



GE Healthcare
% Mr. Bryan Behn
RA Director
9900 Innovation Drive
WAUWATOSA WI 53226

December 20, 2017

Re: K173555
Trade/Device Name: LOGIQ E10
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: November 15, 2017
Received: November 17, 2017

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.

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style. Behind the signature, there is a large, light blue watermark of the letters "FDA".

Robert Ochs, Ph.D.
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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K173555

Device Name
LOGIQ E10

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 (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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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.

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Indications for Use Forms

The following forms represent indications with clinical applications and exam types along with the modes of operation for the LOGIQ E10 system and for all of its probe/mode combinations. Combinations identified by “P” for probes represent those previously cleared with another GE Ultrasound system. “N” is new in this submission.

The subject modification does not alter the previously cleared system level indications and clinical applications.



Diagnostic Ultrasound Indications for Use Form
LOGIQ E10 Ultrasound Systems

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	N	N	N	N	N	N	N	N	N	N	3,5,6,9
Abdominal ^[1]	N	N	N	N	N	N	N	N	N	N	3,5,6,9,10
Pediatric	N	N	N	N	N	N	N	N	N	N	3,5,6,9,10
Small Organ ^[2]	N	N	N	N	N	N	N	N	N	N	3,5,6,9,10
Neonatal Cephalic	N	N	N	N	N	N	N	N	N	N	3,5,9
Adult Cephalic	N	N	N	N	N	N	N	N	N	N	3,5,9
Cardiac	N	N	N	N	N	N	N	N	N	N	
Peripheral Vascular	N	N	N	N	N	N	N	N	N	N	3,5,6,9
Musculo-skeletal Conventional	N	N	N	N	N	N	N	N	N	N	3,5,6,9,10
Musculo-skeletal Superficial	N	N	N	N	N	N	N	N	N	N	3,5,6,9,10
Other ^[4]	N	N	N	N	N	N	N	N	N	N	3,5,6,9,10
<i>Exam Type, Means of Access</i>											
Transesophageal	N	N	N	N	N	N	N	N	N	N	
Transrectal	N	N	N	N	N	N	N	N	N	N	3,5,6,9
Transvaginal	N	N	N	N	N	N	N	N	N	N	3,5,6,7,9
Transurethral											
Intraoperative ^[8]	N	N	N	N	N	N	N	N	N	N	3,5,6,9
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 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, GYN
 [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
 [9] Volume navigation
 [10] Shear wave elastography
 [*] 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
LOGIQ E10 with L2-9-D/L2-9VN-D Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	N	N	N		N		N	N	N	N	3,5,6,9
Abdominal ^[1]	N	N	N		N		N	N	N	N	3,5,6,9,10
Pediatric	N	N	N		N		N	N	N	N	3,5,6,9,10
Small Organ ^[2]	N	N	N		N		N	N	N	N	3,5,6,9,10
Neonatal Cephalic	N	N	N		N		N	N	N	N	
Adult Cephalic											
Cardiac											
Peripheral Vascular	N	N	N		N		N	N	N	N	3,5,6,9
Musculo-skeletal Conventional	N	N	N		N		N	N	N	N	3,5,6,9,10
Musculo-skeletal Superficial	N	N	N		N		N	N	N	N	3,5,6,9,10
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[8]											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
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 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, GYN
 - [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
 - [9] Volume navigation
 - [10] Shear wave elastography
 - [*] 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

LOGIQ E10 with ML6-15-D Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Code d Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]											
Abdominal ^[1]											
Pediatric	P	P	P		P		P	P	P	P	3,5,6,9
Small Organ ^[2]	P	P	P		P		P	P	P	P	3,5,6,9
Neonatal Cephalic	P	P	P		P		P	P	P	P	9
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P		P	P	P	P	3,5,6,9
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	3,5,6,9
Musculo-skeletal Superficial	P	P	P		P		P	P	P	P	3,5,6,9
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[8]											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K163077)

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, GYN

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[10] Shear wave elastography

[*] 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
LOGIQ E10 with ML4-16-D/ML4-16VN-D Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Code d Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]											
Abdominal ^[1]											
Pediatric	N	N	N		N		N	N	N	N	3,5,6,9,10
Small Organ ^[2]	N	N	N		N		N	N	N	N	3,5,6,9,10
Neonatal Cephalic	N	N	N		N		N	N	N	N	9
Adult Cephalic											
Cardiac											
Peripheral Vascular	N	N	N		N		N	N	N	N	3,5,6,9
Musculo-skeletal Conventional	N	N	N		N		N	N	N	N	3,5,6,9,10
Musculo-skeletal Superficial	N	N	N		N		N	N	N	N	3,5,6,9,10
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[8]											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
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 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, GYN

