



October 19, 2018

GE Medical Systems Ultrasound and Primary Care Diagnostics
Tracey Ortiz
Regulatory Affairs Director
9900 W. Innovation Drive
WAUWATOSA, WI 53226

Re: K182450

Trade/Device Name: Vivid S60N, Vivid S70N
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: September 6, 2018
Received: September 7, 2018

Dear Tracey Ortiz:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink, appearing to read "Rob A. Ochs", is written over a large, light blue, semi-transparent "FDA" watermark.

for
Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K182450

Device Name

Vivid S60N, Vivid S70N

Indications for Use (Describe)

Vivid S60N/Vivid S70N is a general-purpose ultrasound system, specialized for use in cardiac imaging. It is intended for use by, or under the direction of a qualified physician for ultrasound imaging and analysis for the following applications: Fetal/Obstetrics; Abdominal (Including Renal & Gyn); Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional; Musculo-skeletal Superficial; Urology (including prostate); Transesophageal; Transvaginal; Transrectal; Intra-cardiac; Intra-luminal and Intraoperative (abdominal, thoracic, & vascular).

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 S60N / Vivid S70N. Combinations identified as “P” represent those previously cleared with another GE Ultrasound system. Combinations identified as “N” are new.

The following Indication for Use forms are appended:

System: Vivid S60N / Vivid S70N

Transducer: 3Sc-RS

Transducer: 6S-D

Transducer: 12S-D

Transducer: 9L-D

Transducer: 11L-D

Transducer: L8-18i-D

Transducer: C1-6-D

Transducer: C1-5-D

Transducer: C2-9-D

Transducer: C3-10-D

Transducer: iC5-9-D

Transducer: 6VT-D

Transducer: 6Tc-RS

Transducer: 9T-RS

Transducer: 10T-D

Transducer: P2D

Transducer: P6D

Transducer: M5Sc-D (only on Vivid S70N)

Transducer: AcuNav 10F (G version)

Transducer: AcuNav 8F (G version)

Transducer: SOUNDSTAR 3D 10F (G version)

Transducer: SOUNDSTAR eco 8F (G version)

Transducer: SOUNDSTAR eco 10F (G version)



Diagnostic Ultrasound Indications for Use Form
GE Vivid S60N / Vivid S70N Ultrasound System

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	P	[8,9]
Abdominal	P	P	P	P	P	P	P	P	P	P	[8,9,1,2]
Pediatric	P	P	P	P	P	P	P	P	P	P	[8,9]
Small Organ	P	P	P		P	P	P	P	P	P	[3,8]
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	[8,9]
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	[9]
Cardiac	P	P	P	P	P	P	P	P	P	P	[4,6,9]
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[8,9]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[8]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[8]
Other	P	P	P	P	P	P	P	P	P	P	[5,8,9]
<i>Exam Type, Means of Access</i>											
Transesophageal	P	P	P	P	P	P	P	P	P	P	[6,9]
Transrectal	P	P	P		P	P	P	P	P	P	[8]
Transvaginal	P	P	P		P	P	P	P	P	P	[8]
Transurethral											
Intraoperative	N	N	N	N	N	N	N	N	N	N	[10]
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal	P	P	P	P	P	P	P	P	P		[9]
Tissue Biopsy	P	P	P	P	P	P	P	P	P	P	[7,8,9]
Vascular Access (IV, PICC)	P	P	P		P	P	P	P	P	P	[8]

P = previously cleared by FDA on Vivid S60N/Vivid S70N (K170878); P1 = previously cleared by FDA on Vivid E95 (K173341); P2 = previously cleared by FDA on LOGIQ E9 (K163077); P3 = added under Appendix E based on Vivid E95 (K173341); N = New indication;

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
 - [2] Abdominal includes Aorto-Iliac Artery
 - [3] Small organ includes breast, testes, thyroid.
 - [4] Cardiac is Adult and Pediatric.
 - [5] Other use includes Urology/Prostate
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

