510(k) Summary

JUN 2 1 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number: K131213

1. **Date of submission:** April 26, 2013

2. **Submitter**

   SonoScape Company Limited
   Address: Yizhe Building, Yuquan Road,Nanshan, Shenzhen 518051, P.R.China
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3. **Proposed Device Identification**

   Trade/Proprietary Name: S40 Digital Color Doppler Ultrasound System
   Common Name: Diagnostic Ultrasound System and Transducers
   Classification:
   21 FR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)
   21 FR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)
   21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)
   Classification Panel: Radiology
   Device Class: II

4. **Legally Marketed Predicate Device**

   SonoScape Company Limited, Diagnostic Ultrasound System, Model S6 has been cleared by FDA through 510(k) No.K112602 (Decision Date – November 07, 2011).

5. Device Description

The SonoScape S40 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 all digital architecture with progressive dynamic receive focusing allows the system to maximize the utility of all imaging transducers to enhance the diagnostic utility and confidence provided by the system. The exam dependent default setting allows the user to have minimum adjustment for imaging the patient, while the in-depth soft-menu control allows the advanced user to set the system for different situations. The architecture allows cost-effective system integration to a variety of upgrade-able options and features.

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

6. Intended Use Statement

The SonoScape S40 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, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

Transducer Information is shown in the table 1.

Table 1 Transducer Information

No.	Probe	Type	Frequency Range	Intended Use
1	C344	curved Array	2.0-5.0 MHz	Fetal / Abdominal/ Ob/GYN
2	C353	curved Array	2.0-6.0 MHz	Fetal / Abdominal/ Ob/GYN
3	C322	curved Array	2.0-6.0 MHz	Fetal / Abdominal/ Ob/GYN
4	VC6-2	curved Array	2.0-6.0 MHz	Fetal / Abdominal/ Ob/GYN
5	6V1	Micro-curved Array	4.0-8.0 MHz	Trans-rectal Trans-vaginal
6	6V3	Micro-curved	5.0-9.0 MHz	Trans-rectal

No.	Probe	Type	Frequency Range	Intended Use
		Array		Trans-vaginal
7	L741	Linear Array	5.0-10.0 MHz	Small Organ (breast, thyroid, testes) Musculo-skeletal (Conventional) Peripheral vessel
8	L742	Linear Array	5.0-12.0 MHz	Small Organ (breast, thyroid, testes) Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Peripheral vessel
9	L752	Linear Array	5.0-12.0 MHz	Small Organ (breast, thyroid, testes) Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Peripheral vessel
10	2P2	Phase Array	1.0-5.0 MHz	Abdominal Cephalic(neonatal and adult) Cardiac (neonatal and adult)
11	3P1	Phase Array	1.0-5.0 MHz	Abdominal Cephalic(neonatal and adult) Cardiac (neonatal and adult)
12	5P2	Phase Array	3.0-8.0 MHz	Pediatric Neonatal Cephalic Cardiac Pediatric
13	8P1	Phase Array	4.0-12.0 MHz	Pediatric Neonatal Cephalic Cardiac Pediatric

7. Testing

Laboratory testing was conducted to verify that the S40 system with added transducer met all design specification and was substantially equivalent to the Predicate Device. The device has been found to conform to applicable medical device safety standards in regards to thermal, mechanical and electrical safety as well as biocompatibility. The acoustic output is measured and calculated per "NEMA UID 2: 2004 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment".

Tab 2 Applicable Safety Standards

Standards No.	Standards Title	Version	Date
IEC 60601-1	Medical Electrical Equipment - Part1. General Requirements for Safety	1988+A1: 1991+A2: 1995	10/31/2005
IEC 60601-1-2	Medical Electrical Equipment, Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests	2007	03/01/2007
IEC 60601-2-37	Medical Electrical Equipment, Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment	2007	08/01/2007
NEMA UD 2	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Version 3	2004	01/01/2004 (R 2009)
NEMA UD3	Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment	2004	01/01/2004 (R 2009)
ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity	1999	05/15/1999
ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity	2002	09/01/2002

8. Clinical Test:

No clinical testing was required.

9. Comparison Table

The differences between the S40 and the predicate device S6 in almost every part are listed in the tables below.

