JUL 2 5 2003

NO32182

Special 510(k) Premarket Notification GE Medical Systems - LOGIQ 7 Ultrasound BT03 July 15, 2003

Attachment B:

Summary of Safety and Effectiveness Prepared in accordance with 21 CFR Part 807.92(c).



GE Medical Systems

General Electric Company P.O. Box 414, Milwaukee, WI 53201

Section a):

1.

Submitter: GE Medical Systems

PO Box 414

Milwaukee, WI 53201

Contact Person: Allen Schuh.

> Manager, Safety and Regulatory Engineering Telephone: 414-647-4385; Fax: 414-647-4090

Date Prepared: July 15, 2003

2. Device Name: GE LOGIQ 7 Diagnostic Ultrasound System, BT03

Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN

3. Marketed Device: GE LOGIQ 7 Diagnostic Ultrasound System K010329 (90-IYO/IYN)

A device currently in commercial distribution.

- 4. Device Description: The GE LOGIQ 7 is a full featured general purpose diagnostic ultrasound system. It consists of a mobile console approximately 60 cm wide, 100 cm deep and 140-160 cm (adjustable) high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls and a color video CRT and LCD touch panel. This modification will provide users with improved image enhancement.
- 5. Indications for Use: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal: Abdominal: Pediatric: Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative (abdominal, thoracic, vascular and neurosurgical).
- 6. Comparison with Predicate Device: The GE LOGIQ 7 BT03 is of a comparable type and substantially equivalent to the current GE LOGIQ 7. It has the same technological characteristics, key safety and effectiveness features, physical design, construction, and materials, and has the same intended uses and basic operating modes as the predicate device.

Section b):

- 1. Non-clinical Tests: The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.
- Clinical Tests: None required.
- 3. Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA quidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001:2000 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Medical Systems that the GE LOGIQ 7 BT03 Diagnostic Ultrasound is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



JUL 2 5 2003

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Mr. Allen Schuh Manager, GE Ultrasound Safety and Regulatory Engineering GE Medical Systems General Electric Company P.O. Box 414 MILWAUKEE WI 53201

Re: K032182

Trade Name: GE LOGIQ 7 Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: 90 IYN, IYO, and ITX

Dated: July 15, 2003 Received: July 17, 2003

Dear Mr. Schuh:

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 GE LOGIQ 7 Ultrasound System, as described in your premarket notification:

Transducer Model Number

3C 5C M7C 8C E8C 7L 10L 12L M12L 3S **M3S 4**S 5S **7S** 10S 6T P2D P6D i8L i12L

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 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

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 determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

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 contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Maney Changdon
Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

Special 510(k) Premarket Notification GE Medical Systems - LOGIQ 7 Ultrasound BT03 July 15, 2003

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ 7 Ultrasound System

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

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominet

and Radiological Devices

510(k) Number

GE LOGIQ 7 with 3.5C Transducer

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

					Mode	of Op	eration	1			
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW	Color Doppler	Color M Doppler		Combined	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	Ε	E	E		E	Ε	E	E	Е	Е	
Abdominal ^[1]	Ε	E	E		Ε	Е	E	E	E	Ε	
Pediatric			<u></u>								
Small Organ (specify)	E	E	E		E	E	E	E	E	E	
Neonatal Cephalic											
Adult Cephalic								L			
Cardiac											
Peripheral Vascular	E	Ε	E		E	E	E	E	E	E	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial			<u> </u>								<u></u>
Other ^[4]	Ε	E	E		E	E	E	E	E	E	
Exam Type, Means of Access			<u> </u>								
Transesophageal			<u> </u>								
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic		Ĺ	11. 504			<u> </u>		<u> </u>			<u> </u>

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N = new ir	ndication; P = pr	eviously	cleared	by FDA	\; E = a	dded und	der Appe	endix E		 =	
Notes: [1]	Abdominal incl	udes G\	/N;								
[4]	Other use inclu	ides Urc	ology;								
[*]	Combined mod	es are E	B/M, B/C	olor M,	B/PWD,	B/Color/	PWD, B	/Power/l	PWD.		
			* ******							 	
				-						 	
		(PLEASE D	NOT WA	ITE BELOW	V THIS LINE	- CONTINUI	E ON ANOT	HER PAGE	IF NEEDED)		
		Co	ncurren	ce of CD	RH, Offic	ce of Dev	ice Evalu	uation (O	DE)		

