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

October 10, 2014

GE MEDICAL SYSTEMS ISRAEL LTD.
% Mr. Bryan Behn
Regulatory Affairs Manager
GE Healthcare
9900 Innovation Drive
WAUWATOSA WI 53226

Re: K142323
Trade/Device Name: Vivid S60/S70 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: August 18, 2014
Received: August 20, 2014

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Vivid S60 Diagnostic Ultrasound System, Vivid S70 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

12S-D	6S-D	P2D
9L-D	6VT-D	C1-6-D
M5Sc-D	6Tc/6Tc-RS	

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142323

Device Name
Vivid S60/S70 Diagnostic Ultrasound System

Indications for Use *(Describe)*
The device is intended for use by a qualified physician for ultrasound evaluation of Fetal/Obstetrics; Abdominal (Including Renal & Gyn); Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatrics); Peripheral Vascular (PV); Musculo-skeletal Conventional; Urology (including prostate) and Transesophageal.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Indications for Use Forms

The following forms represent indications with clinical applications and exam types along with the modes of operation for the Vivid S60/S70 system.
Combinations identified “P” for the transducers represents those previously cleared with another GE Ultrasound system.
Combinations identified “N” for the transducers represents those that are new.

Diagnostic Ultrasound Indications for Use Form
GE Vivid S60/S70 Ultrasound System

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	RT3D Mode♦
Ophthalmic											
Fetal / Obstetrics	N	N	N	N	N	N	N	N	N	N	
Abdominal[1]	N	N	N	N	N	N	N	N	N	N	
Pediatric	N	N	N	N	N	N	N	N	N	N	
Small Organ[2]	N	N	N		N	N	N	N	N	N	
Neonatal Cephalic	N	N	N	N	N	N	N	N	N	N	
Adult Cephalic	N	N	N	N	N	N	N	N	N	N	
Cardiac[3]	N	N	N	N	N	N	N	N	N	N	N
Peripheral Vascular	N	N	N	N	N	N	N	N	N	N	
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N	N	
Musculo-skeletal Superficial											
Other[4]	N	N	N	N	N	N	N	N	N	N	
Exam Type, Means of Access											
Transesophageal	N	N	N	N	N	N	N	N	N	N	N
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology/Prostate
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
[♦] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

System provides real-time 3D and 4D acquisition when used with special 4D probes.

GE Vivid S60/S70 with 12S-D Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	RT3D Mode♦
Ophthalmic											
Fetal / Obstetrics											
Abdominal	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	
Adult Cephalic											
Cardiac[1]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K121063, K131514); E = added under Appendix E

Notes: [1] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.
[♦] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

GE Vivid S60/S70 with 9L-D Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	RT3D Mode♦
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Small Organ[2]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Musculo-skeletal Conventional	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K131514); E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid.
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.
[♦] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

GE Vivid S60/S70 with M5Sc-D Transducer

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

Clinical Application	Mode of Operation										
Anatomy/Region of Interest	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	RT3D Mode♦
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	P	
Abdominal	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	P	P	P	P	P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K131514); E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology/Prostate
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.
[♦] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

GE Vivid S60/S70 with 6S-D Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	RT3D Mode♦
Ophthalmic											
Fetal / Obstetrics	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Abdominal	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Pediatric	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Small Organ[2]											
Neonatal Cephalic	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Adult Cephalic											
Cardiac[3]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K131514); E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.
[♦] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

GE Vivid S60/S70 with 6VT-D Transducer

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

Clinical Application *Anatomy/ Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	RT3D Mode♦
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K141093); E = added under Appendix E

Notes: [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
[♦] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

GE Vivid S60/S70 with 6Tc/6Tc-RS Transducer **

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

Clinical Application *Anatomy/ Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	RT3D Mode♦
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K121063); E = added under Appendix E

Notes: [3] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
[♦] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);
[**] 6Tc differs from 6Tc-RS only in the connector type.

GE Vivid S60/S70 with P2D Transducer

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

Clinical Application *Anatomy/ Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	RT3D Mode♦
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]				**P**							
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K131514); E = added under Appendix E

Notes: [3] Cardiac is Adult and Pediatric.
[♦] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

GE Vivid S60/S70 with C1-6-D Transducer

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

Clinical Application	Mode of Operation										
Anatomy/Region of Interest	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	RT3D Mode♦
Ophthalmic											
Fetal / Obstetrics	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Abdominal[1]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Pediatric	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K123564); E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes, thyroid.

[4] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.

