



November 15, 2018

GE Healthcare
Bryan Behn
Regulatory Affairs Director
9900 Innovation Drive
WAUWATOSA, WI 53226

Re: K181985

Trade/Device Name: Voluson E6, Voluson E8, Voluson E10
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: October 30, 2018
Received: October 31, 2018

Dear Bryan 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. 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)

K181985

Device Name

Voluson E6, Voluson E8, Voluson E10

Indications for Use (Describe)

The device is a general-purpose ultrasound system. Specific clinical applications remain the same as previously cleared: Fetal/OB; Abdominal (including GYN, pelvic and infertility monitoring/follicle development); Pediatric; Small Organ (breast, testes, thyroid etc.); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Musculo-skeletal Conventional and Superficial; Peripheral Vascular; Transvaginal (including GYN); Transrectal

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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"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."



Indications for Use Forms

The following forms represent indications with clinical applications and exam types along with the modes of operation for the Voluson E Series system and for all of its probe/mode combinations. Combinations identified as “P” represents those previously cleared with another GE Ultrasound system. Combinations identified as “E” represents those previously cleared with another GE Ultrasound system and added via Appendix E of the FDA Ultrasound Guidance to this system. This modification does not add to indications to the previously cleared system level or transducer indications or clinical applications.



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form
Voluson E6 / Voluson E8 / Voluson E10

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 ^[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	[5,6,9,11]
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	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											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[8]	P	P	P		P	P	P	P	P	P	[5,6,9]
Transvaginal ^[10]	P	P	P		P	P	P	P	P	P	[5,6,9]
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic, Urology
 - [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
 - [7] Includes infertility monitoring of follicle development
 - [8] Includes urology/prostate
 - [9] Elastography imaging- Elasticity
 - [10] Transvaginal includes GYN
 - [11] Shear Wave Elastography
 - [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD
 - [[#]] 4D color Doppler (only with eM6C probe)

(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 Use (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

Voluson E6 / Voluson E8 / Voluson E10 with RAB2-5-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 ^[7]	P	P	P	P	P	P	P	P	P	P	[5,6]
Abdominal ^[1]	P	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	P	[5,6]
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[5] 3D/4D Imaging Mode

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

[7] Includes infertility monitoring of follicle development

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

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

Prescription Use (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

Voluson E6 / Voluson E8 / Voluson E10 with RIC5-9-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 ^[7]	P	P	P		P	P	P	P	P	P	[5,6,9]
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[8]	P	P	P		P	P	P	P	P	P	[5,6,9]
Transvaginal ^[10]	P	P	P		P	P	P	P	P	P	[5,6,9]
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes: [5] 3D/4D Imaging Mode

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

[7] Includes infertility monitoring of follicle development

[8] Includes urology/prostate

[9] Elastography Imaging- Elasticity

[10] Transvaginal includes GYN

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

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

Prescription Use (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form
Voluson E6 / Voluson E8 / Voluson E10 with 4C-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 ^[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											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[6]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[6] Includes imaging of guidance of biopsy (2D)

[7] Includes infertility monitoring of follicle development

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

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



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

Voluson E6 / Voluson E8 / Voluson E10 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 ^[7]	P	P	P		P	P	P	P	P	P	[6,9]
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[8]	P	P	P		P	P	P	P	P	P	[6,9]
Transvaginal ^[10]	P	P	P		P	P	P	P	P	P	[6,9]
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes: [6] Includes imaging of guidance of biopsy (2D)

[7] Includes infertility monitoring of follicle development

[8] Includes urology/prostate

[9] Elastography Imaging- Elasticity

[10] Transvaginal includes GYN

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

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

Prescription Use (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

Voluson E6 / Voluson E8 / Voluson E10 with RSP6-16-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 ^[7]											
Abdominal ^[1]											
Pediatric	P	P	P		P	P	P	P	P	P	[5,6]
Small Organ ^[2]	P	P	P		P	P	P	P	P	P	[5,6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[5,6]
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[8]											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[5] 3D/4D Imaging Mode

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

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

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

Prescription Use (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

Voluson E6 / Voluson E8 / Voluson E10 with RIC6-12-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 ^[7]	P	P	P		P	P	P	P	P	P	[5,6]
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[8]	P	P	P		P	P	P	P	P	P	[5,6]
Transvaginal ^[10]	P	P	P		P	P	P	P	P	P	[5,6]
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes: [5] 3D/4D Imaging Mode

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

[7] Includes infertility monitoring of follicle development

[8] Includes urology/prostate

[10] Transvaginal includes GYN

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

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

Prescription Use (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form
Voluson E6 / Voluson E8 / Voluson E10 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 ^[7]	P	P	P	P	P	P	P	P	P	P	[6]
Abdominal ^[1]											
Pediatric	P	P	P	P	P	P	P	P	P	P	[6]
Small Organ ^[2]	P	P	P	P	P	P	P	P	P	P	[6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[6]
Musculo-skeletal Conventional	P	P	P	P	P	P	P	P	P	P	[6]
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[6] Includes imaging of guidance of biopsy (2D)