Table 3 Intended Use Comparison

ID	Items	Proposed Device SonoScape S40	Predicate Device SonoScape S6	Remark
1	**Intended Use**	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, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), Urology and OB/Gyn.	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, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.	Same

Table 4 General Comparison

ID	Comparison Items	Proposed Device SonoScape S40	Predicate Device SonoScape S6	Remark
2	**Classification Name**	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasound Transducer	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasound Transducer	Same
3	**Product Code**	90-IYN/90-IYO/90-ITX	90-IYN/90-IYO/90-ITX	Same
4	**Regulation Number**	892.1550/892.1560/892.1570	892.1550/892.1560/892.1570	Same
5	**Panel**	Radiology	Radiology	Same
6	**Class**	II	II	Same
7	**Probe Type & Connectors**	L741 Linear Array, 5.0-10.0 MHz L742 Linear Array, 5.0-12.0 MHz L752 Linear Array, 5.0-12.0 MHz	L741 Linear Array, 5.0-10.0 MHz L742 Linear Array, 5.0-12.0 MHz L743 Linear Array, 5.0-10.0 MHz	SE **Analysis 1**

ID	Comparison Items	Proposed Device SonoScape S40	Predicate Device SonoScape S6	Remark
		C344 Curved Array, 2.0-5.0 MHz C322 Curved Array, 2.0-6.0 MHz C353 Curved Array, 2.0-6.0 MHz	C344 Curved Array, 2.0-5.0 MHz C362 Curved Array, 2.0-6.0 MHz	
		/	C611 Micro-curved Array, 4.0-8.0 MHz	
		VC6-2 Curved Array, 2.0-6.0 MHz	VC6-2 Curved Array, 2.0-6.0 MHz	
		6V1 Micro-curved Array, 4.0-8.0 MHz 6V3 Micro-curved Array, 5.0-9.0 MHz	6V1 Micro-curved Array, 4.0-8.0 MHz 6V3 Micro-curved Array, 5.0-9.0 MHz EC9-5 Micro-curved Array, 5.0-9.0 MHz	
		2P2 Phased Array, 1.0-5.0 MHz 3P1 Phased Array, 1.0-5.0 MHz 5P2 Phased Array, 3.0-8.0 MHz 8P1 Phased Array, 4.0-12.0 MHz	2P1 Phased Array, 2.0-4.0 MHz 5P1 Phased Array, 4.0-7.0 MHz	
		Multi-port connector connects 4 transducers	Multi-port connector connects 2 transducers	
8	**Acoustic Track**	TRACK 3	TRACK 3	Same

Table 5 Functions Comparison

ID	Comparison Items	Proposed Device SonoScape S40	Predicate Device SonoScape S6	Remark
9	**Design**	Based on an embedded Linux operating system.	Based on an embedded Linux operating system.	Same
		Based on a 128 channel full digital beam former.	Based on a 64 channel full digital beam former.	SE **Analysis 2**
		Autocorrelation for color processing and FFT for pulse	Autocorrelation for color processing and FFT for pulse	Same

ID	Comparison Items	Proposed Device SonoScape S40	Predicate Device SonoScape S6	Remark
		and CW Doppler processing.	and CW Doppler processing.	
		Supporting Linear, Curve linear and Phase array probes from 2 to 15 MHz.	Supporting Linear, Curve linear and Phase array probes from 2 to 15 MHz.	Same
		Cine play back capability	Cine play back capability	Same
		Image file archive	Image file archive	Same
		Software upgrade with USB flash drive.	Software upgrade with USB flash drive.	Same
		Digital Scan Converter 800×600	Digital Scan Converter 800×600	Same
		With touch panel	With full keyboard	SE **Analysis 3**
10	**Operation Controls**	TGC 8 slider	TGC 8 slider	Same
		Depth Range: 3 to 32 cm	Depth Range: 3 to 32 cm	Same
		Image sector size: 32 lines to full B (512 lines)	Image sector size: 32 lines to full B (256 lines)	SE **Analysis 4**
		Image Sector position: Steering within full maximum	Image Sector position: Steering within full maximum	Same
		B orientation flip :L/R key with marking on the screen	B orientation flip :L/R key with marking on the screen	Same
		B Dynamic range control: preset 14 curves over 140 dB	B Dynamic range control: preset 14 curves over 140 dB	Same
		Gray Scale Control: 7 Settings	Gray Scale Control: 7 Settings	Same
		Focal Number: 12 focal zone setting	Focal Number: 12 focal zone setting	Same
		B persistence: 0-95%	B persistence: 0-95%	Same
		Image Processing: Smoothing, edge enhancement	Image Processing: Smoothing, edge enhancement	Same
		PW sweeping speed 2,4,6,8 sec over display	PW sweeping speed 2,4,6,8 sec over display	Same
		PW Wall filter setting:16 settings,25 to 750 HZ	PW Wall filter setting:16 settings,25 to 750 HZ	Same
		PW sample volume:0.5 to 20mm	PW sample volume:0.5 to 20mm	Same
		PW/B update: with UPDATE key	PW/B update: with UPDATE key	Same
		PW cursor steering: Steer soft key	PW cursor steering: Steer soft key	Same
		PW angle correction:0 to 80 degree user control	PW angle correction:0 to 80 degree user control	Same

