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

March 25, 2016

GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC
% Ms. Tracey Ortiz
Regulatory Affairs Director
9900 W. Innovation Drive
WAUWATOSA WI 53226

Re: K160277
Trade/Device Name: LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: January 29, 2016
Received: February 2, 2016

Dear Ms. Ortiz:

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.

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

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K160277

Device Name
LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6

Indications for Use *(Describe)*

The LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 are general purpose ultrasound imaging and analysis systems providing digital acquisition, processing and display capability, clinical applications including: Abdominal, Obstetrical, Gynecological, Small parts, Vascular/Peripheral Vascular, Transcranial, Pediatric, Musculoskeletal, Urological, Cardiac, Transvaginal, Transrectal, and Biopsy.

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)

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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.

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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 F8 Expert / LOGIQ F8 / LOGIQ F6 systems and for all of its probe/mode combinations. Combinations identified as "P" represents those previously cleared with another GE Ultrasound system.

Diagnostic Ultrasound Indications for Use Form

LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 Ultrasound System

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

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

N = new indication; P= previously cleared by FDA 133034; P^2= previously cleared by FDA K141768; P^3= previously cleared by FDA K151028; P^4=previously cleared by FDA K152758; P^5=previously cleared by FDA K141261

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[*]Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

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

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

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 with 4C-RS Transducer

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

Clinical Application	Mode of Operation										
	B	M	Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse◗	Other
			PW	CW	Color	Color M	Power				
Anatomy/Region of Interest											
Ophthalmic											
Fetal / Obstetrics	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Abdominal[1]	**P**	**N**	**P**		**P**		**P**	**P**	**P**	**P**	
Pediatric	**P**	**N**	**P**		**P**		**P**	**P**	**P**	**P**	
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	**P²**	**P²**	**P²**		**P²**		**P²**	**P²**	**P²**	**P²**	
Musculo-skeletal Conventional	**N**	**N**	**N**		**N**		**N**	**N**	**N**	**N**	
Musculo-skeletal Superficial											
Thoracic/Pleural											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage[4]	**P**	**P**			**P**		**P**	**P**	**P**	**P**	
Vascular Access (IV, PICC)											
Nerve Block											

N = new indication; P= previously cleared by FDA 133034; P²= previously cleared by FDA K141768; P³= previously cleared by FDA K151028; P⁴=previously cleared by FDA K152758; P⁵=previously cleared by FDA K141261

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[*]Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

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

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 with 8C-RS Transducer

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

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

N = new indication; P= previously cleared by FDA 133034; P[2]= previously cleared by FDA K141768; P[3]= previously cleared by FDA K151028; P[4]=previously cleared by FDA K152758; P[5]=previously cleared by FDA K141261

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[*]Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

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

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 with 3Sc-RS Transducer

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

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

N = new indication; P= previously cleared by FDA 133034; P[2]= previously cleared by FDA K141768; P[3]= previously cleared by FDA K151028; P[4]=previously cleared by FDA K152758; P[5]=previously cleared by FDA K141261

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[*]Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

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

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 with L6-12-RS Transducer

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

Clinical Application	Mode of Operation										
	B	M	Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse◗	Other
			PW	CW	Color	Color M	Power				
Anatomy/Region of Interest											
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]											
Pediatric	**P**		**P**		**P**		**P**	**P**	**P**	**P²**	
Small Organ [2]	**P**		**P**		**P**		**P**	**P**	**P**	**P²**	[6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	**P**		**P**		**P**		**P**	**P**	**P**	**P²**	
Musculo-skeletal Conventional	**P**		**P**		**P**		**P**	**P**	**P**	**P²**	
Musculo-skeletal Superficial	**P**		**P**		**P**		**P**	**P**	**P**	**P²**	
Thoracic/Pleural											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage[4]	**P**		**P**		**P**		**P**	**P**	**P**		
Vascular Access (IV, PICC)											
Nerve Block											

N = new indication; P= previously cleared by FDA 133034; P²= previously cleared by FDA K141768; P³= previously cleared by FDA K151028; P⁴=previously cleared by FDA K152758; P⁵=previously cleared by FDA K141261

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[*]Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

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

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 with E8C-RS Transducer

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

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

N = new indication; P= previously cleared by FDA 133034; P^2= previously cleared by FDA K141768; P^3= previously cleared by FDA K151028; P^4=previously cleared by FDA K152758; P^5=previously cleared by FDA K141261

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[*]Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

