Sonoscape Medical Corp.
℅ Toki Wu
Regulatory Affairs Manager
Room 201 & 202, 12th Building, Shenzhen Software Park Phase II
1 Keji Middle 2nd Rd, Yuehai Subdistrict, Nanshan District
Shenzhen, Guangdong 518057
CHINA

July 30, 2020

Re: K201059
Trade/Device Name: S60 Elite Series/S70 Series Digital Color Doppler Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: July 2, 2020
Received: July 6, 2020

Dear Toki Wu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201059

Device Name
S60 Elite Series/S70 Series Digital Color Doppler Ultrasound System

Indications for Use *(Describe)*
The Digital Color Doppler Ultrasound System is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Cerebral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (pediatric and adult), Trans-esoph.(Cardiac), Laparoscopic, OB/Gyn and Urology.
The Modes of Operation include B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Tissue Harmonic Imaging, Power Doppler Imaging, Directional Power Doppler Imaging, Tissues Doppler Imaging, Pulse Inversion Harmonic Imaging, 3D/4D Imaging mode, Elastography Imaging, Contrast imaging, Panoramic Imaging, Trapezoid Imaging and their combination modes, and the system is intended to be used in a hospital or medical clinic.

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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510(k) Summary K201059

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

Submitter:	SONOSCAPE MEDICAL CORP.
Address:	Room 201 & 202, 12th Building, Shenzhen Software Park Phase II, 1 Keji Middle 2nd Road, Yuehai Subdistrict, Nanshan District, Shenzhen, 518057, Guangdong, China
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Email:	ra@sonoscape.net
Date Prepared	July 2, 2020

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

Trade Name:	S60 Elite Series/S70 Series Digital Color Doppler Ultrasound System
Models:	S60 Expert, S60 Classic, S60 Nov, S60 Super, S60 Speci, S60 Elite, S-Light, S70 Exp, S70, S70 Pro, S70S, S70 VO, S60S, S60N
Common Name:	Diagnostic Ultrasound System and Transducers

Classification Regulatory:

	CFR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System (Primary)	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

Classification Panel:	Radiology
Device Class:	II

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

The identified predicate device within this submission is as follows:

Type	Manufacturer	Device	510 (K) Number
Primary Predicate Device	SonoScape Medical Corp.	S60 Series Digital Color Doppler Ultrasound System	K172082
Reference	Philips	EPIQ 5/EPIQ 7 Diagnostic	K172607

Devices	Ultrasound, Inc.	Ultrasound System
Reference Devices	SonoScape Medical Corp.	P10 Series Digital Color Doppler Ultrasound System K173058

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

This SonoScape S60 Elite Series/S70 Series Digital Color Doppler Ultrasound System is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The 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, Power Doppler and Directional Power Doppler Imaging, or the combination of these modes, Contrast Imaging, Elastography, 3D/4D.

Note 1: The S60 Elite Series/S70 Series Digital Color Doppler Ultrasound System is considered as two serial products of S60 Elite Series (including S60 Expert, S60 Classic, S60 Nov, S60 Super, S60 Speci, S60 Elite, S-Light models) and S70 Series (including S70 Exp, S70, S70 Pro, S70S, S70 VO, S60S, S60N models), but they are the same except partial functions, including the same indications for use, configuration probe, design, hardware, software, mechanic construction, power supply board, main board, specification and etc.

5. Intended Use/Indications for Use [21 CFR 807.92(a) (5)]

5.1 Intended use

The Digital Color Doppler Ultrasound System is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal,

Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Cerebral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (pediatric and adult), Trans-esoph.(Cardiac), Laparoscopic, OB/Gyn and Urology.

5.2 Indications for use

The Digital Color Doppler Ultrasound System is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Cerebral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (pediatric and adult), Trans-esoph.(Cardiac), Laparoscopic, OB/Gyn and Urology.

The Modes of Operation include B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Tissue Harmonic Imaging, Power Doppler Imaging, Directional Power Doppler Imaging, Tissues Doppler Imaging, Pulse Inversion Harmonic Imaging, 3D/4D Imaging mode, Elastography Imaging, Contrast imaging, Panoramic Imaging, Trapezoid Imaging and their combination modes, and the system is intended to be used in a hospital or medical clinic.

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

S60 Elite Series/S70 Series Digital Color Doppler Ultrasound System is comparable with and substantially equivalent to the predicate device:

Type	Manufacturer	Device	510 (K) Number
Primary Predicate Device	SonoScape Medical Corp.	S60 Series Digital Color Doppler Ultrasound System	K172082
Reference Devices	Philips Ultrasound, Inc.	EPIQ 5/EPIQ 7 Diagnostic Ultrasound System	K172607
Reference Devices	SonoScape Medical Corp.	P10 Series Digital Color Doppler Ultrasound System	K173058

S60 Elite Series/S70 Series Digital Color Doppler Ultrasound System has the same intended uses, complies with the same regulation and safety standards, has the consistent acoustic output levels, has similar probes and has the same technical characteristics as the predicate device legally marketed S60 Series (K172082).

