



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

GE Medical Systems Ultrasound and Primary Care Diagnostics  
% Mr. Bryan Behn  
Sr. Regulatory Affairs Manager  
9900 Innovation Drive  
WAUWATOSA WI 53226

October 08, 2015

Re: K152309  
Trade/Device Name: LOGIQ E9, LOGIQ E9 XDclear 2.0  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, ITX  
Dated: August 14, 2015  
Received: August 17, 2015

Dear Mr. Behn:

This letter corrects our substantially equivalent letter of September 14, 2015.

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 black ink, appearing to read "Robert Ochs", is written over a faint, large, light-colored "FDA" watermark.

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

## Indications for Use

510(k) Number (if known)

K152309

Device Name

LOGIQ E9, LOGIQ E9 XDclear 2.0

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 and vascular).

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.

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**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ E9, LOGIQ E9 XDclear 2.0 Ultrasound System**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>†</sup>	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	P	[3,5,6,9,10]
Pediatric	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Small Organ <sup>[2]</sup>	P	P	P	P	P	P	P	P	P	P	[3,5,6,9,10]
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Cardiac Adult	P	P	P	P	P	P	P	P	P	P	
Cardiac Pediatric	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Musculo-skeletal Conventional	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Musculo-skeletal Superficial	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Other <sup>[4]</sup>	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P	P	
Transrectal	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Transvaginal	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Transurethral											
Intraoperative <sup>[8]</sup>	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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, Gyn

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[10] Shear wave elastography

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

(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)

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**Diagnostic Ultrasound Indications for Use Form  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with 3CRF Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>	P	P	P		P	P	P	P	P	P	[5,6,9]
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	[5,6,9]
Pediatric	P	P	P		P	P	P	P	P	P	[5,6,9]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	P	P	P		P	P	P	P	P	P	[5,6,9]
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

(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**  
**GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with 3CRF-D Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>	P	P	P		P	P	P	P	P	P	[5,6,9]
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	[5,6,9]
Pediatric	P	P	P		P	P	P	P	P	P	[5,6,9]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	P	P	P		P	P	P	P	P	P	[5,6,9]
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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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  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with 6S-D Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>	P	P	P	P	P	P	P	P	P	P	
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ <sup>[2]</sup>											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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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  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with 6Tc Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult	P	P	P	P	P	P	P	P	P	P	
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P	P	
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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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**  
**GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with 9L-D Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>	P	P	P		P	P	P	P	P	P	[5,6,9]
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	[3,5,6,9,10]
Pediatric	P	P	P		P	P	P	P	P	P	[3,5,6,9]
Small Organ <sup>[2]</sup>	P	P	P		P	P	P	P	P	P	[3,5,6,9,10]
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[3,5,6,9]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[3,5,6,9]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[3,5,6,9]
Other <sup>[4]</sup>	P	P	P		P	P	P	P	P	P	[3,5,6,9]
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

[10] Shear wave elastography

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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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  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with 11L-D Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>	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 <sup>[2]</sup>	P	P	P		P	P	P	P	P	P	[3,5,6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac 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 <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

(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  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with C1-5-D 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 <sup>9</sup>	Other [Notes]
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

(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)

Page 9 of 36

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with IC5-9-D Transducer**

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

Clinical Application	Mode of Operation											
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]	
Anatomy/Region of Interest												
Ophthalmic												
Fetal/Obstetrics <sup>[7]</sup>	<b>P</b>	<b>P</b>	<b>P</b>		<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>[5,6,9]</b>	
Abdominal <sup>[1]</sup>												
Pediatric												
Small Organ <sup>[2]</sup>												
Neonatal Cephalic												
Adult Cephalic												
Cardiac Adult												
Cardiac Pediatric												
Peripheral Vascular												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other <sup>[4]</sup>	<b>P</b>	<b>P</b>	<b>P</b>		<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>[3,5,6,9]</b>	
Exam Type, Means of Access												
Transesophageal												
Transrectal	<b>P</b>	<b>P</b>	<b>P</b>		<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>[3,5,6,9]</b>	
Transvaginal	<b>P</b>	<b>P</b>	<b>P</b>		<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>[3,5,6,9]</b>	
Transurethral												
Intraoperative <sup>[8]</sup>												
Intraoperative Neurological												
Intravascular												
Laparoscopic												