(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)

Prescription User (Per 21 CFR 801.109)



Diagnostic Ultrasound Indications for Use Form
GE Vivid S60N / Vivid S70N with C3-10-D Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal	P	P	P		P	P	P	P	P	P	[8,1]
Pediatric	P	P	P		P	P	P	P	P	P	[8]
Small Organ											
Neonatal Cephalic	P	P	P		P	P	P	P	P	P	[8]
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[8]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[8]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[8]
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy	P	P	P		P	P	P	P	P	P	[7,8]
Vascular Access (IV, PICC)	P	P	P		P	P	P	P	P	P	[8]

P = previously cleared by FDA on Vivid S60N/Vivid S70N (K170878); P1 = previously cleared by FDA on Vivid E95 (K173341); P2 = previously cleared by FDA on LOGIQ E9 (K163077); P3 = added under Appendix E based on Vivid E95 (K173341); N = New indication;

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
 - [2] Abdominal includes Aorto-Iliac Artery
 - [3] Small organ includes breast, testes, thyroid.
 - [4] Cardiac is Adult and Pediatric.
 - [5] Other use includes Urology/Prostate
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

(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)

Prescription User (Per 21 CFR 801.109)



Diagnostic Ultrasound Indications for Use Form
GE Vivid S60N / Vivid S70N with 12S-D Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal	P	P	P	P	P	P	P	P	P	P	[9,1]
Pediatric	P	P	P	P	P	P	P	P	P	P	[9]
Small Organ											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	[9]
Adult Cephalic											
Cardiac	P	P	P	P	P	P	P	P	P	P	[4,9]
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[9]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy											
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid S60N/Vivid S70N (K170878); P1 = previously cleared by FDA on Vivid E95 (K173341); P2 = previously cleared by FDA on LOGIQ E9 (K163077); P3 = added under Appendix E based on Vivid E95 (K173341); N = New indication;

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
 - [2] Abdominal includes Aorto-Iliac Artery
 - [3] Small organ includes breast, testes, thyroid.
 - [4] Cardiac is Adult and Pediatric.
 - [5] Other use includes Urology/Prostate
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

(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)

Prescription User (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form
GE Vivid S60N / Vivid S70N with IC5-9-D Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics	P	P	P		P	P	P	P	P	P	[8]
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other	P	P	P		P	P	P	P	P	P	[5,8]
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal	P	P	P		P	P	P	P	P	P	[8]
Transvaginal	P	P	P		P	P	P	P	P	P	[8]
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy	P	P	P		P	P	P	P	P	P	[7,8]
Vascular Access (IV, PICC)	P	P	P		P	P	P	P	P	P	[8]

P = previously cleared by FDA on Vivid S60N/Vivid S70N (K170878); P1 = previously cleared by FDA on Vivid E95 (K173341); P2 = previously cleared by FDA on LOGIQ E9 (K163077); P3 = added under Appendix E based on Vivid E95 (K173341); N = New indication;

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
 - [2] Abdominal includes Aorto-Iliac Artery
 - [3] Small organ includes breast, testes, thyroid.
 - [4] Cardiac is Adult and Pediatric.
 - [5] Other use includes Urology/Prostate
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

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

Prescription User (Per 21 CFR 801.109)



GE Healthcare

510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Vivid S60N / Vivid S70N with C2-9-D Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics	P	P	P		P	P	P	P	P	P	[8]
Abdominal	P	P	P		P	P	P	P	P	P	[1,8,2]
Pediatric	P	P	P		P	P	P	P	P	P	[8]
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[8]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other	P	P	P		P	P	P	P	P	P	[5,8]
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy	P	P	P		P	P	P	P	P	P	[7,8]
Vascular Access (IV, PICC)	P	P	P		P	P	P	P	P	P	[8]

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- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
 - [2] Abdominal includes Aorto-Iliac Artery
 - [3] Small organ includes breast, testes, thyroid.
 - [4] Cardiac is Adult and Pediatric.
 - [5] Other use includes Urology/Prostate
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