Intended Use Comparison:

Compared with the predicate device S60 Series (K172082), the Subject Device S60 Elite Series/S70 Series has the same intended use.

Table 2 Intended use Comparison

Subject Device SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/ S70/S70 Pro/S70S/S70 VO/S60S/S60N	Primary Predicate Device Legally marketed SonoScape S60 Exp/S60/S60 Pro/S60 VO/S60 Maso/S59 (K172082)	Remark
The Digital Color Doppler Ultrasound 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.	The Digital Color Doppler Ultrasound System is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Cerebral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (pediatric and adult), Trans-esoph.(Cardiac), Laparoscopic, OB/Gyn and Urology.	Same

Technical Characteristics Comparison:

Compared with the predicate device S60 Series (K172082), the Subject Device S60 Elite Series/S70 Series has the similar technical characteristics, including Design, Operation Controls, Display Modes, Operation Modes, Measurement Items, Cine Loop, Operating and Storage Condition. And the differences will not raise new risk and different questions of safety and effectiveness.

Probes Comparison:

Subject device S60 Elite Series/S70 Series has the similar probes as the predicate device SonoScape S60 Series (K172082).

Table 3 a) Probes Comparison

Subject Device SonoScape S60 Expert/S60	Primary Predicate Device Legally marketed	Remark

Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/ S70/S70 Pro/S70S/S70 VO/S60S/S60N	**SonoScape S60 Exp/S60/S60 Pro/S60 VO/S60 Maso/S59 (K172082)**	
C322 Micro-curved Array 3C-A Curved Array C1-6 Curved Array C1-6A Curved Array 6CT-A Curved Array 6CI-A Curved Array C2-9 Curved Array C613 Micro-curved Array VC2-9 Curved Array VC6-2 Micro-curved Array	C322 Micro-curved Array 3C-A Curved Array C1-6 Curved Array C1-6A Curved Array 6CT-A Curved Array 6CI-A Curved Array C2-9 Curved Array C613 Micro-curved Array VC2-9A Curved Array VC2-9 Curved Array	**SE** Analysis 1
6V1 Micro-curved Array 6V3 Micro-curved Array 6V3A Micro-curved Array 6V7 Micro-curved Array BCC9-5 Micro-curved Array BCL10-5 Biplane (Micro-curved + Linear Array) VE9-5 Micro-curved Array C3-10V Micro-curved Array	6V3 Micro-curved Array 6V3A Micro-curved Array 6V7 Micro-curved Array BCC9-5 Micro-curved Array BCL10-5 Biplane (Micro-curved + Linear Array) VE9-5 Micro-curved Array 12C-ER Micro-curved Array C3-10V Micro-curved Array	**SE** Analysis 1
8P1 Phased Array 4P-A Phased Array S1-5 Phased Array 7P-A Phased Array 3P-A Phased Array 7P-B Phased Array	8P1 Phased Array 4P-A Phased Array S1-5 Phased Array 7P-A Phased Array	**SE** Analysis 2
10I2 Linear Array 9L-A Linear Array 12L-A Linear Array 12L-B Linear Array 13L-A Linear Array	10I2 Linear Array 9L-A Linear Array 12L-A Linear Array VL12-5 Linear Array 12L-B Linear Array	**SE** Analysis 3

18L-A Linear Array 12LT-A Linear Array 12LI-A Linear Array L742 Linear Array L741 Linear Array L3-9 Linear Array	13L-A Linear Array 18L-A Linear Array ML3-18 Linear Array 12LT-A Linear Array 12LI-A Linear Array	
CWD2.0 CW MPTEE Phased Array MPTEE mini Phased Array LAP7 Linear Array	PWD2.0 Doppler CWD5.0 CW MPTEE Phased Array MPTEE mini Phased Array LAP7 Linear Array	**SE** Analysis 4

SE Analysis 1:

Compared with the predicate device, there are two new Micro-curved Array probes as followed: VC6-2, which is similar with the probe VC2-9 cleared with predicate device SonoScape S60 Series (K172082); and 6V1, which is similar with the probe 6V3 cleared with predicate device SonoScape S60 Series (K172082). All of these new transducers have been cleared in the P10 Series Digital Color Doppler Ultrasound System (K173058) and other series, manufactured by SONOSCAPE MEDICAL CORP.

SE Analysis 2:

Compared with the predicate device, there are two new Phased Array probes as followed: 3P-A, which is similar with the probe 4P-A cleared with predicate device SonoScape S60 Series (K172082). The new probe 7P-B which is similar with the probe 7P-A cleared with predicate device SonoScape S60 Series (K172082). All of these new transducers have been cleared in the P10 Series Digital Color Doppler Ultrasound System (K173058) and other series, manufactured by SONOSCAPE MEDICAL CORP.

SE Analysis 3:

Compared with the predicate device, there are two new Linear Array probes as followed: L742 and L3-9, which is similar with the probe 9L-A cleared with predicate device SonoScape S60 Series (K172082). The new transducers L742 have been cleared in the P10 Series Digital Color Doppler Ultrasound System (K173058) and other series, manufactured by SONOSCAPE MEDICAL CORP., and L3-9 is also legally marketed in S60 Series Digital Color Doppler Ultrasound System (K172082) and other series, manufactured by SONOSCAPE MEDICAL CORP.