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

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

[2] Small organ includes breast, testes 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, Gyn

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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**Diagnostic Ultrasound Indications for Use Form  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with L8-18i-D Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric	P	P	P		P	P	P	P	P	P	[3,5,6,9]
Small Organ <sup>[2]</sup>	P	P	P		P	P	P	P	P	P	[3,5,6,9]
Neonatal Cephalic	P	P	P		P	P	P	P	P	P	[5,6,9]
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[3,5,6,9]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[3,5,6,9]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[3,5,6,9]
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>	P	P	P		P	P	P	P	P	P	[3,5,6,9]
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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

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**Diagnostic Ultrasound Indications for Use Form  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with M4S-D Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
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	[5,6]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac Adult	P	P	P	P	P	P	P	P	P	P	
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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**Diagnostic Ultrasound Indications for Use Form  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with M5S-D Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>†</sup>	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	[9]
Cardiac Adult	P	P	P	P	P	P	P	P	P	P	
Cardiac Pediatric	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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**Diagnostic Ultrasound Indications for Use Form  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with M6C-D Transducer**

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

Clinical Application	Mode of Operation											
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]	
Anatomy/Region of Interest												
Ophthalmic												
Fetal/Obstetrics <sup>[7]</sup>	P	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	P	[5,6]
Pediatric	P	P	P	P	P	P	P	P	P	P	P	[5,6]
Small Organ <sup>[2]</sup>												
Neonatal Cephalic												
Adult Cephalic												
Cardiac Adult												
Cardiac Pediatric												
Peripheral Vascular												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other <sup>[4]</sup>												
Exam Type, Means of Access												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intraoperative <sup>[8]</sup>												
Intraoperative Neurological												
Intravascular												
Laparoscopic												

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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**Diagnostic Ultrasound Indications for Use Form  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with ML6-15-D Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>†</sup>	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric	P	P	P		P	P	P	P	P	P	[3,5,6,9]
Small Organ <sup>[2]</sup>	P	P	P		P	P	P	P	P	P	[3,5,6,9]
Neonatal Cephalic	P	P	P		P	P	P	P	P	P	[9]
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[3,5,6,9]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[3,5,6,9]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[3,5,6,9]
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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**Diagnostic Ultrasound Indications for Use Form  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with P2D**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic			P	P							
Cardiac Adult			P	P							
Cardiac Pediatric			P	P							
Peripheral Vascular			P	P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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**Diagnostic Ultrasound Indications for Use Form  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with P6D Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic			P	P							
Cardiac Adult			P	P							
Cardiac Pediatric			P	P							
Peripheral Vascular			P	P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with RAB2-5-D Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
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	P	P	P		P	P	P	P	P	P	[5,6]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	P	P	P		P	P	P	P	P	P	[5]
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

(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)**

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**Diagnostic Ultrasound Indications for Use Form  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with RAB4-8-D Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
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	P	P	P		P	P	P	P	P	P	[5,6]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

(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)**

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**Diagnostic Ultrasound Indications for Use Form  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with RIC5-9-D Transducer**

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

Clinical Application	Mode of Operation											
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]	
Anatomy/Region of Interest												
Ophthalmic												
Fetal/Obstetrics <sup>[7]</sup>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>[5,6]</b>
Abdominal <sup>[1]</sup>												
Pediatric												
Small Organ <sup>[2]</sup>												
Neonatal Cephalic												
Adult Cephalic												
Cardiac Adult												
Cardiac Pediatric												
Peripheral Vascular												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other <sup>[4]</sup>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>[3,5,6]</b>
Exam Type, Means of Access												
Transesophageal												
Transrectal	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>[3,5,6]</b>
Transvaginal	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>[3,5,6]</b>
Transurethral												
Intraoperative <sup>[8]</sup>												
Intraoperative Neurological												
Intravascular												
Laparoscopic												