ID	Comparison Items	Proposed Device SonoScape S40	Predicate Device SonoScape S6	Remark
		PW spectrum dynamic range:10 preset curve over 15-48 dB	PW spectrum dynamic range:10 preset curve over 15-48 dB	Same
		Spectrum baseline shift and invert	Spectrum baseline shift and invert	Same
		Color ROI setting: trackball and set key to control size and position	Color ROI setting: trackball and set key to control size and position	Same
		Color steering on flat probe:±20, ±16,0	Color steering on flat probe:±20, ±16,0	Same
		Color Wall Filter: Color wall filter with 16 selection, 25-750 of PRF	Color Wall Filter: Color wall filter with 16 selection, 25-750 of PRF	Same
		Color priority-B priority soft menu	Color priority-B priority soft menu	Same
		Color Packet size: preset per Exam, horizontal, vertical, off	Color Packet size: preset per Exam, horizontal, vertical, off	Same
		Zoom adjustable	Zoom adjustable	Same
		Freeze control: Toggling freeze key	Freeze control: Toggling freeze key	Same
		Cine control: step, play backward, play continuously	Cine control: step, play backward, play continuously	Same
11	**Operation Mode**	B, M, PW, CW, CFM, DPI, TDI, Tissue Harmonic Image 3D/4D Mode Color M Mode	B, M, PW, CW, CFM, DPI, TDI, Tissue Harmonic Image 3D/4D Mode Color M Mode	Same
12	**Display Modes**	Dual B, Quad Display, B and M, B and Doppler B + Color, Dual B(Flow) Triplex mode: B,CFM, and PW/CW ; B,DPI, and PW/CW;B,THI and Color M, steer M Dual B and Color in real time Compound Imaging, Panoramic Imaging, Trapezoid Imaging.	Dual B, Quad Display, B and M, B and Doppler B + Color, Dual B(Flow) Triplex mode: B,CFM, and PW/CW ; B,DPI, and PW/CW;B,THI and Color M, steer M Dual B and Color in real time Compound Imaging, Panoramic Imaging, Trapezoid Imaging.	Same
13	**Measurement Items**	Distance; area; circumference; calipers; volume, velocity, HR, PI, RI. Cardiac. OB/GYN, Urology, Vascular and small	Distance; area; circumference; calipers; volume, velocity, HR, PI, RI. Cardiac. OB/GYN, Urology, Vascular and small	Same

ID	Comparison Items	Proposed Device SonoScape S40	Predicate Device SonoScape S6	Remark
		part package	part package	
14	Cine Loop	Automatic review/ manual review	Automatic review/ manual review	Same
		Review speed can be adjusted	Review speed can be adjusted	Same