SE Analysis 4:

Compared with the predicate device, there is a new CW probes as followed: CWD2.0, which is similar with the probe CWD5.0 cleared with predicate device SonoScape S60 Series (K172082). The new transducers CWD2.0 have been cleared in the P10 Series Digital Color Doppler Ultrasound System (K173058) and other series, manufactured by SONOSCAPE MEDICAL CORP.

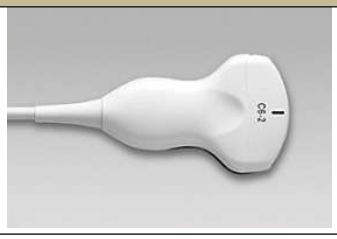
Therefore, they can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

Functional Comparison of probes

Compared with the predicate device SonoScape S60 Series (K172082), there is new function of contrast imaging in probes (3C-A, C1-6A, C1-6, C2-9, C322, 6CT-A, 6CI-A, 12L-A, 12L-B, 9L-A, L3-9, L741, L742, 10I2, 12LT-A, 12LI-A, 4P-A, 3P-A, S1-5, VE9-5, 6V1, 6V3, 6V7), which is similar with the probes (C6-2, L12-5, S5-1, C10-3v and C10-4ec) cleared with reference device EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607). The clinical application is the same, the performance or frequency is similar, and the difference of these doesn't affect the safety, effectiveness and clinical use.

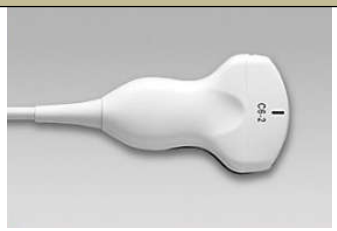
The engineering drawings of the new function transducers(probes) (3C-A, C1-6A, C1-6, C2-9, C322, 6CT-A, 6CI-A, 12L-A, 12L-B, 9L-A, L3-9, L741, L742, 10I2, 12LT-A, 12LI-A, 4P-A, 3P-A, S1-5, VE9-5, 6V1, 6V3, 6V7), and the further comparison are provided as followed.

Table 3 b) Further Comparison for 3C-A Probe

Comparison Items	Subject Device SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/ S70/S70 Pro/S70S/S70 VO/S60S/S60N	Reference Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607)	Remark
Probe 1	**3C-A**	**C6-2**	**/**
Photo			**/**

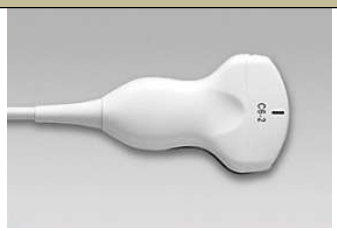
Probe Type	Curved Array	Curved Array	**Same**
Frequency	1.0-7.0MHz	2.0-6.0MHz	**SE** Analysis 5
Indication for use	Fetal, Abdominal, Other(Ob/GYN)	General purpose abdominal (adult and pediatric, including vascular), bowel, obstetrical, gynecological, prostate and interventional applications	**Same**
Operation Mode	B,THI,M,CFM,PDI,DPDI,PW	B,THI,M,CFM,PDI,PW	**SE** Analysis 6
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	**Same**
Functions	Compound Imaging, Contrast Imaging, Elastography	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES, Elastography	**SE** Analysis 7

Table 3 c) Further Comparison for C1-6A Probe

Comparison Items	**Subject Device SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/ S70/S70 Pro/S70S/S70 VO/S60S/S60N**	**Primary Predicate Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607)**	**Remark**
Probe 2	**C1-6A**	**C6-2**	**/**
Photo			**/**
Probe Type	Curved Array	Curved Array	**Same**
Frequency	1.0-8.0MHz	2.0-6.0MHz	**SE** Analysis 5

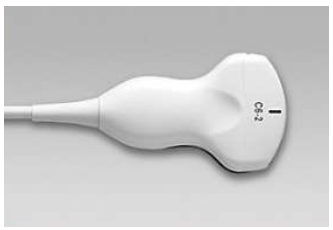
Indication for use	Fetal, Abdominal, Other(Ob/GYN)	General purpose abdominal (adult and pediatric, including vascular), bowel, obstetrical, gynecological, prostate and interventional applications	**Same**
Operation Mode	B,THI,M,CFM,PDI,DPDI, PW	B,THI,M,CFM,PDI,PW	**SE** Analysis 6
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	**Same**
Functions	Compound Imaging, Contrast Imaging, Elastography	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES, Elastography	**SE** Analysis 7

Table 3 d) Further Comparison for C1-6 Probe

Comparison Items	**Subject Device SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/ S70/S70 Pro/S70S/S70 VO/S60S/S60N**	**Reference Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607)**	**Remark**
Probe 3	**C1-6**	**C6-2**	**/**
Photo			**/**
Probe Type	Curved Array	Curved Array	**Same**
Frequency	1.0-8.0MHz	2.0-6.0MHz	**SE** Analysis 5
Indication for use	Fetal, Abdominal, Other(Ob/GYN)	General purpose abdominal (adult and pediatric, including vascular), bowel, obstetrical, gynecological, prostate and	**Same**

