



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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

August 5, 2016

Re: K161224
Trade/Device Name: LOGIQ V5 Expert, LOGIQ V5, LOGIQ V3
Regulation Number: 21CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: June 30, 2016
Received: July 5, 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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style. A faint, large "FDA" watermark is visible in the background behind the signature.

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

Indications for Use

510(k) Number (if known)

K161224

Device Name

LOGIQ V5 Expert / LOGIQ V5 / LOGIQ V3

Indications for Use (Describe)

The LOGIQ V5 Expert / LOGIQ V5 / LOGIQ V3 are general purposed ultrasound imaging and analysis systems providing digital acquisition, processing and display capability and clinical applications including: Abdominal, Obstetrical, Gynecological, Small parts, Vascular/Peripheral Vascular, Adult Cephalic, Pediatric, Musculoskeletal, Transcranial, Neonatal Cephalic, Transvaginal, Urological, Cardiac, Transrectal, and Tissue Biopsy/Fluid Drainage.

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.

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GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form
LOGIQ V5 Expert / LOGIQ V5 / LOGIQ V3 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 ^b	Other
			PW	CW	Color	Color M				
<i>Anatomy/Region of Interest</i>										
Ophthalmic										
Fetal / Obstetrics	P	P	P		P		P	P		[5]
Abdominal ^[1]	P	P	P		P		P	P		[5]
Pediatric	P	P	P		P	P	P	P		
Small Organ ^[2]	P	P	P		P		P	P		
Neonatal Cephalic	P	P	P	P	P		P	P	P	
Adult Cephalic	P	P	P	P	P		P	P	P	
Cardiac ^[3]	P	P	P	P	P	P	P	P		
Peripheral Vascular	P	P	P		P		P	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P	
Musculo-skeletal Superficial	P	P	P		P		P	P	P	
Thoracic/Pleural										
Other										
<i>Exam Type, Means of Access</i>										
Transcranial	P	P	P	P	P		P	P	P	
Transesophageal										
Transrectal	N	N	N		N		N	N	N	
Transvaginal	P	P	P		P		P	P	P	
Intraoperative										
<i>Interventional Guidance</i>										
Tissue Biopsy/Fluid Drainage ^[4]	N	N	N	N	N		N	N	N	[5]
Vascular Access (IV, PICC)										
Nerve Block										

**N = new indication; P= previously cleared by FDA K141768; P²= previously cleared by FDA K160277;
P³= previously cleared by FDA K151028**

- 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;
 [*]Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, 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 Use (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form
LOGIQ V5 Expert / LOGIQ V5 / LOGIQ V3 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				
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics	P	P	P			P		P		P	
Abdominal ^[1]	P	P	P			P		P		P	
Pediatric	P ²	P ²	P ²			P ²		P ²		P ²	
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	P	P	P			P		P		P	
Musculo-skeletal Conventional	P ²	P ²	P ²			P ²		P ²		P ²	
Musculo-skeletal Superficial											
Thoracic/Pleural											
Other											
<i>Exam Type, Means of Access</i>											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage ^[4]	P ²	P ²	P ²			P ²		P ²		P ²	
Vascular Access (IV, PICC)											
Nerve Block											

N = new indication; P= previously cleared by FDA 141768; P²= previously cleared by FDA K160277; P³= previously cleared by FDA K151028

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

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)
 Prescription Use (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form
LOGIQ V5 Expert / LOGIQ V5 / LOGIQ V3 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 ^b	Other
			PW	CW	Color	Color M	Power				
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]											
Pediatric	P ³	P ³	P ³		P ³		P ³	P ³	P ³		
Small Organ ^[2]											
Neonatal Cephalic	P ³	P ³	P ³		P ³		P ³	P ³	P ³		
Adult Cephalic											
Cardiac ^[3]	P ³	P ³	P ³		P ³		P ³	P ³	P ³		
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											
<i>Exam Type, Means of Access</i>											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage ^[4]											
Vascular Access (IV, PICC)											
Nerve Block											

N = new indication; P= previously cleared by FDA K141768; P²= previously cleared by FDA K160277; P³= previously cleared by FDA K151028

- 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;
 [*]Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, 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 Use (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form
LOGIQ V5 Expert / LOGIQ V5 / LOGIQ V3 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				
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	P	P	P		P		P	P	P		
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P		P	P	P		
Cardiac ^[3]	P	P	P	P	P	P	P	P	P		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural											
Other											
<i>Exam Type, Means of Access</i>											
Transcranial	P	P	P	P	P		P	P	P		
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage ^[4]	P²	P²	P²	P²	P²		P²	P²	P²		
Vascular Access (IV, PICC)											
Nerve Block											

N = new indication; P= previously cleared by FDA K141768; P²= previously cleared by FDA K160277; P³= previously cleared by FDA K151028

