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

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

January 4, 2016

Re: K153037
Trade/Device Name: LOGIQ V1/ LOGIQ V2
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: December 22, 2015
Received: December 23, 2015

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,

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)*

K153037

Device Name
LOGIQ V1 / LOGIQ V2

Indications for Use *(Describe)*

The LOGIQ V1 / LOGIQ V2 is intended for ultrasound imaging, measurement and analysis of the human body for multiple clinical applications including: Fetal/OB; GYN; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Musculoskeletal Conventional & Superficial; Urology; Transrectal; Transvaginal; imaging guidance of interventional procedures (e.g. Nerve Block, Vascular Access, 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)

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

FOR FDA USE ONLY

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

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

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

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

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

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

Diagnostic Ultrasound Indications for Use Form
LOGIQ V1 / LOGIQ V2 Ultrasound System

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

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

N = new indication

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Includes image guidance for freehand needle placement
[5] Other is Urology and includes Prostate;
[*]Combined modes are B/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 V1 / V2 with 4C-RS Transducer

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

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

N = new indication; P= previously cleared by FDA 151028; P[1]= previously cleared by FDA K141768

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Includes image guidance for freehand needle placement
[5] Other is Urology and includes Prostate;
[*]Combined modes are B/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 V1 / V2 with 8C-RS Transducer

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

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

N = new indication; P= previously cleared by FDA K151028; P[1]= previously cleared by FDA K141768

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Includes image guidance for freehand needle placement
[5] Other is Urology and includes Prostate;
[*]Combined modes are B/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 V1 / V2 with E8C-RS Transducer

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

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

N = new indication; P= previously cleared by FDA K151028; P[1]= previously cleared by FDA 141768

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Includes image guidance for freehand needle placement
[5] Other is Urology and includes Prostate;
[*]Combined modes are B/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 V1 / V2 with 12L-RS Transducer

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

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

N = new indication; P= previously cleared by FDA K151028; P[1]= previously cleared by FDA K141768

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Includes image guidance for freehand needle placement
[5] Other is Urology and includes Prostate;
[*]Combined modes are B/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 V1 / V2 with 3Sc-RS Transducer

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

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse◗	Other
Anatomy/Region of Interest											
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**		
Cardiac[3]	**P**	**P**	**P**		**P**		**P**	**P**	**P**		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural											
Other[5]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage	**P**	**P**	**P**		**P**		**P**	**P**	**P**		4
Vascular Access (IV, PICC)	**P**	**P**	**P**		**P**		**P**	**P**	**P**		4
Nerve Block											

N = new indication; P= previously cleared by FDA K151028; P[1]= previously cleared by FDA K141768

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Includes image guidance for freehand needle placement
[5] Other is Urology and includes Prostate;
[*]Combined modes are B/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 V1 / V2 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	PW Doppler	CW Doppler	Color Doppler	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse❜	Other
Anatomy/Region of Interest											
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]											
Pediatric	**P[1]**	**P[1]**	**P[1]**		**P[1]**		**P[1]**	**P[1]**	**P[1]**	**P[1]**	
Small Organ [2]	**P[1]**	**P[1]**	**P[1]**		**P[1]**		**P[1]**	**P[1]**	**P[1]**	**P[1]**	
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	**P[1]**	**P[1]**	**P[1]**		**P[1]**		**P[1]**	**P[1]**	**P[1]**	**P[1]**	
Musculo-skeletal Conventional	**P[1]**	**P[1]**	**P[1]**		**P[1]**		**P[1]**	**P[1]**	**P[1]**	**P[1]**	
Musculo-skeletal Superficial	**P[1]**	**P[1]**	**P[1]**		**P[1]**		**P[1]**	**P[1]**	**P[1]**	**P[1]**	
Thoracic/Pleural											
Other[5]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage	**P[1]**	**P[1]**	**P[1]**		**P[1]**		**P[1]**	**P[1]**	**P[1]**	**N**	4
Vascular Access (IV, PICC)	**P[1]**	**P[1]**	**P[1]**		**P[1]**		**P[1]**	**P[1]**	**P[1]**	**N**	4
Nerve Block	**P[1]**	**P[1]**	**P[1]**		**P[1]**		**P[1]**	**P[1]**	**P[1]**	**N**	4

N = new indication; P= previously cleared by FDA K151028; P[1]= previously cleared by FDA K141768

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Includes image guidance for freehand needle placement
[5] Other is Urology and includes Prostate;
[*]Combined modes are B/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 V1 / V2 with LK760-RS Transducer

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

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

N = new indication; P= previously cleared by FDA K151028; P[1]= previously cleared by FDA K141768

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Includes image guidance for freehand needle placement
[5] Other is Urology and includes Prostate;
[*]Combined modes are B/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)

510(k) Summary

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

Date:	October 16, 2015
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 V1 / LOGIQ V2
Common/Usual Name:	Ultrasound system
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
Predicate Device(s):	LOGIQ e - K151028 LOGIQ V3 / LOGIQ V5 – K141768
Device Description:	The LOGIQ V1 / LOGIQ V2 systems are a laptop ultrasound console approximately 120mm in height, 368mm in width and 396mm in length with integrated keyboard, a color video LCD type display, one inbuilt active probe ports and two probe port adapters. It has digital acquisition, processing and display capability and operates from an integrated battery or separate power supply/charger. LOGIQ V1 and LOGIQ V2 have the same hardware and system features.

Intended Use: The LOGIQ V1 / LOGIQ V2 is intended for ultrasound imaging, measurement and analysis of the human body for multiple clinical applications including: Fetal/OB; GYN; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Musculoskeletal Conventional & Superficial; Urology; Transrectal; Transvaginal; imaging guidance of interventional procedures (e.g. Nerve Block, Vascular Access, Tissue Biopsy/Fluid Drainage).

Technology: The LOGIQ V1 / LOGIQ V2 employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Comparison to Predicates

The LOGIQ V1 / LOGIQ V2 is substantially equivalent to the predicate devices with regards to intended use, imaging capabilities, technologicial characteristics and safety and effectiveness.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The LOGIQ V1 / LOGIQ V2 and predicate LOGIQ e have the same intended use and similar clinical applications.
- The LOGIQ V1 / LOGIQ V2 and predicate LOGIQ e system have the same imaging modes.
- The system is 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 V1 / LOGIQ V2 and predicate LOGIQ e system have the same capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The LOGIQ V1 / LOGIQ V2 and predicate LOGIQ e system have been designed in compliance with approved electrical and physical safety standards.
- The transducer L6-12-RS is cleared in predicate LOGIQ V3 / LOGIQ V5 (K141768), other transducers are cleared in predicate LOGIQ e system (K151028).

- Software features are the same as is on the predicate LOGIQ e plus Sonobiometry(AFB) and ScanCoach features have been added from predicate LOGIQ V3 / LOGIQ V5 (K141768).

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 V1 / LOGIQ V2 and its applications comply with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety
- IEC60601-1-2, Medical Electrical Equipment – Part 1-2:General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests
- IEC60601-2-37, Medical Electrical Equipment – Part 2-37:Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
- NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- ISO10993-1, Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing
- NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- ISO14971, Application of risk management to medical devices
- NEMA, 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 V1 / LOGIQ V2, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the LOGIQ V1 / LOGIQ V2 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).