Table 6 Specifications Comparison

ID	Comparison Items	Proposed Device SonoScape S40			Predicate Device SonoScape S6			Remark
15	Power Supply	Voltage: 110-127/220-240 VAC			Voltage: 110-240 VAC			SE Analysis 5
		Frequency: 50/60 Hz			Frequency: 50/60 Hz			
		Power Consumption: 450VA			Power Consumption: 110-240V AC, 2.7-1.2A			
16	Operating Condition	Temperature: 10~40℃			Temperature: 10~40℃			Same
		Relative humidity: 30~75%			Relative humidity: 30~75%			Same
		Air pressure: 700hPa ~1060hPa			Air pressure: 700hPa ~1060hPa			Same
17	Storage Condition	Temperature: -20~55℃			Temperature: -20~55℃			Same
		Relative humidity: 20~90%			Relative humidity: 20~90%			Same
		Air pressure: 700hPa ~1060hPa			Air pressure: 700hPa ~1060hPa			Same
18	Screen Size	18.5 inch Widescreen LCD monitor			15 inch Widescreen LCD monitor			SE Analysis 6
19	Measurement Accuracy	Parameter	Value range	Error range	Parameter	Value range	Error range	
		Display depth	Max 32.9 cm; (Probe depend)	±3%	Display depth	Max 32.9 cm; (Probe depend)	±3%	Same
		Distance	0~31.0 cm	±3%	Distance	0~31.0 cm	±3%	Same
		Area	Max. ≥855 cm^2	±7%	Area	Max. ≥855 cm^2	±7%	Same
		Angle	10~193°	±3%	Angle	10~193°	±3%	Same
		Circumference	200 cm	±3%	Circumference	200 cm	±3%	Same
		Volume	Max. 25000 cm^3	±10%	Volume	Max. 25000 cm^3	±10%	Same
		M-Mode time	2,4,6,8 S	±1%	M-Mode time	2,4,6,8 S	±1%	Same
		Heart Rate	8 ~ 1000 beats/sec	±3%	Heart Rate	8 ~ 1000 beats/sec	±3%	Same
		Slope	1300 cm/s	±3%	Slope	1300 cm/s	±3%	Same

ID	Comparison Items	Proposed Device SonoScape S40			Predicate Device SonoScape S6			Remark
		Velocity (PW)	0.04-2940 cm/s	Angle ≤60°, ≤5%	Velocity (PW)	0.04-2940 cm/s	Angle ≤60°, ≤5%	Same
		Velocity (CW)	0.12-3795 cm/s	Angle ≤60°, ≤5%	Velocity (CW)	0.13-3529 cm/s	Angle ≤60°, ≤5%	SE **Analysis 7**
		Velocity (Color)	1-298 cm/s	Angle ≤60°, ≤5%	Velocity (Color)	2-226cm/s	Angle ≤60°, ≤5%	
20	**Acoustic Output**	Track 3:MI,TIS,TIC,TIB Derated ispta: 720Mw/cm^2 maximum. TIS/TIB/TIC: 6.0 Maximum, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190W/cm^2 max			Track 3: MI,TIS,TIC,TIB Derated ispta: 720Mw/cm^2 maximum. TIS/TIB/TIC: 6.0 Maximum, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190W/cm^2 max			Same

Table 7 Safety Comparison

ID	Comparison Items	Proposed Device SonoScape S40	Predicate Device SonoScape S6	Remark
21	**Electrical Safety**	-IEC 60601-1	-IEC 60601-1	Same
22	**EMC**	-IEC 60601-1-2	-IEC 60601-1-2	Same
23	**Performance**	-IEC 60601-2-37	-IEC 60601-2-37	Same
24	**Biocompatibility**	-ISO 10993-5, -ISO 10993-10	-ISO 10993-5, -ISO 10993-10	Same
25	**Level of Concern Of Software**	Moderate level of concern system	Moderate level of concern system	Same

SE Analysis 1:

Probe Type & Connectors, Compare to the predicate device, the proposed device is with different probe type or frequency, such as L752, C353 etc. But no new intended use is added and all of them comply with IEC 60601-2-37; And the proposed device has 4 probe connection ports and the predicate device has 2 probe connection ports, but both of them comply with IEC 60601-1 and IEC 60601-1-2, therefore they can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

SE Analysis 2:

The proposed device is based on a 128 channel full digital beam former and the predicate device is 64, but the 128 channel is better than 64 channel in terms of the image quality. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.

SE Analysis 3:

The predicate device is with full keyboard and the proposed device is not, but both of them comply with IEC 60601-1 and IEC 60601-1-2. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.