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

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

[2] Small organ includes breast, testes 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, Gyn

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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

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**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with RNA5-9-D Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
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	[5,6]
Small Organ <sup>[2]</sup>	P	P	P	P	P	P	P	P	P	P	[5,6]
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	[5]
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[5,6]
Musculo-skeletal Conventional	P	P	P	P	P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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**Diagnostic Ultrasound Indications for Use Form  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with RSP6-16-D Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric	P	P	P		P	P	P	P	P	P	[3,5,6]
Small Organ <sup>[2]</sup>	P	P	P		P	P	P	P	P	P	[3,5,6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac 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 <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>	P	P	P		P	P	P	P	P	P	
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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

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**Diagnostic Ultrasound Indications for Use Form  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with S1-5 Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Cardiac Adult	P	P	P	P	P	P	P	P	P	P	
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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**Diagnostic Ultrasound Indications for Use Form  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with S4-10 Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Small Organ <sup>[2]</sup>	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with S4-10-D Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Small Organ <sup>[2]</sup>	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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**Diagnostic Ultrasound Indications for Use Form  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with C2-9-D Transducer**

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

Clinical Application	Mode of Operation											
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]	
Anatomy/Region of Interest												
Ophthalmic												
Fetal/Obstetrics <sup>[7]</sup>	P	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Pediatric	P	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Small Organ <sup>[2]</sup>												
Neonatal Cephalic												
Adult Cephalic												
Cardiac Adult												
Cardiac Pediatric												
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other <sup>[4]</sup>	P	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Exam Type, Means of Access												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intraoperative <sup>[8]</sup>												
Intraoperative Neurological												
Intravascular												
Laparoscopic												

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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**Diagnostic Ultrasound Indications for Use Form  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with RAB6-D Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
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	P	P	P		P	P	P	P	P	P	[5,6]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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**Diagnostic Ultrasound Indications for Use Form  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with S1-5-D Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Cardiac Adult	P	P	P	P	P	P	P	P	P	P	
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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

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**Diagnostic Ultrasound Indications for Use Form  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with C1-6-D 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 <sup>9</sup>	Other [Notes]
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	P	[3,5,6,9,10]
Pediatric	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

[10] Shear wave elastography

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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

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**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with C2-9VN-D Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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

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**Diagnostic Ultrasound Indications for Use Form  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with C1-6VN-D Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	P	[3,5,6,9,10]
Pediatric	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

[10] Shear wave elastography

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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

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**Diagnostic Ultrasound Indications for Use Form  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with C2-7-D Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>	N	N	N		N		N	N	N	N	[5,6]
Pediatric	N	N	N		N		N	N	N	N	[5,6]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

[10] Shear wave elastography

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with C2-7VN-D 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 <sup>9</sup>	Other [Notes]
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>	N	N	N		N		N	N	N	N	[5,6,9]
Pediatric	N	N	N		N		N	N	N	N	[5,6,9]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

[10] Shear wave elastography

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with L3-9i-D Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>	N	N	N		N		N	N	N	N	[5]
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

[10] Shear wave elastography

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

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**Diagnostic Ultrasound Indications for Use Form  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with C3-10-D Transducer**

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric	N	N	N		N		N	N	N	N	[5,9]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic	N	N	N		N		N	N	N	N	[5,9]
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	N	N	N		N		N	N	N	N	[5,9]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial	N	N	N		N		N	N	N	N	[5,6,9]
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

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

[2] Small organ includes breast, testes 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] Volume navigation