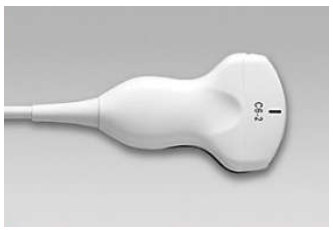
		interventional applications	
Operation Mode	B,THI,M,CFM,PDI,DPDI,PW	B,THI,M,CFM,PDI,PW	**SE** Analysis 6
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	**Same**
Functions	Compound Imaging, Contrast Imaging, Elastography	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES, Elastography	**SE** Analysis 7

Table 3 e) Further Comparison for C2-9 Probe

Comparison Items	**Subject Device SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/ S70/S70 Pro/S70S/S70 VO/S60S/S60N**	**Reference Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607)**	**Remark**
Probe 4	**C2-9**	**C6-2**	**/**
Photo			**/**
Probe Type	Curved Array	Curved Array	**Same**
Frequency	2.0-13.0MHz	2.0-6.0MHz	**SE** Analysis 5
Indication for use	Fetal, Abdominal, Other(Ob/GYN)	General purpose abdominal (adult and pediatric, including vascular), bowel, obstetrical, gynecological, prostate and interventional applications	**Same**
Operation Mode	B,THI,M,CFM,PDI,DPDI,PW	B,THI,M,CFM,PDI,PW	**SE** Analysis 6

Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	**Same**
Functions	Compound Imaging, Contrast Imaging	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES, Elastography	**SE** Analysis 7

Table 3 f) Further Comparison for C322 Probe

Comparison Items	**Subject Device SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/ S70/S70 Pro/S70S/S70 VO/S60S/S60N**	**Reference Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607)**	**Remark**
Probe 5	**C322**	**C6-2**	**/**
Photo			**/**
Probe Type	Micro-curved Array	Curved Array	**Same**
Frequency	2.0-7.0MHz	2.0-6.0MHz	**SE** Analysis 5
Indication for use	Fetal, Abdominal, Other(Ob/GYN)	General purpose abdominal (adult and pediatric, including vascular), bowel, obstetrical, gynecological, prostate and interventional applications	**Same**
Operation Mode	B,THI,M,CFM,PDI,DPDI,PW	B,THI,M,CFM,PDI,PW	**SE** Analysis 6
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	**Same**

Functions	Compound Imaging, THI, Contrast Imaging	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES, Elastography	**SE** Analysis 7

Table 3 g) Further Comparison for 6CT-A Probe

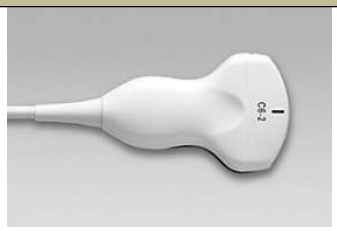
Comparison Items	**Subject Device SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/ S70/S70 Pro/S70S/S70 VO/S60S/S60N**	**Reference Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607)**	**Remark**
Probe 6	**6CT-A**	**C6-2**	**/**
Photo			**/**
Probe Type	Curved Array	Curved Array	**Same**
Frequency	3.0-15.0MHz	2.0-6.0MHz	**SE** Analysis 5
Indication for use	Fetal, Abdominal, Other(Ob/GYN)	General purpose abdominal (adult and pediatric, including vascular), bowel, obstetrical, gynecological, prostate and interventional applications	**Same**
Operation Mode	B,THI,M,CFM,PDI,DPDI,PW	B,THI,M,CFM,PDI,PW	**SE** Analysis 6
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	**Same**
Functions	Compound Imaging, THI, Contrast Imaging	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES, Elastography	**SE** Analysis 7

Table 3 h) Further Comparison for 6CI-A Probe

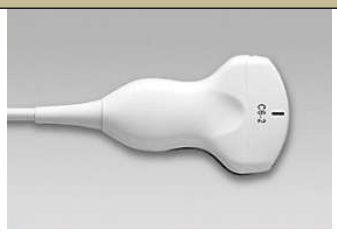
Comparison Items	Subject Device SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/ S70/S70 Pro/S70S/S70 VO/S60S/S60N	Reference Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607)	Remark
Probe 7	**6CI-A**	**C6-2**	**/**
Photo			**/**
Probe Type	Curved Array	Curved Array	**Same**
Frequency	3.0-15.0MHz	2.0-6.0MHz	**SE** Analysis 5
Indication for use	Fetal, Abdominal, Other(Ob/GYN)	General purpose abdominal (adult and pediatric, including vascular), bowel, obstetrical, gynecological, prostate and interventional applications	**Same**
Operation Mode	B,THI,M,CFM,PDI,DPDI,PW	B,THI,M,CFM,PDI,PW	**SE** Analysis 6
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	**Same**
Functions	Compound Imaging, THI, Contrast Imaging	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES, Elastography	**SE** Analysis 7

