



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, LLC  
% Ms. Tracey Ortiz  
Regulatory Affairs Director  
9900 W. Innovation Drive  
WAUWATOSA WI 53226

June 18, 2015

Re: K151028  
Trade/Device Name: LOGIQ e  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, ITX  
Dated: April 17, 2015  
Received: April 20, 2015

Dear Ms. Ortiz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

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

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

Sincerely yours,



Robert Ochs, Ph.D. For  
Acting 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)

K151028

Device Name

LOGIQ e

Indications for Use (Describe)

The LOGIQ e is intended for ultrasound imaging, measurement and analysis of the human body for multiple clinical applications including: ophthalmic: fetal/ob; abdominal (gyn & urology); pediatric; small organ (breast, testes, thyroid); neonatal and adult cephalic; cardiac (adult & pediatric); peripheral vascular; musculoskeletal conventional & superficial; transrectal; transvaginal; transesophageal; intraoperative (abdominal, thoracic and peripheral); thoracic/pleural for motion and fluid detection and imaging guidance of interventional procedures (e.g. Nerve block; vascular access).

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 e Ultrasound System**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>†</sup>	Other
<i>Anatomy/Region of Interest</i>											
Ophthalmic	P	P	P	P	P	P	P	P	P	P	
Fetal / Obstetrics	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>	P	P	P		P		P	P	P	P	
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac <sup>[3]</sup>	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular	P	P	P	P	P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	
Musculo-skeletal Superficial	P	P	P		P		P	P	P	P	
Thoracic/Pleural <sup>[4]</sup>	P	P	P	P	P	P	P	P	P	P	
Other <sup>[5]</sup>	P	P	P	P	P	P	P	P	P	P	
<i>Exam Type, Means of Access</i>											
Transesophageal	N	N	N		N		N	N	N	N	
Transrectal	P	P	P		P		P	P	P		
Transvaginal	P	P	P		P		P	P	P		
Intraoperative <sup>[6]</sup>	P	P	P		P		P	P	P	P	
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage	P	P	P	P	P	P	P	P	P	P	
Vascular Access (IV, PICC)	P	P	P	P	P	P	P	P	P	P	
Nerve Block	P	P	P	P	P	P	P	P	P	P	

**N = new indication; P= previously cleared by FDA K133533 ; P<sup>1</sup>= previously cleared by FDA K113690**

- Notes: [1] Abdominal includes GYN and Urological;  
 [2] Small Organ includes breast, testes, thyroid;  
 [3] Cardiac is Adult and Pediatric;  
 [4] For detection of fluid and pleural motion/sliding;  
 [5] Other use includes Urology/Prostate;  
 [6] Intraoperative includes abdominal, thoracic and peripheral;  
 [\*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD;  
 [†] Coded Pulse is for digitally encoded harmonics.

(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 Use (Per 21 CFR 801.109)



**Diagnostic Ultrasound Indications for Use Form**

**GE LOGIQ e with C1-5-RS Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>1</sup>	Other
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics	P	P	P		P		P	P	P	P	
Abdominal <sup>[1]</sup>	P	P	P		P		P	P	P	P	
Pediatric	P	P	P		P		P	P	P	P	
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	
Musculo-skeletal Superficial	P	P	P		P		P	P	P	P	
Thoracic/Pleural <sup>[4]</sup>											
Other <sup>[5]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative <sup>[6]</sup>											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage	P	P	P		P		P	P	P	P	
Vascular Access (IV, PICC)											
Nerve Block	P	P	P		P		P	P	P	P	

**N = new indication; P= previously cleared by FDA K133533 ; P<sup>1</sup>= previously cleared by FDA K113690**

- Notes: [1] Abdominal includes GYN and Urological;  
 [2] Small Organ includes breast, testes, thyroid;  
 [3] Cardiac is Adult and Pediatric;  
 [4] For detection of fluid and pleural motion/sliding;  
 [5] Other use includes Urology/Prostate;  
 [6] Intraoperative includes abdominal, thoracic and peripheral;  
 [\*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD;  
 [1] Coded Pulse is for digitally encoded harmonics.

