

FEB - 8 2011



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: April 30, 2010

Submitter: GE Healthcare [GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC]
9900 Innovation Dr
Wauwatosa, WI 53226

Primary Contact Person: Bryan Behn
Regulatory Affairs Manager
GE Healthcare, GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC.]
T:(414)721-4214
F:(414)918-8275

Secondary Contact Person: Jim Turner
Regulatory Affairs Manager America's Service
GE Healthcare, GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC
T:(262) 544-3359
F:(414)908-9225

Device: Trade Name: Voluson E6/E8/E8 Expert Diagnostic Ultrasound System

Common/Usual Name: Voluson E6/E8/E8 Expert

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): K061682 Voluson E8 Diagnostic Ultrasound System

Device Description: The Voluson **E6/E8/E8Expert** BT10 system is a full-featured Track 3 ultrasound system, primarily for general radiology use and specialized for OB/GYN with particular features for realtime 3D/4D acquisition. It consists of a mobile console with keyboard control panel; color LCD/TFT touch panel, color video display and optional image storage and printing devices. It provides high performance ultrasound imaging and analysis and has comprehensive networking and DICOM capability. It utilizes a variety of linear, curved linear, matrix phased array transducers including mechanical scanning transducers, which provide highly accurate realtime three dimensional imaging supporting all standard acquisition modes.



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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); Musculo-skeletal Conventional and Superficial; Peripheral Vascular; Transvaginal; Transrectal; and Intraoperative (abdominal, PV and neurological).

Technology: The Voluson E6/E8/E8 Expert employs the same fundamental scientific technology as its predicate devices. In additions to the original 21 transducers commercially released: RAB2-5-D, RAB4-8-D, RIC5-9-D, RNA5-9-D, RRE6-10-D, AB2-7-D, 4C-D, IC5-9-D, PA6-8-D, SP10-16-D, RSP6-16-D, RIC6-12-D, M12LW, RAM3-8, RSM5-14, 9L-D, 3S-D, P2D, P6D, 11L-D, M6C the Voluson E6/E8/E8 Expert will be released with these additional 7 transducers: C1-5-D, ML6-15-D, RRE5-10-D, RM6C, RM14L, C4-8-D, 3Sp-D.

Additional Features Description:

1. **Elastography Mode** on the Voluson E6/E8/E8 Expert is similar to the Elastography imaging mode on the GE Logiq E9 (K092271). Elastography is a method to extract and display mechanical properties of tissue. This imaging method involves applying manual pressure with the hand on the transducer. The actual imaging sequence is similar to the B mode sequence except that the system will acquire the RF signal instead of acquiring B mode data. The algorithm extracts a strain value information for every point of the image. The Elastography image then color-codes the stiff versus softer structures. The clinical benefits of elastography are still under evaluation. This feature allows the user to be able to determine whether or not a structure inside the patient is stiffer than another one; no clinical diagnostic claims are being made.

2. **Contrast Imaging with contrast agent** – Volume Contrast Imaging (VCI) is a feature which is already cleared on the Voluson E8, K061682 which improves the contrast resolution and the signal to noise ratio (without the use of contrast agents for radiological use).

The use of FDA approved contrast agents in 2D and 3D Volume mode for Cardiac LVO application is part of the modification and is already implemented and cleared on the GE Logiq E9 Ultrasound System (K092271). Injected contrast agents re-emit



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incident acoustic energy at a harmonic frequency much more efficiently than the surrounding tissue.

Determination of
Substantial Equivalence:

Summary of Non-Clinical Tests:

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform with applicable medical device safety standards. The Voluson E6/E8/E8 Expert BT10 and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were 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 E6/E8/E8/Expert BT10, did not require clinical studies to support substantial equivalence.

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



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Bryan Behn
Regulatory Affairs Manager
GE Healthcare, GE Medical Systems
Ultrasound and Primary Care Diagnostics, LLC
9900 Innovation Dr. RP-2138
WAUWATOSA WI 53226

FEB - 8 2011

Re: K101236
Trade/Device Name: Voluson E6/E8/E8 Expert Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: September 9, 2010
Received: September 10, 2010

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the Voluson E6/E8/E8 Expert Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

<u>RAB2-5-D</u>	<u>IC5-9-D</u>	<u>9L-D</u>	<u>C1-5-D</u>
<u>RAB4-8-D</u>	<u>PA6-8-D</u>	<u>M12LW</u>	<u>ML6-15-D</u>
<u>RIC5-9-D</u>	<u>SP10-16-D</u>	<u>3S-D</u>	<u>RM6C</u>
<u>RNA5-9-D</u>	<u>RSP6-16-D</u>	<u>P2D</u>	<u>RRE5-10-D</u>
<u>RRE6-10-D</u>	<u>RIC6-12-D</u>	<u>P6D</u>	<u>RM14L</u>
<u>AB2-7-D</u>	<u>RAM3-8</u>	<u>M6C</u>	<u>3Sp-D</u>
<u>4C-D</u>	<u>RSM5-14</u>	<u>11L-D</u>	<u>C4-8-D</u>

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. 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); 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.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Mary Pastel", with a stylized flourish at the end.

