



GE Healthcare
% Mr. Bryan Behn
Regulatory Affairs Director
9900 Innovation Drive, RP2130
WAUWATOSA WI 53226

March 13, 2018

Re: K180374

Trade/Device Name: Voluson S8/ Voluson S10/ Voluson S10 Expert
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO and ITX
Dated: February 8, 2018
Received: February 12, 2018

Dear Mr. Behn:

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

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

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

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.

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,

 For

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

Enclosure



GE Healthcare
510(k) Premarket Notification Submission

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2020

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K180374

Device Name

Voluson S8/ Voluson S10/ Voluson S10 Expert

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 renal and GYN/pelvic); Pediatric; Small Organ (breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular (PV); Musculo-skeletal Conventional and Superficial; Transrectal (TR); Transvaginal (TV).

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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GE Healthcare
510(k) Premarket Notification Submission

Indications for Use Forms

The following forms represent indications with clinical applications and exam types along with the modes of operation for the Voluson S8, Voluson S10 and Voluson S10 Expert systems. Combinations identified “P” for the system represents those previously cleared in K160184. Combinations identified “N” for the transducers represents those not previously cleared any GE Ultrasound system. This modification does not add to indications to the previously cleared system level.



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form
Voluson S8 / Voluson S10 / Voluson S10 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]
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[5,6,9]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6,9]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[5,6,9]
Other											
<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

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

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

Prescription User (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

Voluson S10 Expert with C2-9-RS Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[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											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
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

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

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

Prescription User (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

Voluson S8 / Voluson S10 / Voluson S10 Expert with IC9-RS Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	P	P	P		P	P	P	P	P	P	[6,9]
Abdominal ^[1]	P	P	P		P	P	P	P	P	P	[6,9]
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

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

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

Prescription User (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

Voluson S8 / Voluson S10 / Voluson S10 Expert with 4C-RS Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	P	P	P		P	P	P	P	P	P	[6]
Abdominal ^[1]	P	P	P		P	P	P	P	P	P	[6]
Pediatric	P	P	P		P	P	P	P	P	P	[6]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[6]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[6]
Musculo-skeletal Superficial											
Other											
<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
 - [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
 - [3] Cardiac is Adult and Pediatric.
 - [5] 3D/4D Imaging Mode.
 - [6] Includes imaging of guidance of biopsy (2D/3D/4D).
 - [7] Includes infertility monitoring of follicle development.
 - [8] Includes urology/prostate.
 - [9] Elastography imaging- Elasticity
 - [*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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

Prescription User (Per 21 CFR 801.109)



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510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

Voluson S8 / Voluson S10 / Voluson S10 Expert with C1-5-RS Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[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 ^[8]											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

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

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

Prescription User (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

Voluson S8 / Voluson S10 / Voluson S10 Expert with 8C-RS Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	P	P	P		P	P	P	P	P	P	
Abdominal ^[1]	P	P	P		P	P	P	P	P	P	
Pediatric	P	P	P		P	P	P	P	P	P	
Small Organ ^[2]	P	P	P		P	P	P	P	P	P	
Neonatal Cephalic	P	P	P		P	P	P	P	P	P	
Adult Cephalic											
Cardiac ^[3]	P	P	P		P	P	P	P	P	P	
Peripheral Vascular	P	P	P		P	P	P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	
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

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

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

Prescription User (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

Voluson S8 / Voluson S10 / Voluson S10 Expert with 12L-RS Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[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 ^[8]											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

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

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

Prescription User (Per 21 CFR 801.109)



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510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

Voluson S8 / Voluson S10 / Voluson S10 Expert with 9L-RS Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[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]	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 ^[8]											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

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

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Prescription User (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

Voluson S8 / Voluson S10 / Voluson S10 Expert with 3Sc-RS Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	P	P	P	P	P	P	P	P	P	P	[6]
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	[6]
Pediatric	P	P	P	P	P	P	P	P	P	P	[6]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	[6]
Cardiac ^[3]	P	P	P	P	P	P	P	P	P	P	[6]
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<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
 - [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
 - [3] Cardiac is Adult and Pediatric.
 - [5] 3D/4D Imaging Mode.
 - [6] Includes imaging of guidance of biopsy (2D/3D/4D).
 - [7] Includes infertility monitoring of follicle development.
 - [8] Includes urology/prostate.
 - [9] Elastography imaging- Elasticity
 - [*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

