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

March 29, 2018

Re: K180535
Trade/Device Name: Voluson P6 and Voluson P8
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: February 26, 2018
Received: February 28, 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,

Michael D. O'Hara 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180535

Device Name
Voluson P6 and Voluson P8

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 (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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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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 P6 and Voluson P8 systems. Combinations identified "P" for the system represents those previously cleared in K160162. This modification does not add to indications to the previously cleared system level.

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 *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	[5,6]
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**	[6]
Small Organ[2]	**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[3]	**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											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[5,6]
Transvaginal	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[5,6]
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

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

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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 *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes)
Ophthalmic											
Fetal / Obstetrics[7]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[6]
Abdominal[1]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[6]
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[6]
Transvaginal[10]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[6]
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

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

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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 *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes)
Ophthalmic											
Fetal / Obstetrics[7]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[6]
Abdominal[1]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[6]
Pediatric	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[6]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[6]
Musculo-skeletal Conventional	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[6]
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

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

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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 *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[6]
Abdominal[1]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[6]
Pediatric											
Small Organ[2]											
Neonatal Cephalic	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[6]
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[6]
Transvaginal	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[6]
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

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

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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 *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes)
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[6]
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											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

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

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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 *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	[6]
Abdominal[1]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	[6]
Pediatric	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	[6]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	[6]
Cardiac[3]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	[6]
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

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

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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 *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[5,6]
Abdominal[1]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[5,6]
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[5,6]
Transvaginal	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[5,6]
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

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

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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 *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes)
Ophthalmic											
Fetal / Obstetrics[7]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[5,6]
Abdominal[1]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[5,6]
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[5,6]
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

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

510(k) Summary

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

Date:	February 26, 2018
Submitter:	GE Healthcare 9900 Innovation Dr Wauwatosa, WI 53226
Primary Contact Person:	Bryan Behn Regulatory Affairs Director GE Healthcare T:(262)247-5502 F:(414)918-8275
Secondary Contact Person:	Jiyeon Park Regulatory Affairs Leader GE Ultrasound Korea, Ltd. T: +82 31 740 6307 F: +82 31 740 6431
Device: Trade Name:	Voluson P6 / Voluson P8
Common/Usual Name:	Ultrasound system
Classification Names: Product Code:	Class II 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):	K160162 Voluson P Series; Voluson P6/P8 Diagnostic Ultrasound System
Reference Predicate:	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 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 electronic scanning transducers, which provide 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 (Including Urology and Prostate) (TR); Transvaginal (TV).

Technology: The Voluson P Series (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, technologicial characteristics and safety and effectiveness.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The Voluson P Series and predicate Voluson P Series systems have the same clinical intended use.
- The Voluson P Series and predicate Voluson P Series systems have the same imaging modes.
- The Voluson P Series and predicate Voluson P Series systems transducers are identical.
- The Voluson P Series 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.
- The systems have acoustic power levels which are below the applicable FDA limits.
- The proposed Voluson P Series and predicate Voluson P Series systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.

- The proposed Voluson P Series and predicate Voluson P series systems have been designed in compliance with approved electrical and physical safety standards.
- The proposed Voluson P Series adds an improved version of existing software feature IOTA LR2 model called **IOTA Simple Rules** (previously cleared with K172342).
- The proposed Voluson P Series adds a 3D Analysis feature of the endometrial cavity called **SonoMetrium**. (previously cleared with K172342).
- The proposed Voluson P Series adde a software **Coded Contrast** (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 P6/P8 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
- 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

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).