K072797

OCT 17 2007

# Attachment B:

*Summary of Safety and Effectiveness*
*Prepared in accordance with 21 CFR Part 807.92(c).*

*GE Healthcare*

*General Electric Company*
*P.O. Box 414, Milwaukee, WI 53201*

**Section a):**

1. Submitter: GE Medical Systems, Ultrasound and Primary Care Diagnostics, LLC
PO Box 414
Milwaukee, WI 53201

Contact Person: Allen Schuh,
Manager, Ultrasound Regulatory Affairs
Telephone: 414-721-3992; Fax: 414-721-3899

Date Prepared: September 25, 2007

2. Device Name: GE LOGIQ-i/e & Vivid-e Compact Ultrasound
Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN
Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO
Diagnostic Ultrasonic Transducer, 21 CFR 892.1570, 90-ITX

3. Marketed Device: GE LOGIQ-i/e & Vivid-e Compact Ultrasound, 510(k) No: K050126.

4. Device Description: The GE Compact Ultrasound is a very compact and portable diagnostic ultrasound system having three variations: LOGIQ-i, LOGIQ-e and Vivid-e, each with options and features suited for its market niche. It has an integrated keyboard, LCD display and several interchangeable electronic-array transducers with an approximate size of 34 cm wide, 29 cm deep and 6 cm high in transport configuration and provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, an intuitive layout of specialized controls, color GUI display and Doppler audio.

5. Indications for Use: The device is intended for use by a qualified physician for ultrasound evaluation of 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, Transrectal and Transvaginal.

6. Comparison with Predicate Device: The modified and unmodified Compact Ultrasound devices are virtually identical having the same design, construction, materials, brand names and intended uses. All technological characteristics and safety and effectiveness features are equivalent. The modified device has additional transducers, enhanced imaging to better visualize invasive needles and electrical docking carts for greater flexibility and ease of use.

**Section b):**

1. Non-clinical Tests: The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.

2. Clinical Tests: None required.

3. Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001 and 13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation by a Nationally Recognized Testing Lab. (NRTL) with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Healthcare that the GE Compact Ultrasound is substantially equivalent with respect to safety and effectiveness to diagnostic ultrasound devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2007

Mr. Allen Schuh
Manager, Regulatory Affairs
GE Medical Systems, Ultrasound and Primary Care Diagnostics, LLC
9900 Innovation Drive
WAUWATOSA WI 53226 USA

Re: K072797
Trade/Device Name: GE LOGIQ-i/e & Vivid-e Compact Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: September 28, 2007
Received: October 1, 2007

Dear Mr. Schuh:

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/e & Vivid-e Compact Ultrasound System, as described in your premarket notification:

Transducer Model Number

| | |
|---|---|
| 4C-RS | i12L-RS |
| 8C-RS | i/t739-RS |
| E8C-RS | 3S-RS |
| 8L-RS | 6S-RS |
| 9L-RS | P2D |
| 12L-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 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); 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 determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Paul Hardy at (240) 276-3666.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

**Diagnostic Ultrasound Indications for Use Form**

## GE Compact Ultrasound System

**LOGIQ-*i*, LOGIQ-*e*, Vivid-*e***

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

| Clinical Application<br>*Anatomy/Region of Interest* | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | M | PW Doppler | CW Doppler | Color Doppler | Color M Doppler | Power Doppler | Combined Modes* | Harmonic Imaging | Coded Pulse† | Other |
| 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 | E | P | | P | P | P | P | |
| Musculo-skeletal Conventional | P | P | P | | P | | P | P | P | P | |
| Musculo-skeletal Superficial | | | | | | | | | | | |
| Other[4] | 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 | | |
| Transuretheral | | | | | | | | | | | |
| Intraoperative | P | P | P | | P | | P | P | P | E | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

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

Notes: [1] Abdominal includes renal, GYN/Pelvic
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] 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 and B-flow.

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072797

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

## GE Compact Ultrasound with 4C-RS Transducer

**LOGIQ-*i*, LOGIQ-*e*, Vivid-*e***

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

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

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

Notes: [1] Abdominal includes GYN;
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology;
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.
[▸] Coded Pulse is for digitally encoded harmonics and B-flow.

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072797

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

## GE Compact Ultrasound with 8C-RS Transducer

**LOGIQ-*i*, LOGIQ-*e*, Vivid-*e***

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

| Clinical Application<br>*Anatomy/Region of Interest* | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | M | PW Doppler | CW Doppler | Color Doppler | Color M Doppler | Power Doppler | Combined Modes | Harmonic Imaging | Coded Pulse | Other |
| Ophthalmic | | | | | | | | | | | |
| Fetal / Obstetrics | | | | | | | | | | | |
| Abdominal[1] | P | P | P | | P | | P | P | P | | |
| Pediatric | P | P | P | | P | | P | P | P | | |
| Small Organ (specify) | 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 | | | | | | | | | | | |
| Other[4] | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Transuretheral | | | | | | | | | | | |
| Intraoperative (specify) | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

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

Notes: [1] Abdominal includes GYN/Pelvic, Renal and Aorta-iliac artery;

[3] Cardiac is Adult and Pediatric.

