



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

SONOSCAPE MEDICAL CORP.

April 4, 2016

Toki Wu  
4/f, 5/f, 8/f, 9/f & 10/f, Yizhe Building, Yuquan Road  
Nanshan, Shenzhen 518051, Guangdong  
CHINA

Re: K160283

Trade/Device Name: S45 Digital Color Doppler Ultrasound System  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, ITX  
Dated: January 22, 2016  
Received: February 1, 2016

Dear Ms. Wu:

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 Small Manufacturers, International and Consumer Assistance 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” (21CFR 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned above the typed name of the signatory.

For

Robert A. 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)  
K160283

Device Name  
S45 Digital Color Doppler Ultrasound System

### Indications for Use (Describe)

The SonoScape S45 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), Laparoscopic, 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 S45  
 Diagnostic Ultrasound Pulsed Echo System  
 Diagnostic Ultrasound Pulsed Doppler Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1	Notes 2,4,5
	Abdominal	N	N	N		N	N	Note 1	Notes 2,4,5
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic	N	N	N		N	N	Note 1	Notes 2,4
	Pediatric	N	N	N		N	N	Note 1	Notes 2,4
	Small Organ (specify)	N	N	N		N	N	Note 1	Notes 2,4,5,6,7
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Adult Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Trans-rectal	N	N	N		N	N	Note 1	Notes 2,4,5
	Trans-vaginal	N	N	N		N	N	Note 1	Notes 2,4,5
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Notes 2,4
	Intravascular								
Other (Ob/GYN)	N	N	N		N	N	Note 1	Notes 2,4,5	
Other (Urology)	N	N	N		N	N	Note 1	Notes 2,4,5	
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Intra-cardiac								
Other (specify)									
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Notes 2,4
	Cerebral vascular			N					

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

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

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

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

Note 6: Small Organ: breast, thyroid, testes

Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

Transducer: C322 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 2,4
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	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 2,4
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: 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 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Notes 2,4
	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								
	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: 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 2,4
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	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 2,4
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: 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 2,4
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	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 2,4
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: 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 2,4,5
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4,5
	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 2,4,5
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 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Notes 2,4
	Small Organ (specify)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	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 2,3,4
	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: 5P2 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 2,4
	Small Organ (specify)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	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 2,3,4
	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: 8P1 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 2,4
	Small Organ (specify)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	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 2,3,4
	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: 4P-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 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Adult Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	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 2,3,4
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3,4
	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: 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 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Adult Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	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 2,3,4
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3,4
	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-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								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Notes 2,4
	Small Organ (specify)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	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 2,3,4
	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: L742 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 2,4,6
	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 2,4
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Notes 2,4
	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 2,4
	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: L743 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 2,4,6
	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 2,4
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Notes 2,4
	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 2,4
	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: L752 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 2,4,6,7
	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 2,4
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Notes 2,4
	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 2,4
	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: 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 2,4,6	
	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 2,4
	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 2,4	
	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: 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)	N	N	N		N	N	Note 1	Notes 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Notes 2,4
	Intravascular								
Other (Ob/GYN)									
Other (Urology)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Other (specify)									
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Notes 2,4
	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: 12L-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 2,4,6	
	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 2,4
	Musculo-skeletal (Superficial)		P	P	P			P	P	Note 1	Notes 2,4
	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 2,4	
	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: VL12-5 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 2,4,5,6
	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 2,4
	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 2,4
	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 2,4
	Trans-vaginal		P	P	P		P	P	Note 1	Notes 2,4
	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 2,4	
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: 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 2,4
	Trans-vaginal		P	P	P		P	P	Note 1	Notes 2,4
	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 2,4	
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: 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 2,4
	Trans-vaginal	P	P	P			P	P	Note 1	Notes 2,4
	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 2,4	
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: 6V1A 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 2,4
	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

### 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 2,4
	Trans-vaginal		P	P	P		P	P	Note 1	Notes 2,4
	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 2,4	
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: BCC9-5 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 2,4
	Trans-vaginal		P	P	P		P	P	Note 1	Notes 2,4
	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 2,4	
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: BCL10-5 Biplane 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 2,4
	Trans-vaginal		P	P	P		P	P	Note 1	Notes 2,4
	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 2,4	
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: VE9-5 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 2,4,5
	Trans-vaginal		P	P	P		P	P	Note 1	Notes 2,4,5
	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 2,4,5	
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: 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 2,3,4
	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: 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 2,3,4
	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: LAP7 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	P	P	P		P	P	Note 1	Notes 2,4
	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								
	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: 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

### 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.  
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 Date Prepared January 22, 2016

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

Trade Name: S45 Digital Color Doppler Ultrasound System  
 Common Name: Diagnostic Ultrasound System and Transducers

Classification Regulatory:

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

Classification Panel: Radiology

Device Class: II

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

The identified predicate device within this submission is as follows:

SonoScape S50 Digital Color Doppler Ultrasound System K152854

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

This SonoScape S45 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 basic principle is that system transmits ultrasonic energy into patient body and implements post processing of received echoes to generate onscreen display of

anatomic structures and fluid flow within the body.