(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number

GE LOGIQ 7 with 3.5Cs Transducer

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

					Mode	of Op	eřatior	1			-
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color	Color M	Power	Combined	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	E	Ε	E		Ε	Ε	E	E	Ε	E	
Abdominal ^[1]	E	E	E		E	E	E	E	E	E	
Pediatric											
Small Organ (specify)	E	Ε	E		E	Е	Ε	E	E	E	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	E	_ E	E		E	E	Е	E	E	Ε	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	E	Е	E		E	E	E	E	E	ш	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic N = new indication: P = pr											

				1	1	1				í
N = n	ew indication; $P = p$	reviously cleare	d by FDA	; E = a	dded und	der Appe	endix E			
Notes	: [1] Abdominal inc	ludes GYN;								
	[4] Other use incli	udes Urology;								
	[*] Combined mod	des are B/M, B/	Color M,	B/PWD,	B/Color/	PWD, B	/Power/f	PWD.		
								<u>-</u>	 	
		(PLEASE DO NOT W	RITE BELOW	THIS LINE	- CONTINU	E ON ANOT	HER PAGE	F NEEDED)		
		Concurre	nce of CD	RH, Offic	ce of Dev	ice Eval	uation (O	DE)		

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number_

GE LOGIQ 7 with 3C Transducer

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

	· · · · · · · · · · · · · · · · · · ·	Mode of Operation PW CW Color Color M Power Combined Harmonic Coded Other												
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	Other			
Ophthalmic														
Fetal / Obstetrics	Р	P	P		P	Р	Р	Р	Р	Р	ļ			
Abdominal ^[1]	Р	Р	P		Р	Р	Р	P	Р	Р				
Pediatric	P	Р	Р		Р	Р	Р	Р	P	_ Р				
Small Organ (specify)														
Neonatal Cephalic														
Adult Cephalic			<u> </u>	<u> </u>										
Cardiac							ļ <u>.</u>			<u> </u>				
Peripheral Vascular														
Musculo-skeletal Conventional					ļ						<u> </u>			
Musculo-skeletal Superficial											<u> </u>			
Other ^[4]	Р	Р	P		P	P	Р	Р	Р	P				
Exam Type, Means of Access						L					<u> </u>			
Transesophageal				<u> </u>										
Transrectal						ļ								
Transvaginal						l		ļ			<u> </u>			
Transuretheral														
Intraoperative (specify)														
Intraoperative Neurological			<u> </u>								<u> </u>			
Intravascular														
Laparoscopic		<u></u>									<u> </u>			

N = new indication; P = p	reviously	cleared	by FDA	E = ac	dded und	er Appe	ndix E			
Notes: [1] Abdominal inc	ludes GY	N;								
[4] Other use inc	udes Urol	ogy;								
[*] Combined mo	des are B	/M, B/C	olor M, I	B/PWD,	B/Color/	PWD, B	/Power/l	PWD.		
	(PLEASE D	O NOT WE	RITE BELOW	THIS LINE	- CONTINUE	ON ANOT	HER PAGE	IF NEEDED)		
	Co	ncurren	ce of CD	RH, Offic	ce of Devi	ce Evalu	iation (O	DE)	· 	

Prescription Use (Per 21 CFR 801.109)

GE LOGIQ 7 with 5C Transducer

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

					Mode	of Ope	ration				
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	Othe
Ophthalmic											
Fetal / Obstetrics	Р	Р	Р		P	P	Р	P	P		
Abdominal ^[1]	P	Р	P		Р	P	Р	P	P		
Pediatric	E	Ε	E		E	Ε	E	Ε	E		
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	_ P	Р	P	<u> </u>	P	P	Р	P	P		
Musculo-skeletal Conventional				<u> </u>							
Musculo-skeletal Superficial											
Other ^[4]	E	E	E		E	E	E	E	E		
Exam Type, Means of Access											
Transesophageal			<u> </u>								<u> </u>
Transrectal											<u> </u>
Transvaginal			<u> </u>								
Transuretheral			<u> </u>	<u> </u>						 	
Intraoperative (specify)											
Intraoperative Neurological											<u> </u>
Intravascular				ļ. <u>.</u>				ļ			
Laparoscopic								J		<u> </u>	<u> </u>

