



K 123564

DEC 18 2012

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: November 19, 2012

Submitter: GE Healthcare, GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC.
9900 Innovation Dr.
Wauwatosa, WI 53226

Contact Person: Bryan Behn
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 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): K110943; K092271 GE LOGIQ E9 Diagnostic Ultrasound System

K122327 GE Voluson E6/E8/E8ExpertE10 Diagnostic Ultrasound System

K113690 GE LOGIQ e 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, 86cm deep and 141 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 19-inch LCD 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, vascular and neurosurgical).

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

Determination of Substantial Equivalence: 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. IEC60601-1, 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- Third Edition
6. NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
7. ISO14971, Application of risk management to medical devices
8. NEMA, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)



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

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



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 18, 2012

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

Re: K123564

Trade/Device Name: GE LOGIQ E9 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasound pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: November 19, 2012
Received: November 20, 2012

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the GE LOGIQ E9 Ultrasound System, as described in your premarket notification:

Transducer Model Number

<u>3CRF</u>	<u>M5S-D</u>	<u>RSP6-16-D</u>
<u>6S-D</u>	<u>M6C-D</u>	<u>S1-5</u>
<u>6Tc</u>	<u>ML6-15-D</u>	<u>S4-10</u>
<u>9L-D</u>	<u>P2D</u>	<u>S4-10-D</u>
<u>11L-D</u>	<u>P6D</u>	<u>C2-9-D</u>
<u>C1-5-D</u>	<u>RAB2-5D</u>	<u>RAB6-D</u>
<u>IC5-9-D</u>	<u>RAB4-8-D</u>	<u>S1-5-D</u>
<u>L8-18i-D</u>	<u>RIC5-9-D</u>	<u>C1-6-D</u>
<u>M4S-D</u>	<u>RNA5-9-D</u>	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA),

it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. 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); 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.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely Yours,

Janine M. Morris -S

Janine M. Morris
Director
Division of Radiological Health
Office of *In Vitro* Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K123564

Device Name: LOGIQ E9 Diagnostic Ultrasound System

Indications for 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 and neurosurgical).

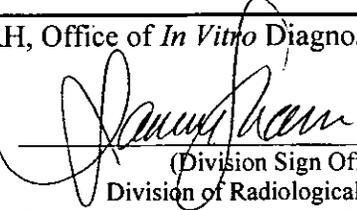
Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use (21 CFR 807 Subpart C)

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



(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k)_K123564_____

**Diagnostic Ultrasound Indications for Use Form
GE LOGIQ E9 with 3CRF 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 ⁹	Other [Notes]
Ophthalmic											
Fetal/Obstetrics ^[7]	P	P	P		P	P	P	P	P	P	[5,6,9]
Abdominal ^[1]	P	P	P		P	P	P	P	P	P	[5,6,9]
Pediatric	P	P	P		P	P	P	P	P	P	[5,6,9]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	P	P	P		P	P	P	P	P	P	[5,6,9]
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[6]											
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

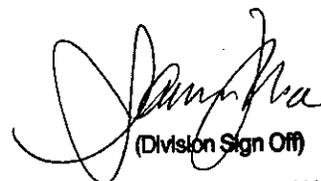
(* Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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)


(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

**Diagnostic Ultrasound Indications for Use Form
GE LOGIQ E9 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*	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics ^[7]	P	P	P	P	P	P	P	P	P	P	
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	
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											
Cardiac 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											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

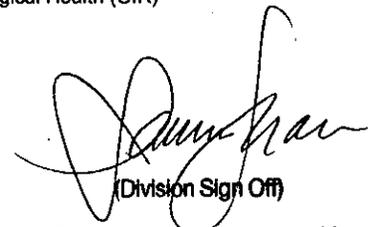
N = new indication; P = previously cleared by FDA; E = added under Appendix E

- 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)


