

K113690

DEC 29 2011



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: December 14, 2011

Submitter: GE Healthcare
9900 W. Innovation Dr.
Wauwatosa, WI 53226

Primary Contact Person: Bryan Behn
Regulatory Affairs Manager
GE Healthcare
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F:(414)918-8275

Secondary Contact Person: Yalan Wu
Regulatory Affairs Manager
GE Healthcare
T: +86 510 8527 8652
F: +86 510 8527 7347

Device: Trade Name: LOGIQ i, LOGIQ e, Vivid e

Common/Usual Name: LOGIQ i, LOGIQ e, Vivid e

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 i, LOGIQ e, Vivid e, K102256
LOGIQ E9 K110943

Device Description: The LOGIQ i/e & Vivid e is a full-featured, compact and extremely portable ultrasound system consisting of a main console chassis 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. It is used primarily where portability, size and convenience are essential and is available in three variations: LOGIQ e is for general purpose radiology imaging having a variety of options to tailor it for use by the medical specialist for use in various departments and patient care areas (e.g., OR,



GE Healthcare

510(k) Premarket Notification Submission

ER & outpatient care). Accordingly it has various configurations (Software option/standard and probes supporting) for different packages (Nerve, ED, and GI).

LOGIQ i is a full-featured premium radiology system suitable for physician rounds in a hospital, nursing home where a broader range of high performance is needed.

Vivid e is similar to the LOGIQ e with an emphasis on cardiology examinations.

Intended Use: The LOGIQ i/e & Vivid e is a general purpose ultrasound system intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Intra-operative (abdominal, thoracic and PV), Musculo-skeletal Conventional & Superficial, Transesophageal, Transrectal and Transvaginal, and Thoracic/Pleural for motion/sliding and fluid detection.

Technology: The LOGIQ i/e & Vivid e employs the same fundamental scientific technology as its predicate.

Determination of Substantial Equivalence: **Summary of Non-Clinical Tests:** The LOGIQ i/e & Vivid e and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. 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.



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Summary of Clinical Tests:

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

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



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

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

JAN 19 2012

Re: K113690
Trade/Device Name: GE LOGIQ I, LOGIQ e and Vivid e Diagnostic Ultrasound
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: December 14, 2011
Received: December 15, 2011

Dear Mr. Behn:

This letter corrects our substantially equivalent letter of December 29, 2011.

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 I, LOGIQ e and Vivid e Diagnostic Ultrasound, as described in your premarket notification:

Transducer Model Number

4C-RS
8C-RS
E8C-RS
8L-RS
9L-RS

12L-RS
16L-RS
i12L-RS
i/t739-RS
3S-RS

6S-RS
P2D
6Tc-RS
L8-18i-RS

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" (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.

If you have any questions regarding the content of this letter, please contact Michael O'Hara at (301) 796-0294.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)



510(k) Number (if known):

Device Name: GE LOGIQ I, LOGIQ e and Vivid e Diagnostic Ultrasound

Indications for Use:

The LOGIQ i/e & Vivid e is a general purpose ultrasound system intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Intra-operative (abdominal, thoracic and PV), Musculo-skeletal Conventional & Superficial, Transesophageal, Transrectal and Transvaginal, and Thoracic/Pleural for motion/sliding and fluid detection.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use N/A
(Part 21 CFR 801 Subpart C)

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IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary Spital

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

510(k) Number K113690



Indications For Use Forms

The following Indication for Use forms are attached.

System: GE LOGIQ i/e & Vivid e

Transducer: 4C-RS

Transducer: 8C-RS

Transducer: E8C-RS

Transducer: 8L-RS

Transducer: 9L-RS

Transducer: 12L-RS

Transducer: 16L-RS

Transducer: i12L-RS

Transducer: i/t739-RS

Transducer: 3S-RS

Transducer: 6S-RS

Transducer: P2D

Transducer: 6Tc-RS

Transducer: L8-18i-RS

The following forms represent indications with clinical applications and exam types along with the modes of operation for the LOGIQ i/e & Vivid e system and for all of its probe/mode combinations. Combinations identified by "N" are new while "P" represents those previously cleared with the unmodified LOGIQ i/e & Vivid e. The subject modification does not alter the previously cleared system level indications or clinical applications.



DIVISION 8111-011
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K113690

Diagnostic Ultrasound Indications for Use Form
GE Compact Ultrasound System LOGIO i, LOGIO e, Vivid e

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse [†]	Other
Ophthalmic											
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	
<i>Exam Type, Means of Access</i>											
Transesophageal	P	P	P	P	P	P	P	P	P	P	
Transrectal	P	P	P		P		P	P	P		
Transvaginal	P	P	P		P		P	P	P		
Transurethral											
Intraoperative(specify) ^[6]	P	P	P		P		P	P	P	P	
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

- Notes: [1] Abdominal includes 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.