Lapan	oscopic			L	<u> 1</u>	1		L			<u> </u>
N = ne	w indication; l	P = previou	sly cleared	by FDA	\; E = ac	dded und	der Appe	ndix E			
Notes	[1] Abdomina	al includes	GYN/Pelvi	c, Rena	and Ao	rta-iliac a	artery;				
	[*] Combined	d modes are	e B/M, B/C	olor M,	B/PWD,	B/Color/	PWD, B	/Power/f	PWD.		
		(PLEAS	SE DO NOT WE	RITE BELOV	V THIS LINE	- CONTINU	E ON ANOT	HER PAGE	IF NEEDED)	 	
			Concurren	ce of CD	RH, Offic	ce of Dev	ice Evalu	ation (O	DE)	 	

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number ____

GE LOGIQ 7 with M7C Transducer

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

					Mode	of Ope	eration	, —————			
Clinical Application Anatomy/Region of Interest	В	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	·
Ophthalmic											
Fetal / Obstetrics	Р	Р	Р		Р	Р	Р	Р	P	Р	
Abdominal	Р	Р	P		Р	P	Р	Р	Р	P	
Pediatric	Р	Р	P		P	Р	Р	P	P	Р	<u></u>
Small Organ ^[2]	Р	Р	P		P	Р	Р	P	P	P	
Neonatal Cephalic											
Adult Cephalic											Ĺ
Cardiac											
Peripheral Vascular	Р	Р	Р		P	Р	Р	Р	P	Р	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)			<u> </u>	<u> </u>							
Exam Type, Means of Access			<u> </u>								
Transesophageal			<u> </u>								
Transrectal											
Transvaginal											_
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

Laparoscopic										 l
N = new indication; P = pr	eviously	cleared	by FDA	; E = ac	lded und	ler Appe	ndix E			
Notes: [2] Small organ in	cludes b	reast, te	stes, thy	roid.						
[*] Combined mod	es are B	/M, B/C	olor M, E	B/PWD,	B/Color/i	PWD, B	/Power/F	PWD.		
									· · · · · · · · · · · · · · · · · · ·	
	(PLEASE D	O NOT WR	ITE BELOW	THIS LINE	CONTINUE	ON ANOT	HER PAGE	IF NEEDED)		
	Co	ncurren	ce of CD	RH, Offic	e of Devi	ice Evalu	ration (O	DE)		

Division of Reproductive, Abdominal,

and Radiological Devices 510(k) Number _____

(Division Sign-Off)

GE LOGIQ 7 with 8C Transducer

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

					Mode	of Ope	ration				
Clinical Application Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	E	E	E		Ε	E	E	E	E	Е	
Pediatric	Ε	E	E		E	E	E	E	Ε	E	
Small Organ (specify)	Ε	E	E		E	Ε	Ε	Ε	Е	Е	
Neonatal Cephalic	E	E	E		E	E	E	E	E	E	
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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N = new indication; P =	previously	/ cleared	by FDA	E = a	dded und	der Appe	endix E	-		-
Notes: [1] Abdominal in	cludes G'	YN/Pelvi	c;							
[*] Combined m	odes are l	B/M, B/C	olor M, I	B/PWD,	B/Color/	PWD, B	/Power/I	PWD.		
	(PLEASE (DO NOT WE	ITE BELOW	THIS LINE	- CONTINUI	E ON ANOT	HER PAGE	IF NEEDED)		
	Co	oncurren	ce of CD	RH, Offic	ce of Dev	ice Evalı	uation (O	DE)		