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

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)
 Prescription Use (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form
LOGIQ V5 Expert / LOGIQ V5 / LOGIQ V3 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				
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]											
Pediatric	P	P	P		P		P	P	P		
Small Organ ^[2]	P	P	P		P		P	P	P		
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	P	P	P		P		P	P	P		
Musculo-skeletal Conventional	P	P	P		P		P	P	P		
Musculo-skeletal Superficial	P	P	P		P		P	P	P		
Thoracic/Pleural											
Other											
<i>Exam Type, Means of Access</i>											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage ^[4]	P ²	P ²	P ²		P ²		P ²	P ²	P ²		
Vascular Access (IV, PICC)											
Nerve Block											

N = new indication; P= previously cleared by FDA K141768; P²= previously cleared by FDA K160277; P³= previously cleared by FDA K151028

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

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)
 Prescription Use (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form
LOGIQ V5 Expert / LOGIQ V5 / LOGIQ V3 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				
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics	P	P	P			P		P	P		
Abdominal ^[1]	P	P	P			P		P	P		
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural											
Other											
<i>Exam Type, Means of Access</i>											
Transcranial											
Transesophageal											
Transrectal	P²	P²	P²			P²		P²	P²		
Transvaginal	P	P	P			P		P	P		
Intraoperative											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage ^[4]	P²	P²	P²			P²		P²	P²		
Vascular Access (IV, PICC)											
Nerve Block											

N = new indication; P= previously cleared by FDA K141768; P²= previously cleared by FDA K160277; P³= previously cleared by FDA K151028

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

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)
 Prescription Use (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

LOGIQ V5 Expert / LOGIQ V5 / LOGIQ V3 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 ^b	Other
			PW	CW	Color	Color M				
<i>Anatomy/Region of Interest</i>										
Ophthalmic										
Fetal / Obstetrics	P ²	P ²	P ²		P ²		P ²	P ²		[5]
Abdominal ^[1]	P ²	P ²	P ²		P ²		P ²	P ²		[5]
Pediatric										
Small Organ ^[2]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac ^[3]										
Peripheral Vascular										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Thoracic/Pleural										
Other										
<i>Exam Type, Means of Access</i>										
Transcranial										
Transesophageal										
Transrectal										
Transvaginal										
Intraoperative										
<i>Interventional Guidance</i>										
Tissue Biopsy/Fluid Drainage ^[4]	P ²	P ²	P ²		P ²	P ²	P ²	P ²		[5]
Vascular Access (IV, PICC)										
Nerve Block										

N = new indication; P= previously cleared by FDA K141768; P²= previously cleared by FDA K160277;

P³= previously cleared by FDA K151028

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

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)
 Prescription Use (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form
LOGIQ V5 Expert / LOGIQ V5 / LOGIQ V3 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				
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]											
Pediatric	P ²	P ²	P ²		P ²			P ²	P ²		
Small Organ ^[2]											
Neonatal Cephalic	P ³	P ³	P ³	P ³	P ³			P ³	P ³		
Adult Cephalic											
Cardiac ^[3]	P ²	P ²	P ²	P ²	P ²	P ²		P ²	P ²		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural											
Other											
<i>Exam Type, Means of Access</i>											
Transcranial	P ²	P ²	P ²	P ²	P ²			P ²	P ²	P ²	
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage ^[4]											
Vascular Access (IV, PICC)											
Nerve Block											

N = new indication; P= previously cleared by FDA K141768; P²= previously cleared by FDA K160277; P³= previously cleared by FDA K151028

- 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;
 [*] Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, 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 Use (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form
LOGIQ V5 Expert / LOGIQ V5 / LOGIQ V3 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				
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics	P ²	P ²	P ²		P ²		P ²	P ²	P ²		
Abdominal ^[1]	P ²	P ²	P ²		P ²		P ²	P ²	P ²		
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural											
Other											
<i>Exam Type, Means of Access</i>											
Transcranial											
Transesophageal											
Transrectal	P ²	P ²	P ²		P ²		P ²	P ²	P ²		
Transvaginal	P ²	P ²	P ²		P ²		P ²	P ²	P ²		
Intraoperative											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage ^[4]	P ²	P ²	P ²		P ²		P ²	P ²	P ²		
Vascular Access (IV, PICC)											
Nerve Block											

N = new indication; P= previously cleared by FDA K141768; P²= previously cleared by FDA K160277; P³= previously cleared by FDA K151028

- 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;
 [*] Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, 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 Use (Per 21 CFR 801.109)