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**  
 Prescription Use (Per 21 CFR 801.109)



**Diagnostic Ultrasound Indications for Use Form**

**GE LOGIQ e with 4C-RS Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>†</sup>	Other
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>		P <sup>1</sup>		P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	
Abdominal <sup>[1]</sup>	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>		P <sup>1</sup>		P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	
Pediatric	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>		P <sup>1</sup>		P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional	N	N	N		N		N	N	N	N	
Musculo-skeletal Superficial	N	N	N		N		N	N	N	N	
Thoracic/Pleural <sup>[4]</sup>	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>		P <sup>1</sup>		P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	
Other <sup>[5]</sup>	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>		P <sup>1</sup>		P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative <sup>[6]</sup>											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage	N	N	N		N		N	N	N	N	
Vascular Access (IV, PICC)											
Nerve Block	N	N	N		N		N	N	N	N	

**N = new indication; P= previously cleared by FDA K133533 ; P<sup>1</sup>= previously cleared by FDA K113690**

- Notes: [1] Abdominal includes GYN and Urological;  
 [2] Small Organ includes breast, testes, thyroid;  
 [3] Cardiac is Adult and Pediatric;  
 [4] For detection of fluid and pleural motion/sliding;  
 [5] Other use includes Urology/Prostate;  
 [6] Intraoperative includes abdominal, thoracic and peripheral;  
 [\*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD;  
 [†] Coded Pulse is for digitally encoded harmonics.

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**  
 Prescription Use (Per 21 CFR 801.109)



**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ e with 8C-RS Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>†</sup>	Other
<i>Anatomy/Region of Interest</i>											
Ophthalmic	P	P	P		P		P	P	P		
Fetal / Obstetrics											
Abdominal <sup>[1]</sup>	P	P	P		P		P	P	P		
Pediatric	P	P	P		P		P	P	P		
Small Organ <sup>[2]</sup>	P	P	P		P		P	P	P		
Neonatal Cephalic	P	P	P		P		P	P	P		
Adult Cephalic	P	P	P		P		P	P	P		
Cardiac <sup>[3]</sup>	P	P	P		P		P	P	P		
Peripheral Vascular	P	P	P		P		P	P	P		
Musculo-skeletal Conventional	P	P	P		P		P	P	P		
Musculo-skeletal Superficial	P	P	P		P		P	P	P		
Thoracic/Pleural <sup>[4]</sup>	P	P	P		P		P	P	P		
Other <sup>[5]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative <sup>[6]</sup>											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage											
Vascular Access (IV, PICC)	P	P	P		P		P	P	P		
Nerve Block											

N = new indication; P= previously cleared by FDA K133533 ; P<sup>1</sup>= previously cleared by FDA K113690

**Notes:** [1] Abdominal includes GYN and Urological;

[2] Small Organ includes breast, testes, thyroid;

[3] Cardiac is Adult and Pediatric;

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate;

[6] Intraoperative includes abdominal, thoracic and peripheral;

[\*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD;

[<sup>†</sup>] Coded Pulse is for digitally encoded harmonics.

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**  
Prescription Use (Per 21 CFR 801.109)



GE Healthcare  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ e with E8C-RS Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>†</sup>	Other
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics	P	P	P		P		P	P	P		
Abdominal <sup>[1]</sup>	P	P	P		P		P	P	P		
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural <sup>[4]</sup>											
Other <sup>[5]</sup>	P	P	P		P		P	P	P		
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal	P	P	P		P		P	P	P		
Transvaginal	P	P	P		P		P	P	P		
Intraoperative <sup>[6]</sup>											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage	P	P	P		P		P	P	P		
Vascular Access (IV, PICC)											
Nerve Block											

N = new indication; P= previously cleared by FDA K133533 ; P<sup>1</sup>= previously cleared by FDA K113690

**Notes:** [1] Abdominal includes GYN and Urological;

[2] Small Organ includes breast, testes, thyroid;

[3] Cardiac is Adult and Pediatric;

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate;

[6] Intraoperative includes abdominal, thoracic and peripheral;

[\*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD;

[<sup>†</sup>] Coded Pulse is for digitally encoded harmonics.

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**  
Prescription Use (Per 21 CFR 801.109)



**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ e with 9L-RS Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>†</sup>	Other
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics											
Abdominal <sup>[1]</sup>	P	P	P		P		P	P	P	P	
Pediatric	P	P	P		P		P	P	P	P	
Small Organ <sup>[2]</sup>	P	P	P		P		P	P	P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular	P	P	P		P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	
Musculo-skeletal Superficial	P	P	P		P		P	P	P	P	
Thoracic/Pleural <sup>[4]</sup>	P	P	P		P		P	P	P	P	
Other <sup>[5]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative <sup>[6]</sup>	P	P	P		P		P	P	P	P	
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage	P	P	P		P		P	P	P		
Vascular Access (IV, PICC)	P	P	P		P		P	P	P		
Nerve Block	P	P	P		P		P	P	P		

**N** = new indication; **P** = previously cleared by FDA K133533 ; **P<sup>1</sup>** = previously cleared by FDA K113690

- Notes: [1] Abdominal includes GYN and Urological;  
 [2] Small Organ includes breast, testes, thyroid;  
 [3] Cardiac is Adult and Pediatric;  
 [4] For detection of fluid and pleural motion/sliding;  
 [5] Other use includes Urology/Prostate;  
 [6] Intraoperative includes abdominal, thoracic and peripheral;  
 [\*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD;  
 [†] Coded Pulse is for digitally encoded harmonics.