(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

**Diagnostic Ultrasound Indications for Use Form
GE LOGIQ E9 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 ⁹	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics ^[7]											
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]											
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 ^[4]											
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P	P	
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
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.
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 - [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)


 (Division Sign Off)
 Division of Radiological Health

**Diagnostic Ultrasound Indications for Use Form
GE LOGIQ E9 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*	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics ^[7]	P	P	P		P	P	P	P	P	P	[5,6,9]
Abdominal ^[1]	P	P	P		P	P	P	P	P	P	[3,5,6,9]
Pediatric	P	P	P		P	P	P	P	P	P	[3,5,6,9]
Small Organ ^[2]	P	P	P		P	P	P	P	P	P	[3,5,6,9]
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 ^[4]	P	P	P		P	P	P	P	P	P	[3,5,6,9]
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

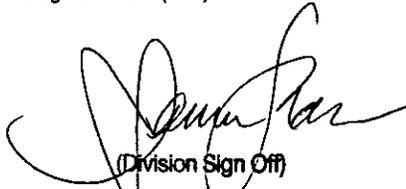
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- Notes: [1] Abdominal includes Renal, GYN/Pelvic.
 [2] Small organ includes breast, testes and thyroid
 [3] Elastography Imaging - Elasticity.
 [4] Other use includes Urology/Prostate
 [5] 3D/4D Imaging mode
 [6] Needle guidance imaging
 [7] Includes 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)


(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

**Diagnostic Ultrasound Indications for Use Form
GE LOGIQ E9 with 11L-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 ⁹	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											
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 ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
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)


(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

**Diagnostic Ultrasound Indications for Use Form
GE LOGIQ E9 with C1-5-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 ⁹	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics ^[7]	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Small Organ ^[2]											
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 ^[4]	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

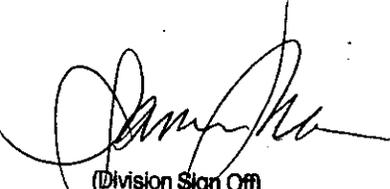
N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Notes:
- [1] Abdominal includes Renal, GYN/Pelvic.
 - [2] Small organ includes breast, testes and thyroid
 - [3] Elastography Imaging - Elasticity.
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 - [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)


 (Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

**Diagnostic Ultrasound Indications for Use Form
GE LOGIQ E9 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 ⁹	Other [Notes]	
Anatomy/Region of Interest												
Ophthalmic												
Fetal/Obstetrics ^[7]	P	P	P		P	P	P	P	P	P		[5,6,9]
Abdominal ^[1]												
Pediatric												
Small Organ ^[2]												
Neonatal Cephalic												
Adult Cephalic												
Cardiac Adult												
Cardiac Pediatric												
Peripheral Vascular												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other ^[4]	P	P	P		P	P	P	P	P	P		[3,5,6,9]
Exam Type, Means of Access												
Transesophageal												
Transrectal	P	P	P		P	P	P	P	P	P		[3,5,6,9]
Transvaginal	P	P	P		P	P	P	P	P	P		[3,5,6,9]
Transurethral												
Intraoperative ^[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.
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 [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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Prescription User (Per 21 CFR 801.109)


(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

**Diagnostic Ultrasound Indications for Use Form
GE LOGIQ E9 with L8-18i-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*	Other [Notes]
Ophthalmic											
Fetal/Obstetrics ^[7]											
Abdominal ^[1]											
Pediatric	P	P	P		P	P	P	P	P	P	[3,5,6,9]
Small Organ ^[2]	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 ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]	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

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Office of In Vitro Diagnostics and Radiological Health

**Diagnostic Ultrasound Indications for Use Form
GE LOGIQ E9 with M4S-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 ⁹	Other [Notes]
Ophthalmic											
Fetal/Obstetrics ^[7]	P	P	P	P	P	P	P	P	P	P	[5,6]
Abdominal ^[2]	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	P	P	P	P	P	P	P	P	P	P	
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

