro-curved Array 6V7 Micro-curved Array EC9-5 Micro-curved Array BCC9-5 Micro-curved Array BCL10-5 Biplane (Micro-curved + Linear Array)	
CWD2.0 CW CWD5.0 CW MPTEE Phased Array MPTEE mini Phased Array	PWD2.0 Doppler CWD2.0 CW MPTEE Phased Array MPTEE mini Phased Array	<b>SE</b> Analysis 1



	LAP7 Linear Array	
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**SE Analysis 1:**

Compared with the predicate device, there is new CW probes (CWD5.0), which is similar with the probe D5cwc cleared with predicate device EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K160807). 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.

The engineering drawings of the additional transducers/probes (CWD5.0), and the further comparison are provided as follows.

**Table 3 b) Further Comparison for CWD5.0 Probes**

Comparison Items	Subject Device SonoScape X5/X5 Exp/X5 Pro/X6 /X6Exp/X6 Pro	Predicate Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K160807)	Remark
Probe1	CWD5.0	D5cwc	/
Photo			/
Probe Type	Doppler	Doppler	Same
Frequency	5.0MHz	5.0MHz	Same
Indication for use	Peripheral vessel, Cerebral Vascular	Peripheral vessel, Cerebral Vascular	Same
Operation Mode	CW	CW	Same
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Same

Therefore, they can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.


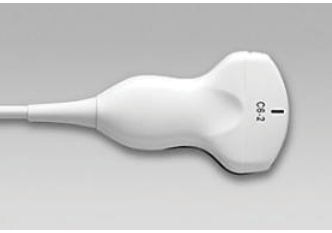
**Functional Comparison of probes**

Compared with the predicate device (K173058), there is new function of contrast

imaging in probes (C322, 3C-A and C1-6), which is similar with the probe (C6-2 and C5-1) cleared with predicate device EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K160807). 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.



The engineering drawings of the new function transducers(probes) (C322, 3C-A, C1-6), and the further comparison are provided as follows.

**Table 3 c) Further Comparison for C322 Probes**

Comparison Items	Subject Device SonoScape X5/X5 Exp/X5 Pro/X6 /X6Exp/X6 Pro	Predicate Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K160807)	Remark
Probe2	C322	C6-2	/
Photo			/
Probe Type	Micro-curved Array	Curved Array	Same
Frequency	2.0-7.0MHz	2.0-6.0MHz	SE Analysis 2
Indication for use	Fetal, Abdominal, Other(Ob/GYN)	General purpose abdominal (adult and pediatric, including vascular), bowel, obstetrical, gynecological, prostate and interventional applications	Same
Operation Mode	B,THI,M,CFM,PDI,PW	B,THI,M,CFM,PDI,PW	Same
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Same
Functions	Compound Imaging, THI, Contrast Imaging	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES, Elastography	SE Analysis 3





**Table 3 d) Further Comparison for 3C-A Probes**

Comparison Items	Subject Device SonoScape X5/X5 Exp/X5 Pro/X6 /X6Exp/X6 Pro	Predicate Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K160807)	Remark
Probe3	3C-A	C6-2	/
Photo			/
Probe Type	Curved Array	Curved Array	Same
Frequency	1.0-7.0MHz	2.0-6.0MHz	SE Analysis 2
Indication for use	Fetal, Abdominal, Other(Ob/GYN)	General purpose abdominal (adult and pediatric, including vascular), bowel, obstetrical, gynecological, prostate and interventional applications	Same
Operation Mode	B,THI,M,CFM,PDI,PW	B,THI,M,CFM,PDI,PW	Same
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Same
Functions	Compound Imaging, THI, Contrast Imaging	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES, Elastography	SE Analysis 3

**Table 3 e) Further Comparison for C1-6 Probes**

Comparison Items	Subject Device SonoScape X5/X5 Exp/X5 Pro/X6 /X6Exp/X6 Pro	Predicate Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System	Remark
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		(K160807)	
Probe4	C1-6	C5-1	/
Photo			/
Probe Type	Micro-curved Array	Curved Array	Same
Frequency	1.0-8.0MHz	1.0-5.0MHz	SE Analysis 2
Indication for use	Fetal, Abdominal, Other(Ob/GYN)	General purpose abdominal (adult and pediatric, including vascular), bowel, obstetrical, gynecological, prostate and interventional applications	Same
Operation Mode	B,THI,M,CFM,PDI,PW	B,THI,M,CFM,PDI,PW	Same
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Same
Functions	Compound Imaging, THI, Contrast Imaging	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES, PercuNav	SE Analysis 3

**SE Analysis 2:**

Although the frequency is different, the parameters of the subject device are included in the predicated device, and no new risk is raised.

**SE Analysis 3:**

Although the functions is different, the functions of the subject device are included in the predicated device, and no new risk is raised.

Moreover, compared with predicate device, the subject device (X5 Series) complies with the same regulation and safety standards and has the consistent acoustic output levels.

**Summary of the comparison**

Compared with the the predicate device legally marketed SonoScape X5 (K160258), the additional transducers, additional functions and updated intended use of the subjective device (X5 Series Digital Color Doppler Ultrasound System) are all analyzed with the predicate device P10 Series (K173058) and EPIQ 5/EPIQ (K160807). The comparison showed that they can be considered Substantially Equivalent in safety and effectiveness. Therefore, there is no new risk raised, and the SE is not affected.

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

Non-clinical testing to assure compliance with electrical, mechanical, thermal and electromagnetic compatibility safety, acoustic output and biocompatibility were performed and have been found to conform to applicable standards. The X5 Series 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];

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].

The new added probes and software feature are also verified through system tests and did not raise any concerns regarding safety or effectiveness. The relevant summarized information are as followed:

Performance test	Testing protocols and fail/acceptance criteria	Testing results
Electrical safety testing	IEC 60601-1:2005+A1:2012	Passed

EMC testing	IEC 60601-1-2:2007	Passed
Acoustic testing	IEC 60601-2-37:2007 AIUM/NEMA UD 2:2004 (R2009)	Passed
Software Verification and Validation	IEC 62304:2006 +A 1:2015	Passed

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

#### **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 Series Digital Color Doppler Ultrasound System is substantially equivalent to the predicate device with regard to safety and effectiveness.