K 141261
Page 1 of 4

JUN 05 2014

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: | May 14, 2014 |
| Submitter: | GE Healthcare<br>9900 Innovation Dr<br>Wauwatosa, WI 53226 |
| Primary Contact Person: | Bryan Behn<br>Regulatory Affairs Manager<br>GE Healthcare<br>T:(414)721-4214<br>F:(414)918-8275 |
| Secondary Contact Person: | Chan Sook Kim<br>Regulatory Affairs Leader<br>GE Healthcare<br>GE Ultrasound Korea, Ltd.<br>T: +82 31 740 6307 |

| | |
|---|---|
| Device: Trade Name: | LOGIQ S7 Expert and LOGIQ S7 Pro Ultrasound System |
| Common/Usual Name: | LOGIQ S7 Expert and LOGIQ S7 Pro |
| Classification Names: | Class II |
| Product Code: | Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550 90-IYN<br>Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO<br>Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX |
| Predicate Device(s): | K122114 LOGIQ S7 Expert and LOGIQ S7 Pro<br>Diagnostic Ultrasound Systems<br>K131527 LOGIQ S8 Diagnostic Ultrasound System<br>K101874 LOGIQ P6 Diagnostic Ultrasound System |
| Device Description: | The LOGIQ S7 Expert AND LOGIQ S7 Pro is a full featured, general purpose diagnostic ultrasound system which consists of a mobile console approximately 62 cm wide, 86 cm deep and 175 cm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls, 7-inch LCD touch screen and color 19-inch LCD image display. |

The purpose of this 510k is an incremental improvement to the LOGIQ S7 Expert and LOGIQ S7 Pro to add additional software features, probes and the Transesophageal indication

Intended Use: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative (abdominal, thoracic, vascular).

Technology: The LOGIQ S7 Expert and LOGIQ S7 Pro employs the same fundamental scientific technology as its predicate devices

Determination of Substantial Equivalence:

Comparison to Predicate Devices

The LOGIQ S7 Expert and Pro systems are 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 S7 and predicate LOGIQ S7 systems have the same clinical intended use with the exception of Transesophageal which is substantially equivalent to Transesophageal on the LOGIQ S8 (K131527).
- The LOGIQ S7 and predicate LOGIQ S7 systems have the same imaging modes.
- The LOGIQ S7 and predicate LOGIQ S7 systems transducers are identical except for the 6S-D, RIC5-9-D, 10C-D, 6Tc-RS which are the same transducers on predicate LOGIQ S8 (K131527), the BE9CS which is the same transducer on predicate LOGIQ P6 (K101874) and L3-12-D and S1-4-D, which are new and equivalent to existing transducers.
- 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 S7 and predicate LOGIQ S7 systems have similar capability in terms of performing measurements,

capturing digital images, reviewing and reporting studies.

- New software features added to LOGIQ S7: AutoEF, Autosweep, Breast Measure Assistant, OB Measure Assistant, Compare Assistant and Preset Manager are the same features cleared on predicate LOGIQ S8 (K131527).
- The LOGIQ S7 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 conform to applicable medical device safety standards. LOGIQ S7 Expert and LOGIQ S7 Pro 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
6. NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
7. ISO14971, Application of risk management to medical devices: Second edition
8. NEMA Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)



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

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

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, LOGIQ S7 Expert and LOGIQ S7 Pro, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the LOGIQ S7 Expert and LOGIQ S7 Pro 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

June 5, 2014

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

Re: K141261
Trade/Device Name: LOGIQ S7 Expert, LOGIQ S7 Pro
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: May 14, 2014
Received: May 15, 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 S7 Expert and Logiq S7 Pro, as described in your premarket notification:

Transducer Model Number

| | | |
|---|---|---|
| C1-5-D | P2D | RIC5-9-D |
| 9L-D | P6D | 10C-D |
| ML6-15 | RAB4-8-D | 6Tc-RS-D |
| IC5-9-D | 11L-D | BE9CS |
| 3CRF-D | 8C | L3-12-D |
| L8-18i-D | 3Sp-D | S1-4-D |
| S4-10-D | 6S-D | |

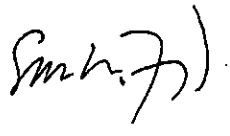
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K141261

Device Name
LOGIQ S7 Expert and LOGIQ S7 Pro

Indications for Use *(Describe)*

The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative (abdominal, thoracic, vascular).

