



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

April 26, 2016

GE Healthcare  
% Ms. Tracey Ortiz  
Regulatory Affairs Director  
9900 W. Innovation Drive  
WAUWATOSA WI 53226

Re: K160162  
Trade/Device Name: Voluson P6 / Voluson P8 Ultrasound Systems  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, ITX  
Dated: March 31, 2016  
Received: April 1, 2016

Dear Ms. Ortiz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned above the typed name and title.

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: January 31, 2017  
See PRA Statement on last page.

**Indications for Use**

510(k) Number (if known)

**K160162**

Device Name

Voluson P6 / Voluson P8

Indications for Use (Describe)

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

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

Prescription Use (Part 21 CFR 801 Subpart D)

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

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**FOR FDA USE ONLY**

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



**GE Healthcare**  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**  
**Voluson P6 / Voluson P8 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 <sup>[7]</sup>	P	P	P	P	P	P	P	P	P	P	[ 5,6]
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	P	[ 5,6]
Pediatric	P	P	P	P	P	P	P	P	P	P	[6]
Small Organ <sup>[2]</sup>	P	P	P		P	P	P	P	P	P	[6]
Neonatal Cephalic	P	P	P		P	P	P	P	P	P	[6]
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	[6]
Cardiac <sup>[3]</sup>	P	P	P	P	P	P	P	P	P	P	[6]
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[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	[6]
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[8]</sup>	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

- 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  
 [\*] 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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**Diagnostic Ultrasound Indications for Use Form**

**Voluson P6 / Voluson P8 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 <sup>[7]</sup>	N	N	N		N	N	N	N	N	N	[ 6]
Abdominal <sup>[1]</sup>	N	N	N		N	N	N	N	N	N	[ 6]
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[8]</sup>	N	N	N		N	N	N	N	N	N	[ 6]
Transvaginal <sup>[10]</sup>	N	N	N		N	N	N	N	N	N	[ 6]
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
  - [\*] 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 P6 / Voluson P8 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 <sup>[7]</sup>	P	P	P		P	P	P	P	P	P	[6]
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	[6]
Pediatric	P	P	P		P	P	P	P	P	P	[6]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
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 <sup>[8]</sup>											
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.
  - [\*] 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 P6 / Voluson P8 with E8C-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 <sup>[7]</sup>	P	P	P		P	P	P	P	P	P	[6]
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	[6]
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic	P	P	P		P	P	P	P	P	P	[6]
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[8]</sup>	P	P	P		P	P	P	P	P	P	[6]
Transvaginal	P	P	P		P	P	P	P	P	P	[6]
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
  - [\*] 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)



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**Diagnostic Ultrasound Indications for Use Form**

Voluson P6 / Voluson P8 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 <sup>[7]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric	P	P	P		P	P	P	P	P	P	[6]
Small Organ <sup>[2]</sup>	P	P	P		P	P	P	P	P	P	[6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
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 <sup>[8]</sup>											
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.
  - [\*] 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 P6 / Voluson P8 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 <sup>[7]</sup>	P	P	P	P	P	P	P	P	P	P	[6]
Abdominal <sup>[1]</sup>	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 <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	[6]
Cardiac <sup>[3]</sup>	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 <sup>[8]</sup>											
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.
  - [\*] 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 P6 / Voluson P8 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 <sup>[7]</sup>	N	N	N		N	N	N	N	N	N	[ 5,6]
Abdominal <sup>[1]</sup>	N	N	N		N	N	N	N	N	N	[ 5,6]
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[8]</sup>	N	N	N		N	N	N	N	N	N	[ 5,6]
Transvaginal	N	N	N		N	N	N	N	N	N	[ 5,6]
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.  
 [\*] 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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**Diagnostic Ultrasound Indications for Use Form**

Voluson P6 / Voluson P8 with RAB2-6-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 <sup>[7]</sup>	P	P	P		P	P	P	P	P	P	[5,6]
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	[5,6]
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
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 <sup>[8]</sup>											
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.
  - [\*] 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

**510(k) Summary**

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

Date: January 26, 2016

Submitter: GE Healthcare  
9900 Innovation Dr  
Wauwatosa, WI 53226

Primary Contact Person: Tracey Ortiz  
Regulatory Affairs Director  
GE Healthcare  
T:(262)676-6120  
F:(414)918-8275

Secondary Contact Person: Chan Sook Kim  
Regulatory Affairs Leader  
GE Healthcare  
T: +82 31 740 6307  
F: +82 31 740 6431

Device: Trade Name: Voluson P6 / Voluson P8 Ultrasound Systems

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

Predicate Device(s): K141675 Voluson P Series; Voluson P6/P8 Diagnostic  
Ultrasound System

K152567 Voluson E Series; E6/E8/E10 Diagnostic Ultrasound  
System

K142472 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 realtime 3D/4D acquisition. They consist of a mobile console with keyboard control panel; color LCD display, 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



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### 510(k) Premarket Notification Submission

electronic scanning transducers, which provide accurate realtime 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 (Including Urology and Prostate) (TR); Transvaginal (TV).

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

Determination of Substantial Equivalence: Comparison to Predicates  
The Voluson P6 / Voluson P8 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 Voluson P6 / Voluson P8 and predicate Voluson P Series systems have the same clinical intended use.
- The Voluson P6 / Voluson P8 and predicate Voluson P Series systems have the same imaging modes.
- The Voluson P6 / Voluson P8 and predicate Voluson P Series systems transducers are identical except for the removal of two transducers for RIC5-9W-RS and RAB2-5-RS; the addition of two new transducers IC9-RS (similar to IC9-D on predicate Voluson E Series K152567), and RIC5-9A-RS (similar to RIC5-9W-RS on predicate Voluson P Series K141675)
- The Voluson P6 / Voluson P8 and predicate Voluson P 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.



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- The systems have acoustic power levels which are below the applicable FDA limits.
- The Voluson P6 / Voluson P8 and predicate Voluson P Series systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The Voluson P6 / Voluson P8 and predicate systems have been designed in compliance with approved electrical and physical safety standards.
- The Voluson P6 / Voluson P8 adds a SIM card to the system to allow users to send images and text via MMS\_SMS wirelessly (previously cleared with K142472).
- The Voluson P6 / Voluson P8 adds a GYN measurement tool created by IOTA Group called IOTA LR2 model (previously cleared with K142472).
- The proposed Voluson P6 / Voluson P8 beam former has changed to STB MLA4 (previously cleared with K152567 / K142472).

#### 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 P6 / Voluson P8 and its applications comply with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 2005/C1:2012
- IEC60601-1-2, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests 2007
- IEC60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment, 2007
- NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment: 2004
- ISO10993-1, Biological Evaluation of Medical Devices-



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Part 1: Evaluation and Testing- Third Edition, 2009

- NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment:2004
- ISO14971, Application of risk management to medical devices: Second edition 2007
- NEMA PS 3.1 - 3.20 (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 P6 / Voluson P8, did not require clinical studies to support substantial equivalence.

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