This system is a Track 3 device that employs a wide array of probes that include linear array, convex array and phased array.

This system consists of a mobile console with touch screen and keyboard control panel, power supply module, color LCD monitor and optional probes.

This system is a mobile, general purpose, software controlled, color diagnostic ultrasound system. Its basic function is to acquire ultrasound data and to display the image in B-Mode (including Tissue Harmonic Image), M-Mode, TDI, Color-Flow Doppler, Pulsed Wave Doppler, Continued Wave Doppler and Power Doppler, or the combination of these modes, Elastography, 3D/4D.

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

The SonoScape S45 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), Transrectal, Trans-vaginal, Peripheral Vascular, Cerebral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (pediatric and adult), Trans-esoph.(Cardiac), Laparoscopic, OB/Gyn and Urology.

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

S45 Digital Color Doppler Ultrasound System is comparable with and substantially equivalent to the predicate device:

SonoScape S50 Digital Color Doppler Ultrasound System	K152854
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*Intended Use Comparison:*

Compared with the predicate device SonoScape S50 (K152854), the Subject Device S45 has the same intended use.

*Technical Characteristics Comparison:*

The basic and key technical features of the Subject Device S45 are the same as the predicate device SonoScape S50 (K152854), including Design, Operation Controls, Display Modes, Operation Modes, Measurement Items, Cine Loop, Operating and Storage Condition.

The detailed technical features can be found in **General Device Descriptions** of this submission.

*Probes Comparison:*

Subject device S45 has the similar probes as the predicate device SonoScape S50 (K152854).

**Table 1 Probes Comparison**

<b>Subject device SonoScape S45</b>	<b>Predicate Device SonoScape S50 (K152854)</b>	<b>Remark</b>
C322 Micro-curved Array C542 Curved Array 3C-A Curved Array C1-6 Curved Array	C322 Micro-curved Array C542 Curved Array 3C-A Curved Array C1-6 Curved Array	<b>SE</b> Analysis1
VC6-2 Curved Array C613 Micro-curved Array	VC6-2 Curved Array C613 Micro-curved Array	
5P2 Phased Array 8P1 Phased Array 4P-A Phased Array S1-5 Phased Array 7P-A Phased Array	5P2 Phased Array 8P1 Phased Array 4P-A Phased Array S1-5 Phased Array 7P-A Phased Array	
L742 Linear Array L743 Linear Array L752 Linear Array 10I2 Linear Array 9L-A Linear Array 12L-A Linear Array VL12-5 Linear Array	L742 Linear Array L743 Linear Array L752 Linear Array 10I2 Linear Array 12L-A Linear Array VL12-5 Linear Array	
6V1 Micro-curved Array 6V3 Micro-curved Array 6V7 Micro-curved Array 6V1A Micro-curved Array EC9-5 Micro-curved Array BCC9-5 Micro-curved Array BCL10-5 Biplane (Micro-curved + Linear Array) VE9-5 Micro-curved Array	6V1 Micro-curved Array 6V3 Micro-curved Array 6V7 Micro-curved Array 6V1A Micro-curved Array EC9-5 Micro-curved Array BCC9-5 Micro-curved Array BCL10-5 Biplane (Micro-curved + Linear Array) VE9-5 Micro-curved Array	
MPTEE Phased Array (Multi-plane) MPTEE mini Phased Array (Multi-plane) LAP7 Linear Array CWD2.0 CW PWD2.0 TCD	MPTEE Phased Array (Multi-plane) MPTEE mini Phased Array (Multi-plane) LAP7 Linear Array CWD2.0 CW PWD2.0 TCD	

**SE Analysis 1:**

Compared with the predicate device, there is a new probe (9L-A), which is similar with the probe L743 cleared with predicate device SonoScape S50 (K152854). The clinical application is the same, the performance or frequency is similar, and the difference of these doesn't affect the safety, effectiveness and clinical use.

*Note: detailed description information about the new probe can be found in **Substantial Equivalence Comparison** of this submission.*

Moreover, compared with predicate device, the subject device (S45) 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 S45 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 S45 system met all design specifications and the S45 system conformed to applicable medical device standards.

The S45 system has been designed and manufactured to meet the following standards: IEC 60601-1:12005+A1:2012, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance [08/20/2012];

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

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

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

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

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

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

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

No clinical testing was required.

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

In accordance with the 21 CFR Part 807 and based on the information provided in this premarket notification, SONOSCAPE MEDICAL CORP. concludes that S45 Digital Color Doppler Ultrasound System is substantially equivalent to the predicate device with regard to safety and effectiveness.