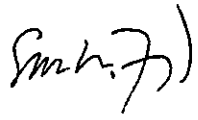
Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## *Indications for Use Forms*

The following forms represent indications with clinical applications and exam types along with the modes of operation for the LOGIQ S7 Expert and LOGIQ S7 Pro system. Combinations identified "P" for the transducers represents those previously cleared with this or another GE Ultrasound system and those identified and "N" are new. Please see section 11 Table 11.2.1 for information on previous clearance information on these transducers.

## Diagnostic Ultrasound Indications for Use Form

**GE LOGIQ S7 Expert and LOGIQ S7 Pro Ultrasound System**

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

| Clinical Application *Anatomy/Region of Interest* | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | M | PW Doppler | CW Doppler | Color Doppler | Color M Doppler | Power Doppler | Combined Modes* | Harmonic Imaging | Coded Pulse | Other [Notes] |
| Ophthalmic | | | | | | | | | | | |
| Fetal / Obstetrics[7] | P | P | P | P | P | P | P | P | P | P | 5,6 |
| Abdominal[1] | P | P | P | P | P | P | P | P | P | P | 3,5,6 |
| Pediatric | P | P | P | P | P | P | P | P | P | P | 3,5,6 |
| Small Organ[2] | P | P | P | P | P | P | P | P | P | P | 3,5,6 |
| Neonatal Cephalic | P | P | P | P | P | P | P | P | P | P | 5,6 |
| Adult Cephalic | P | P | P | P | P | P | P | P | P | P | 5,6 |
| Cardiac Adult & Pediatric | P | P | P | P | P | P | P | P | P | P | |
| Peripheral Vascular | P | P | P | P | P | P | P | P | P | P | 3,5,6 |
| Musculo-skeletal Conventional | P | P | P | P | P | P | P | P | P | P | 3,5,6 |
| Musculo-skeletal Superficial | P | P | P | P | P | P | P | P | P | P | 3,5,6 |
| Other[4] | P | P | P | P | P | P | P | P | P | P | 3,5,6 |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transesophageal | N | N | N | N | N | N | N | N | N | N | |
| Transrectal[8] | P | P | P | P | P | P | P | P | P | P | 3,5,6 |
| Transvaginal | P | P | P | P | P | P | P | P | P | P | 3,5,6 |
| Transurethral | | | | | | | | | | | |
| Intraoperative[8] | P | P | P | P | P | P | P | P | P | P | 3,5,6 |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance Imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**GE LOGIQ S7 Expert and LOGIQ S7 Pro with C1-5-D Transducer**

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

| Clinical Application *Anatomy/Region of Interest* | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | M | PW Doppler | CW Doppler | Color Doppler | Color M Doppler | Power Doppler | Combined Modes* | Harmonic Imaging | Coded Pulse | Other (Notes) |
| Ophthalmic | | | | | | | | | | | |
| Fetal / Obstetrics[7] | P | P | P | P | P | P | P | P | P | P | 5,6 |
| Abdominal[1] | P | P | P | P | P | P | P | P | P | P | 3,5,6 |
| Pediatric | P | P | P | P | P | P | P | P | P | P | 3,5,6 |
| Small Organ[2] | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | |
| Cardiac Adult & Pediatric | | | | | | | | | | | |
| Peripheral Vascular | P | P | P | P | P | P | P | P | P | P | 3,5,6 |
| Musculo-skeletal Conventional | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | |
| Other[4] | P | P | P | P | P | P | P | P | P | P | 3,5,6 |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal[8] | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Transuretheral | | | | | | | | | | | |
| Intraoperative[8] | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA

Notes:
[1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**GE LOGIQ S7 Expert and LOGIQ S7 Pro with 9L-D Transducer**

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

| Clinical Application *Anatomy/Region of Interest* | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | M | PW Doppler | CW Doppler | Color Doppler | Color M Doppler | Power Doppler | Combined Modes* | Harmonic Imaging | Coded Pulse | Other [Notes] |
| Ophthalmic | | | | | | | | | | | |
| Fetal / Obstetrics[7] | P | P | P | | P | P | P | P | P | P | 5,6 |
| Abdominal[1] | P | P | P | | P | P | P | P | P | P | 3,5,6 |
| Pediatric | P | P | P | | P | P | P | P | P | P | 3,5,6 |
| Small Organ[2] | P | P | P | | P | P | P | P | P | P | 3,5,6 |
| Neonatal Cephalic | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | |
| Cardiac Adult & Pediatric | | | | | | | | | | | |
| Peripheral Vascular | P | P | P | | P | P | P | P | P | P | 3,5,6 |
| Musculo-skeletal Conventional | P | P | P | | P | P | P | P | P | P | 3,5,6 |
| Musculo-skeletal Superficial | P | P | P | | P | P | P | P | P | P | 3,5,6 |
| Other[4] | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal[8] | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Transuretheral | | | | | | | | | | | |
| Intraoperative[8] | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA