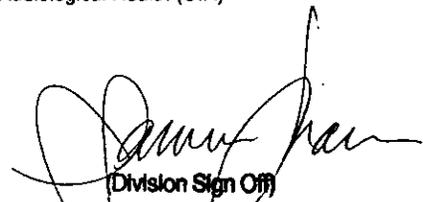
N = new indication; P = previously cleared by FDA; E = added under Appendix E

- 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 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*	Other [Notes]	
Anatomy/Region of Interest												
Ophthalmic												
Fetal/Obstetrics ^[7]	P	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Pediatric	P	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Small Organ ^[2]												
Neonatal Cephalic												
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	P	[9]
Cardiac Adult	P	P	P	P	P	P	P	P	P	P	P	
Cardiac Pediatric	P	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												
Transvaginal												
Transurethral												
Intraoperative ^[8]												
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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15123564

**Diagnostic Ultrasound Indications for Use Form
GE LOGIQ E9 with M6C-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 ^b	Other [Notes]
Ophthalmic											
Fetal/Obstetrics ^[7]	P	P	P	P	P	P	P	P	P	P	[5,6]
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	[5,6]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5,6]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[6]											
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 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*	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics ^[7]											
Abdominal ^[1]											
Pediatric	P	P	P		P	P	P	P	P	P	[3,5,6,9]
Small Organ ^[2]	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 ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

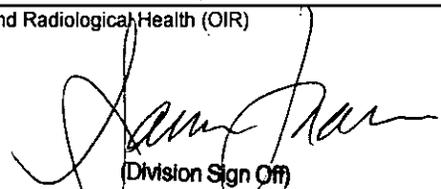
N = new indication; P = previously cleared by FDA; E = added under Appendix E

- 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 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 ⁹	Other (Notes)
Ophthalmic											
Fetal/Obstetrics ^[7]											
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]											
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 ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[6]											
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 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 ⁹	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics ^[7]											
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]											
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 ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[6]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

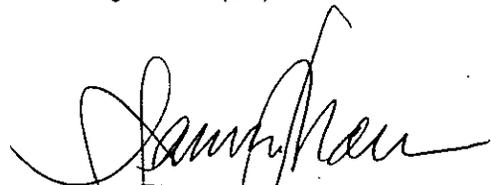
N = new indication; P = previously cleared by FDA; E = added under Appendix E

- 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 with RAB2-5D 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	P	P	P		P	P	P	P	P	P	[5,6]
Small Organ ^[2]											
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 ^[4]	P	P	P		P	P	P	P	P	P	[5]
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
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 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 [†]	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics ^[7]	P	P	P		P	P	P	P	P	P	[5,6]
Abdominal ^[1]	P	P	P		P	P	P	P	P	P	[5,6]
Pediatric	P	P	P		P	P	P	P	P	P	[5,6]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial											
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[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

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K123564

**Diagnostic Ultrasound Indications for Use Form
GE LOGIQ E9 with RIC5-9-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 ⁹	Other [Notes]
Ophthalmic											
Fetal/Obstetrics ^[7]	P	P	P	P	P	P	P	P	P	P	[5,6]
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular											
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	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]
Transurethral											
Intraoperative ^[8]											
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 with RNA5-9-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 ⁹	Other [Notes]
Ophthalmic											
Fetal/Obstetrics ^[7]	P	P	P	P	P	P	P	P	P	P	[5,6]
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	[5,6]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5,6]
Small Organ ^[2]	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 ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
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

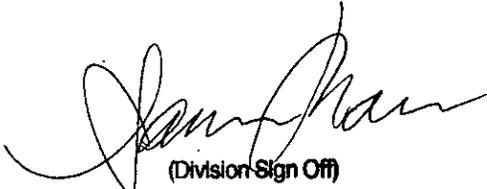
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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 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*	Other [Notes]
Anatomy/Region of Interest											
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											
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 ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]	P	P	P		P	P	P	P	P	P	
Intraoperative Neurological	P	P	P		P	P	P	P	P	P	
Intravascular											
Laparoscopic											