[7] Includes infertility monitoring of follicle development

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

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

Prescription Use (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form
Voluson E6 / Voluson E8 / Voluson E10 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 ^[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											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[6] Includes imaging of guidance of biopsy (2D)

[9] Elastography Imaging- Elasticity

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/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 Use (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

Voluson E6 / Voluson E8 / Voluson E10 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 ^[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											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[6]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[6] Includes imaging of guidance of biopsy (2D)

[7] Includes infertility monitoring of follicle development

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

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

Prescription Use (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

Voluson E6 / Voluson E8 / Voluson E10 with ML6-15-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 ^[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											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[6] Includes imaging of guidance of biopsy (2D)

[9] Elastography Imaging-Elasticity

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

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

Prescription Use (Per 21 CFR 801.109)



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510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form
Voluson E6 / Voluson E8 / Voluson E10 with RM6C 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 ^[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	P	P	P		P	P	P	P	P	P	[5,6]
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											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[5] 3D/4D Imaging Mode

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

[7] Includes infertility monitoring of follicle development

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

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

Prescription Use (Per 21 CFR 801.109)



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Diagnostic Ultrasound Indications for Use Form
Voluson E6 / Voluson E8 / Voluson E10 with 3Sp-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 ^[7]	P	P	P	P	P	P	P	P	P	P	
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac ^[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[3] Cardiac is adult and Pediatric

[7] Includes infertility monitoring of follicle development

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

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



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Diagnostic Ultrasound Indications for Use Form

Voluson E6 / Voluson E8 / Voluson E10 with C4-8-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 ^[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											
Cardiac ^[3]											
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[6]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[6] Includes imaging of guidance of biopsy (2D)

[7] Includes infertility monitoring of follicle development

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

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

Prescription Use (Per 21 CFR 801.109)



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510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

Voluson E6 / Voluson E8 / Voluson E10 with RAB6-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 ^[7]	P	P	P	P	P	P	P	P	P	P	[5,6]
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	[5,6]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5,6]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P	P	P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[5] 3D/4D Imaging Mode

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

[7] Includes infertility monitoring of follicle development

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

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

Prescription Use (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form
Voluson E6 / Voluson E8 / Voluson E10 with eM6C 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 ^[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	P	P	P		P	P	P	P	P	P	[5,6]
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											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[5] 3D/4D Imaging Mode

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

[7] Includes infertility monitoring of follicle development

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

[[#]] 4D color Doppler (only with eM6C, eM6C G2 probe)

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



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510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

Voluson E6 / Voluson E8 / Voluson E10 with S4-10-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 ^[7]	P	P	P	P	P	P	P	P	P	P	
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ ^[2]	P	P	P	P	P	P	P	P	P	P	
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	
Adult Cephalic											
Cardiac ^[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
<i>Exam Type, Means of Access</i>											
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, Urology

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

[3] Cardiac is Adult and Pediatric

[7] Includes infertility monitoring of follicle development

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

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

Prescription Use (Per 21 CFR 801.109)



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510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form
Voluson E6 / Voluson E8 / Voluson E10 with eM6C G2 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 ^[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	P	P	P		P	P	P	P	P	P	[5,6]
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											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[5] 3D/4D Imaging Mode

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

[7] Includes infertility monitoring of follicle development

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

[[#]] 4D color Doppler (only with eM6C, eM6C G2 probe)

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

Prescription Use (Per 21 CFR 801.109)



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510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

Voluson E6 / Voluson E8 / Voluson E10 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 ^[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											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

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

[6] Includes imaging of guidance of biopsy (2D)

[7] Includes infertility monitoring of follicle development

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

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

Prescription Use (Per 21 CFR 801.109)



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510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

Voluson E6 / Voluson E8 / Voluson E10 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 ^[7]	P	P	P	P	P	P	P	P	P	P	[6]
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	[6,11]
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

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

[6] Includes imaging of guidance of biopsy (2D)

[7] Includes infertility monitoring of follicle development

[11] Shear Wave Elastography

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

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

Prescription Use (Per 21 CFR 801.109)



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510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form
Voluson E Series with IC4-10-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 ^[7]	P	P	P		P	P	P	P	P	P	[6,9]
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[8]	P	P	P		P	P	P	P	P	P	[6,9]
Transvaginal ^[10]	P	P	P		P	P	P	P	P	P	[6,9]
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes: [6] Includes imaging of guidance of biopsy (2D)

[7] Includes infertility monitoring of follicle development

[8] Includes urology/prostate

[9] Elastography Imaging- Elasticity

[10] Transvaginal includes GYN

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

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



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Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Voluson E6 / Voluson E8 / Voluson E10 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 ^[7]	P	P	P	P	P	P	P	P	P	P	[6]
Abdominal ^[1]											
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											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA;

Notes:

[3] Cardiac is adult and Pediatric

[6] Includes imaging of guidance of biopsy (2D)

[7] Includes infertility monitoring of follicle development

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

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

Prescription Use (Per 21 CFR 801.109)



