September 20, 2018

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

Re: K181783
Trade/Device Name: LOGIQ P9; LOGIQ P7
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: July 2, 2018
Received: July 3, 2018

Dear Bryan Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*
K181783

Device Name
LOGIQ P9; LOGIQ P7

Indications for Use *(Describe)*
The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative (abdominal, thoracic, vascular).

When Pinpoint GT Technology, from C.R. Bard, Inc., is included with the system, the Indications for Use include: Pinpoint GT Technology is intended to provide clinicians with visual tools for passive magnetic tracking of a needle with respect to ultrasound image data.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Indications for Use Forms

The following forms represent indications with clinical applications and exam types along with the modes of operation for the LOGIQ P9 and LOGIQ P7 system. Combinations identified "P" for the transducers represents those previously cleared with LOGIQ P9 and LOGIQ P7 and *P for those cleared on another GE Ultrasound system and those identified and "N" are new. Please see section 11 Table 11.2.1 for information on previous clearance information on these transducers.

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 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	3,5,6,10
Pediatric	P	P	P	P	P	P	P	P	P	P	3,5,6
Small Organ[2]	P	P	P	P	P	P	P	P	P	P	3,5,6,10
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	5,6
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	5,6
Cardiac Adult & Pediatric	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	3,5,6
Musculo-skeletal Conventional	P	P	P	P	P	P	P	P	P	P	3,5,6,10
Musculo-skeletal Superficial	P	P	P	P	P	P	P	P	P	P	3,5,6,9, 10
Other[4]	P	P	P	P	P	P	P	P	P	P	3,5,6
Exam Type, Means of Access											
Transesophageal	N	N	N	N	N	N	N	N	N	N	
Transrectal[8]	P	P	P	P	P	P	P	P	P	P	3,5,6
Transvaginal	P	P	P	P	P	P	P	P	P	P	3,5,6
Transuretheral											
Intraoperative[8]	P	P	P	P	P	P	P	P	P	P	3,5,6
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 and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[9] Needle guidance with PinpointTM GT needle technology
[10] Shear Wave Elastography
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7with L12n-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	P	P			P		P	P	P		
Fetal / Obstetrics[7]											
Abdominal[1]	P	P			P		P	P	P		
Pediatric	P	P			P		P	P	P		
Small Organ[2]	P	P			P		P	P	P		
Neonatal Cephalic	P	P			P		P	P	P		
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular	P	P			P		P	P	P		
Musculo-skeletal Conventional	P	P			P		P	P	P		
Musculo-skeletal Superficial	P	P			P		P	P	P		[9]
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]	P	P			P		P	P	P		
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 and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[9] Needle guidance with PinpointTM GT needle technology;
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 with P6D 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											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic			**P**	**P**							
Cardiac Adult & Pediatric			**P**	**P**							
Peripheral Vascular			**P**	**P**							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
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 and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 with L4-12t-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**	[3,6]
Small Organ[2]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[3,6]
Neonatal Cephalic	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[3,6]
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[3,6]
Musculo-skeletal Conventional	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[3,6]
Musculo-skeletal Superficial	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[3,6]
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
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 and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 with L10-22-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											
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 Adult & Pediatric											
Peripheral Vascular											
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[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
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 and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 with L3-9i-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											
Small Organ[2]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
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[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
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 and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 with E8CS-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**	[3,6]
Abdominal[1]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[3,6]
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[3,6]
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[3,6]
Transvaginal	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[3,6]
Transuretheral											
Intraoperative[8]											
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 and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 with BE9CS-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											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[3,6]
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[3,6]
Transvaginal											
Transuretheral											
Intraoperative[8]											
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 and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 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 Adult & Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[5,6]
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	[5,6]
Transuretheral											
Intraoperative[8]											
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 and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 with 12S-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**	**P**	
Small Organ[2]											
Neonatal Cephalic	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
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 and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 with C1-5-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**	5,6
Abdominal[1]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6, 10
Pediatric	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
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 and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[10] Shear Wave Elastography
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 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**	**P**	5,6
Abdominal[1]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6, 10
Pediatric	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
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 and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[10] Shear Wave Elastography
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 with 9L-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]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Pediatric	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Small Organ[2]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
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 and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 with ML6-15-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**	3,5,6
Small Organ[2]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Neonatal Cephalic	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Conventional	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Superficial	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
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 and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 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**	5,6
Abdominal[1]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Transvaginal	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3.5,6
Transuretheral											
Intraoperative[8]											
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 and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 with L8-18i-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**	5,6
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 Adult & Pediatric											
Peripheral Vascular	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Conventional	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Superficial	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
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 and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 with P8D 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											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic			**P**	**P**							
Cardiac Adult & Pediatric			**P**	**P**							
Peripheral Vascular			**P**	**P**							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
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 and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 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 Adult & Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	5,6
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
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 and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 with L6-12-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]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Pediatric	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Small Organ[2]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Conventional	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Superficial	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
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 and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 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]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Pediatric	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Small Organ[2]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Conventional	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Superficial	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
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 and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 with 8C-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]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	5
Pediatric	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	5
Small Organ[2]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	5
Neonatal Cephalic	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	5
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
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 and thyroid
[3] Elastography Imaging – Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 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]											
Abdominal[1]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	5,6
Pediatric	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	5,6
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Cardiac Adult & Pediatric	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
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 and thyroid
[3] Elastography Imaging – Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 with 6S-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**	**P**	
Small Organ[2]											
Neonatal Cephalic	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Adult Cephalic											
Cardiac Adult & Pediatric	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
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 and thyroid
[3] Elastography Imaging – Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 with L3-12-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]	N	N	N		N	N	N	N	N	N	5,6
Abdominal[1]	N	N	N		N	N	N	N	N	N	3,5,6, 10
Pediatric	N	N	N		N	N	N	N	N	N	3,5,6
Small Organ[2]	N	N	N		N	N	N	N	N	N	3,5,6, 10
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular	N	N	N		N	N	N	N	N	N	3,5,6
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N	N	3,5,6, 10
Musculo-skeletal Superficial	N	N	N		N	N	N	N	N	N	3,5,6, 10
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
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 and thyroid
[3] Elastography Imaging – Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[10] Shear Wave Elastography
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 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 Adult & Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal	***P**	***P**	***P**		***P**	***P**	***P**	***P**	***P**	***P**	**6**
Transuretheral	***P**	***P**	***P**		***P**	***P**	***P**	***P**	***P**	***P**	**6**
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; ***P = previously cleared by FDA in (K160162)**