Voluson S8 / Voluson S10 / Voluson S10 Expert with RIC5-9A-RS Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	P	P	P		P	P	P	P	P	P	[5,6,9]
Abdominal ^[1]	P	P	P		P	P	P	P	P	P	[5,6,9]
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

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

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Diagnostic Ultrasound Indications for Use Form

Voluson S8 / Voluson S10 / Voluson S10 Expert with RAB6-RS Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[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 ^[8]											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

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

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Diagnostic Ultrasound Indications for Use Form

Voluson S8 / Voluson S10 / Voluson S10 Expert with ML6-15-RS Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]											
Abdominal ^[1]	P	P	P		P	P	P	P	P	P	[6,9]
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 ^[8]											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

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

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Diagnostic Ultrasound Indications for Use Form

Voluson S8 / Voluson S10 / Voluson S10 Expert with 12S-RS Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]											
Abdominal ^[1]											
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	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 ^[8]											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

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

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Voluson S Series
(Voluson S8 / Voluson S10 / Voluson S10 Expert)

Section 5: 510(k) Summary



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510(k) Summary

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

Date: February 8, 2018

Submitter: GE Healthcare
9900 Innovation Dr
Wauwatosa, WI 53226

Primary Contact Person: Bryan Behn
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Regulatory Affairs Leader
GE Ultrasound Korea, Ltd.
T: +82 31 740 6307
F: +82 31 740 6431

Device: Trade Name: Voluson S8 / Voluson S10 / Voluson S10 Expert

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

Main Predicate Device(s): K160184 Voluson S Series, Voluson S6/S8/S10 Diagnostic
Ultrasound System

Reference Predicates: K172342 Voluson E Series; E6/E8/E10 Diagnostic Ultrasound
System

K162269 Voluson E Series; E6/E8/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. 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



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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 renal and GYN/pelvic); Pediatric; Small Organ (breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular (PV); Musculo-skeletal Conventional and Superficial; Transrectal (TR); Transvaginal (TV).

Technology: The Voluson S8 / Voluson S10 / Voluson S10 Expert employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence: Comparison to Predicates

The Voluson S8 / Voluson S10 / Voluson S10 Expert 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 S Series and predicate Voluson S series systems have the same clinical intended use.
- The proposed Voluson S Series and predicate Voluson S series systems have the same imaging modes.
- The proposed Voluson S Series and predicate Voluson S series transducers are identical except for the removal of a transducer (E8C-RS); the addition of a new transducer **C2-9-RS** (similar to C2-9-D on predicate Voluson E Series K162269).
- The proposed Voluson S Series and predicate Voluson S series systems have the same indications for use.
- The systems are manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The systems have acoustic power levels which are below



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the applicable FDA limits.

- The proposed Voluson S Series and predicate Voluson S series systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The proposed Voluson S Series and predicate Voluson S series systems have been designed in compliance with approved electrical and physical safety standards.
- The proposed Voluson S Series adds an improved version of existing software feature IOTA LR2 model called **IOTA Simple Rules** (previously cleared with K172342).
- The proposed Voluson S Series adds a 3D Analysis feature of the endometrial cavity called **SonoMetrium**. (previously cleared with K172342).
- The proposed Voluson S Series adds an enhanced feature of existing software feature HDlive called **HDlive Silhouette** (previously cleared with K172342).
- The proposed Voluson S Series adds an enhanced feature of existing software feature SRI called **VSRI** (previously cleared with K172342).
- The proposed Voluson S Series adds a software feature **Radiantflow** (previously cleared with 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 S8/S10/S10 Expert systems 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, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text)
- IEC60601-1-2, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests 2007



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- IEC60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment, 2015
- ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Third Edition, 2009/(R)2013
- NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment:2004 (R2009)
- ISO14971, Application of risk management to medical devices: Second edition 2007
- NEMA PS 3.1 - 3.20 (2011), Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)

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)
- 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 S8 / Voluson S10 / Voluson S10 Expert, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Voluson S8 / Voluson S10 / Voluson S10 Expert to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).