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Diagnostic Ultrasound Indications for Use Form

Voluson E6 / Voluson E8 / Voluson E10 with RM7C 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 ^[7]	N	N	N		N	N	N	N	N	N	[5]
Abdominal ^[1]	N	N	N		N	N	N	N	N	N	[5,]
Pediatric	N	N	N		N	N	N	N	N	N	[5]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[5] 3D/4D Imaging Mode

[7] Includes infertility monitoring of follicle development

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

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

Prescription Use (Per 21 CFR 801.109)



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510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

Voluson E6 / Voluson E8 / Voluson E10 with L2-9-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 ^[7]	E	E	E	E	E	E	E	E	E	E	
Abdominal ^[1]											
Pediatric	E	E	E	E	E	E	E	E	E	E	
Small Organ ^[2]	E	E	E	E	E	E	E	E	E	E	
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	E	E	E	E	E	E	E	E	E	E	
Musculo-skeletal Conventional	E	E	E	E	E	E	E	E	E	E	
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E (Previously cleared in K173555)

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

[7] Includes infertility monitoring of follicle development

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

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



K181985

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510(k) Premarket Notification Submission

510(k) Summary

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

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Device: Trade Voluson E6, Voluson E8, Voluson E10
Name: Models: Voluson E6 / Voluson E8 / Voluson E10

Common/Usual
Name: 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(s): K172342 Voluson E6_E8_E10 Diagnostic Ultrasound System

Secondary
Predicate(s): K173555 Logiq E10 Diagnostic Ultrasound System

Device Description: The systems are full-featured Track 3 ultrasound systems, primarily for general radiology use and specialized for OB/GYN with particular features for real-time 3D/4D acquisition. They consist of a mobile console with keyboard control panel; color LCD/TFT touch panel, color video display and optional image storage and printing devices.



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They provide high performance ultrasound imaging and analysis and have comprehensive networking and DICOM capability. They utilize a variety of linear, curved linear, matrix phased array transducers including mechanical and electronic scanning transducers, which provide highly accurate real-time three-dimensional imaging supporting all standard acquisition modes.

Intended Use: The device is a general-purpose ultrasound system. Specific clinical applications remain the same as previously cleared: Fetal/OB; Abdominal (including GYN, pelvic and infertility monitoring/follicle development); Pediatric; Small Organ (breast, testes, thyroid etc.); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Musculoskeletal Conventional and Superficial; Peripheral Vascular; Transvaginal (including GYN); Transrectal

Technology: The Voluson E Series (Voluson E6 / Voluson E8 / Voluson E10) employs the same fundamental scientific technology as its predicate devices.

Determination of Comparison to Predicates

Substantial Equivalence:

The proposed Voluson E Series (Voluson E6 / Voluson E8 / Voluson E10) is substantially equivalent to the predicate devices with regards 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 proposed Voluson E Series and predicate Voluson E Series systems have the same clinical intended use.
- The proposed Voluson E Series and predicate Voluson E Series systems have the same imaging modes.
- The proposed Voluson E Series and predicate Voluson E Series systems transducers are equivalent. The proposed Voluson E Series adds two new transducers RM7C and L2-9-D to the system and one probe IC9-D deleted. Applications for this probe is within the indications for use of the predicate system.
- The Software feature Shear Wave Elastography has been migrated from the predicate LOGIQ E10 (K173555).
- There is no change to the system indications for use.
- The systems are manufactured with materials which have



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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 proposed Voluson E Series and predicate Voluson E Series systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The proposed Voluson E Series and predicate systems have been designed in compliance with approved electrical and physical safety standards.
- The proposed Voluson E Series adds an improved version of existing software feature IOTA LR2 and IOTA Simple Rules model called **IOTA Adnex Model**. This software cannot be used to diagnose cancer. It can be used as a tool to aid in diagnosis of cancer by giving a probability of risk, but the tool itself is NOT a diagnostic test for cancer.
- The proposed Voluson E Series adds a feature of fetal brain diagnosis called **SonoCNS (Sone Central Nervous System)**
- The proposed Voluson E Series is adding a Fetal Cardio preset to one new RM7C transducer. Fetal Cardio setting is already implemented and cleared with probes eM6C, eM6CG2, RM6C, C1-5-D, C4-8-D, C1-6-D, C2-9-D and M5Sc-D (K172342).

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. The Voluson E Series and its applications comply with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 2005/(R)2012 And A1:2012
- IEC60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard:



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Electromagnetic Compatibility Requirements and Tests, 2007

- IEC60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment, 2007
- ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Third Edition, 2009
- NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment:2004
- ISO14971, Application of risk management to medical devices: Second edition 2007
- NEMA PS 3.1 - 3.20 (2016), 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)
- Performance testing (Verification)
- Safety testing (Verification)
- Final Acceptance Testing (Validation)

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, Voluson E Series (Voluson E6 / Voluson E8 / Voluson E10), did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Voluson E Series (Voluson E6 / Voluson E8 / Voluson E10) to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).