Table 3 i) Further Comparison for 12L-A Probe

Comparis	Subject Device	Reference Device	Remark

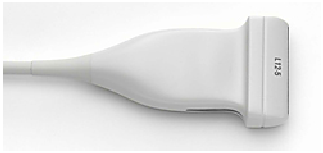
on Items	SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/ S70/S70 Pro/S70S/S70 VO/S60S/S60N	Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607)	
Probe 8	**12L-A**	**L12-5 50**	**/**
Photo			**/**
Probe Type	Linear Array	Linear Array	**Same**
Frequency	3.0-17.0MHz	5.0-12.0MHz	**SE** Analysis 5
Indication for use	Small Organ (breast, thyroid, testes), Musculo-skeletal (Conventional & Superficial), Peripheral vessel	Breast, thyroid and superficial small parts; musculoskeletal tendon, abdomen bowel, and vascular applications	**Same**
Operation Mode	B,THI,M,CFM,PDI,DPDI,PW	B,THI,M,CFM,PDI,PW	**SE** Analysis 6
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	**Same**
Functions	Compound Imaging, Contrast Imaging, Elastography	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES, Elastography	**SE** Analysis 7

Table 3 j) Further Comparison for 12L-B Probe

Comparison Items	Subject Device SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/ S70/S70 Pro/S70S/S70	Reference Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607)	Remark

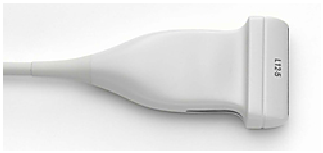
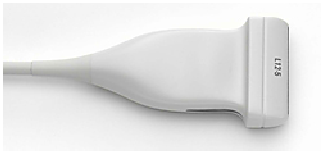
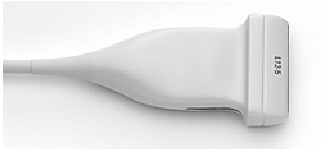
	VO/S60S/S60N		
Probe 9	**12L-B**	**L12-5 50**	**/**
Photo			**/**
Probe Type	Linear Array	Linear Array	**Same**
Frequency	3.0-17.0MHz	5.0-12.0MHz	**SE** Analysis 5
Indication for use	Small Organ (breast, thyroid, testes), Musculo-skeletal (Conventional & Superficial), Peripheral vessel	Breast, thyroid and superficial small parts; musculoskeletal tendon, abdomen bowel, and vascular applications	**Same**
Operation Mode	B,THI,M,CFM,PDI,DPDI,PW	B,THI,M,CFM,PDI,PW	**SE** Analysis 6
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	**Same**
Functions	Compound Imaging, Contrast Imaging, Elastography	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES, Elastography	**SE** Analysis 7

Table 3 k) Further Comparison for 9L-A Probe

Comparison Items	**Subject Device SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/ S70/S70 Pro/S70S/S70 VO/S60S/S60N**	**Reference Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607)**	**Remark**
Probe 10	**9L-A**	**L12-5 50**	**/**
Photo			**/**

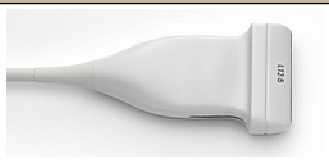
Probe Type	Linear Array	Linear Array	**Same**
Frequency	2.0-13.0MHz	5.0-12.0MHz	**SE** Analysis 5
Indication for use	Small Organ (breast, thyroid, testes), Musculo-skeletal (Conventional & Superficial), Peripheral vessel	Breast, thyroid and superficial small parts; musculoskeletal tendon, abdomen bowel, and vascular applications	**Same**
Operation Mode	B,THI,M,CFM,PDI,DPDI,PW	B,THI,M,CFM,PDI,PW	**SE** Analysis 6
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	**Same**
Functions	Compound Imaging, Contrast Imaging, Elastography	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES, Elastography	**SE** Analysis 7

Table 3 I) Further Comparison for L3-9 Probe

Comparison Items	**Subject Device SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/ S70/S70 Pro/S70S/S70 VO/S60S/S60N**	**Reference Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607)**	**Remark**
Probe 11	**L3-9**	**L12-5 50**	**/**
Photo			**/**
Probe Type	Linear Array	Linear Array	**Same**
Frequency	2.0-13.0MHz	5.0-12.0MHz	**SE** Analysis 5
Indication for use	Small Organ (breast, thyroid, testes), Musculo-skeletal (Conventional & Superficial),	Breast, thyroid and superficial small parts; musculoskeletal tendon, abdomen bowel, and	**Same**

	Peripheral vessel	vascular applications	
Operation Mode	B,THI,M,CFM,PDI,DPDI,PW	B,THI,M,CFM,PDI,PW	**SE** Analysis 6
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	**Same**
Functions	Compound Imaging, Contrast Imaging, Elastography	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES, Elastography	**SE** Analysis 7