Division of Reproductive, Abdominal, and Radiological Devices

(Division Sign-Off)

and Radiological Devices 510(k) Number _____

GE LOGIQ 7 with E8C Transducer

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

		Mode of Operation									
Clinical Application Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	Р	Р	P		Р	Р	Р	P	P		
Abdominal ^[1]	Р	Р	Р		P	Р	Р	P	Р		
Pediatric											Ĺ
Small Organ (specify)											
Neonatal Cephalic											ļ
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	Р	Р	P		P	Р	P	Р	Р		
Exam Type, Means of Access			L								
Transesophageal											<u> </u>
Transrectal	P	Р	P		P	Р	P	P	Р		
Transvaginal	Р	Р	P		P	P	P	Р	Р		
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular							<u> </u>				
Laparoscopic]		<u></u>	

Empare o copio				 <i>i</i>
N = new indication; P =	previously cleared by FDA	; E = added under	Appendix E	
Notes: [1] Abdominal in	cludes GYN/Pelvic;			
[4] Other use inc	cludes Urology/Prostate;			
[*] Combined mo	odes are B/M, B/Color M, E	B/PWD, B/Color/PW	D, B/Power/PWD.	
	(PLEASE DO NOT WRITE BELOW	THIS LINE - CONTINUE ON	ANOTHER PAGE IF NEEDED)	
	Concurrence of CD	RH. Office of Device	Evaluation (ODE)	

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number _

D32/82

GE LOGIQ 7 with 7L Transducer

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

					Mode	of Ope	ration				
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	Р	P	P		Р	Р	P	Р	Р		
Abdominal	P	Р	Р		Р	Р	Р	Р	Р		
Pediatric											
Small Organ ^[2]	_ P	P	P		Р	Р	Р	Р	P		
Neonatal Cephalic											
Adult Cephalic											
Cardiac											<u> </u>
Peripheral Vascular	Р	Р	P		Р	Р	Р	Р	Р		
Musculo-skeletal Conventional	Р	P	Р		Р	Р	Р	Р	Р		
Musculo-skeletal Superficial	Р	Р	Р	<u></u>	Р	P	Р	Р	Р		
Other ^[4]					<u></u>						
Exam Type, Means of Access					<u> </u>						
Transesophageal				<u></u>							
Transrectal											_
Transvaginal		ļ <u>.</u>									
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E
Notes: [2] Small organ includes breast, testes, thyroid.
[*] 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 Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number ____

GE LOGIQ 7 with 10L Transducer

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

1					Mode	of Ope	ration				
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	
Ophthalmic											L
Fetal / Obstetrics	Р	Р	Р		Р	Р	P	Р	Р	Р	
Abdominal	_P	Р	Р		Р	P	P	Р	Р	Р	
Pediatric	Р	P	Р		Р	Р	Р	Р	P	Р	
Small Organ ^[2]	Р	P	P		Р	Р	P	Р_	Р	Р	
Neonatal Cephalic											
Adult Cephalic	_										
Cardiac											
Peripheral Vascular	Р	P	P		Р	Р	Р	Р	P	Р	
Musculo-skeletal Conventional	Р	P	Р		Р	Р	P	Р	P	Р	
Musculo-skeletal Superficial	Р	P	Р		Р	Р	Р	Р	P	Р	_
Other (specify)											
Exam Type, Means of Access	_										
Transesophageal			ļ								
Transrectal			<u> </u>								
Transvaginal											
Transuretheral	_										<u> </u>
Intraoperative ^[5]	P	P	P		P	P	Р	Р	Р	P	<u> </u>
Intraoperative Neurological	P	Р	P		Р	P	Р	Р	Р	Р	
Intravascular							<u> </u>				<u> </u>
Laparoscopic			1							1	

Laparoscopic

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

Notes: [2] Small organ includes breast, testes, thyroid.

[5] Intraoperative includes abdominal, thoracic, and vascular. Neurosurgical added via K970901.