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**  
 Prescription Use (Per 21 CFR 801.109)



**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ e with 12L-RS Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>¶</sup>	Other
<i>Anatomy/Region of Interest</i>											
Ophthalmic	P	P	P		P		P	P	P	P	
Fetal / Obstetrics											
Abdominal <sup>[1]</sup>	P	P	P		P		P	P	P	P	
Pediatric	P	P	P		P		P	P	P	P	
Small Organ <sup>[2]</sup>	P	P	P		P		P	P	P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular	P	P	P		P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	
Musculo-skeletal Superficial	P	P	P		P		P	P	P	P	
Thoracic/Pleural <sup>[4]</sup>	P	P	P		P		P	P	P	P	
Other <sup>[5]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative <sup>[6]</sup>											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage	P	P	P		P		P	P	P	P	
Vascular Access (IV, PICC)	P	P	P		P		P	P	P	P	
Nerve Block	P	P	P		P		P	P	P	P	

**N = new indication; P= previously cleared by FDA K133533 ; P<sup>1</sup>= previously cleared by FDA K113690**

- Notes: [1] Abdominal includes GYN and Urological;  
 [2] Small Organ includes breast, testes, thyroid;  
 [3] Cardiac is Adult and Pediatric;  
 [4] For detection of fluid and pleural motion/sliding;  
 [5] Other use includes Urology/Prostate;  
 [6] Intraoperative includes abdominal, thoracic and peripheral;  
 [\*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD;  
 [¶] Coded Pulse is for digitally encoded harmonics.

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**  
 Prescription Use (Per 21 CFR 801.109)



GE Healthcare  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ e with L4-12t-RS Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>†</sup>	Other
<i>Anatomy/Region of Interest</i>											
Ophthalmic	P	P	P		P		P	P	P		
Fetal / Obstetrics											
Abdominal <sup>[1]</sup>											
Pediatric	P	P	P		P		P	P	P		
Small Organ <sup>[2]</sup>	P	P	P		P		P	P	P		
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular	P	P	P		P		P	P	P		
Musculo-skeletal Conventional	P	P	P		P		P	P	P		
Musculo-skeletal Superficial	P	P	P		P		P	P	P		
Thoracic/Pleural <sup>[4]</sup>	P	P	P		P		P	P	P		
Other <sup>[5]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative <sup>[6]</sup>											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage	P	P	P		P		P	P	P	P	
Vascular Access (IV, PICC)	P	P	P		P		P	P	P	P	
Nerve Block	P	P	P		P		P	P	P	P	

**N = new indication; P= previously cleared by FDA K133533 ; P<sup>1</sup>= previously cleared by FDA K113690**

- Notes: [1] Abdominal includes GYN and Urological;  
 [2] Small Organ includes breast, testes, thyroid;  
 [3] Cardiac is Adult and Pediatric;  
 [4] For detection of fluid and pleural motion/sliding;  
 [5] Other use includes Urology/Prostate;  
 [6] Intraoperative includes abdominal, thoracic and peripheral;  
 [\*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD;  
 [†] Coded Pulse is for digitally encoded harmonics.

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**  
 Prescription Use (Per 21 CFR 801.109)



**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ e with L8-18i-RS Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>†</sup>	Other
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics											
Abdominal <sup>[1]</sup>	P	P	P		P		P	P	P	P	
Pediatric	P	P	P		P		P	P	P	P	
Small Organ <sup>[2]</sup>	P	P	P		P		P	P	P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular	P	P	P		P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	
Musculo-skeletal Superficial	P	P	P		P		P	P	P	P	
Thoracic/Pleural <sup>[4]</sup>	P	P	P		P		P	P	P	P	
Other <sup>[5]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative <sup>[6]</sup>	P	P	P		P		P	P	P	P	
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage	P	P	P		P		P	P	P	P	
Vascular Access (IV, PICC)	P	P	P		P		P	P	P	P	
Nerve Block	P	P	P		P		P	P	P	P	

**N = new indication; P= previously cleared by FDA K133533 ; P<sup>1</sup>= previously cleared by FDA K113690**

- Notes: [1] Abdominal includes GYN and Urological;  
 [2] Small Organ includes breast, testes, thyroid;  
 [3] Cardiac is Adult and Pediatric;  
 [4] For detection of fluid and pleural motion/sliding;  
 [5] Other use includes Urology/Prostate;  
 [6] Intraoperative includes abdominal, thoracic and peripheral;  
 [\*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD;  
 [†] Coded Pulse is for digitally encoded harmonics.