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

Prescription User (Per 21 CFR 801.109)



Diagnostic Ultrasound Indications for Use Form
GE Vivid S60N / Vivid S70N with 9L-D Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal	P	P	P		P	P	P	P	P	P	[8,1]
Pediatric	P	P	P		P	P	P	P	P	P	[8]
Small Organ	P	P	P		P	P	P	P	P	P	[3,8]
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[8]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[8]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[8]
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy	P	P	P		P	P	P	P	P	P	[7,8]
Vascular Access (IV, PICC)	P	P	P		P	P	P	P	P	P	[8]

P = previously cleared by FDA on Vivid S60N/Vivid S70N (K170878); P1 = previously cleared by FDA on Vivid E95 (K173341); P2 = previously cleared by FDA on LOGIQ E9 (K163077); P3 = added under Appendix E based on Vivid E95 (K173341); N = New indication;

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
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 - [3] Small organ includes breast, testes, thyroid.
 - [4] Cardiac is Adult and Pediatric.
 - [5] Other use includes Urology/Prostate
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

(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)

Prescription User (Per 21 CFR 801.109)



Diagnostic Ultrasound Indications for Use Form
GE Vivid S60N / Vivid S70N with 11L-D Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric	P	P	P		P	P	P	P	P	P	[8]
Small Organ	P	P	P		P	P	P	P	P	P	[3,8]
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[8]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[8]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[8]
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy	P	P	P		P	P	P	P	P	P	[7,8]
Vascular Access (IV, PICC)	P	P	P		P	P	P	P	P	P	[8]

P = previously cleared by FDA on Vivid S60N/Vivid S70N (K170878); P1 = previously cleared by FDA on Vivid E95 (K173341); P2 = previously cleared by FDA on LOGIQ E9 (K163077); P3 = added under Appendix E based on Vivid E95 (K173341); N = New indication;

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- [1] Abdominal includes renal, GYN/Pelvic
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 - [6] 3D/4D Imaging mode
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 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

(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)

Prescription User (Per 21 CFR 801.109)



GE Healthcare

510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Vivid S60N / Vivid S70N with L8-18i-D Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ	P1	P1	P1		P1	P1	P1	P1	P1	P1	[2,8]
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P1	P1	P1		P1	P1	P1	P1	P1	P1	[8]
Musculo-skeletal Conventional	P1	P1	P1		P1	P1	P1	P1	P1	P1	[8]
Musculo-skeletal Superficial	P1	P1	P1		P1	P1	P1	P1	P1	P1	[8]
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative	P1	P1	P1		P1	P1	P1	P1	P1	P1	[10,8]
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy											
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid S60N/Vivid S70N (K170878); P1 = previously cleared by FDA on Vivid E95 (K173341); P2 = previously cleared by FDA on LOGIQ E9 (K163077); P3 = added under Appendix E based on Vivid E95 (K173341); N = New indication;

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
 - [2] Abdominal includes Aorto-Iliac Artery
 - [3] Small organ includes breast, testes, thyroid.
 - [4] Cardiac is Adult and Pediatric.
 - [5] Other use includes Urology/Prostate
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

(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)

Prescription User (Per 21 CFR 801.109)



Diagnostic Ultrasound Indications for Use Form
GE Vivid S60N / Vivid S70N with 3Sc-RS Transducer

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

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	P	[9]
Abdominal	P	P	P	P	P	P	P	P	P	P	[1,2,9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[9]
Small Organ											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	[9]
Cardiac	P	P	P	P	P	P	P	P	P	P	[4,9]
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[9]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy	P	P	P	P	P	P	P	P	P	P	[9]
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid S60N/Vivid S70N (K170878); P1 = previously cleared by FDA on Vivid E95 (K173341); P2 = previously cleared by FDA on LOGIQ E9 (K163077); P3 = added under Appendix E based on Vivid E95 (K173341); N = New indication;