[*] 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 Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number

GE LOGIQ 7 with 12L Transducer

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

T						· · · · · · · · · · · · · · · · · · ·					====
					Mode	of Ope	ration				
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal		ļ 	<u> </u>								
Pediatric	P	Р	P		P	P	Р	P	Р		
Small Organ ^[2]	Р	Р	P		Р	Р	P	Р	P		
Neonatal Cephalic											
Adult Cephalic											L
Cardiac											
Peripheral Vascular	Р	P	Р		Р	Р	Р	Р	Р		
Musculo-skeletal Conventional	Р	P	P		Р	P	Р	Р	Р		
Musculo-skeletal Superficial	Р	Р	P		Р	Р	Р	Р	P		
Other (specify)											
Exam Type, Means of Access			<u> </u>								
Transesophageal											
Transrectal											
Transvaginal											L
Transuretheral											
Intraoperative ^[5] (specify)	P	Р	P		Р	Р	Р	Р	P		
Intraoperative Neurological											
Intravascular			<u> </u>								
Laparoscopic			<u> </u>								

Laparoscopic				l		1	l	1
N = new indication; P = pr	eviously cleared	by FDA; E	= added u	nder App	endix E	- <u> </u>		
Notes: [2] Small organ in	cludes breast, te	estes, thyroid.						
[5] Intraoperative i	includes abdom	inal, thoracic,	and vasc	ular.				
[*] Combined mod	les are B/M, B/C	Color M, B/PW	D, B/Colo	or/PWD,	B/Power/	PWD.		
			<u></u>					
	(PLEASE DO NOT WE	RITE BELOW THIS I	LINE - CONTI	NUE ON ANC	THER PAGE	IF NEEDED)		
	Concurrer	ce of CDRH, C	Office of D	evice Eva	luation (C	DE)		

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 233/82

Special 510(k) Premarket Notification GE Medical Systems - LOGIQ 7 Ultrasound BT03 July 15, 2003

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ 7 with M12L Transducer

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

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal			<u> </u>								
Pediatric	Р	P	Р		Р	Р	Р	P	Р	Р	
Small Organ ^[2]	P	P	P		Р	Р	Р	Р	Р	Р	
Neonatal Cephalic	_								<u> </u>		
Adult Cephalic											
Cardiac											
Peripheral Vascular	Р	Р	P		Р	Р	P	P	Р	Р	
Musculo-skeletal Conventional	Р	P	P		P	P	Р	P	Р	P	
Musculo-skeletal Superficial	Р	P	Р		P	P	Р	Р	Р	P	
Other (specify)						<u> </u>					
Exam Type, Means of Access											
Transesophageal								<u> </u>			
Transrectal											
Transvaginal											
Transuretheral											ļ
Intraoperative [5] (specify)	Р	Р	P		Р	P	Р	Р	Р	Р	
Intraoperative Neurological			<u> </u>				<u> </u>				
Intravascular	L										
Laparoscopic									Ĺ. <u>.</u>		[

N	= new indication: P =	previously	cleared by FDA:	E = added und	ler Appendix F	=

Notes:	[2]	Small organ	includes	breast,	testes.	thyroid.

[*]	Combined modes are	R/M	B/Color M	R/PW/D	B/Color/PWD	R/Power/PM/D
	i Combined modes are	D/IVI.	B/COIOLIVI.	D/MVVD.	. D/COIOI/FVVD.	D/FOWer/PVVD

	(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)	
	Concurrence of CDRH, Office of Device Evaluation (ODE)	

Prescription Use (Per 21 CFR 801.109)

(Division Sigh-Off) Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number _____

^[5] Intraoperative includes abdominal, thoracic, and vascular.

GE LOGIQ 7 with 3S Transducer

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

		Mode of Operation									
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	Р	Р	P	P	Р	Р	Р	P	P	Р	
Abdominal ^[1]	Р	P	Р	Р	Р	P_	Р	P	P	Р	
Pediatric	Р	Р	Р	Р	Р	Р	P	P	P	Р	
Small Organ (specify)											
Neonatal Cephalic	Р	Р	P	Р	Р	Р	Р	P	P	Р	<u> </u>
Adult Cephalic	P	Р	Р	Р	Р	Р	Р	P	Р	Р	
Cardiac ^[3]	P	Р	Р	Р	Р	P	Р	Р	P	Р	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	Р	Р	Р	P	P	Р	Р	Р	P	Р	<u> </u>
Exam Type, Means of Access											<u> </u>
Transesophageal										,	
Transrectal			,				L	l			<u> </u>
Transvaginal					<u> </u>					<u> </u>	<u> </u>
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological							<u> </u>				
Intravascular											1
Laparoscopic											<u> </u>