Notes:
[1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**GE LOGIQ S7 Expert and LOGIQ S7 Pro with ML6-15 Transducer**

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

| Clinical Application *Anatomy/Region of Interest* | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | M | PW Doppler | CW Doppler | Color Doppler | Color M Doppler | Power Doppler | Combined Modes* | Harmonic Imaging | Coded Pulse | Other (Notes) |
| Ophthalmic | | | | | | | | | | | |
| Fetal / Obstetrics[7] | | | | | | | | | | | |
| Abdominal[1] | | | | | | | | | | | |
| Pediatric | P | P | P | | P | P | P | P | P | P | 3,5,6 |
| Small Organ[2] | P | P | P | | P | P | P | P | P | P | 3,5,6 |
| Neonatal Cephalic | P | P | P | | P | P | P | P | P | P | |
| Adult Cephalic | | | | | | | | | | | |
| Cardiac Adult & Pediatric | | | | | | | | | | | |
| Peripheral Vascular | P | P | P | | P | P | P | P | P | P | 3,5,6 |
| Musculo-skeletal Conventional | P | P | P | | P | P | P | P | P | P | 3,5,6 |
| Musculo-skeletal Superficial | P | P | P | | P | P | P | P | P | P | 3,5,6 |
| Other[4] | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal[8] | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Transuretheral | | | | | | | | | | | |
| Intraoperative[8] | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**GE LOGIQ S7 Expert and LOGIQ S7 Pro with IC5-9-D Transducer**

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

| Clinical Application *Anatomy/Region of Interest* | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | M | PW Doppler | CW Doppler | Color Doppler | Color M Doppler | Power Doppler | Combined Modes* | Harmonic Imaging | Coded Pulse | Other (Notes) |
| Ophthalmic | | | | | | | | | | | |
| Fetal / Obstetrics[7] | P | P | P | | P | P | P | P | P | P | 5,6 |
| Abdominal[1] | P | P | P | | P | P | P | P | P | P | |
| Pediatric | | | | | | | | | | | |
| Small Organ[2] | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | |
| Cardiac Adult & Pediatric | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | |
| Other[4] | P | P | P | | P | P | P | P | P | P | 3,5,6 |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal[6] | P | P | P | | P | P | P | P | P | P | 3,5,6 |
| Transvaginal | P | P | P | | P | P | P | P | P | P | 3,5,6 |
| Transuretheral | | | | | | | | | | | |
| Intraoperative[8] | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance Imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**GE LOGIQ S7 Expert and LOGIQ S7 Pro with 3CRF-D Transducer**

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

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**GE LOGIQ S7 Expert and LOGIQ S7 Pro with L8-18I-D Transducer**

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

| Clinical Application *Anatomy/Region of Interest* | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | M | PW Doppler | CW Doppler | Color Doppler | Color M Doppler | Power Doppler | Combined Modes* | Harmonic Imaging | Coded Pulse | Other [Notes] |
| Ophthalmic | | | | | | | | | | | |
| Fetal / Obstetrics[7] | | | | | | | | | | | |
| Abdominal[1] | | | | | | | | | | | |
| Pediatric | P | P | P | | P | P | P | P | P | P | 5,6 |
| Small Organ[2] | P | P | P | | P | P | P | P | P | P | |
| Neonatal Cephalic | P | P | P | | P | P | P | P | P | P | |
| Adult Cephalic | | | | | | | | | | | |
| Cardiac Adult & Pediatric | | | | | | | | | | | |
| Peripheral Vascular | P | P | P | / | P | P | P | P | P | P | 3,5,6 |
| Musculo-skeletal Conventional | P | P | P | | P | P | P | P | P | P | 3,5,6 |
| Musculo-skeletal Superficial | P | P | P | | P | P | P | P | P | P | 3,5,6 |
| Other[4] | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal[8] | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Transuretheral | | | | | | | | | | | |
| Intraoperative[8] | P | P | P | | P | P | P | P | P | P | 3,5,6 |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**GE LOGIQ S7 Expert and LOGIQ S7 Pro with S4-10-D Transducer**