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging – Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 with 6Tc-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											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric	***P**	***P**	***P**	***P**	***P**	***P**	***P**	***P**	***P**	***P**	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal	***P**	***P**	***P**	***P**	***P**	***P**	***P**	***P**	***P**	***P**	
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; ***P = previously cleared by FDA in K170445**

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging – Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ P9; LOGIQ P7 with P2D 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											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic				***P**							
Cardiac Adult & Pediatric				***P**							
Peripheral Vascular				***P**							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; ***P = previously cleared by FDA in K170445**

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging – Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

510(k) Summary

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

Date:	July 2, 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:	Soyoung Park Regulatory Affairs Specialist GE Healthcare GE Ultrasound Korea, Ltd. T: +82-31-740-6136
Device: Trade Name:	LOGIQ P9; LOGIQ P7
Common/Usual Name:	LOGIQ P9; LOGIQ P7
Classification Names:	Class II
Product Code:	Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550 90-IYN Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX
Primary Predicate Device:	K163596 LOGIQ P9; LOGIQ P7 Diagnostic Ultrasound System
Reference Predicate Device(s):	K170445 LOGIQ S8 Diagnostic Ultrasound System K160162 Voluson P6 And Voluson P8 K173555 LOGIQ E10
Device Description:	The LOGIQ P9; LOGIQ P7 is a full featured, general purpose diagnostic ultrasound system which consists of a mobile console approximately 53 cm wide, 74 cm deep and 157 cm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls, 10.4-inch LCD touch screen and color 21.5-inch LCD image display.