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[10] Shear wave elastography

[*] 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
LOGIQ E10 with M5Sc-D Transducer

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

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

N = new indication; P = previously cleared by FDA (K170445)

- 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, GYN
 - [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
 - [9] Volume navigation
 - [10] Shear wave elastography
 - [*] 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

LOGIQ E10 with IC5-9-D Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	P	P	P		P		P	P	P	P	3,5,6,9
Abdominal ^[1]	P	P	P		P		P	P	P	P	3,5,6,9
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	P	P	P		P		P	P	P	P	3,5,6,9
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[8]	P	P	P		P		P	P	P	P	3,5,6,9
Transvaginal	P	P	P		P		P	P	P	P	3,5,6,7,9
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K163077)

- 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, GYN
 - [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
 - [9] Volume navigation
 - [10] Shear wave elastography
 - [*] 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
LOGIQ E10 with L8-18i-D Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]											
Abdominal ^[1]											
Pediatric	P	P	P		P		P	P	P	P	5,6,9
Small Organ ^[2]	P	P	P		P		P	P	P	P	5,6,9
Neonatal Cephalic	P	P	P		P		P	P	P	P	5,9
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P		P	P	P	P	5,6,9
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	5,6,9
Musculo-skeletal Superficial	P	P	P		P		P	P	P	P	5,6,9
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[8]											
Transvaginal											
Transurethral											
Intraoperative ^[8]	P	P	P		P		P	P	P	P	5,6,9
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K163077)

- 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, GYN
 - [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
 - [9] Volume navigation
 - [10] Shear wave elastography
 - [*] 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

LOGIQ E10 with P2D Transducer

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

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

N = new indication; P = previously cleared by FDA (K163077)

- 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, GYN
 - [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
 - [9] Volume navigation
 - [10] Shear wave elastography
 - [*] 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
LOGIQ E10 with C2-9-D/C2-9VN-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	3,5,6,9
Abdominal ^[4]	P	P	P		P		P	P	P	P	3,5,6,9
Pediatric	P	P	P		P		P	P	P	P	3,5,6,9
Small Organ ^[2]											
Neonatal Cephalic	P	P	P		P		P	P	P	P	3,5,9
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	P	P	P		P		P	P	P	P	3,5,6,9
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	3,5,6,9
Musculo-skeletal Superficial	P	P	P		P		P	P	P	P	3,5,6,9
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[6]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K163077)

- 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, GYN
 - [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
 - [9] Volume navigation
 - [10] Shear wave elastography
 - [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

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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
LOGIQ E10 with RAB6-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	5,6
Abdominal ^[4]	P	P	P		P		P	P	P	P	5,6
Pediatric	P	P	P		P		P	P	P	P	5,6
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[6]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P* = previously cleared by FDA (K163077)

- 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, GYN
 - [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
 - [9] Volume navigation
 - [10] Shear wave elastography
 - [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes

(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
LOGIQ E10 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	5,6
Abdominal ^[4]	P	P	P	P	P			P	P	P	P	5,6
Pediatric												
Small Organ ^[2]												
Neonatal Cephalic												
Adult Cephalic												
Cardiac Adult												
Cardiac 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	P	P	P	P	P			P	P	P	P	5,6
Transvaginal	P	P	P	P	P			P	P	P	P	5,6
Transurethral												
Intraoperative ^[6]												
Intraoperative Neurological												
Intravascular												
Laparoscopic												

N = new indication; P* = previously cleared by FDA (K163077)

- 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, GYN
 - [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
 - [9] Volume navigation
 - [10] Shear wave elastography
 - [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes

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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

LOGIQ E10 with 6Tc-RS Transducer

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse*	Other [Notes]
Anatomy/Region of Interest											
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	
Cardiac Pediatric											
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											
Transvaginal											
Transurethral											
Intraoperative ^[6]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K170445)

- 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, GYN
 - [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
 - [9] Volume navigation
 - [10] Shear wave elastography
 - [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes