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**  
 Prescription Use (Per 21 CFR 801.109)



**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ e with L10-22-RS Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>†</sup>	Other
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics											
Abdominal <sup>[1]</sup>											
Pediatric											
Small Organ <sup>[2]</sup>	P	P	P		P		P	P	P		
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular	P	P	P		P		P	P	P		
Musculo-skeletal Conventional	P	P	P		P		P	P	P		
Musculo-skeletal Superficial	P	P	P		P		P	P	P		
Thoracic/Pleural <sup>[4]</sup>											
Other <sup>[5]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative <sup>[6]</sup>											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage	P	P	P		P		P	P	P		
Vascular Access (IV, PICC)	P	P	P		P		P	P	P		
Nerve Block	P	P	P		P		P	P	P		

**N = new indication; P= previously cleared by FDA K133533 ; P<sup>1</sup>= previously cleared by FDA K113690**

- Notes: [1] Abdominal includes GYN and Urological;  
 [2] Small Organ includes breast, testes, thyroid;  
 [3] Cardiac is Adult and Pediatric;  
 [4] For detection of fluid and pleural motion/sliding;  
 [5] Other use includes Urology/Prostate;  
 [6] Intraoperative includes abdominal, thoracic and peripheral;  
 [\*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD;  
 [†] Coded Pulse is for digitally encoded harmonics.

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**  
 Prescription Use (Per 21 CFR 801.109)



**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ e with 3Sc-RS Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>†</sup>	Other
<i>Anatomy/Region of Interest</i>											
Ophthalmic	P	P	P	P	P	P	P	P	P		
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P		
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P		
Pediatric	P	P	P	P	P	P	P	P	P		
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P		
Cardiac <sup>[3]</sup>	P	P	P	P	P	P	P	P	P		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural <sup>[4]</sup>	P	P	P	P	P	P	P	P	P		
Other <sup>[5]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative <sup>[6]</sup>											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage	P	P	P	P	P	P	P	P	P		
Vascular Access (IV, PICC)	P	P	P	P	P	P	P	P	P		
Nerve Block											

**N = new indication; P= previously cleared by FDA K133533 ; P<sup>†</sup>= previously cleared by FDA K113690**

- Notes: [1] Abdominal includes GYN and Urological;  
 [2] Small Organ includes breast, testes, thyroid;  
 [3] Cardiac is Adult and Pediatric;  
 [4] For detection of fluid and pleural motion/sliding;  
 [5] Other use includes Urology/Prostate;  
 [6] Intraoperative includes abdominal, thoracic and peripheral;  
 [\*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD;  
 [†] Coded Pulse is for digitally encoded harmonics.

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**  
 Prescription Use (Per 21 CFR 801.109)



**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ e with LK760-RS Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>†</sup>	Other
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics											
Abdominal <sup>[1]</sup>											
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional	N	N	N	N	N	N	N	N	N	N	
Musculo-skeletal Superficial	N	N	N	N	N	N	N	N	N	N	
Thoracic/Pleural <sup>[4]</sup>											
Other <sup>[5]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative <sup>[6]</sup>											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage											
Vascular Access (IV, PICC)											
Nerve Block											

**N = new indication; P= previously cleared by FDA K133533 ; P<sup>†</sup>= previously cleared by FDA K113690**

- Notes: [1] Abdominal includes GYN and Urological;  
 [2] Small Organ includes breast, testes, thyroid;  
 [3] Cardiac is Adult and Pediatric;  
 [4] For detection of fluid and pleural motion/sliding;  
 [5] Other use includes Urology/Prostate;  
 [6] Intraoperative includes abdominal, thoracic and peripheral;  
 [\*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD;  
 [†] Coded Pulse is for digitally encoded harmonics.

