K133533
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GE Healthcare

510(k) Premarket Notification Submission

FEB 12 2014

510(k) Summary

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

Date:	November 15, 2013
Submitter:	GE Healthcare 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Bryan Behn Regulatory Affairs Manager GE Healthcare T:(414)721-4214 F:(414)918-8275
Secondary Contact Person:	Jiawei ZHANG Regulatory Affairs GE Healthcare T: +86 510 8527 8259 F: +86 510 8522 7347
Device: Trade Name:	LOGIQ e Diagnostic Ultrasound System
Common/Usual Name:	LOGIQ e
Classification Names: Product Code:	Class II Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550 90-IYN Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX
Predicate Device(s):	LOGIQ i/e, Vivid e - K113690 LOGIQ S8 – K131527 SonoSite Edge - K113156 Voluson S6/S8 - K120741
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 a separate power supply/charger.
Intended Use:	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; 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 Predicate Devices

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

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The LOGIQ e and predicate LOGIQ e systems have the same clinical intended use with the exception of Ophthalmic which is substantially equivalent to Ophthalmic on the SonoSite Edge (K113156) and the transesophageal application has been removed from the new version of the LOGIQ e.
- The LOGIQ e and predicate LOGIQ e systems have the same imaging modes.
- The LOGIQ e and predicate LOGIQ e systems transducers are identical accept for the C1-5-RS and 3Sc-RS which are the same transducers on predicate Voluson S6/S8 (K120741), and the L4-12t-RS and L10-22-RS, which are linear transducers similar to the L8-18i-RS.
- 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 similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies. TVD and High-Res PDI are similar to predicate LOGIQ S8 (K131527).
- The LOGIQ e and predicate systems have been designed in compliance with approved electrical and physical safety standards.

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 comply with applicable medical device safety standards. The LOGIQ e and its applications comply with voluntary standards:

1. AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety
2. IEC60601-1-2, Medical Electrical Equipment – Part 1-2:General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests
3. IEC60601-2-37, Medical Electrical Equipment – Part 2-37:Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
4. NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
5. ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- 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)

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)
- Simulated use testing (Validation)

Transducer material and other patient contact materials such as needle guidance kits 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).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 12, 2014

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

Re: K133533
Trade/Device Name: GE LOGIQ e Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: January 3, 2014
Received: January 6, 2014

Dear Mr. Behn:

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

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

Transducer Model Number

C1-5-RS	8C-RS
E8C-RS	9L-RS
12L-RS	L4-12t-RS
L8-18i-RS	L10-22-RS
3Sc-RS	6S-RS

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

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

Enclosure

510(k) Number (if known): K133533

Device Name: LOGIQ e

Indications for Use:

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

Prescription Use_X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use_N/A_ (Part 21 CFR 801 Subpart C)

(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)

(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) _____K133533_____

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ e Ultrasound

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

Clinical Application	Mode of Operation										
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse♭	Other
Anatomy/Region of Interest											
Ophthalmic	N	N	N	N	N	N	N	N	N	N	
Fetal / Obstetrics	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]	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[3]	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(specify)[4]	P	P	P	P	P	P	P	P	P	P	
Other[5]	P	P	P	P	P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal											
Transrectal	P	P	P		P		P	P	P		
Transvaginal	P	P	P		P		P	P	P		
Intraoperative(specify)[6]	P	P	P		P		P	P	P	P	
Interventional Guidance											
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 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	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse*	Other
Anatomy/Region of Interest											
Ophthalmic											
Fetal / Obstetrics	P	P	P		P		P	P	P	P	
Abdominal[1]	P	P	P		P		P	P	P	P	
Pediatric	P	P	P		P		P	P	P	P	
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	
Musculo-skeletal Superficial	N	N	N		N		N	N	N	N	
Thoracic/Pleural(specify)[4]											
Other[5]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative(specify)[6]											
Interventional Guidance											
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 (K120741)

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	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse*	Other
Anatomy/Region of Interest											
Ophthalmic	N	N	N		N		N	N	N		
Fetal / Obstetrics											
Abdominal[1]	P	P	P		P		P	P	P		
Pediatric	P	P	P		P		P	P	P		
Small Organ [2]	P	P	P		P		P	P	P		
Neonatal Cephalic	P	P	P		P		P	P	P		
Adult Cephalic	N	N	N		N		N	N	N		
Cardiac[3]	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(specify)[4]	P	P	P		P		P	P	P		
Other[5]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative(specify)[6]											
Interventional Guidance											
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 (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 E8C-RS Transducer

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

Clinical Application	Mode of Operation										
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse♭	Other
Anatomy/Region of Interest											
Ophthalmic											
Fetal / Obstetrics	P	P	P		P		P	P	P		
Abdominal[1]	P	P	P		P		P	P	P		
Pediatric											
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural(specify)[4]											
Other[5]	P	P	P		P		P	P	P		
Exam Type, Means of Access											
Transesophageal											
Transrectal	P	P	P		P		P	P	P		
Transvaginal	P	P	P		P		P	P	P		
Intraoperative(specify)[6]											
Interventional Guidance											
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(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 9L-RS Transducer

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

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

N = new indication

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
[P] 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 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	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse*	Other
Anatomy/Region of Interest											
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]	P	P	P		P		P	P	P	P	
Pediatric	P	P	P		P		P	P	P	P	
Small Organ [2]	P	P	P		P		P	P	P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
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(specify)[4]	P	P	P		P		P	P	P	P	
Other[5]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative(specify)[6]	N	N	N		N		N	N	N	N	
Interventional Guidance											
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 (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)

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

N = new indication

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

N = new indication; P = previously cleared by FDA(K120741)

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	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse[b]	Other
Anatomy/Region of Interest											
Ophthalmic											
Fetal / Obstetrics											
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	P	P	P	P	P	P	P	P	P	P	
Cardiac[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural(specify)[4]	P	P	P	P	P	P	P	P	P	P	
Other[5]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative(specify)[6]											
Interventional Guidance											
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 (K113690)

Notes: [1] Abdominal includes GYN and Urological;
[3] Cardiac is Adult and Pediatric;
[4] For detection of fluid and pleural motion/sliding;
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[b] 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)

(Division Sign-Off)
Division of Radiological Devices Office of In Vitro Diagnostic Device Evaluation and Safety
510(k) Number