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
 - [2] Abdominal includes Aorto-Iliac Artery
 - [3] Small organ includes breast, testes, thyroid.
 - [4] Cardiac is Adult and Pediatric.
 - [5] Other use includes Urology/Prostate
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

(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)

Prescription User (Per 21 CFR 801.109)



Diagnostic Ultrasound Indications for Use Form
GE Vivid S60N / Vivid S70N with 6S-D Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	P	[9]
Abdominal	P	P	P	P	P	P	P	P	P	P	[1,9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[9]
Small Organ											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	[9]
Adult Cephalic											
Cardiac	P	P	P	P	P	P	P	P	P	P	[4,9]
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy											
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid S60N/Vivid S70N (K170878); P1 = previously cleared by FDA on Vivid E95 (K173341); P2 = previously cleared by FDA on LOGIQ E9 (K163077); P3 = added under Appendix E based on Vivid E95 (K173341); N = New indication;

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
 - [2] Abdominal includes Aorto-Iliac Artery
 - [3] Small organ includes breast, testes, thyroid.
 - [4] Cardiac is Adult and Pediatric.
 - [5] Other use includes Urology/Prostate
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

(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)

Prescription User (Per 21 CFR 801.109)



Diagnostic Ultrasound Indications for Use Form
GE Vivid S60N / Vivid S70N with C1-6-D Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics	P	P	P		P	P	P	P	P	P	[8]
Abdominal	P	P	P		P	P	P	P	P	P	[1, 2, 8]
Pediatric	P	P	P		P	P	P	P	P	P	[8]
Small Organ											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[8]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other	P	P	P		P	P	P	P	P	P	[5,8]
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy	P	P	P		P	P	P	P	P	P	[7,8]
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid S60N/Vivid S70N (K170878); P1 = previously cleared by FDA on Vivid E95 (K173341); P2 = previously cleared by FDA on LOGIQ E9 (K163077); P3 = added under Appendix E based on Vivid E95 (K173341); N = New indication;

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
 - [2] Abdominal includes Aorto-Iliac Artery
 - [3] Small organ includes breast, testes, thyroid.
 - [4] Cardiac is Adult and Pediatric.
 - [5] Other use includes Urology/Prostate
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)
Prescription User (Per 21 CFR 801.109)



Diagnostic Ultrasound Indications for Use Form
GE Vivid S60N / Vivid S70N with C1-5-D Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics	P2	P2	P2		P2	P2	P2	P2	P2	P2	[8]
Abdominal	P2	P2	P2		P2	P2	P2	P2	P2	P2	[1, 2, 8]
Pediatric											
Small Organ											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P2	P2	P2		P2	P2	P2	P2	P2	P2	[8]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other	P2	P2	P2		P2	P2	P2	P2	P2	P2	[5,8]
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy	P2	P2	P2		P2	P2	P2	P2	P2	P2	[7,8]
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid S60N/Vivid S70N (K170878); P1 = previously cleared by FDA on Vivid E95 (K173341); P2 = previously cleared by FDA on LOGIQ E9 (K163077); P3 = added under Appendix E based on Vivid E95 (K173341); N = New indication;

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
 - [2] Abdominal includes Aorto-Iliac Artery
 - [3] Small organ includes breast, testes, thyroid.
 - [4] Cardiac is Adult and Pediatric.
 - [5] Other use includes Urology/Prostate
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

(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)
Prescription User (Per 21 CFR 801.109)



Diagnostic Ultrasound Indications for Use Form
GE Vivid S60N / Vivid S70N with 6VT-D Transducer

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

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac	P	P	P	P	P	P	P	P	P	P	[6,9]
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal	P	P	P	P	P	P	P	P	P	P	[6,9]
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy											
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid S60N/Vivid S70N (K170878); P1 = previously cleared by FDA on Vivid E95 (K173341); P2 = previously cleared by FDA on LOGIQ E9 (K163077); P3 = added under Appendix E based on Vivid E95 (K173341); N = New indication;

