K101878

GE Healthcare
510(k) Premarket Notification Submission

AUG 31 2010

Section 5: 510(k) Summary

LOGIQ P5 BT11

K101878

AUG 31 2010

GE Healthcare

510(k) Premarket Notification Submission

510(k) Summary

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

Date:	July 1, 2010
Submitter:	GE Healthcare [GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC] 9900 Innovation Dr Wauwatosa, WI 53226
Primary Contact Person:	Bryan Behn Regulatory Affairs Manager GE Healthcare, GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC.] T:(414)721-4214 F:(414)918-8275
Secondary Contact Person:	Jim Turner Regulatory Affairs Manager America's Service GE Healthcare, GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC T:(262) 544-3359 F:(414)908-9225
Device: Trade Name:	LOGIQ P5 BT11 Ultrasound System
Common/Usual Name:	LOGIQ P5 BT11
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):	K060993 LOGIQ P5/A5 Ultrasound System K092271 LOGIQ E9 Ultrasound System
Device Description:	The subject device consists of a mobile console with keyboard, specialized controls, a color video LCD display with electronic-array transducers. It has the same general appearance, dimensions and weight as the unmodified device, it is a Track 3 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:	The device is a general-purpose ultrasound system. Specific clinical applications and exam types include: Fetal; Abdominal

(renal & GYN/pelvic); Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular (PV); Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transesophageal (TE); Transrectal (TR); Transvaginal (TV); and Intraoperative (abdominal, thoracic, vascular and neuro.

Technology: The LOGIQ P5 BT11 employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform with applicable medical device safety standards. The LOGIQ P5 and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. 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)
- Final Acceptance Testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, LOGIQ P5, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the LOGIQ P5 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Bryan Behn
Regulatory Affairs Manager
GE Healthcare
9900 Innovation Dr.
WAUWATOSA WI 53226

AUG 31 2010

Re: K101878
Trade/Device Name: LOGIQ P5 BT11 Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: July 26, 2010
Received: July 27, 2010

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the LOGIQ P5 BT11 Ultrasound System, as described in your premarket notification:

Transducer Model Number

i12L
BE9CS
3CRF
3Sp
5Sp
4D8C
11L

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. 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); 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.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (301) 796-6881.

Sincerely yours,

Donald St. Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

K101878

GE Healthcare

510(k) Premarket Notification Submission

510(k) Number (if known):

AUG 31 2010

Device Name: LOGIQ P5 BT11

Indications for Use:

The device is a general-purpose ultrasound system. Specific clinical applications and exam types include: Fetal; Abdominal (renal & GYN/pelvic); Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular (PV); Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transesophageal (TE); Transrectal (TR); Transvaginal (TV); and Intraoperative (abdominal, thoracic, vascular and neurol.

Prescription Use X AND/OR Over-The-Counter Use_NA_
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of ~~Device Evaluation (ODE)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101878

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P5 Ultrasound System

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

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

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, and thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

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

[6] Elastography Imaging

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

[**] Other mode is 4D / Realtime 3D

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Concurrence of CDRH, Office of ~~Device Evaluation (ODE)~~ OIVD

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101878

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P6 with i12L Transducer

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

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

N = new indication; P = previously cleared by FDA (Logiq 9 K030934); E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic
[2] Small organ includes breast, testes, and thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology/Prostate
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
[**] Other mode is 4D / Realtime 3D

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Concurrence of CDRH, Office of ~~Device Evaluation (ODE)~~ OIVD

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101878

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P6 with BE9CS Transducer

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

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

N = new indication; P = previously cleared by FDA; E = added under Appendix E(Minor modification to BE9C)

Notes: [1] Abdominal includes renal, GYN/Pelvic
[2] Small organ includes breast, testes, and thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology/Prostate
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
[**] Other mode is 4D / Realtime 3D

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Concurrence of CDRH, Office of ~~Device Evaluation (ODE)~~ OIVD

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101828

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P6 with 3CRF Transducer

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

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

N = new indication; P = previously cleared by FDA(LOGIQ E9 K092271); E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic
[2] Small organ includes breast, testes, and thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology/Prostate
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
[**] Other mode is 4D / Realtime 3D

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Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101878

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P6 with 3Sp Transducer

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

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

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, and thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

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

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

[**] Other mode is 4D / Realtime 3D

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Concurrence of CDRH, Office of Device Evaluation (ODE) CDRH

Prescription User (Per 21 CFR 801.109)

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101878

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P6 with 5Sp Transducer

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

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

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, and thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

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

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

[**] Other mode is 4D / Realtime 3D

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Concurrence of CDRH, Office of ~~Device Evaluation (ODE)~~ OIVD

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101878

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P6 with 4D8C Transducer

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

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

N = new indication; P = previously cleared by FDA (LOGIQ 9 K061129); E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, and thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

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

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

[**] Other mode is 4D / Realtime 3D

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Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101878

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P6 with 11L Transducer

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

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

N = new indication; P = previously cleared by FDA(LOGIQ E9 K092271); E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic
[2] Small organ includes breast, testes, and thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology/Prostate
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[6] Elastography Imaging
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
[**] Other mode is 4D / Realtime 3D

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Prescription User (Per 21 CFR 801.109)

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