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

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072797

**Diagnostic Ultrasound Indications for Use Form**

## GE Compact Ultrasound with E8C-RS Transducer

**LOGIQ-*i*, LOGIQ-*e*, Vivid-*e***

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

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

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

Notes: [1] Abdominal includes GYN/Pelvic;

[4] Other use includes Urology/Prostate;

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

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072797

**Diagnostic Ultrasound Indications for Use Form**

## GE Compact Ultrasound with 8L-RS Transducer

**LOGIQ-*i*, LOGIQ-*e*, Vivid-*e***

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

| Clinical Application<br>*Anatomy/Region of Interest* | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | M | PW Doppler | CW Doppler | Color Doppler | Color M Doppler | Power Doppler | Combined Modes* | Harmonic Imaging | Coded Pulse♦ | Other |
| Ophthalmic | | | | | | | | | | | |
| Fetal / Obstetrics | | | | | | | | | | | |
| Abdominal[1] | P | P | P | | P | | P | P | P | P | |
| Pediatric | P | P | P | | P | | P | P | P | P | |
| Small Organ (specify)[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 | | | | | | | | | | | |
| Other[4] | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Transuretheral | | | | | | | | | | | |
| Intraoperative (specify)[5] | 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/Pelvic.
[3] Cardiac is Adult and Pediatric.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.
[♦] Coded Pulse is for digitally encoded harmonics and B-flow.

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072797

**Diagnostic Ultrasound Indications for Use Form**

## GE Compact Ultrasound with 9L-RS Transducer

**LOGIQ-*i*, LOGIQ-*e*, Vivid-*e***

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

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

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

Notes: [1] Abdominal includes GYN/Pelvic.
[3] Cardiac is Adult and Pediatric.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.
[♦] Coded Pulse is for digitally encoded harmonics and B-flow.

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072197

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

## GE Compact Ultrasound with 12L-RS Transducer

**LOGIQ-*i*, LOGIQ-*e*, Vivid-*e***

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

| Clinical Application<br>*Anatomy/Region of Interest* | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | M | PW Doppler | CW Doppler | Color Doppler | Color M Doppler | Power Doppler | Combined Modes[*] | Harmonic Imaging | Coded Pulse[▸] | |
| 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 | | | | | | | | | | | |
| Other (specify) | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Transuretheral | | | | | | | | | | | |
| Intraoperative [5] (specify) | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

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

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

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

[▸] Coded Pulse is for digitally encoded harmonics and B-flow.

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072797

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

## GE Compact Ultrasound with i12L-RS Transducer

**LOGIQ-*i*, LOGIQ-*e*, Vivid-*e***

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

| Clinical Application | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| *Anatomy/Region of Interest* | 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 (specify)[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 | | | | | | | | | | | |
| Other[4] | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Transuretheral | | | | | | | | | | | |
| Intraoperative (specify)[5] | 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.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.
[♦] Coded Pulse is for digitally encoded harmonics and B-flow.

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(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072797

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

## GE Compact Ultrasound with i/t739-RS Transducers

**LOGIQ-*i*, LOGIQ-*e*, Vivid-*e***

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

| Clinical Application<br>*Anatomy/Region of Interest* | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | M | PW Doppler | CW Doppler | Color Doppler | Color M Doppler | Power Doppler | Combined Modes | Harmonic Imaging | Coded Pulse | Other |
| Ophthalmic | | | | | | | | | | | |
| Fetal / Obstetrics | | | | | | | | | | | |
| Abdominal[1] | P | P | P | | P | | P | P | P | | |
| Pediatric | P | P | P | | P | | P | P | P | | |
| Small Organ (specify)[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 | | | | | | | | | | | |
| Other[4] | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Transuretheral | | | | | | | | | | | |
| Intraoperative (specify)[5] | 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: [3] Cardiac is Adult and Pediatric via intraoperative.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

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**Diagnostic Ultrasound Indications for Use Form**

## GE Compact Ultrasound with 3S-RS Transducer

**LOGIQ-*i*, LOGIQ-*e*, Vivid-*e***

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

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

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

Notes: [1] Abdominal includes GYN/Pelvic, Renal and Aorta-iliac artery;

[3] Cardiac is Adult and Pediatric.

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

[†] Coded Pulse is for digitally encoded harmonics and B-flow.

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**Diagnostic Ultrasound Indications for Use Form**

## GE Compact Ultrasound with 6S-RS Transducer

**LOGIQ-*i*, LOGIQ-*e*, Vivid-*e***

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

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

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

Notes: [1] Abdominal includes GYN.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology.
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.
[▸] Coded Pulse is for digitally encoded harmonics and B-flow.

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**Diagnostic Ultrasound Indications for Use Form**

## GE Compact Ultrasound with P2D Transducer

**LOGIQ-*i*, LOGIQ-*e*, Vivid-*e***

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

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

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

Notes: [1] Abdominal includes GYN.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology.
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.
[P] Coded Pulse is for digitally encoded harmonics and B-flow.

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