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
 - [2] Abdominal includes Aorto-Iliac Artery
 - [3] Small organ includes breast, testes, thyroid.
 - [4] Cardiac is Adult and Pediatric.
 - [5] Other use includes Urology/Prostate
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

(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)

Prescription User (Per 21 CFR 801.109)



Diagnostic Ultrasound Indications for Use Form
GE Vivid S60N / Vivid S70N with 6Tc-RS Transducer

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

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac	P	P	P	P	P	P	P	P	P	P	[9]
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal	P	P	P	P	P	P	P	P	P	P	[9]
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy											
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid S60N/Vivid S70N (K170878); P1 = previously cleared by FDA on Vivid E95 (K173341); P2 = previously cleared by FDA on LOGIQ E9 (K163077); P3 = added under Appendix E based on Vivid E95 (K173341); N = New indication;

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
 - [2] Abdominal includes Aorto-Iliac Artery
 - [3] Small organ includes breast, testes, thyroid.
 - [4] Cardiac is Adult and Pediatric.
 - [5] Other use includes Urology/Prostate
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

(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)

Prescription User (Per 21 CFR 801.109)



Diagnostic Ultrasound Indications for Use Form
GE Vivid S60N / Vivid S70N with 9T-RS Transducer

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

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac	P	P	P	P	P	P	P	P	P	P	[9, 4]
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal	P	P	P	P	P	P	P	P	P	P	[9]
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy											
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid S60N/Vivid S70N (K170878); P1 = previously cleared by FDA on Vivid E95 (K173341); P2 = previously cleared by FDA on LOGIQ E9 (K163077); P3 = added under Appendix E based on Vivid E95 (K173341); N = New indication;

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
 - [2] Abdominal includes Aorto-Iliac Artery
 - [3] Small organ includes breast, testes, thyroid.
 - [4] Cardiac is Adult and Pediatric.
 - [5] Other use includes Urology/Prostate
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

(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)
Prescription User (Per 21 CFR 801.109)



Diagnostic Ultrasound Indications for Use Form
GE Vivid S60N / Vivid S70N with 10T-D Transducer

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

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac	P3	P3	P3	P3	P3	P3	P3	P3	P3	P3	[4,9]
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal	P3	P3	P3	P3	P3	P3	P3	P3	P3	P3	[9]
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy											
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid S60N/Vivid S70N (K170878); P1 = previously cleared by FDA on Vivid E95 (K173341); P2 = previously cleared by FDA on LOGIQ E9 (K163077); P3 = added under Appendix E based on Vivid E95 (K173341); N = New indication;

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
 - [2] Abdominal includes Aorto-Iliac Artery
 - [3] Small organ includes breast, testes, thyroid.
 - [4] Cardiac is Adult and Pediatric.
 - [5] Other use includes Urology/Prostate
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

(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)

Prescription User (Per 21 CFR 801.109)



Diagnostic Ultrasound Indications for Use Form
GE Vivid S60N / Vivid S70N with P2D Transducer

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

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ											
Neonatal Cephalic											
Adult Cephalic											
Cardiac			P	P							[4]
Peripheral Vascular			P	P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy											
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid S60N/Vivid S70N (K170878); P1 = previously cleared by FDA on Vivid E95 (K173341); P2 = previously cleared by FDA on LOGIQ E9 (K163077); P3 = added under Appendix E based on Vivid E95 (K173341); N = New indication;

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
 - [2] Abdominal includes Aorto-Iliac Artery
 - [3] Small organ includes breast, testes, thyroid.
 - [4] Cardiac is Adult and Pediatric.
 - [5] Other use includes Urology/Prostate
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

(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)

Prescription User (Per 21 CFR 801.109)



Diagnostic Ultrasound Indications for Use Form
GE Vivid S60N / Vivid S70N with P6D Transducer