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

| Clinical Application *Anatomy/Region of Interest* | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | M | PW Doppler | CW Doppler | Color Doppler | Color M Doppler | Power Doppler | Combined Modes* | Harmonic Imaging | Coded Pulse | Other (Notes) |
| Ophthalmic | | | | | | | | | | | |
| Fetal / Obstetrics[7] | P | P | P | P | P | P | P | P | P | P | 5 |
| Abdominal[1] | P | P | P | P | P | P | P | P | P | P | 5 |
| Pediatric | P | P | P | P | P | P | P | P | P | P | 5 |
| Small Organ[2] | P | P | P | P | P | P | P | P | P | P | 5 |
| Neonatal Cephalic | P | P | P | P | P | P | P | P | P | P | 5 |
| Adult Cephalic | | | | | | | | | | | |
| Cardiac Adult & Pediatric | P | P | P | P | P | P | P | P | P | P | |
| Peripheral Vascular | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | |
| Other[4] | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal[6] | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Transuretheral | | | | | | | | | | | |
| Intraoperative[8] | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**GE LOGIQ S7 Expert and LOGIQ S7 Pro with P2D Transducer**

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

| Clinical Application *Anatomy/Region of Interest* | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | M | PW Doppler | CW Doppler | Color Doppler | Color M Doppler | Power Doppler | Combined Modes* | Harmonic Imaging | Coded Pulse | Other (Notes) |
| Ophthalmic | | | | | | | | | | | |
| Fetal / Obstetrics[7] | | | | | | | | | | | |
| Abdominal[1] | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | |
| Small Organ[2] | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | |
| Adult Cephalic | | | P | P | | | | | | | |
| Cardiac Adult & Pediatric | | | P | P | | | | | | | |
| Peripheral Vascular | | | P | P | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | |
| Other[4] | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal[8] | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Transuretheral | | | | | | | | | | | |
| Intraoperative[8] | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA

Notes:
[1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**GE LOGIQ S7 Expert and LOGIQ S7 Pro with P6D Transducer**

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

| Clinical Application *Anatomy/Region of Interest* | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | M | PW Doppler | CW Doppler | Color Doppler | Color M Doppler | Power Doppler | Combined Modes* | Harmonic Imaging | Coded Pulse | Other (Notes) |
| Ophthalmic | | | | | | | | | | | |
| Fetal / Obstetrics[7] | | | | | | | | | | | |
| Abdominal[1] | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | |
| Small Organ[2] | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | |
| Adult Cephalic | | | P | P | | | | | | | |
| Cardiac Adult & Pediatric | | | P | P | | | | | | | |
| Peripheral Vascular | | | P | P | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | |
| Other[4] | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal[6] | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | |
| Intraoperative[8] | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**GE LOGIQ S7 Expert and LOGIQ S7 Pro with RAB4-8-D Transducer**

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

| Clinical Application *Anatomy/Region of Interest* | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | M | PW Doppler | CW Doppler | Color Doppler | Color M Doppler | Power Doppler | Combined Modes* | Harmonic Imaging | Coded Pulse | Other (Notes) |
| Ophthalmic | | | | | | | | | | | |
| Fetal / Obstetrics[7] | P | P | P | | P | P | P | P | P | P | 5,6 |
| Abdominal[1] | P | P | P | | P | P | P | P | P | P | 5,6 |
| Pediatric | P | P | P | | P | P | P | P | P | P | 5,6 |
| Small Organ[2] | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | |
| Cardiac Adult & Pediatric | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | |
| Musculo-skeletal Conventional | P | P | P | | P | P | P | P | P | P | 5,6 |
| Musculo-skeletal Superficial | | | | | | | | | | | |
| Other[4] | P | P | P | | P | P | P | P | P | P | 5,6 |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal[8] | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Transuretheral | | | | | | | | | | | |
| Intraoperative[8] | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA

Notes:
[1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**GE LOGIQ S7 Expert and LOGIQ S7 Pro with 11L-D Transducer**

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

| Clinical Application *Anatomy/Region of Interest* | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | M | PW Doppler | CW Doppler | Color Doppler | Color M Doppler | Power Doppler | Combined Modes* | Harmonic Imaging | Coded Pulse | Other (Notes) |
| Ophthalmic | | | | | | | | | | | |
| Fetal / Obstetrics[7] | | | | | | | | | | | |
| Abdominal[1] | P | P | P | | P | P | P | P | P | P | 3,5,6 |
| Pediatric | P | P | P | | P | P | P | P | P | P | 3,5,6 |
| Small Organ[2] | P | P | P | | P | P | P | P | P | P | 3,5,6 |
| Neonatal Cephalic | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | |
| Cardiac Adult & Pediatric | | | | | | | | | | | |
| Peripheral Vascular | P | P | P | | P | P | P | P | P | P | 3,5,6 |
| Musculo-skeletal Conventional | P | P | P | | P | P | P | P | P | P | 3,5,6 |
| Musculo-skeletal Superficial | P | P | P | | P | P | P | P | P | P | 3,5,6 |
| Other[4] | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal[8] | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Transuretheral | | | | | | | | | | | |
| Intraoperative[8] | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA