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**  
 Prescription Use (Per 21 CFR 801.109)



**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ e with 6S-RS Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>†</sup>	Other
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics											
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	P	P	P	P	P	P	P	P	P	P	
Cardiac <sup>[3]</sup>	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural <sup>[4]</sup>	P	P	P	P	P	P	P	P	P	P	
Other <sup>[5]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative <sup>[6]</sup>											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage											
Vascular Access (IV, PICC)	P	P	P	P	P	P	P	P	P	P	
Nerve Block											

**N = new indication; P= previously cleared by FDA K133533 ; P<sup>1</sup>= previously cleared by FDA K113690**

- Notes: [1] Abdominal includes GYN and Urological;  
 [2] Small Organ includes breast, testes, thyroid;  
 [3] Cardiac is Adult and Pediatric;  
 [4] For detection of fluid and pleural motion/sliding;  
 [5] Other use includes Urology/Prostate;  
 [6] Intraoperative includes abdominal, thoracic and peripheral;  
 [\*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD;  
 [†] Coded Pulse is for digitally encoded harmonics.

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**  
 Prescription Use (Per 21 CFR 801.109)



**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ e with 6Tc-RS Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse <sup>†</sup>	Other
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics											
Abdominal <sup>[1]</sup>											
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural <sup>[4]</sup>											
Other <sup>[5]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	P <sup>1</sup>	
Transrectal											
Transvaginal											
Intraoperative <sup>[6]</sup>											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage											
Vascular Access (IV, PICC)											
Nerve Block											

**N = new indication; P = previously cleared by FDA K133533; P<sup>1</sup> = previously cleared by FDA K113690**

- Notes: [1] Abdominal includes GYN and Urological;  
 [2] Small Organ includes breast, testes, thyroid;  
 [3] Cardiac is Adult and Pediatric;  
 [4] For detection of fluid and pleural motion/sliding;  
 [5] Other use includes Urology/Prostate;  
 [6] Intraoperative includes abdominal, thoracic and peripheral;  
 [\*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD;  
 [†] Coded Pulse is for digitally encoded harmonics.

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**  
 Prescription Use (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: April 15, 2015  
Submitter: GE Medical Systems Ultrasound and Primary Care Diagnostics,  
9900 Innovation Drive  
Wauwatosa, WI 53226

Primary Contact Person: Tracey Ortiz  
Regulatory Affairs Director  
GE Healthcare  
T:(414)721-6120  
F:(414)918-8275

Secondary Contact Person: Jiawei Zhang  
Regulatory Affairs  
GE Medical Systems (China) Co, Ltd.  
T: +86 510 8527 8259  
F: +86 510 8522 7347

Device: Trade Name: LOGIQ e  
Common/Usual Name: Ultrasound system  
Classification Names: Class II  
Product Code: Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550 90-IYN  
Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO  
Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX  
Predicate Device(s): LOGIQ e - K133533  
LOGIQ e, LOGIQ i, Vivid e - K113690

Device Description: The LOGIQ e device is a laptop ultrasound console approximately 70mm in height, 295mm in width and 346mm in length with integrated keyboard, a color video LCD type display and several interchangeable electronic-array transducers. It has digital acquisition, processing and display capability and operates from an integrated battery or separate power supply/charger.

Intended Use: The device is a general purpose ultrasound system intended for ultrasound imaging, measurement and analysis of the human body for multiple clinical applications including: Ophthalmic; Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Musculoskeletal



## GE Healthcare

### 510(k) Premarket Notification Submission

Conventional & Superficial; Transrectal; Transvaginal; Transesophageal; Intraoperative (abdominal, thoracic and peripheral); Thoracic/Pleural for motion and fluid detection and imaging guidance of interventional procedures (e.g. Nerve Block; Vascular Access).

Technology: The LOGIQ e employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence: Comparison to Predicates

The LOGIQ e is substantially equivalent to the predicate devices with regards to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The LOGIQ e and predicate LOGIQ e systems have the same clinical intended use with the addition of the transesophageal application
- The LOGIQ e and predicate LOGIQ e systems have the same imaging modes.
- The transducers of LOGIQ e and predicate LOGIQ e system are the same except for:
  - Adding 6Tc-RS, cleared in LOGIQ e (K113690)
  - Adding 4C-RS, cleared in LOGIQ e (K113690), expanding indications for use to include musculoskeletal(conventional & superficial), Tissue Biopsy/Fluid Drainage, Nerve Block
  - Adding new transducer for GE, LK760-RS, it is a linear transducer similar to the 9L-RS that was cleared on the predicate LOGIQ e system (K133533).
- 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 e and predicate LOGIQ e systems have the same capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The LOGIQ e and predicate systems have been designed in compliance with approved electrical and physical safety standards.



## GE Healthcare

### 510(k) Premarket Notification Submission

- The Advanced Isolation Cart is being added.
- The embedded operating system has been changed from Windows XP to Windows 7.

#### Summary of Non-Clinical Tests:

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

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

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

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



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

- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use Testing (Validation)

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

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

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