[♦] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	August 18, 2014
Submitter:	GE Healthcare 9900 Innovation Dr Wauwatosa, WI 53226
Primary Contact Person:	Bryan Behn Regulatory Affairs Manager GE Healthcare T:(414)721-4214 F:(414)918-8275
Alternate Contact Person:	Karin Shimoni Regulatory Affairs Leader GE Healthcare T: +972-4-8519-619 F: +972-4-8519-500
Device: Trade Name:	Vivid S60 and Vivid S70 Diagnostic Ultrasound System
Common/Usual Name:	Vivid S60, Vivid S70
Classification Names:	Class II
Product Code:	Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550 90-IYN Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX
Predicate Device(s):	K1315141 Vivid E9 Diagnostic Ultrasound System. K121063 Vivid S5/S6 Diagnostic Ultrasound System. K141093 6VT-D Diagnostic Ultrasound Transducer. K123564 Logiq E9 Diagnostic Ultrasound System.
Device Description:	The Vivid S60/S70 is a Track 3 diagnostic ultrasound system, which is primarily intended for echocardiography imaging and analysis, with additional capability in vascular and general ultrasound imaging. The Vivid S60/S70 incorporates a variety of electronic array transducers that provide digital acquisition, processing and display capabilities, and operate in linear, curved linear, sector/ phased array format or matrix array format, including CW transducer and a real time 3D transducer. Vivid S60/S70 consists of a mobile console approximately 56 cm wide, 77 cm deep and 120 cm high, and includes multiple electronic array transducers that provide digital acquisition, processing and display capabilities. The user interface includes a variable height, rotatable, user control panel with specialized controls, a 19-inch wide screen LCD display and a separate 12.1-inch touch panel with a resolution of 1280x800 with multi-touch capabilities.

Intended Use: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal/Obstetrics; Abdominal (Including Renal & Gyn); Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatrics); Peripheral Vascular (PV); Musculo-skeletal Conventional; Urology (including prostate) and Transesophageal.

Technology: The Vivid S60/S70 employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Comparison to predicate

The Vivid S60/S70 systems are substantially equivalent to the predicate devices with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

	Proposed Device Vivid S60/S70	**Predicate Device Vivid E9 (K131514)**
Indications and Clinical Applications:		
• Fetal/Obstetrics;	✓	✓
• Abdominal (Including Renal & Gyn)	✓	✓
• Pediatric	✓	✓
• Small Organ (breast, testes, thyroid);	✓	✓
• Neonatal Cephalic;	✓	✓
• Adult Cephalic;	✓	✓
• Cardiac (adult and pediatrics);	✓	✓
• Peripheral Vascular;	✓	✓
• Musculo-skeletal Conventional	✓	✓
• Urology (including prostate);	✓	✓
• Transesophageal;	✓	✓
• Transrectal (TR);		✓
• Transvaginal (TV);		✓
• Intraoperative (abdominal, thoracic, & vascular).		✓
Probe Array: Phased Array, Matrix Single Crystal Phased Array Probe, Linear, Curved, pencil (Doppler), Transesophageal	✓	✓

Image modes: B, M, Color M, Color/Power Doppler, Pulsed & CW Doppler, Combined modes: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD. Harmonic, Coded Pulse, Realtime 3D & Multi-plane.	✓	✓
Transducers		
• M5Sc-D	✓	✓
• 6S-D	✓	✓
• 12S-D	✓	✓
• 6VT-D	✓	✓
• 6Tc-RS/6Tc	✓ (K121063)	✓
• 9L-D	✓	✓
• C1-6-D	✓ (same transducer as that on the predicate LOGIQ E9 K123564)	
• P2D	✓	✓
• 4V-D		✓
• ML6-15-D		✓
• i13L		✓
• 4C-D		✓
• 11L-D		✓
• M4S-D		✓
• M5S-D		✓
• 3V-D		✓
• E8C-D		✓
• 9T		✓
• P6D		✓
• 8C		✓
• iC5-9-D		✓
• C1-5-D		✓
• C2-9-D		✓

Processing &Display features: Image mapping (color & gray), Time/ spatial filtering and enhancement, TGC, TVI, SI/SRI, TSI, Harmonic Imaging, Pulsatile-Flow, B-Flow, Extended FOV, Tissue Tracking, Realtime 3D and Multi-plane processing, 2D Stress, Blood Flow Imaging (BFI), Spatial Compounding / Speckle Reduction imaging, Slice View, LaserLines, Continuous Tissue Optimization (CTO), Realtime 3D Color Flow, Automated Functional Imaging (AFI w/ Bull's Eye display), LCD display, StereoVision	✓	✓
Multiplane Stress, 4D Stress, TSI w/ surface rendering, Triplane AFI		✓
AFI Stress, Smart Depth	✓ (same features as that on the predicate Vivid S5/S6 K121063)	
Tested to meet Electrical Safety, EMC and Biocompatibility Standards	✓	✓
Track 3 (within FDA limits)	✓	✓

Summary of Non-Clinical Tests:

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety, and has been found to conform with applicable medical device safety standards. The Vivid S60/S70 and its applications comply with voluntary standards:

1. AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety
2. IEC60601-1-2,Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral

Standard: Electromagnetic Compatibility Requirements and Tests

3. IEC60601-2-37, Medical Electrical Equipment – Part 2-37:Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
4. NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
5. ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Third Edition
6. NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
7. ISO14971, Application of risk management to medical devices
8. NEMA, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)

The following quality assurance measures are applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final Acceptance Testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, Vivid S60/S70, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Vivid S60/S70 to be as safe, as effective, and performance is substantially equivalent to the predicate devices.