Mary Spittel
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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

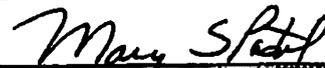
GE Compact Ultrasound LOGIQ i, LOGIQ e, Vivid e with 4C-RS Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse†	Other
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											
Musculo-skeletal Superficial											
Thoracic/Pleural(specify) ^[4]	P	P	P		P		P	P	P	P	
Other ^[5]	P	P	P		P		P	P	P	P	
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify) ^[6]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

- 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.
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Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

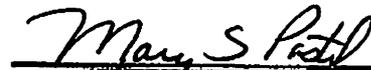
GE Compact Ultrasound LOGIO i, LOGIO e, Vivid e with 8C-RS Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
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											
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	N	N	N		N		N	N	N		
Thoracic/Pleura(specify) ^[4]	P	P	P		P		P	P	P		
Other ^[5]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify) ^[6]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

- 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;
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Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Compact Ultrasound LOGIQ i, LOGIQ e, Vivid e with E8C-RS Transducer

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

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation									
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse
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										
Peripheral Vascular										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Thoracic/Pleura(specify) ^[4]										
Other ^[5]	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	
Transurethral										
Intraoperative (specify) ^[6]										
Intraoperative Neurological										
Intravascular										
Laparoscopic										

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

- 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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Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

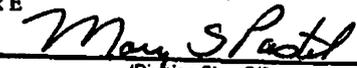
GE Compact Ultrasound LOGIQ i, LOGIQ e, Vivid e with 8L-RS Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse*	Other
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]	P	P	P		P		P	P	P		
Peripheral Vascular	P	P	P		P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P		
Musculo-skeletal Superficial											
Thoracic/Pleural(specify) ^[4]											
Other ^[5]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify) ^[6]	P	P	P		P		P	P	P		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

- Notes: [1] Abdominal includes GYN and Urological
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Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

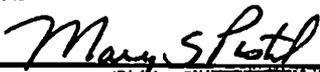
GE Compact Ultrasound LOGIQ i, LOGIQ e, Vivid e with 9L-RS Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse*	Other
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	N	N	N		N		N	N	N	N	
Thoracic/Pleural(specify) ^[4]	N	N	N		N		N	N	N	N	
Other ^[5]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify) ^[6]	P	P	P		P		P	P	P	P	
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

- Notes: [1] Abdominal includes GYN and Urological
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 [5] Other use includes Urology/Prostate
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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Compact Ultrasound LOGIQ i, LOGIQ e, Vivid e with 12L-RS Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation									
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse [†]
Ophthalmic										
Fetal / Obstetrics										
Abdominal	N	N	N		N		N	N	N	
Pediatric	P	P	P		P		P	P	P	
Small Organ ^[2]	P	P	P		P		P	P	P	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
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 (specify) ^[5]										
<i>Exam Type, Means of Access</i>										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intraoperative(specify) ^[6]										
Intraoperative Neurological										
Intravascular										
Laparoscopic										

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

- Notes: [1] Abdominal includes GYN and Urological
 [2] Small organ includes breast, testes, thyroid.
 [3] Cardiac is Adult and Pediatric.
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Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Compact Ultrasound LOGIQ i, LOGIQ e, Vivid e with 16L-RS Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation									
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse [†]
Ophthalmic										
Fetal / Obstetrics										
Abdominal										
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										
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]										
Other (specify) ^[5]										
<i>Exam Type, Means of Access</i>										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intraoperative(specify) ^[6]										
Intraoperative Neurological										
Intravascular										
Laparoscopic										

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

- 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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Diagnostic Ultrasound Indications for Use Form

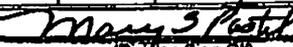
GE Compact Ultrasound LOGIO i, LOGIO e, Vivid e with i12L-RS Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse*	Other
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]	P	P	P		P		P	P	P		
Peripheral Vascular	P	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]											
Other ^[5]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify) ^[6]	P	P	P		P		P	P	P		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

- Notes: [1] Abdominal includes 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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Diagnostic Ultrasound Indications for Use Form

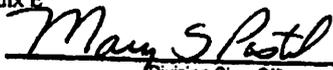
GE Compact Ultrasound LOGIQ i, LOGIQ e, Vivid e with i/t739-RS Transducers

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
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											
Adult Cephalic											
Cardiac ^[3]	P	P	P		P		P	P	P		
Peripheral Vascular	P	P	P		P		P	P	P		
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural(specify) ^[4]											
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify) ^[6]	P	P	P		P		P	P	P		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

- Notes:
- [1] Abdominal includes 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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Diagnostic Ultrasound Indications for Use Form

GE Compact Ultrasound LOGIQ i, LOGIQ e, Vivid e with 3S-RS Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse [†]	Other
Ophthalmic											
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]											
Neonatal Cephalic											
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	N	N	N	N	N	N	N	N	N	N	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
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	
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify) ^[6]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

- 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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Diagnostic Ultrasound Indications for Use Form

GE Compact Ultrasound LOGIO i, LOGIO e, Vivid e with 6S-RS Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse ⁹	Other
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]											
Other ^[5]	P	P	P	P	P	P	P	P	P	P	
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify) ^[6]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

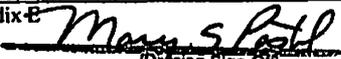
[4] For detection of fluid and pleural motion/sliding;

[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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Diagnostic Ultrasound Indications for Use Form

GE Compact Ultrasound LOGIO i, LOGIO e, Vivid e with P2D Transducer

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

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

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

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

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

[†] Coded Pulse is for digitally encoded harmonics.


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Diagnostic Ultrasound Indications for Use Form

GE Compact Ultrasound LOGIQ i, LOGIQ e, Vivid e with 6Tc-RS Transducer

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

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

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

- 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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Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Compact Ultrasound LOGIQ i, LOGIQ e, Vivid e with L8-18i-RS Transducer

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

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

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

- 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.
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