[10] Shear wave elastography

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

System provides real-time 3D and 4D acquisition when used with special 4D probes

(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)**

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**Diagnostic Ultrasound Indications for Use Form  
GE LOGIQ E9, LOGIQ E9 XDclear 2.0 with C2-6b-D Transducer**

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

Clinical Application	Mode of Operation											
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>9</sup>	Other [Notes]	
Anatomy/Region of Interest												
Ophthalmic												
Fetal/Obstetrics <sup>[7]</sup>												
Abdominal <sup>[1]</sup>	E	E	E		E		E	E	E	E	[5,6,9]	
Pediatric												
Small Organ <sup>[2]</sup>												
Neonatal Cephalic												
Adult Cephalic												
Cardiac Adult												
Cardiac Pediatric												
Peripheral Vascular												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other <sup>[4]</sup>												
Exam Type, Means of Access												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intraoperative <sup>[8]</sup>												
Intraoperative Neurological												
Intravascular												
Laparoscopic												

N = new indication; P = previously cleared; E = added via Appendix E- previously cleared by FDA on LOGIQ S8 K131527

- 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] Volume navigation  
 [10] Shear wave elastography  
 [\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.  
 System provides real-time 3D and 4D acquisition when used with special 4D probes

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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: August 12, 2015
- Submitter/Manufacturer: GE Healthcare, GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC.  
9900 Innovation Dr.  
Wauwatosa, WI 53226
- Contact Person: Bryan Behn  
Sr. Regulatory Affairs Manager  
GE Healthcare, GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC.  
Phone: 414-721-4214  
Fax: 414-918-8275
- Device: Trade Name: GE LOGIQ E9, LOGIQ E9 XDClear 2.0 Diagnostic Ultrasound System
- Common/Usual Name: LOGIQ E9
- Classification Names: Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN  
Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO
- Product Code: Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX
- Predicate Device(s): K142160 GE LOGIQ E9 Diagnostic Ultrasound System  
K131527 GE LOGIQ S8 Diagnostic Ultrasound System  
K131514 GE Vivid E9 Diagnostic Ultrasound System
- Device Description: The LOGIQ E9 is a full featured, general purpose diagnostic ultrasound system which consists of a mobile console approximately 58 cm wide, 87cm deep and 130 cm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls, 10-inch LCD touch screen and color wide screen image display.
- 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



GE Healthcare  
510(k) Premarket Notification Submission

and Intraoperative (abdominal, thoracic and vascular).

Technology: The LOGIQ E9 employs the same fundamental scientific technology as its predicate device(s).

Determination of Substantial Equivalence: Comparison to Predicates  
The LOGIQ E9 is 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 E9 and predicate LOGIQ E9 systems have the same clinical intended use.
- The LOGIQ E9 and predicate LOGIQ E9 systems have the same imaging modes.
- 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 E9 and predicate LOGIQ E9 systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The LOGIQ E9 and predicate systems have been designed in compliance with approved electrical and physical safety standards.
- The LOGIQ E9 and predicate LOGIQ E9 systems transducers are identical except for the C2-7-D, C2-7VN-D, C3-10-D and L3-9i-D which are an incremental improvement to the existing transducers and are equivalent.
- The LOGIQ E9 adds two software features AutoEF and AFI that were not available on the predicate LOGIQ E9 and have been migrated from Vivid E9 K131514.



## GE Healthcare

### 510(k) Premarket Notification Submission

#### Summary of Non-Clinical Tests:

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety, and has been found to conform with applicable medical device safety standards. The LOGIQ E9 and its applications comply with voluntary standards:

1. AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety
2. IEC60601-1-2, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests
3. IEC60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
4. NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
5. ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing
6. NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
7. ISO14971, Application of risk management to medical devices: Second edition
8. NEMA Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)

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)



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

- Performance testing (Verification)
- Safety testing (Verification)
- Final Acceptance testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, LOGIQ E9, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the LOGIQ E9 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).