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

August 4, 2014

GE HEALTHCARE
BRYAN BEHN
REGULATORY AFFAIRS MANAGER
9900 INNOVATION DRIVE RP-2138
WAUWATOSA WI 53226

Re: K141768
Trade/Device Name: Logiq V5 / Logiq V3
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: June 30, 2014
Received: July 1, 2014

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Logiq V5 and Logiq V3, as described in your premarket notification:

Transducer Model Number

4C-RS
E8C-RS
3Sc-RS
L6-12-RS

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

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

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

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

Sincerely yours,

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number (*if known*)

K141768

Device Name

LOGIQ V5/LOGIQ V3 Diagnostic Ultrasound System

Indications for Use (*Describe*)

The LOGIQ V5/LOGIQ V3 is 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 and Cardiac.

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.

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

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

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

Indications for Use Forms

The following Indications for Use forms are appended.

System: LOGIQ V5/LOGIQ V3

Transducer: 4C-RS

Transducer: 3Sc-RS

Transducer: L6-12-RS

Transducer: E8C-RS

The following forms represent indications with clinical applications and exam types along with the modes of operation for the LOGIQ V5 and LOGIQ V3. Combinations identified “P” for the transducers represents those previously cleared with another GE Ultrasound system. Combinations identified as “N” are new.

Diagnostic Ultrasound Indications for Use Form

LOGIQ V5 Ultrasound System

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

Clinical Application	Mode of Operation										
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Ophthalmic											
Fetal/OB	N	N	N		N	N	N	N	N	N	
Abdominal[1]	N	N	N	N	N	N	N	N	N	N	
Pediatric	N	N	N	N	N	N	N	N	N	N	
Small Organ (specify)[2]	N	N	N		N	N	N	N	N	N	
Neonatal Cephalic	N	N	N	N	N	N	N	N	N	N	
Adult Cephalic	N	N	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	N	
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N	N	
Musculo-skeletal Superficial	N	N	N		N	N	N	N	N	N	
Thoracic/Pleural (specify)											
Other (specify)											
Exam Type, Means of Access											
Transcranial	N	N	N	N	N	N	N	N	N	N	
Transorbital											
Transesophageal											
Transrectal											
Transvaginal	N	N	N		N	N	N	N	N	N	
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular/Intraluminal											
Intracardiac											
Laparoscopic											

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, and thyroid;
[3] Cardiac is Adult and Pediatric;
[*] Combined modes are color/power Doppler with B-mode

(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 V3 Ultrasound System

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

Clinical Application	Mode of Operation										
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Ophthalmic											
Fetal/OB	N	N	N		N	N	N	N	N	N	
Abdominal[1]	N	N	N	N	N	N	N	N	N	N	
Pediatric	N	N	N	N	N	N	N	N	N	N	
Small Organ (specify)[2]	N	N	N		N	N	N	N	N	N	
Neonatal Cephalic	N	N	N	N	N	N	N	N	N	N	
Adult Cephalic	N	N	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	N	
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N	N	
Musculo-skeletal Superficial	N	N	N		N	N	N	N	N	N	
Thoracic/Pleural (specify)											
Other (specify)											
Exam Type, Means of Access											
Transcranial	N	N	N	N	N	N	N	N	N	N	
Transorbital											
Transesophageal											
Transrectal											
Transvaginal	N	N	N		N	N	N	N	N	N	
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular/Intraluminal											
Intracardiac											
Laparoscopic											

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, and thyroid;
[3] Cardiac is Adult and Pediatric;
[*] Combined modes are color/power Doppler with B-mode

(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 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										
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Ophthalmic											
Fetal/OB	P	P	P		P	P	P	P	P	P	
Abdominal[1]	P	N	P		P	N	P	P	P	P	
Pediatric											
Small Organ (specify)[2]	N	N	N		N	N	N	N	N	N	
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	N	N	N		N	N	N	N	N	N	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify)											
Other (specify)											
Exam Type, Means of Access											
Transcranial											
Transorbital											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular/Intraluminal											
Intracardiac											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K133034)

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, and thyroid;
[3] Cardiac is Adult and Pediatric;
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PDI

(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 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										
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power				
Ophthalmic											
Fetal/OB	P	P	P		P	P	P	P	P	N	
Abdominal[1]	N	N	N		N	N	N	N	N	N	
Pediatric											
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify)											
Other (specify)											
Exam Type, Means of Access											
Transcranial											
Transorbital											
Transesophageal											
Transrectal											
Transvaginal	P	P	P		P	P	P	P	P	N	
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular/Intraluminal											
Intracardiac											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K133034)

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, and thyroid
[3] Cardiac is Adult and Pediatric;
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PDI

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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 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
Anatomy/Region of Interest			PW	CW	Color	Color M	Power				
Ophthalmic											
Fetal/OB											
Abdominal[1]	P	P	P	N	P	P	P	P	P	N	
Pediatric	P	P	P	N	P	P		P	P	N	
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic	N	N	N	N	N	N	N	N	N	N	
Cardiac[3]	P	P	P	N	P	P	P	P	P	N	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify)											
Other (specify)											
Exam Type, Means of Access											
Transcranial	P	P	P	N	P	P	P	P	P	N	
Transorbital											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular/Intraluminal											
Intracardiac											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K133034)

Notes: [1] Abdominal includes GYN and Urological
[2] Small Organ includes breast, testes, and thyroid
[3] Cardiac is Adult and Pediatric
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PDI