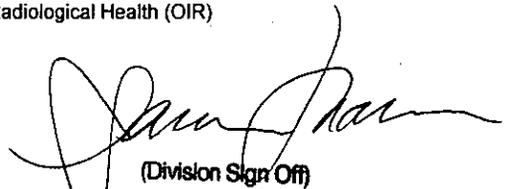
N = new indication; P = previously cleared by FDA; E = added under Appendix E

- 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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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

**Diagnostic Ultrasound Indications for Use Form
GE LOGIQ E9 with S1-5 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	[5,6,9]
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Small Organ ^[2]											
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 ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[6]											
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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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k)

K123564

**Diagnostic Ultrasound Indications for Use Form
GE LOGIQ E9 with S4-10 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	[5,6,9]
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Small Organ ^[2]	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	[5,6,9]
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 ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

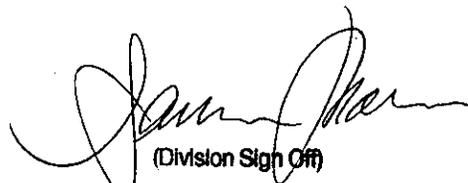
N = new indication; P = previously cleared by FDA; E = added under Appendix E

- 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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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k)

K123564

**Diagnostic Ultrasound Indications for Use Form
GE LOGIQ E9 with S4-10-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*	Other [Notes]
Ophthalmic											
Fetal/Obstetrics ^[7]	E	E	E	E	E	E	E	E	E	E	[5,6,9]
Abdominal ^[1]	E	E	E	E	E	E	E	E	E	E	[5,6,9]
Pediatric	E	E	E	E	E	E	E	E	E	E	[5,6,9]
Small Organ ^[2]	E	E	E	E	E	E	E	E	E	E	[5,6,9]
Neonatal Cephalic	E	E	E	E	E	E	E	E	E	E	[5,6,9]
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric	E	E	E	E	E	E	E	E	E	E	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[6]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E (previously cleared K111582)

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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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123564

**Diagnostic Ultrasound Indications for Use Form
GE LOGIQ E9 with C2-9-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 ⁹	Other [Notes]
Ophthalmic											
Fetal/Obstetrics ^[7]	E	E	E	E	E	E	E	E	E	E	[5,6,9]
Abdominal ^[1]	E	E	E	E	E	E	E	E	E	E	[3,5,6,9]
Pediatric	E	E	E	E	E	E	E	E	E	E	[3,5,6,9]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	E	E	E	E	E	E	E	E	E	E	[3,5,6,9]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	E	E	E	E	E	E	E	E	E	E	[3,5,6,9]
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E (previously cleared K122515)

- 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 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 ⁸	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics ^[7]	E	E	E		E	E	E	E	E	E	[5,6]
Abdominal ^[1]	E	E	E		E	E	E	E	E	E	[5,6]
Pediatric	E	E	E		E	E	E	E	E	E	[5,6]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional	E	E	E		E	E	E	E	E	E	[5,6]
Musculo-skeletal Superficial											
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[6]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E (previously cleared K122327)

- 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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Office of In Vitro Diagnostics and Radiological Health

**Diagnostic Ultrasound Indications for Use Form
GE LOGIQ E9 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*	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics ^[7]	E	E	E	E	E	E	E	E	E	E	[5,6,9]
Abdominal ^[1]	E	E	E	E	E	E	E	E	E	E	[5,6,9]
Pediatric	E	E	E	E	E	E	E	E	E	E	[5,6,9]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic	E	E	E	E	E	E	E	E	E	E	[5,6,9]
Cardiac Adult	E	E	E	E	E	E	E	E	E	E	
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
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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Office of In Vitro Diagnostics and Radiological Health

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

N = new indication; P = previously cleared by FDA; E = added under Appendix E (previously cleared K122921)

- 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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