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)



GE Healthcare

510(k) Premarket Notification Submission

510(k) Number (if known): K 101236

Device Name: Voluson E6/E8/E8 Expert Diagnostic Ultrasound System

Indications for 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); Musculo-skeletal Conventional and Superficial; Peripheral Vascular; Transvaginal; Transrectal; and Intraoperative (abdominal, PV and neurological).

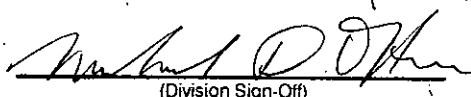
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use NA
(Part 21 CFR 801 Subpart C)

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IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD



(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety


510K K101236



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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 Voluson E6/E8/E8Expert BT10 system and for all of its probe/mode combinations. Combinations identified "P" represents those previously cleared with the unmodified Voluson E8. In a similar manner, "E" represents combinations added to the unmodified Voluson E8 via Guidance Appendix E. This modification did not alter the previously cleared system level indications, clinical applications or modes of operation.


(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K16123C

Diagnostic Ultrasound Indications for Use Form
GE Voluson E6/E8/E8 Expert 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 ^[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	[5,10]
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	P	P	P		P	P	P	P	P	P	[5,6,9]
Transurethral											
Intraoperative	P	P	P		P	P	P	P	P	P	
Intraoperative Neurological	P	P	P		P	P	P	P	P	P	
Intravascular											
Laparoscopic											

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

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

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

[10] contrast Imaging (contrast agent for LVO)

[*] 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 Device Evaluation (ODE) *ATVD*

Prescription User (Per 21 CFR 801.109)

[Signature]
(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101236



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Diagnostic Ultrasound Indications for Use Form
GE Voluson E6/E8/E8Expert 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	[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											
<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

[5] 3D/4D Imaging Mode

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

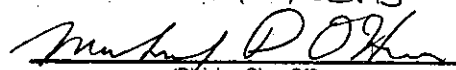
[7] Includes infertility monitoring of follicle development

[*] 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 Device Evaluation (ODE) OIVD

Prescription User (Per 21 CFR 801.109)


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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K

K101234



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Diagnostic Ultrasound Indications for Use Form
GE Voluson E6/E8/E8Expert with RAB4-8-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	[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)

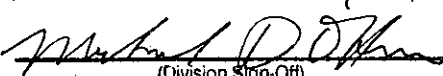
[7] Includes infertility monitoring of follicle development

[*] 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 Device Evaluation (ODE) OIVD

Prescription User (Per 21 CFR 801.109)


(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety



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Diagnostic Ultrasound Indications for Use Form

GE Voluson E6/E8/E8Expert 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	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

[*] 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 Device Evaluation (ODE) *QIVD*

Prescription User (Per 21 CFR 801.109)

M. J. O'Brien
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Diagnostic Ultrasound Indications for Use Form
GE Voluson E6/E8/E8 Expert with RNA5-9-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	[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]	P	P	P	P	P	P	P	P	P	P	[5,6]
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	[5]
Adult Cephalic											
Cardiac ^[3]	P	P	P	P	P	P	P	P	P	P	[5,10]
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[5,6]
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 ^[8]											
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Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes: [1] Abdominal is Neonatal and pediatric

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

[3] Cardiac is Neonatal and Pediatric.

[5] 3D/4D Imaging Mode

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

[10] Contrast Imaging (contrast agent for LVO)

[*] 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 Device Evaluation (ODE) *OTVD*

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[Signature]
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Diagnostic Ultrasound Indications for Use Form
GE Voluson E6/E8/E8Expert with RRE6-10-D Transducer

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	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
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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	P	P	P		P	P	P	P	P	P	[5,6]
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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


[8] Includes urology/prostate

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

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510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Voluson E6/E8/E8Expert with AB2-7-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]
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											
Musculo-skeletal Conventional	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											

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[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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Prescription User (Per 21 CFR 801.109)


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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K 15101230



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Voluson E6/E8/E8Expert 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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Diagnostic Ultrasound Indications for Use Form

GE Voluson E6/E8/E8Expert 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	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

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

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E6/E8/E8Expert with PA6-8-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 ^[1]											
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	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 ^[5]											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes: [1] Abdominal is Neonatal, pediatric and obstetrics

[3] Cardiac is Adult and Pediatric.