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

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 with RAB2-6-RS Transducer

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

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

N = new indication; P= previously cleared by FDA 133034; P[2]= previously cleared by FDA K141768; P[3]= previously cleared by FDA K151028; P[4]=previously cleared by FDA K152758; P[5]=previously cleared by FDA K141261

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[*]Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

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

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 with 6S-RS Transducer

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

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

N = new indication; P= previously cleared by FDA 133034; P[2]= previously cleared by FDA K141768; P[3]= previously cleared by FDA K151028; P[4]=previously cleared by FDA K152758; P[5]=previously cleared by FDA K141261

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[*]Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

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

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 with L8-18i-RS Transducer

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

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

N = new indication; P= previously cleared by FDA 133034; P[2]= previously cleared by FDA K141768; P[3]= previously cleared by FDA K151028; P[4]=previously cleared by FDA K152758; P[5]=previously cleared by FDA K141261

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[*]Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

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

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 with E8Cs-RS Transducer

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

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

N = new indication; P= previously cleared by FDA 133034; P[2]= previously cleared by FDA K141768; P[3]= previously cleared by FDA K151028; P[4]=previously cleared by FDA K152758; P[5]=previously cleared by FDA K141261

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[*]Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

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

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 with BE9CS-RS Transducer

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

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

N = new indication; P= previously cleared by FDA 133034; P[2]= previously cleared by FDA K141768; P[3]= previously cleared by FDA K151028; P[4]=previously cleared by FDA K152758; P[5]=previously cleared by FDA K141261

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[*]Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

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

Prescription Use (Per 21 CFR 801.109)

510(k) Summary

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

Date:	January 29, 2016
Submitter:	GE Medical Systems Ultrasound and Primary Care Diagnostics, 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Tracey Ortiz Regulatory Affairs Director GE Healthcare T:(262)676-6120 F:(414)918-8275
Secondary Contact Person:	Jian Xie Regulatory Affairs GE Medical Systems (China) Co, Ltd. T: +86 510 8527 8651 F: +86 510 8522 7347
Device: Trade Name:	LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6
Common/Usual Name:	Ultrasound system
Classification Names:	Class II Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550 90-IYN
Product Code:	Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX
Predicate Device(s):	LOGIQ F Series - K133034 LOGIQ S7 – K141261Venue 50 - K152758 LOGIQ V3 / LOGIQ V5 -K141768 LOGIQ e-K151028
Device Description:	The LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 are general purpose diagnostic ultrasound systems which consists of a mobile console approximately 1600mm high, 810mm in width and 720mm deep that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, 19 or 17 inch color LCD display and Touch panel. LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 have the same hardware and system features.

Intended Use: The LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 are general purpose ultrasound imaging and analysis systems providing digital acquisition, processing and display capability, clinical applications including: Abdominal, Obstetrical, Gynecological, Small parts, Vascular/Peripheral Vascular, Transcranial, Pediatric, Musculoskeletal, Urological, Cardiac, Transvaginal, Transrectal, and Biopsy.

Technology: The LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 employ the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Comparison to Predicates

The following is an overview of the difference between the prosed LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 and the predicate LOGIQ F series (K133034), The proposed LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 has had serval fearture and probes migrated to it curenlty cleared on other GE ultrousund systems.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 and the predicate LOGIQ F series have the same clinical intended use except the addition of the transrectal application that is on the LOGIQ e predicate (K151028).
- The LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 and the predicate LOGIQ F series have the same imaging modes.
- The LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 and the predicate LOGIQ F series have the same probes except for 4 being added: 6S-RS and L8-18i-RS are cleared in predicate LOGIQ e system (K151028);
  E8Cs-RS has the same transducer as Venue 50 (K152758) with different connector; BE9CS-RS has the same transducer on LOGIQ S7 (K141261) with different connector
- The following features have been migrated from LOGIQ S7 (K141261): Auto-EF, TUI, stress Echo advance 3D and Curved AMM.
- The Sonobiometry features has been migrated from predicate LOGIQ V3 / LOGIQ V5 (K141768).
- Adding a wireless adaptor to allow for wireless connectivity like that in predicate LOGIQ e K151028
- The systems are manufactured with materials which have

been evaluated and found to be safe for the intended use of the device.

- The system has acoustic power levels which are below the applicable FDA limits.
- The LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 and the predicate LOGIQ F series have the same capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 and the predicate LOGIQ F series 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. The LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 and its applications comply with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 2005
- 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
- NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment: 2004
- 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 were applied to the development of the system:

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

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).