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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 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
Anatomy/Region of Interest			PW	CW	Color	Color M	Power				
Ophthalmic											
Fetal/OB											
Abdominal[1]	N	N	N		N	N	N	N	N	N	
Pediatric	P	N	P		P	N	P	P	P	N	
Small Organ (specify)[2]	P	N	P		P	N	P	P	P	N	
Neonatal Cephalic	N	N	N		N	N	N	N	N	N	
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	P	N	P		P	N	P	P	P	N	
Musculo-skeletal Conventional	P	N	P		P	N	P	P	P	N	
Musculo-skeletal Superficial	P	N	P		P	N	P	P	P	N	
Thoracic/Pleural (specify)											
Other (specify)											
Exam Type, Means of Access											
Transcranial											
Transorbital											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular/Intraluminal											
Intracardiac											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K133034)

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, and thyroid;
[3] Cardiac is Adult and Pediatric;
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PDI

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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:	June 30, 2014
Submitter:	GE Healthcare 9900 Innovation Dr Wauwatosa, WI 53226
Primary Contact Person:	Bryan Behn Regulatory Affairs Manager GE Healthcare T:(414)721-4214 F:(414)918-8275
Secondary Contact Person:	Jiawei ZHANG Regulatory Affairs GE Healthcare T: +86 510 8527 8259 F: +86 510 8522 7347
Device: Trade Name:	LOGIQ V5, LOGIQ V3
Common/Usual Name:	LOGIQ V5, LOGIQ V3
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):	K133034 GE LOGIQ F Series K131267 Voluson E series
Device Description:	The LOGIQ V5/LOGIQ V3 is a general-purpose entry level ultrasound scanner from LOGIQ family for private clinics focusing on OB/GYN. The device is a general-purpose imaging and analysis system providing real-time digital acquisition, processing and display capability intended for general radiology imaging and evaluation with some cardiology and vascular applications.
Intended Use:	LOGIQ V5/LOGIQ V3 is a general-purpose ultrasound system used for acquiring and storing ultrasound images for applications such as: Obstetrics; Abdominal, Obstetrical, Gynecological, Small parts, Vascular/Peripheral Vascular, Adult Cephalic, Pediatric, Musculoskeletal, Transcranial, Neonatal Cephalic, Urological and Cardiac. The system used for performing measurements, annotating, printing/reporting on the

acquired/stored images.

Technology: LOGIQ V5 and LOGIQ V3 employ the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Comparison to Predicate Devices

The LOGIQ V5 and LOGIQ V3 systems are substantially equivalent to the predicate devices with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The LOGIQ V5/LOGIQ V3 has a subset of clinical indications for use available on the predicate LOGIQ F series.
- The LOGIQ V5/LOGIQ V3 has a subset of imaging modes on the predicate LOGIQ F series.
- The LOGIQ V5/LOGIQ V3 has a subset of transducers on the predicate LOGIQ F series.
- 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 V5/LOGIQ V3 and the predicate LOGIQ F series systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The LOGIQ V5/LOGIQ V3 and predicate systems have been designed in compliance with approved electrical and physical safety standards.

	Proposed Device LOGIQ V5/LOGIQ V3	**Predicate Device LOGIQ F Series (K133034)**
Indications and Clinical Applications:		
• Fetal/Obstetrics;	✓	✓
• Abdominal/ GYN and Urological	✓	✓
• Small Organ (breast, testes, thyroid);	✓	✓

• Pediatric		✓
• Neonatal Cephalic;	✓	✓
• Adult Cephalic;	✓	✓
• Cardiac (adult and pediatric);	✓	✓
• Peripheral Vascular;	✓	✓
• Musculo-skeletal Conventional and Superficial;	✓	✓
• Transcranial	✓	✓
• Transvaginal;	✓	✓
Contact Type • Surface, Cavitary , TEE	✓	✓
Image modes: • B; M; Color, Power, PW& CW Doppler modes, Color M-mode, Harmonic imaging, Combined modes	✓	✓
Transducers		
• 3Sc-RS	✓	✓
• 4C-RS	✓	✓
• E8C-RS	✓	✓
• L6-12-RS	✓	✓
• 8C-RS		✓
• RAB2-6-RS		✓
Processing &Display features: Image freeze, Multiple images, Pan /Zoom, Image maps (color & gray), Cine loop, Spatial & temporal filters, L-R / T-B image rev., Digital harmonics, TGC, Raw data access, LOGIQ View, CrossXBeam, SRI-HD, B-Flow, TVI, Anatomical-M mode (AMM), Auto Optimization.	✓	✓
Tested to meet Electrical Safety, EMC and Biocompatibility Standards	✓	✓
Track 3 (within FDA limits)	✓	✓

Summary of Non-Clinical Tests:

LOGIQ V5/LOGIQ V3 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 V5/LOGIQ V3 complies with voluntary standards:

1. AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety
2. IEC60601-1-2, Medical Electrical Equipment – Part 1-2:General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests
3. IEC60601-2-37, Medical Electrical Equipment – Part 2-37:Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
4. NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
5. ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Third Edition
6. NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
7. ISO14971, Application of risk management to medical devices
8. NEMA, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)

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

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

- Simulated use testing (Validation)

Transducer material and other patient contact materials such as needle guidance kits are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, LOGIQ V5/LOGIQ V5, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the LOGIQ V5/LOGIQ V3 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).