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

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac			P	P							[4]
Peripheral Vascular			P	P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy											
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid S60N/Vivid S70N (K170878); P1 = previously cleared by FDA on Vivid E95 (K173341); P2 = previously cleared by FDA on LOGIQ E9 (K163077); P3 = added under Appendix E based on Vivid E95 (K173341); N = New indication;

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
 - [2] Abdominal includes Aorto-Iliac Artery
 - [3] Small organ includes breast, testes, thyroid.
 - [4] Cardiac is Adult and Pediatric.
 - [5] Other use includes Urology/Prostate
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

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

Prescription User (Per 21 CFR 801.109)



Diagnostic Ultrasound Indications for Use Form
GE Vivid S60N / Vivid S70N with AcuNav 10F (G version) Transducer

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

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal	P	P	P	P	P	P	P	P	P		[9]
Tissue Biopsy											
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid S60N/Vivid S70N (K170878); P1 = previously cleared by FDA on Vivid E95 (K173341); P2 = previously cleared by FDA on LOGIQ E9 (K163077); P3 = added under Appendix E based on Vivid E95 (K173341); N = New indication;

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
 - [2] Abdominal includes Aorto-Iliac Artery
 - [3] Small organ includes breast, testes, thyroid.
 - [4] Cardiac is Adult and Pediatric.
 - [5] Other use includes Urology/Prostate
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

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

Prescription User (Per 21 CFR 801.109)



Diagnostic Ultrasound Indications for Use Form
GE Vivid S60N / Vivid S70N with AcuNav 8F (G version) Transducer

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

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal	P	P	P	P	P	P	P	P	P		[9]
Tissue Biopsy											
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid S60N/Vivid S70N (K170878); P1 = previously cleared by FDA on Vivid E95 (K173341); P2 = previously cleared by FDA on LOGIQ E9 (K163077); P3 = added under Appendix E based on Vivid E95 (K173341); N = New indication;

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
 - [2] Abdominal includes Aorto-Iliac Artery
 - [3] Small organ includes breast, testes, thyroid.
 - [4] Cardiac is Adult and Pediatric.
 - [5] Other use includes Urology/Prostate
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

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

Prescription User (Per 21 CFR 801.109)



Diagnostic Ultrasound Indications for Use Form
GE Vivid S60N / Vivid S70N with SOUNDSTAR 3D 10F (G version) Transducer

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

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal	P	P	P	P	P	P	P	P	P		[9]
Tissue Biopsy											
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid S60N/Vivid S70N (K170878); P1 = previously cleared by FDA on Vivid E95 (K173341); P2 = previously cleared by FDA on LOGIQ E9 (K163077); P3 = added under Appendix E based on Vivid E95 (K173341); N = New indication;

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
 - [2] Abdominal includes Aorto-Iliac Artery
 - [3] Small organ includes breast, testes, thyroid.
 - [4] Cardiac is Adult and Pediatric.
 - [5] Other use includes Urology/Prostate
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

(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)

Prescription User (Per 21 CFR 801.109)



Diagnostic Ultrasound Indications for Use Form
GE Vivid S60N / Vivid S70N with SOUNDSTAR eco 10F (G version) Transducer

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

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal	P	P	P	P	P	P	P	P	P		[9]
Tissue Biopsy											
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid S60N/Vivid S70N (K170878); P1 = previously cleared by FDA on Vivid E95 (K173341); P2 = previously cleared by FDA on LOGIQ E9 (K163077); P3 = added under Appendix E based on Vivid E95 (K173341); N = New indication;

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Abdominal includes Aorto-Iliac Artery

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

[4] Cardiac is Adult and Pediatric.