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

Notes:	[1] Abdominal includes GYN;
	[3] Cardiac is Adult and Pediatric;
	[4] Other use includes Urology;
	[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
	(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number

GE LOGIQ 7 with M3S Transducer

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

		Mode of Operation									
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	Р	_ P	Р_	P	Р	P	Р	Р	Р		
Abdominal ^[1]	P	P	Р	Р	Р	Р	Р	P	Р		
Pediatric	Р	Р	Р	Р	P	Р	Р	Р	Р		
Small Organ (specify)											
Neonatal Cephalic	P	Р	Р	Р	Р	Р	P	Р	Р		
Adult Cephalic	Р	Р	Р	Р	Р	Р	Р	Р	Р		
Cardiac ^[3]	Р	Р	Р	Р	P	Р	Р	Р	Р		
Peripheral Vascular											
Musculo-skeletal Conventional											<u> </u>
Musculo-skeletal Superficial											
Other (specify)	Р	Р	Р	Р	P	Р	P	P	Р		
Exam Type, Means of Access											
Transesophageal								<u></u>			
Transrectal						_					
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological			<u> </u>								
Intravascular											
Laparoscopic											

Notes:	[1] Abdominal includes Renal and GYN;
	[3] Cardiac is Adult and Pediatric.
	[4] Other use includes Urology;
	[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,

and Radiological Devices 510(k) Number _____

GE LOGIQ 7 with 4S Transducer

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

		Mode of Operation									
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											i
Fetal / Obstetrics	Р	P	P	P	P	Р	Р	Р	P	Р	
Abdominal ^[1]	P	P	P	Р	Р	Ρ	Ρ	P	Р	P	
Pediatric	Р	Р	Р	Р	P	Р	Р	Р	P	Р	
Small Organ (specify)											
Neonatal Cephalic	P	Р	Р	Р	P	Р	Р	P	Р	P	
Adult Cephalic	Р	Р	Р	P	Р	P	Р	Р	Р	Р	<u></u>
Cardiac ^[3]	P	Р	Р	Р	Р	P	Р	Р	P	P	L
Peripheral Vascular					<u> </u>			<u> </u>			
Musculo-skeletal Conventional				. <u>.</u>				<u> </u>			
Musculo-skeletal Superficial				İ				<u> </u>			
Other (specify)	Р	Р	P	P	Р	Р	Р	P	Р	Р	
Exam Type, Means of Access								L			
Transesophageal											
Transrectal				<u> </u>							
Transvaginal								<u> </u>			
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic			<u> </u>		<u> </u>			<u> </u>			<u> </u>

N	=	new indicati	on: P	= previo	ously a	cleared t	ov FDA:	E =	added i	under	Append	dix E	÷

Notes:	[1] Abdominal includes Renal and GYN;
	[3] Cardiac is Adult and Pediatric.
	[4] Other use includes Urology;
	[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

and Radiological Devices 510(k) Number _____

GE LOGIQ 7 with 5S Transducer

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

		Mode of Operation									
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M	Power		Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	P_	P	Р	Р	P	Р	P	P	P		
Abdominal ^[1]	Ρ	Р	P	Р	P	Р	Р	P	P		
Pediatric	Р	Р	Р	Р	Р	P	Р	Р	P		
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic	Р	P	Р	P	Р	Р	Ρ	Р	Р		
Cardiac ^[3]	Р	Р	Р	Р	Р	P	Р	P	Р		
Peripheral Vascular											
Musculo-skeletal Conventional								_			
Musculo-skeletal Superficial											
Other ^[4]	Р	P	Р	P	Р	P	Р	Р	P		
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

14 = 116	w indication, F = previously cleared by FDA, E = added under Appendix E
Notes:	[1] Abdominal includes GYN;
	[3] Cardiac is Adult and Pediatric;
	[4] Other use includes Urology;
	[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number -