Table 3 m) Further Comparison for L741 Probe

Comparison Items	**Subject Device SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/ S70/S70 Pro/S70S/S70 VO/S60S/S60N**	**Reference Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607)**	**Remark**
Probe 12	**L741**	**L12-5 50**	**/**
Photo			**/**
Probe Type	Linear Array	Linear Array	**Same**
Frequency	4.0-16.0MHz	5.0-12.0MHz	**SE** Analysis 5
Indication for use	Small Organ (breast, thyroid, testes), Musculo-skeletal (Conventional & Superficial), Peripheral vessel	Breast, thyroid and superficial small parts; musculoskeletal tendon, abdomen bowel, and vascular applications	**Same**
Operation Mode	B,THI,M,CFM,PDI,DPDI,PW	B,THI,M,CFM,PDI,PW	**SE** Analysis 6
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	**Same**

Functions	Compound Imaging, Contrast Imaging, Elastography	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES, Elastography	**SE** Analysis 7

Table 3 n) Further Comparison for L742 Probe

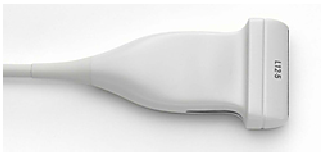
Comparison Items	**Subject Device SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/ S70/S70 Pro/S70S/S70 VO/S60S/S60N**	**Reference Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607)**	**Remark**
Probe 13	**L742**	**L12-5 50**	**/**
Photo			**/**
Probe Type	Linear Array	Linear Array	**Same**
Frequency	4.0-16.0MHz	5.0-12.0MHz	**SE** Analysis 5
Indication for use	Small Organ (breast, thyroid, testes), Musculo-skeletal (Conventional & Superficial), Peripheral vessel	Breast, thyroid and superficial small parts; musculoskeletal tendon, abdomen bowel, and vascular applications	**Same**
Operation Mode	B,THI,M,CFM,PDI,DPDI,PW	B,THI,M,CFM,PDI,PW	**SE** Analysis 6
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	**Same**
Functions	Compound Imaging, Contrast Imaging, Elastography	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES, Elastography	**SE** Analysis 7

Table 3 o) Further Comparison for 10l2 Probe

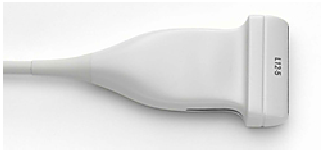
Comparison Items	Subject Device SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/ S70/S70 Pro/S70S/S70 VO/S60S/S60N	Reference Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607)	Remark
Probe 14	**10l2**	**L12-5 50**	**/**
Photo			**/**
Probe Type	Linear Array	Linear Array	**Same**
Frequency	4.0-16.0MHz	5.0-12.0MHz	**SE** Analysis 5
Indication for use	Small Organ (breast, thyroid, testes), Musculo-skeletal (Conventional & Superficial), Peripheral vessel	Breast, thyroid and superficial small parts; musculoskeletal tendon, abdomen bowel, and vascular applications	**Same**
Operation Mode	B,THI,M,CFM,PDI,DPDI,PW	B,THI,M,CFM,PDI,PW	**SE** Analysis 6
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	**Same**
Functions	Compound Imaging, Contrast Imaging	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES, Elastography	**SE** Analysis 7

Table 3 p) Further Comparison for 12LT-A Probe

Comparison Items	Subject Device SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/	Reference Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607)	Remark

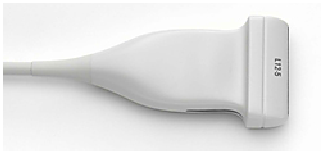
	S70/S70 Pro/S70S/S70 VO/S60S/S60N		
Probe 15	**12LT-A**	**L12-5 50**	**/**
Photo			**/**
Probe Type	Linear Array	Linear Array	**Same**
Frequency	4.0-16.0MHz	5.0-12.0MHz	**SE** Analysis 5
Indication for use	Small Organ (breast, thyroid, testes), Musculo-skeletal (Conventional & Superficial), Peripheral vessel	Breast, thyroid and superficial small parts; musculoskeletal tendon, abdomen bowel, and vascular applications	**Same**
Operation Mode	B,THI,M,CFM,PDI,DPDI,PW	B,THI,M,CFM,PDI,PW	**SE** Analysis 6
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	**Same**
Functions	Compound Imaging, Contrast Imaging	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES, Elastography	**SE** Analysis 7

Table 3 q) Further Comparison for 12LI-A Probe

Comparison Items	**Subject Device SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/ S70/S70 Pro/S70S/S70 VO/S60S/S60N**	**Reference Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607)**	**Remark**
Probe 16	**12LI-A**	**L12-5 50**	**/**