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

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Office of In Vitro Diagnostic Device Evaluation and Safety



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Diagnostic Ultrasound Indications for Use Form
GE Voluson E6/E8/E8Expert with SP10-16-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	[6]
Small Organ ^[2]	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	[6]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[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

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

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

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Diagnostic Ultrasound Indications for Use Form
GE Voluson E6/E8/E8Expert 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 ^[6]											
Transvaginal											
Transurethral											
Intraoperative	P	P	P		P	P	P	P	P	P	
Intraoperative Neurological	P	P	P		P	P	P	P	P	P	
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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Diagnostic Ultrasound Indications for Use Form
GE Voluson E6/E8/E8Expert 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										Other [Notes]
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
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	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

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

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E6/E8/E8Expert with RAM3-8 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)

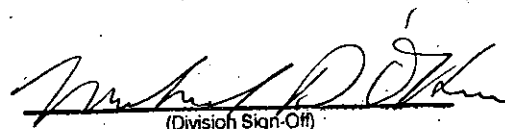
[7] Includes infertility monitoring of follicle development

[*] 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 Device Evaluation (ODE) **ODE OIVD**

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E6/E8/E8Expert with RSM5-14 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 ^[2]											
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											
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 Device Evaluation (ODE) **OIVD**

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E6/E8/E8Expert 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]											
Abdominal ^[1]											
Pediatric	P	P	P	N	P	P	P	P	P	P	[6]
Small Organ ^[2]	P	P	P	N	P	P	P	P	P	P	[6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	P	P	P	N	P	P	P	P	P	P	[6]
Musculo-skeletal Conventional	P	P	P	N	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)

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

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E6/E8/E8Expert with M12LW 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]
Small Organ ^[2]	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	[6]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[6]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[6]
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)

[*] 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 Device Evaluation (ODE) *61VD*

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Michael D. O'Brien
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Office of In Vitro Diagnostic Device Evaluation and Safety

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E6/E8/E8Expert with 3S-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

[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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Diagnostic Ultrasound Indications for Use Form

GE Voluson E6/E8/E8Expert 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 ^[7]											
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic				P							
Cardiac ^[3]				P							
Peripheral Vascular				P							
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: [3] Cardiac is adult and Pediatric

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Michael D. O'Dell
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Diagnostic Ultrasound Indications for Use Form

GE Voluson E6/E8/E8Expert 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 ^[1]											
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]				P							
Peripheral Vascular				P							
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: [3] Cardiac is adult and Pediatric

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E6/E8/E8Expert with M6C 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; E = added under Appendix E

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

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

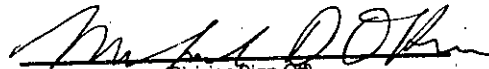
[7] Includes infertility monitoring of follicle development

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

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Office of In Vitro Diagnostic Device Evaluation and Safety



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510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Voluson E6/E8/E8Expert 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 ^[2]											
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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GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Voluson E6/E8/E8Expert 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	Combine d Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics ^[7]	E	E	E	E	E	E	E	E	E	E	[6]
Abdominal ^[1]	E	E	E	E	E	E	E	E	E	E	[6]
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	E	E	E	E	E	E	E	E	E	E	[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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Diagnostic Ultrasound Indications for Use Form

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Office of In Vitro Diagnostic Device Evaluation and Safety



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GE Voluson E6/E8/E8Expert 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	E	E	E		E	E	E	E	E	E	[6,9]
Small Organ ^[2]	E	E	E		E	E	E	E	E	E	[6,9]
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	E	E	E		E	E	E	E	E	E	[6,9]
Musculo-skeletal Conventional	E	E	E		E	E	E	E	E	E	[6,9]
Musculo-skeletal Superficial	E	E	E		E	E	E	E	E	E	[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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Diagnostic Ultrasound Indications for Use Form

GE Voluson E6/E8/E8Expert 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]	E	E	E		E	E	E	E	E	E	[5,6]
Abdominal ^[1]	E	E	E		E	E	E	E	E	E	[5,6]
Pediatric	E	E	E		E	E	E	E	E	E	[5,6]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional	E	E	E		E	E	E	E	E	E	[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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Diagnostic Ultrasound Indications for Use Form
GE Voluson E6/E8/E8Expert with RRE5-10-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]											
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]	N	N	N		N	N	N	N	N	N	[5,6,9]
Transvaginal	N	N	N		N	N	N	N	N	N	[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)

[8] Includes urology/prostate


[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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Diagnostic Ultrasound Indications for Use Form

GE Voluson E6/E8/E8Expert with RM14L 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 ^[2]											
Abdominal ^[1]											
Pediatric	N	N	N		N	N	N	N	N	N	[5,6]
Small Organ ^[2]	N	N	N		N	N	N	N	N	N	[5,6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	N	N	N		N	N	N	N	N	N	[5,6]
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N	N	[5,6]
Musculo-skeletal Superficial	N	N	N		N	N	N	N	N	N	[5,6]
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

[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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Diagnostic Ultrasound Indications for Use Form
GE Voluson E6/E8/E8Expert 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]	N	N	N	N	N	N	N	N	N	N	
Abdominal ^[1]	N	N	N	N	N	N	N	N	N	N	
Pediatric	N	N	N	N	N	N	N	N	N	N	
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic	N	N	N	N	N	N	N	N	N	N	
Cardiac ^[3]	N	N	N	N	N	N	N	N	N	N	10
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

[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.

[10] Contrast Imaging (contrast agent for LVO)

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E6/E8/E8Expert 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]	N	N	N		N	N	N	N	N	N	[6]
Abdominal ^[1]	N	N	N		N	N	N	N	N	N	[6]
Pediatric	N	N	N		N	N	N	N	N	N	[6]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	N	N	N		N	N	N	N	N	N	[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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