[5] Other use includes Urology/Prostate

[6] 3D/4D Imaging mode

[7] Includes image guidance for freehand needle placement

[8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD

[9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD

[10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

(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)

Prescription User (Per 21 CFR 801.109)



Diagnostic Ultrasound Indications for Use Form
GE Vivid S60N / Vivid S70N with SOUNDSTAR eco 8F (G version) Transducer

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

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal	P	P	P	P	P	P	P	P	P		[9]
Tissue Biopsy											
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid S60N/Vivid S70N (K170878); P1 = previously cleared by FDA on Vivid E95 (K173341); P2 = previously cleared by FDA on LOGIQ E9 (K163077); P3 = added under Appendix E based on Vivid E95 (K173341); N = New indication;

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
 - [2] Abdominal includes Aorto-Iliac Artery
 - [3] Small organ includes breast, testes, thyroid.
 - [4] Cardiac is Adult and Pediatric.
 - [5] Other use includes Urology/Prostate
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

(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)

Prescription User (Per 21 CFR 801.109)



Diagnostic Ultrasound Indications for Use Form
GE Vivid S70N with M5Sc-D Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	P	[9]
Abdominal	P	P	P	P	P	P	P	P	P	P	[1,2,9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[9]
Small Organ											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	[9]
Cardiac	P	P	P	P	P	P	P	P	P	P	[4,9]
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[9]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other	P	P	P	P	P	P	P	P	P	P	[5,9]
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy	P	P	P	P	P	P	P	P	P	P	[9]
Vascular Access (IV, PICC)											

P = previously cleared by FDA on Vivid S60N/Vivid S70N (K170878); P1 = previously cleared by FDA on Vivid E95 (K173341); P2 = previously cleared by FDA on LOGIQ E9 (K163077); P3 = added under Appendix E based on Vivid E95 (K173341); N = New indication;

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
 - [2] Abdominal includes Aorto-Iliac Artery
 - [3] Small organ includes breast, testes, thyroid.
 - [4] Cardiac is Adult and Pediatric.
 - [5] Other use includes Urology/Prostate
 - [6] 3D/4D Imaging mode
 - [7] Includes image guidance for freehand needle placement
 - [8] Combined modes are: B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD
 - [9] Combined modes are: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [10] Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

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

(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)

Prescription User (Per 21 CFR 801.109)



510(k) Summary

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

Date: September 6, 2018

Submitter: GE Medical Systems Ultrasound and Primary Care Diagnostics
9900 Innovation Drive
Wauwatosa, WI 53226

Primary Contact Person: Tracey Ortiz
Regulatory Affairs Director
GE Healthcare
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Secondary Contact Person: Carmel Lehrer
Regulatory Affairs Specialist
GE Vingmed Ultrasound AS

Device: Trade Name: Vivid S60N, Vivid S70N
Common/Usual Name: Diagnostic Ultrasound System
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

Primary Predicate Device: Vivid S60N, Vivid S70N (K170878)

Secondary Predicate
Device(s): Vivid E95 (K173341)
LOGIQ E9 (K163077)

Device Description: Vivid S60N / Vivid S70N is a Track 3 diagnostic ultrasound system, which is primarily intended for cardiac imaging and analysis but also includes vascular and general radiology applications. It is a full featured diagnostic ultrasound system that provides digital acquisition, processing, analysis and display capability.

The Vivid S60N / Vivid S70N consists of a mobile console with a height-adjustable control panel, color LCD touch panel, LCD display monitor and optional image storage and printing devices. It includes a variety of electronic array transducers operating in linear, curved, sector/phased array, matrix array or dual array format, including dedicated CW transducers and real time 3D transducer.



GE Healthcare
510(k) Premarket Notification Submission

The system includes electronics for transmit and receive of ultrasound data, ultrasound signal processing, software computing, hardware for Image storage, hard copy printing, and network access to the facility through both LAN and wireless (supported by use of a wireless LAN USB-adapter) connection.

Intended Use: Vivid S60N/Vivid S70N is a general-purpose ultrasound system, specialized for use in cardiac imaging. It is intended for use by, or under the direction of a qualified physician for ultrasound imaging and analysis for the following applications: Fetal/Obstetrics; Abdominal (Including Renal & Gyn); Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional; Musculo-skeletal Superficial; Urology (including prostate); Transesophageal; Transvaginal; Transrectal; Intra-cardiac; Intra-luminal and Intraoperative (abdominal, thoracic, & vascular).