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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
LOGIQ E10 with C1-6-D/C1-6VN-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	3,5,6,9
Abdominal ^[4]	P	P	P		P		P	P	P	P	3,5,6,9,10
Pediatric	P	P	P		P		P	P	P	P	3,5,6,9,10
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	P	P	P		P		P	P	P	P	3,5,6,9
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	3,5,6,9
Musculo-skeletal Superficial	P	P	P		P		P	P	P	P	3,5,6,9
Other ^[4]	P	P	P		P		P	P	P	P	3,5,6,9
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[6]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K163077)

- 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, GYN
 - [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
 - [9] Volume navigation
 - [10] Shear wave elastography
 - [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes

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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
LOGIQ E10 with C2-7-D/C2-7VN-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	5,6,9
Pediatric	P	P	P		P		P	P	P	P	5,6,9
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
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 (K163077)

- 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, GYN
 - [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
 - [9] Volume navigation
 - [10] Shear wave elastography
 - [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

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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
LOGIQ E10 with C3-10-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 ⁹	Other [Notes]
Ophthalmic											
Fetal/Obstetrics ^[7]											
Abdominal ^[1]											
Pediatric	P	P	P		P		P	P	P	P	5,6,9
Small Organ ^[2]	P	P	P		P		P	P	P	P	5,6,9
Neonatal Cephalic	P	P	P		P		P	P	P	P	5,9
Adult Cephalic											
Cardiac Adult	P	P	P		P		P	P	P	P	5,6,9
Cardiac Pediatric	P	P	P		P		P	P	P	P	5,6,9
Peripheral Vascular	P	P	P		P		P	P	P	P	5,6,9
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 (K163077)

- 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, GYN
 - [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
 - [9] Volume navigation
 - [10] Shear wave elastography
 - [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

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

Prescription User (Per 21 CFR 801.109)



510(k) Summary

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

Date: November 15, 2017

Submitter: GE Healthcare
9900 Innovation Dr
Wauwatosa, WI 53226

Manufacturer: GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC.
9900 Innovation Drive
Wauwatosa, WI 53226 USA

Primary Contact Person: Bryan Behn
Regulatory Affairs Director
GE Healthcare
T:(414)721-4214
F:(414)918-8275

Alternate Contact Person:

Device: Trade Name: LOGIQ E10

Common/Usual Name: LOGIQ E10

Additional Marketing Names: LOGIQ E10 Pro, LOGIQ E11, LOGIQ E20

Classification Names: Class II

Product Code: Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550 90-IYN
Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO
Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX

Primary Predicate Device: K163077 LOGIQ E9 Diagnostic Ultrasound System

Reference Predicate K170445 LOGIQ S8 Diagnostic Ultrasound System

Device(s): K172342 Voluson E6/E8/E10 Diagnostic Ultrasound System

Device Description: The LOGIQ E10 is a full featured, general purpose diagnostic ultrasound system which consists of a mobile console approximately 585 mm wide (keyboard), 900 mm deep and 1300 mm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls, 12-inch LCD touch screen and color widescreen monitor.

Intended Use: The device is intended for use by a qualified physician for



ultrasound evaluation of Fetal/Obstetrics; 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 (vascular).

Technology: The LOGIQ E10 employs the same fundamental scientific technology as its predicate device(s).

Determination of Substantial Equivalence: Comparison to Predicates

The proposed LOGIQ E10 is a new platform substantially equivalent to the predicate devices. The following is an overview of the differences between the proposed LOGIQ E10 and the predicate LOGIQ E9 (K163077). The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.

- The LOGIQ E10 and predicate LOGIQ E9 systems have the same clinical intended use.
- The LOGIQ E10 and predicate LOGIQ E9 systems have the same imaging modes
- 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 E10 and predicate LOGIQ E9 systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The LOGIQ E10 and predicate systems have been designed in compliance with approved electrical and physical safety standards.
- The following probe and feature has been migrated from the LOGIQ S8 (K170445): M5Sc-D probe and power assistant.
- The following features have been migrated from the VOLUSON E Series (K172342) STIC, Elastography Analysis and Omniview with VCI.
- The new probes L2-9-D, L2-9VN-D, ML4-16-D, ML4-16VN-D are incremental technology improvements to predicate probes 9L-D and ML6-15-D on the predicate LOGIQ E9 (K163077)



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 with applicable medical device safety standards. The LOGIQ E10 and its applications comply with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 2005/(R)2012 And A1:2012
- IEC60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests, 2007
- IEC60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment, 2007
- ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Third Edition, 2009
- NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment:2004
- ISO14971, Application of risk management to medical devices: Second edition 2007
- NEMA PS 3.1 - 3.20 (2011), 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 E10, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the LOGIQ E10 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).