New technology added:	Shear wave elastography on the LOGIQ P9; LOGIQ P7 is an ultrasound imaging mode in which shear waves are generated in-vivo acoustically via the imaging ultrasound transducer. The motion of the shear waves is then tracked to determine their velocity of propagation as an indicator of the mechanical properties of the tissue. HDlive allows the user can alter the position of the light source to get a more natural image display. Connectivity to LOGIQ P Apps which allows the user to take a picture of scanning area with a smart device to attach to the patient record and duplicate the UI of the touch panel onto a smart device to control the touch panel UI from the smart device. HRes contrast imaging is used for developing harmonic signals of the contrast agent. Additionally, LOGIQ P9; LOGIQ P7 enhance Contrast imaging, B steer+ and B-flow/B-flow color previously on the system.
Intended Use:	The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative (abdominal, thoracic, vascular). When Pinpoint™ GT Technology, from C.R. Bard, Inc., is included with the system, the Indications for Use include: Pinpoint GT Technology is intended to provide clinicians with visual tools for passive magnetic tracking of a needle with respect to ultrasound image data.
Technology:	The LOGIQ P9; LOGIQ P7 employs the same fundamental scientific technology as its predicate devices
Determination of Substantial Equivalence:	Comparison to Predicate Devices The LOGIQ P9; LOGIQ P7 systems are substantially equivalent to the predicate devices with regard 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 LOGIQ P9; LOGIQ P7and predicate LOGIQ P9; LOGIQ P7 systems have the same clinical intended uses.
- The LOGIQ P9; LOGIQ P7 and predicate LOGIQ P9; LOGIQ P7systems have the same imaging modes except Shearwave Elastography which is migrated from LOGIQ S8 (K170445).
- The LOGIQ P9; LOGIQ P7 and predicate LOGIQ P9; LOGIQ P7 systems transducers are identical except for the addition of 4 new transducers L3-12-RS (smilar to L3-12-D on predicate LOGIQ S8 K170445, only change os the connector type D to RS), 6Tc-RS and P2D (identical to LOGIQ S8 K170445) and IC9-RS on predicate Voluson P6/P8 (K160162)
- The LOGIQ P9; LOGIQ P7 and predicate LOGIQ P9; LOGIQ P7 systems have the same indications for use with the addition of Transesophageal exams
- 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 LOGIQ P9; LOGIQ P7 and predicate LOGIQ P9; LOGIQ P7 systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The LOGIQ P9; LOGIQ P7 and predicate LOGIQ P9; LOGIQ P7systems have been designed in compliance with approved electrical and physical safety standards.
- The following feature has been migrated from Voluson P6/P8 (K180535) HD live.
- The following features have been migrated from LOGIQ E10 (K173555) Tricefy and LOGIQ P Apps.
- The following feature has been migrated from LOGIQ S8 (K170445) Hres contrast mode.
- The LOGIQ P9; LOGIQ P7 extends supportable probes on contrast image mode and B steer+ mode. And it enhances B-flow/B-flow color mode with high definition color as a minor change.
- The systems can recall non-ultrasound DICOM images on the image history page and provides probe light on probe holder.

Summary of Non-Clinical Performance 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. LOGIQ P9 and LOGIQ P7 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
- ISO10993-1, Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing- Third Edition, 2009
- NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment:2004
- ISO14971, Application of risk management to medical devices: Second edition 2007
- NEMA PS 3.1 - 3.20 (2011), Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)

The proposed LOGIQ P9; LOGIQ P7 Ultrasound Systems also comply with the FDA ultrasound specific guidance, Guidance for Industry and FDA Staff – Information for manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (September 9, 2008).

Non-Clinical verification testing has been performed to cover system level requirements and the risk control measures. Non-Clinical validation testing covered the intended use and commercial claims as well as usability testing with representative intended users.

All these tests were used to support substantial equivalence of the subject device and demonstrate that the proposed LOGIQ P9; LOGIQ P7 Ultrasound Systems comply with international and FDA-recognized consensus standards and FDA ultrasound guidance document and meet the acceptance criteria and are adequate for their intended use.

Therefore, the proposed LOGIQ P9; LOGIQ P7 Diagnostic Ultrasound Systems are substantially equivalent to the predicate in terms of safety and effectiveness.

The following quality assurance measures are applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, LOGIQ P9; LOGIQ P7, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the LOGIQ P9; LOGIQ P7 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).