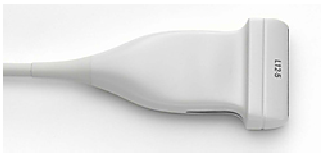
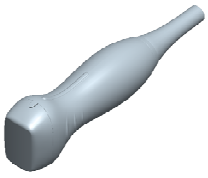
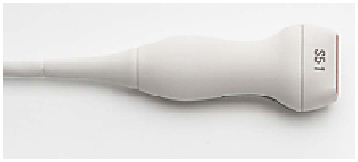
Photo			**/**
Probe Type	Linear Array	Linear Array	**Same**
Frequency	4.0-16.0MHz	5.0-12.0MHz	**SE** Analysis 5
Indication for use	Small Organ (breast, thyroid, testes), Musculo-skeletal (Conventional & Superficial), Peripheral vessel	Breast, thyroid and superficial small parts; musculoskeletal tendon, abdomen bowel, and vascular applications	**Same**
Operation Mode	B,THI,M,CFM,PDI,DPDI,PW	B,THI,M,CFM,PDI,PW	**SE** Analysis 6
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	**Same**
Functions	Compound Imaging, Contrast Imaging	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES, Elastography	**SE** Analysis 7

Table 3 r) Further Comparison for 4P-A Probe

Comparison Items	**Subject Device SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/ S70/S70 Pro/S70S/S70 VO/S60S/S60N**	**Reference Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607)**	**Remark**
Probe 17	**4P-A**	**S5-1**	**/**
Photo			**/**
Probe Type	Phased Array	Phased Array	**Same**

Frequency	1.0-6.0MHz	1.0-5.0MHz	**SE** Analysis 5
Indication for use	Abdominal, Cephalic, Cardiac	Abdominal, Cephalic, Cardiac	**Same**
Operation Mode	B,THI,M,CFM,PDI,DPDI,PW	B,THI,M,CFM,PDI,PW	**SE** Analysis 6
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	**Same**
Functions	Compound Imaging, Contrast Imaging	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES	**SE** Analysis 7

Table 3 s) Further Comparison for 3P-A Probe

Comparison Items	**Subject Device SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/ S70/S70 Pro/S70S/S70 VO/S60S/S60N**	**Reference Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607)**	**Remark**
Probe 18	**3P-A**	**S5-1**	**/**
Photo			**/**
Probe Type	Phased Array	Phased Array	**Same**
Frequency	1.0-6.0MHz	1.0-5.0MHz	**SE** Analysis 5
Indication for use	Abdominal, Cephalic, Cardiac	Abdominal, Cephalic, Cardiac	**Same**
Operation Mode	B,THI,M,CFM,PDI,DPDI,PW	B,THI,M,CFM,PDI,PW	**SE** Analysis 6
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum	**Same**

	MI: 1.9 maximum	MI: 1.9 maximum	
Functions	Compound Imaging, Contrast Imaging	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES	**SE** Analysis 7

Table 3 t) Further Comparison for S1-5 Probe

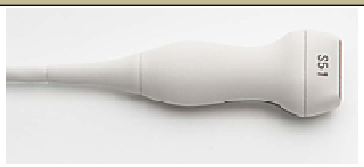
Comparison Items	**Subject Device SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/ S70/S70 Pro/S70S/S70 VO/S60S/S60N**	**Reference Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607)**	**Remark**
Probe 19	**S1-5**	**S5-1**	**/**
Photo			**/**
Probe Type	Phased Array	Phased Array	**Same**
Frequency	1.0-7.0MHz	1.0-5.0MHz	**SE** Analysis 5
Indication for use	Abdominal, Cephalic, Cardiac	Abdominal, Cephalic, Cardiac	**Same**
Operation Mode	B,THI,M,CFM,PDI,DPDI,PW	B,THI,M,CFM,PDI,PW	**SE** Analysis 6
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	**Same**
Functions	Compound Imaging, Contrast Imaging	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES	**SE** Analysis 7

Table 3 u) Further Comparison for VE9-5 Probe

Comparison Items	Subject Device SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/ S70/S70 Pro/S70S/S70 VO/S60S/S60N	Reference Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607)	Remark
Probe 20	**VE9-5**	**C10-3v**	**/**
Photo			**/**
Probe Type	Micro-curved Array	Curved Array	**Same**
Frequency	2.0-13.0MHz	3.0-10.0MHz	**SE** Analysis 5
Indication for use	Trans-vaginal	Fetal/OB, Trans-vaginal, Other: GYN/Urology	**Same**
Operation Mode	B,THI,M,CFM,PDI,DPDI,PW	B,THI,M,CFM,PDI,PW	**SE** Analysis 6
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	**Same**
Functions	Compound Imaging, Contrast Imaging, 3D/4D	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES	**SE** Analysis 7

Table 3 v) Further Comparison for 6V1 Probe

Comparison Items	Subject Device SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/	Reference Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607)	Remark

	S70/S70 Pro/S70S/S70 VO/S60S/S60N		
Probe 21	**6V1**	**C10-4ec**	**/**
Photo			**/**
Probe Type	Micro-curved Array	Curved Array	**Same**
Frequency	3.0-15.0MHz	3.0-10.0MHz	**SE** Analysis 5
Indication for use	Trans-rectal, Trans-vaginal	Fetal/OB, Trans-rectal, Trans-vaginal, Peripheral vessel, Other: GYN/Urology	**Same**
Operation Mode	B,THI,M,CFM,PDI,DPDI,PW	B,THI,M,CFM,PDI,PW	**SE** Analysis 6
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	**Same**
Functions	Compound Imaging, Contrast Imaging	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES	**SE** Analysis 7