Technology: The Vivid S60N / Vivid S70N employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence: Comparison to Predicate Devices
The Vivid S60N / Vivid S70N is substantially equivalent to the predicate devices with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

The following is an overview of the differences between the proposed Vivid S60N / Vivid S70N and its predicates.

Transducers:

- Adding transducers: C1-5-D convex array transducer previously cleared in LOGIQ E9 (K163077) and L8-18i-D linear transducer previously cleared in Vivid E95 (K173341)
- Removed transducer M5Sc-D from Vivid S60N

Indications for Use:

- Adding new indication for use: Intraoperative includes abdominal, thoracic (including cardiac), and vascular (including PV)

Features/Functionality:

- The new feature “4D Marker” allows the user to manually place annotations/markers into 3D/4D datasets on the system when upgraded to 4D. This is an extension of



existing image annotation capabilities on the predicate Vivid S60N / Vivid S70N (K170878).

- “AFI 2.0” and “AutoEF 2.0” provide workflow improvements of functionality already cleared on the predicate Vivid S60N / Vivid S70N (K170878).
- Two additional sets of Z-score values are added, based on published literature, to the “Z Score” functionality cleared in predicate Vivid S60N / Vivid S70N (K170878).
- “Stream Server” functionality is added for streaming 2D and 4D ultrasound data real time over LAN or WLAN network connection, using secure authentication and encryption. Real-time remote viewing was previously cleared (K170878). The stream server expands the viewing capability to an enabled device that is not physically connected to the system.
- “Tricefy Uplink” is available with the subject Vivid S60N / Vivid S70N enabling data flow to the Tricefy Cloud service. Both Tricefy Uplink and Tricefy are products of Trice Imaging Inc.
- The software features of the subject Vivid S60N / Vivid S70N are installed and are running under Windows 10 Embedded Operating software environment. This is substantially equivalent to the cleared Vivid S60N / Vivid S70N (K170878) where the software features were installed and were running under Windows 7 Embedded.
- “Whitelisting” is implemented on the subject Vivid S60N / Vivid S70N. Whitelisting is a cyber security technology available with Windows 10 Embedded and is implemented as additional protection against running and infecting the ultrasound system with malware. The addition of “Whitelisting” will have no impact on the safety or effectiveness of the clinical functionality of the systems.
- “Flexible video out” is an enhancement of the external video out capability that was cleared in predicate Vivid S60N/S70N (K170878). Flexible video out will allow the image to be scaled to fit the external monitor.
- “cSound 2.0” is an improvement of the existing cSound software image processing platform. The functionality is the same as what was cleared in predicate Vivid S60N/S70N (K170878).



Summary of Non-Clinical Tests:

Vivid S60N / Vivid S70N were evaluated for acoustic output, biocompatibility, cleaning and disinfection as well as thermal, electrical, electromagnetic, and mechanical safety, and have been found to comply with applicable medical device safety standards. The Vivid S60N / Vivid S70N comply with voluntary standards:

- ANSI / AAMI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 2005/A1:2012
- IEC 60601-1-2, Medical Electrical Equipment – Part 1-2: general Requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility —Requirements and tests, 2007
- IEC 60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment, 2015.
- ISO 10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Third Edition, 2009
- IEC 62359, Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2010
- ISO 14971, Application of risk management to medical devices, 2007
- NEMA PS3.1-3.20, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology), 2016

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

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

Transducer materials and other patient contact materials are biocompatible.



GE Healthcare

510(k) Premarket Notification Submission

Successful results and compliance of the described non-clinical tests ensure the differences between the predicate device and the subject device do not affect the safety and effectiveness and are substantially equivalent to the predicate devices.

Summary of Clinical Tests:

The subject of this premarket submission, Vivid S60N / Vivid S70N, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Vivid S60N / Vivid S70N to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).