JUL 25 2014

K141675
Page 1 of 4

GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

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

Date:	June 24, 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
Secondary Contact Person:	Chansook KIM Regulatory Affairs Leader GE Healthcare T:(+82) 31 740-6307
Device: Trade Name:	Voluson P6, Voluson P8 Ultrasound System
Common/Usual Name:	Voluson P6, Voluson P8
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):	K122387 Voluson P6/P8 K132913 Voluson E Series
Device Description:	The subject device consists of a mobile console with keyboard, specialized controls, a color video LCD display with electronic-array transducers. It has the same general appearance, dimensions and weight as the unmodified device, it is a Track 3 general-purpose imaging and analysis system providing real-time digital acquisition, processing and display capability intended for general radiology imaging and evaluation with some cardiology and vascular applications.
Intended Use:	The device is a general-purpose ultrasound system. Specific clinical applications and exam types include: Fetal (Obstetrics); Abdominal (including renal and GYN/pelvic); Pediatric; Small Organ (breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular (PV);

Musculo-skeletal Conventional and Superficial; Transrectal (TR); Transvaginal (TV).

Technology: The Voluson P6, Voluson P8 employs the same fundamental scientific technology as its predicate devices

Determination of Substantial Equivalence:

Comparison to Predicate Device(s):

The Voluson P6/P8 systems are substantially equivalent to the predicate devices with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The Voluson P6/P8 and predicate Voluson P6/P8 systems have the same clinical intended use
- The Voluson P6/P8 and predicate Voluson P6/P8 systems have the same imaging modes.
- The Voluson P6/P8 and predicate Voluson P6/P8 systems transducers are identical.
- The systems are manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The systems have acoustic power levels which are below the applicable FDA limits.
- The Voluson P6/P8 and predicate Voluson P6/P8 systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- New software features added to Voluson P6/P8: HDLive, Sono IT, SonoBiometry and Sono L&D are the same features cleared on predicate Voluson E Series(K132913).
- The Voluson P6/P8 and predicate systems have been designed in compliance with approved electrical and physical safety standards.

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 to applicable medical device safety standards. Voluson P6/P8 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, Voluson P6, Voluson P8, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Voluson P6, Voluson P8 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

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

July 25, 2014

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

Re: K141675
Trade/Device Name: Voluson P6, Voluson P8 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: June 24, 2014
Received: June 25, 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 Voluson S6, Voluson S8 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number		
RAB2-6-RS	4C-RS	E8C-RS
12L-RS	RIC5-9W-RS	RAB2-5-RS
3Sc-RS		

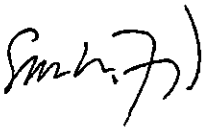
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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)*
K141675

Device Name
Voluson P6/Voluson P8 Diagnostic Ultrasound System

Indications for Use *(Describe)*

The device is a general-purpose ultrasound system. Specific clinical applications and exam types include: Fetal (Obstetrics); Abdominal (including renal and GYN/pelvic); Pediatric; Small Organ (breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular (PV); Musculo-skeletal Conventional and Superficial; Transrectal (Including Urology and Prostate) (TR); Transvaginal (TV).

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Diagnostic Ultrasound Indications for Use Form

GE Voluson P6/P8 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	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Small Organ[2]	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	[5]
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac[3]	P	P	P	P	P	P	P	P	P	P	[5]
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[5,6,9]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6,9]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[5,6,9]
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	P	P	P		P	P	P	P	P	P	[5,6,9]
Transvaginal	P	P	P		P	P	P	P	P	P	[5,6,9]
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

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

[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

[3] Cardiac is Adult and Pediatric.

[5] 3D/4D Imaging Mode.

[6] Includes imaging of guidance of biopsy (2D/3D/4D).

[7] Includes infertility monitoring of follicle development.

[8] Includes urology/prostate.