SE Analysis 4:

The proposed device is with 512 lines image sector size and the predicate device is 256, but the 512 lines is better than 256 lines in terms of the image quality. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.

SE Analysis 5

The Power Supply of the proposed device and the predicate device are 110-127/220-240 VAC, 450VA and 110-240VAC, 2.7-1.2A respectively, but both of them comply with IEC60601-1 and IEC 60601-1-2. Therefore, power supply can be considered Substantially Equivalent in safety and effectiveness.

SE Analysis 6

The screen size of the proposed is larger than that of the S6. This difference is considered to have no effect on effectiveness and safety.

SE Analysis 7:

The proposed device and the predicate device are with different measurement accuracy in Velocity (CW/ Color), but the proposed device is better. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.

Discussion of Substantially Equivalent

The subject device has same intended use, similar product design, and same performance effectiveness, performance safety as the predicate device. The differences above between the subject device and predicate device do not affect the basic design

principle, usage, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety.

10. Substantially Equivalent Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, SonoScape Company Limited concludes that S40 Digital Color Doppler Ultrasound System is substantially equivalent to predicate devices with regard to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 21, 2013

SonoScape Company Limited
% Ms. Toki Wu
Yizhe Building, Yuquan Road, NanShan
Shenzhen, Guangdong 518051
P.R. CHINA

Re: K131213
Trade/Device Name: S40 Digital Color Doppler Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, and ITX
Dated: April 26, 2013
Received: May 2, 2013

Dear Ms. Wu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the S40 Digital Color Doppler Ultrasound System, as described in your premarket notification:

Transducer Model Number

2P2 Phase Array	3P1 Phase Array	5P2 Phase Array
8P1 Phase Array	6V1 Micro-curved Array	6V3 Micro-curved Array
C344 Curved Array	C353 Curved Array	C322 Curved Array
VC6-2 Curved Array	L741 Linear Array	L742 Linear Array
	L752 Linear Array	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. 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); 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.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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.

If you have any questions regarding the content of this letter, please contact Shing Chun Benny Lam, Ph.D. at (301) 796-9328.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosures

Indications for Use

510(k) Number: K131213

Device Name: S40 Digital Color Doppler Ultrasound System

Indications for Use: The SonoScape S40 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, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K131213

Diagnostic Ultrasound Indications for Use Form

System: SonoScape S40
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								
	Pediatric	N	N	N		N	N	Note 1	Notes 2,4
	Small Organ (specify)	N	N	N		N	N	Note 1	Notes 2,4,6
	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
	Trans-vaginal	N	N	N		N	N	Note 1	Notes 2,4
	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
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)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Notes 2,4
	Other (specify)								

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

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(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) _____

Diagnostic Ultrasound Indications for Use Form

Transducer: 2P2 Phase 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	CW D	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal	N	N	N		N	N	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	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								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
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)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

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

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Diagnostic Ultrasound Indications for Use Form

Transducer: 3P1 Phase Array
Diagnostic Ultrasound Transducer

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

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

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

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Diagnostic Ultrasound Indications for Use Form

Transducer: 5P2 Phase Array
Diagnostic Ultrasound Transducer

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Notes 2,4
	Small Organ (specify)								
	Neonatal Cephalic	N	N	N	N	N	N	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)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

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

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Diagnostic Ultrasound Indications for Use Form

Transducer: 8P1 Phase Array
Diagnostic Ultrasound Transducer

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Notes 2,4
	Small Organ (specify)								
	Neonatal Cephalic	N	N	N	N	N	N	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)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

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

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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)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

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

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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)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

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

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Diagnostic Ultrasound Indications for Use Form

Transducer: C344 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
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

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

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Diagnostic Ultrasound Indications for Use Form

Transducer: C353 Curved Array
Diagnostic Ultrasound Transducer
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal	N	N	N		N	N	Note 1	Notes 2,4
	Abdominal	N	N	N		N	N	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)	N	N	N		N	N	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

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

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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	N	N	N		N	N	Note 1	Notes 2,4
	Abdominal	N	N	N		N	N	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)	N	N	N		N	N	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

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

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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
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

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

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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 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	P	P	P	P	P	P	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
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
	Other (specify)								

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

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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)								
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
	Other (specify)								

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

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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)	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)								
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
	Other (specify)								

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

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