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form
LOGIQ V5 Expert / LOGIQ V5 / LOGIQ V3 with 12L-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				
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]											
Pediatric	P ³	P ³	P ³		P ³		P ³	P ³	P ³		
Small Organ ^[2]	P ³	P ³	P ³		P ³		P ³	P ³	P ³		
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	P ³	P ³	P ³		P ³		P ³	P ³	P ³		
Musculo-skeletal Superficial	P ³	P ³	P ³		P ³		P ³	P ³	P ³		
Thoracic/Pleural											
Other											
<i>Exam Type, Means of Access</i>											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
<i>Interventional Guidance</i>											
Tissue Biopsy/Fluid Drainage ^[4]	P ³	P ³	P ³		P ³		P ³	P ³	P ³		
Vascular Access (IV, PICC)											
Nerve Block											

N = new indication; P= previously cleared by FDA K141768; P²= previously cleared by FDA K1602777; P³= previously cleared by FDA K151028

- 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;
 [*]Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, 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 Use (Per 21 CFR 801.109)



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510(k) Summary

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

Date: April 28, 2016

Submitter: GE Medical Systems Ultrasound and Primary Care Diagnostics,
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Device: Trade Name: LOGIQ V5 Expert / LOGIQ V5 / LOGIQ V3
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

Primary Predicate Device(s): LOGIQ V3 / LOGIQ V5 - K141768

Reference Predicate Device(s): LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 - K160277
LOGIQ e - K151028

Device Description: The LOGIQ V5 Expert / LOGIQ V5 / LOGIQ V3 are entry level ultrasound scanners from the LOGIQ family for private clinics focusing on OB/GYN. The systems are for general purpose imaging and analysis providing real-time digital acquisition, processing and display capability intended for general radiology imaging, evaluation with some cardiology and vascular applications, and providing guidance during tissue biopsy and fluid drainage procedures.

The track 3 systems consist of a mobile console with keyboard control panel; color display and optional image storage, wireless



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capability, and printing devices. They utilize a variety of linear, curved linear and matrix phased array transducers. The systems have the same hardware and software but may have different options available.

Intended Use: The LOGIQ V5 Expert / LOGIQ V5 / LOGIQ V3 are general purposed ultrasound imaging and analysis systems providing digital acquisition, processing and display capability and clinical applications including: Abdominal, Obstetrical, Gynecological, Small parts, Vascular/Peripheral Vascular, Adult Cephalic, Pediatric, Musculoskeletal, Transcranial, Neonatal Cephalic, Transvaginal, Urological, Cardiac, Transrectal, and Tissue Biopsy/Fluid Drainage

Technology: The LOGIQ V5 Expert / LOGIQ V5 / LOGIQ V3 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 proposed LOGIQ V5 Expert / LOGIQ V5 / LOGIQ V3 and the predicate LOGIQ V5 / LOGIQ V3 (K141768). Most of features and probes are currently cleared on other GE ultrasound systems.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The proposed LOGIQ V5 Expert / LOGIQ V5 / LOGIQ V3 and the predicate LOGIQ V5 / LOGIQ V3 have the same intended use and clinical applications except the addition of the transrectal and biopsy applications that were cleared on the LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 predicate (K160277).
- The proposed LOGIQ V5 Expert / LOGIQ V5 / LOGIQ V3 and the predicate LOGIQ V5 / LOGIQ V3 have the same probes except for 5 being added: 6S-RS, E8Cs-RS, and RAB2-6-RS were cleared in predicate the LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 predicate (K160277); 12L-RS and 8C-RS were cleared in predicate LOGIQ e system (K151028).
- The 6S-RS probe application is being expanded to include Neonatal Cephalic which was cleared in the LOGIQ e predicate system (K151028).



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- Adding a 3D/4D mode with the RAB2-6-RS probe that was cleared on the predicate LOGIQ F8 Expert / LOGIQ F8 / LOGIQ F6 (K160277).
- A USB wireless adaptor is being added to allow for wireless connectivity like that in predicate LOGIQ e (K151028).
- Adding optional LCD monitor display sizes and a VGA/S-video/composite output.
- Expanding the Scan Coach software feature
- Adding 3D/4D imaging which was cleared in predicate device LOGIQ F8 Expert/LOGIQ F8/LOGIQ F6 (K160277).
- The LOGIQ V5 Expert / LOGIQ V5 / LOGIQ V3 and the predicate LOGIQ V5 / LOGIQ V3 have been designed in compliance with electrical and physical safety standards.
- The LOGIQ V5 Expert / LOGIQ V5 / LOGIQ V3 and the predicate LOGIQ V5 / LOGIQ V3 have the same capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- 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.

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 V5 Expert / LOGIQ V5 / LOGIQ V3 and its applications comply with voluntary standards:

- AAMI/ANSI ES 60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 2005
- IEC 60601-1-2, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests, 2007
- IEC 60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic



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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
- ISO 10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing, 2009
- NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, 2004
- ISO 14971, Application of risk management to medical devices, 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 V5 Expert / LOGIQ V5 / LOGIQ V3, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the proposed LOGIQ V5 Expert / LOGIQ V5 / LOGIQ V3 to be as safe, as effective, and performance is substantially equivalent to the predicate devices.