[9] Elastography imaging- Elasticity

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

(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 Voluson P6/P8 with RAB2-6-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	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P		P	P	P	P	P	P	(5,6)
Abdominal[1]	P	P	P		P	P	P	P	P	P	(5,6)
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	(5,6)
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication: P = previously cleared by FDA

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

[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

[3] Cardiac is Adult and Pediatric.

[5] 3D/4D Imaging Mode.

[6] Includes imaging of guidance of biopsy (2D/3D/4D).

[7] Includes infertility monitoring of follicle development.

[8] Includes urology/prostate.

[9] Elastography imaging- Elasticity

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

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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 Voluson P6/P8 with 4C-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	Other (Notes)
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P		P	P	P	P	P	P	[6]
Abdominal[1]	P	P	P		P	P	P	P	P	P	[6]
Pediatric	P	P	P		P	P	P	P	P	P	[6]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[6]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[6]
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes renal, GYN/Pelvic
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode.
[6] Includes imaging of guidance of biopsy (2D/3D/4D).
[7] Includes infertility monitoring of follicle development.
[8] Includes urology/prostate.
[9] Elastography imaging- Elasticity
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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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 Voluson P6/P8 with E8C-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	Other (Notes)
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P		P	P	P	P	P	P	[6]
Abdominal[1]	P	P	P		P	P	P	P	P	P	[6]
Pediatric											
Small Organ[2]											
Neonatal Cephalic	P	P	P		P	P	P	P	P	P	[6]
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	P	P	P		P	P	P	P	P	P	[6]
Transvaginal	P	P	P		P	P	P	P	P	P	[6]
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

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

[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

[3] Cardiac is Adult and Pediatric.

[5] 3D/4D Imaging Mode.

[6] Includes imaging of guidance of biopsy (2D/3D/4D).

[7] Includes infertility monitoring of follicle development.

[8] Includes urology/prostate.

[9] Elastography imaging- Elasticity

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

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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 Voluson P6/P8 with 12L-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	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric	P	P	P		P	P	P	P	P	P	[6,9]
Small Organ[2]	P	P	P		P	P	P	P	P	P	[6,9]
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[6,9]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[6,9]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[6,9]
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication: P = previously cleared by FDA

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

[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

[3] Cardiac is Adult and Pediatric.

[5] 3D/4D Imaging Mode.

[6] Includes imaging of guidance of biopsy (2D/3D/4D).

[7] Includes infertility monitoring of follicle development.

[8] Includes urology/prostate.

[9] Elastography imaging- Elasticity

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

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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 Voluson P6/P8 with RIC5-9W-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	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P		P	P	P	P	P	P	[5,6]
Abdominal[1]	P	P	P		P	P	P	P	P	P	[5,6]
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	P	P	P		P	P	P	P	P	P	[5,6]
Transvaginal	P	P	P		P	P	P	P	P	P	[5,6]
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes renal, GYN/Pelvic
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode.
[6] Includes imaging of guidance of biopsy (2D/3D/4D).
[7] Includes infertility monitoring of follicle development.
[8] Includes urology/prostate.
[9] Elastography imaging- Elasticity
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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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 Voluson P6/P8 with RAB2-5-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	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P		P	P	P	P	P	P	(5,6)
Abdominal[1]	P	P	P		P	P	P	P	P	P	(5,6)
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	(5,6)
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes renal, GYN/Pelvic
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode.
[6] Includes imaging of guidance of biopsy (2D/3D/4D).
[7] Includes infertility monitoring of follicle development.
[8] Includes urology/prostate.
[9] Elastography imaging- Elasticity
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

(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 Voluson P6/P8 with 3Sc-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	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P	P	P	P	P	P	P	P	[6]
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	[6]
Pediatric	P	P	P	P	P	P	P	P	P	P	[6]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	[6]
Cardiac[3]	P	P	P	P	P	P	P	P	P	P	[6]
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes renal, GYN/Pelvic
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode.
[6] Includes imaging of guidance of biopsy (2D/3D/4D).
[7] Includes infertility monitoring of follicle development.
[8] Includes urology/prostate.
[9] Elastography imaging- Elasticity
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

(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)