Notes:
[1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**GE LOGIQ S7 Expert and LOGIQ S7 Pro with 8C Transducer**

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

| Clinical Application *Anatomy/Region of Interest* | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | M | PW Doppler | CW Doppler | Color Doppler | Color M Doppler | Power Doppler | Combined Modes* | Harmonic Imaging | Coded Pulse | Other (Notes) |
| Ophthalmic | | | | | | | | | | | |
| Fetal / Obstetrics[7] | | | | | | | | | | | |
| Abdominal[1] | P | P | P | | P | P | P | P | P | P | 5 |
| Pediatric | P | P | P | | P | P | P | P | P | P | 5 |
| Small Organ[2] | P | P | P | | P | P | P | P | P | P | 5 |
| Neonatal Cephalic | P | P | P | | P | P | P | P | P | P | 5 |
| Adult Cephalic | | | | | | | | | | | |
| Cardiac Adult & Pediatric | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | |
| Other[4] | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal[6] | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Transuretheral | | | | | | | | | | | |
| Intraoperative[8] | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**GE LOGIQ S7 Expert and LOGIQ S7 Pro with 3Sp-D Transducer**

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

| Clinical Application *Anatomy/Region of Interest* | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | M | PW Doppler | CW Doppler | Color Doppler | Color M Doppler | Power Doppler | Combined Modes* | Harmonic Imaging | Coded Pulse | Other (Notes) |
| Ophthalmic | | | | | | | | | | | |
| Fetal / Obstetrics[7] | P | P | P | P | P | P | P | P | P | P | 5,6 |
| Abdominal[1] | P | P | P | P | P | P | P | P | P | P | 5,6 |
| Pediatric | P | P | P | P | P | P | P | P | P | P | 5,6 |
| Small Organ[2] | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | |
| Adult Cephalic | P | P | P | P | P | P | P | P | P | P | |
| Cardiac Adult & Pediatric | P | P | P | P | P | P | P | P | P | P | |
| Peripheral Vascular | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | |
| Other[4] | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal[8] | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Transuretheral | | | | | | | | | | | |
| Intraoperative[8] | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA

Notes:
[1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**GE LOGIQ S7 Expert and LOGIQ S7 Pro with 6S-D Transducer**

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 (Notes) |
| Ophthalmic | | | | | | | | | | | |
| Fetal / Obstetrics[7] | P | P | P | P | P | P | P | P | P | P | |
| Abdominal[1] | P | P | P | P | P | P | P | P | P | P | |
| Pediatric | P | P | P | P | P | P | P | P | P | P | |
| Small Organ[2] | | | | | | | | | | | |
| Neonatal Cephalic | P | P | P | P | P | P | P | P | P | P | |
| Adult Cephalic | | | | | | | | | | | |
| Cardiac Adult & Pediatric | P | P | P | P | P | P | P | P | P | P | |
| Peripheral Vascular | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | |
| Other[4] | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal[6] | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Transuretheral | | | | | | | | | | | |
| Intraoperative[8] | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA(K131527)

Notes:
[1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**GE LOGIQ S7 Expert and LOGIQ S7 Pro with RIC5-9-D Transducer**

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

| Clinical Application *Anatomy/Region of Interest* | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | M | PW Doppler | CW Doppler | Color Doppler | Color M Doppler | Power Doppler | Combined Modes* | Harmonic Imaging | Coded Pulse | Other (Notes) |
| Ophthalmic | | | | | | | | | | | |
| Fetal / Obstetrics[7] | P | P | P | P | P | P | P | P | P | P | 5,6 |
| Abdominal[1] | P | P | P | P | P | P | P | P | P | P | |
| Pediatric | | | | | | | | | | | |
| Small Organ[2] | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | |
| Cardiac Adult & Pediatric | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | |
| Other[4] | P | P | P | P | P | P | P | P | P | P | 3,5,6 |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal[6] | P | P | P | P | P | P | P | P | P | P | 3,5,6 |
| Transvaginal | P | P | P | P | P | P | P | P | P | P | 3,5,6 |
| Transurethral | | | | | | | | | | | |
| Intraoperative[8] | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA(K131527)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**GE LOGIQ S7 Expert and LOGIQ S7 Pro with 10C-D Transducer**