Table 3 w) Further Comparison for 6V3 Probe

Comparison Items	**Subject Device SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/ S70/S70 Pro/S70S/S70 VO/S60S/S60N**	**Reference Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607)**	**Remark**
Probe 22	**6V3**	**C10-4ec**	**/**

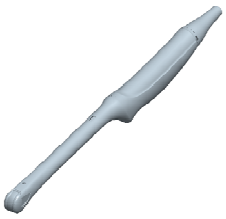
Photo			/
Probe Type	Micro-curved Array	Curved Array	**Same**
Frequency	3.0-15.0MHz	3.0-10.0MHz	**SE** Analysis 5
Indication for use	Trans-rectal, Trans-vaginal	Fetal/OB, Trans-rectal, Trans-vaginal, Peripheral vessel, Other: GYN/Urology	**Same**
Operation Mode	B,THI,M,CFM,PDI,DPDI,PW	B,THI,M,CFM,PDI,PW	**SE** Analysis 6
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	**Same**
Functions	Compound Imaging, Contrast Imaging, Elastography	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES	**SE** Analysis 7

Table 3 x) Further Comparison for 6V7 Probe

Comparison Items	**Subject Device SonoScape S60 Expert/S60 Classic/S60 Nov/S60 Super/S60 Speci/S60 Elite/S-Light/S70 Exp/ S70/S70 Pro/S70S/S70 VO/S60S/S60N**	**Reference Device Legally marketed EPIQ 5/EPIQ 7 Diagnostic Ultrasound System (K172607)**	**Remark**
Probe 23	**6V7**	**C10-4ec**	/
Photo			/

Probe Type	Micro-curved Array	Curved Array	**Same**
Frequency	3.0-15.0MHz	3.0-10.0MHz	**SE** Analysis 5
Indication for use	Trans-rectal, Trans-vaginal	Fetal/OB, Trans-rectal, Trans-vaginal, Peripheral vessel, Other: GYN/Urology	**Same**
Operation Mode	B,THI,M,CFM,PDI,DPDI,PW	B,THI,M,CFM,PDI,PW	**SE** Analysis 6
Acoustic Output Limits	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	Derated ISPTA: 720mW/cm2 maximum TIS/TIB/TIC: 6.0 maximum MI: 1.9 maximum	**Same**
Functions	Compound Imaging, Contrast Imaging, Elastography	Compound Imaging, CPA, harmonic Imaging, Contrast Imaging, 3D/4D Imaging, XRES	**SE** Analysis 7

SE Analysis 5：

Although the frequency is different, all of them comply with the requirements of IEC 60601-1 & IEC 60601-1-2 & IEC 60601-2-37 and meet clinical requirements, and no new risk is raised.

SE Analysis 6：

Although the operation mode is different, the new operation mode of DPDI (Directional Power Doppler Imaging) is similar to the PDI mode sequence with direction, and no new risk is raised.

SE Analysis 7：

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

Moreover, compared with predicate device, the subject device (S60 Elite Series/S70 Series) complies with the same regulation and safety standards and has the consistent acoustic output levels.

Summary of the comparison

Compared with the predicate device legally marketed SonoScape S60 Series (K172082), Philips EPIQ 5 and EPIQ 7 Diagnostic Ultrasound Systems (K172607) and SonoScape P10 Series (K173058), the subjective device (S60 Elite Series/S70 Series

Digital Color Doppler Ultrasound System) are all analyzed with the predicate device. The comparison showed that they can be considered Substantially Equivalent in safety and effectiveness. Therefore, there is no new risk raised, and the SE is not affected.

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

Non-clinical testing to assure compliance with electrical, mechanical, thermal and electromagnetic compatibility safety, acoustic output and biocompatibility were performed and have been found to conform to applicable standards. The S60 Elite Series/S70 Series system has been designed and manufactured to meet the following standards:

IEC 60601-1:2005+A1:2012, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance [08/20/2012];
IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2 General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests [2014-02];
IEC 60601-2-37:2015 Medical Electrical Equipment-Part 2-37: Particular requirements for basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment [Edition 2.1, 2015];
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].

The Digital Color Doppler Ultrasound System is verified through the relevant summarized information as followed:

Performance test	Testing protocols and fail/acceptance criteria	Testing results
Electrical safety testing	IEC 60601-1:2005+A1:2012	Passed
EMC testing	IEC 60601-1-2:2014	Passed
Acoustic testing	IEC 60601-2-37:2015 AIUM/NEMA UD 2:2004 (R2009)	Passed
Software Verification and Validation	IEC 62304:2006 +A 1:2015	Passed

Laboratory tests (including Phantom tests) were conducted to verify that the S60 Elite Series/S70 Series system met all design specifications and the S60 Elite Series/S70 Series system conformed to applicable medical device standards.

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

No clinical testing was required.

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

In accordance with the 21 CFR Part 807 and based on the information provided in this premarket notification, SONOSCAPE MEDICAL CORP. concludes that S60 Elite Series/S70 Series Digital Color Doppler Ultrasound System is substantially equivalent to the predicate device with regard to safety and effectiveness.