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

| Clinical Application *Anatomy/Region of Interest* | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | M | PW Doppler | CW Doppler | Color Doppler | Color M Doppler | Power Doppler | Combined Modes* | Harmonic Imaging | Coded Pulse | Other (Notes) |
| Ophthalmic | | | | | | | | | | | |
| Fetal / Obstetrics[2] | | | | | | | | | | | |
| Abdominal[1] | | | | | | | | | | | |
| Pediatric | P | P | P | | P | | P | P | P | P | 5,6 |
| Small Organ[2] | | | | | | | | | | | |
| Neonatal Cephalic | P | P | P | | P | | P | P | P | P | 5,6 |
| Adult Cephalic | | | | | | | | | | | |
| Cardiac Adult & Pediatric | P | P | P | | P | | P | P | P | P | 5,6 |
| Peripheral Vascular | P | P | P | | P | | P | P | P | P | 5,6 |
| Musculo-skeletal Conventional | P | P | P | | P | | P | P | P | P | 5,6 |
| Musculo-skeletal Superficial | P | P | P | | P | | P | P | P | P | 5,6 |
| Other[4] | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal[8] | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Transuretheral | | | | | | | | | | | |
| Intraoperative[8] | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA(K131527)

Notes:
[1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**GE LOGIQ S7 Expert and LOGIQ S7 Pro with 6Tc-RS-D Transducer**

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 [Notes] |
| Ophthalmic | | | | | | | | | | | |
| Fetal / Obstetrics[7] | | | | | | | | | | | |
| Abdominal[1] | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | |
| Small Organ[2] | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | |
| Cardiac Adult | P | P | P | P | P | P | P | P | P | P | |
| Peripheral Vascular | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | |
| Other[4] | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transesophageal | P | P | P | P | P | P | P | P | P | P | |
| Transrectal[8] | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Transuretheral | | | | | | | | | | | |
| Intraoperative[8] | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA(K131527)

Notes:
[1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**GE LOGIQ S7 Expert and LOGIQ S7 Pro with BE9CS Transducer**

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

| Clinical Application *Anatomy/Region of Interest* | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | M | PW Doppler | CW Doppler | Color Doppler | Color M Doppler | Power Doppler | Combined Modes* | Harmonic Imaging | Coded Pulse | Other (Notes) |
| Ophthalmic | | | | | | | | | | | |
| Fetal / Obstetrics[7] | | | | | | | | | | | |
| Abdominal[1] | 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 Adult & Pediatric | | | | | | | | | | | |
| 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[5] | P | P | P | | P | | P | P | P | P | |
| Transvaginal | P | P | P | | P | | P | P | P | P | |
| Transuretheral | | | | | | | | | | | |
| Intraoperative[8] | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA (K101874)

Notes:
[1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**GE LOGIQ S7 Expert and LOGIQ S7 Pro with L3-12-D Transducer**

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

| Clinical Application *Anatomy/Region of Interest* | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | M | PW Doppler | CW Doppler | Color Doppler | Color M Doppler | Power Doppler | Combined Modes* | Harmonic Imaging | Coded Pulse | Other (Notes) |
| Ophthalmic | | | | | | | | | | | |
| Fetal / Obstetrics[7] | N | N | N | | N | N | N | N | N | N | 5,6 |
| Abdominal[1] | N | N | N | | N | N | N | N | N | N | 3,5,6 |
| Pediatric | N | N | N | | N | N | N | N | N | N | 3,5,6 |
| Small Organ[2] | N | N | N | | N | N | N | N | N | N | 3,5,6 |
| Neonatal Cephalic | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | |
| Cardiac Adult & Pediatric | | | | | | | | | | | |
| Peripheral Vascular | N | N | N | | N | N | N | N | N | N | 3,5,6 |
| Musculo-skeletal Conventional | N | N | N | | N | N | N | N | N | N | 3,5,6 |
| Musculo-skeletal Superficial | N | N | N | | N | N | N | N | N | N | 3,5,6 |
| Other[4] | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | |
| Intraoperative[8] | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**GE LOGIQ S7 Expert and LOGIQ S7 Pro with S1-4-D Transducer**

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

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Prescription User (Per 21 CFR 801.109)