GE LOGIQ 7 with 7S Transducer

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

	# 	Mode of Operation									
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	P	P	Р	Р	Р	P	Р	Р	Р		
Abdominal ^[1]	Р	P	Р	P	Р	Р	Р	P	Р		
Pediatric	P	P	P	Р	Р	Р	Р	P	P		
Small Organ (specify)				<u> </u>							
Neonatal Cephalic	Р	Р	Р	Р	Р	P	P	Ъ	Р		
Adult Cephalic	P	P	Р	Р	Р	Р	Р	P	P		
Cardiac ^[3]	P	Р	P	P	Р	Р	Р	P	Р		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal	<u> </u>						L				
Transrectal											
Transvaginal											L
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											<u> </u>
Intravascular											
Laparoscopic											

N = new indication; P = previously cle	red bv FDA: $E = i$	added under A	Appendix E
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Notes:	[1]	Ahdo	minal	includes	CVNI
notes:	,,,,	Abac	mınaı	includes	GYN:

- [3] Cardiac is Adult and Pediatric.
- [4] Other use includes Urology and GYN.
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDBH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Special 510(k) Premarket Notification GE Medical Systems - LOGIQ 7 Ultrasound BT03 July 15, 2003

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ 7 with 10S Transducer

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

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal	P	þ	P	P	Р	Р	P	Р	Р		_
Pediatric	Р	P	P	Р	P	Р	Р	Р	Р		_
Small Organ (specify)											
Neonatal Cephalic	Р	P	Р	P	Р	P	Р	Р	Р		
Adult Cephalic	Р	P	Р	P	P	P	P	P	P		
Cardiac ^[3]	Р	Р	P	P	Р	Р	Р	Р	Р		
Peripheral Vascular									<u> </u>		
Musculo-skeletal Conventional			<u> </u>								
Musculo-skeletal Superficial		<u></u>						<u> </u>			
Other (specify)				<u> </u>				<u> </u>			
Exam Type, Means of Access	····							<u> </u>			
Transesophageal											
Transrectal											
Transvaginal										 _	
Transuretheral		<u> </u>						<u> </u>			
Intraoperative (specify)				ļ		<u> </u>	<u> </u>	<u> </u>			_
Intraoperative Neurological			<u> </u>				<u> </u>				
Intravascular						<u> </u>					
Laparoscopic			<u> </u>		<u> </u>	<u></u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	

N = new indication; P = previously cleared by FDA; E = added under Appendix E
Notes: [3] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) / Division of Reproductive

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number __

Special 510(k) Premarket Notification GE Medical Systems - LOGIQ 7 Ultrasound BT03 July 15, 2003

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ 7 with 6T Transducer

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

	Mode of Operation										
Clinical Application Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)			<u> </u>								
Neonatal Cephalic											
Adult Cephalic											
Cardiac	Р	P	P	Р	Р	Р	P	Р	P]]	
Peripheral Vascular		ļ									
Musculo-skeletal Conventional			1								
Musculo-skeletal Superficial											
Other (specify)		<u> </u>					<u></u>				
Exam Type, Means of Access											
Transesophageal	Р	P	P	P	Р	Р	Р	P	P		
Transrectal			<u> </u>	ļ	ļ	<u> </u>		ļ			
Transvaginal				L		ļ		ļ			
Transuretheral					ļ			<u> </u>			
Intraoperative (specify)					<u> </u>	ļ		<u> </u>			
Intraoperative Neurological		ļ			<u> </u>	ļ		<u> </u>	ļ		
Intravascular		<u> </u>			<u> </u>			<u> </u>	ļ		
Laparoscopic				ļ				<u> </u>			

(Division Sign-Off)
Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number.

Prescription Use (Per 21 CFR 801.109)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form GE LOGIQ 7 with P2D Transducer

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

	Mode of Operation										
Clinical Application Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]				Р							
Peripheral Vascular				Р							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											_

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices \$10(k) Number \$\mu 032187\$

Special 510(k) Premarket Notification GE Medical Systems - LOGIQ 7 Ultrasound BT03 July 15, 2003

Diagnostic Ultrasound Indications for Use Form GE LOGIQ 7 with P6D Transducer

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

				,	моде	of Ope	ration			·	
Clinical Application Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]				Р							
Peripheral Vascular				Р							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											_
Exam Type, Means of Access											_
Transesophageal											
Transrectal			<u> </u>								
Transvaginal				<u> </u>							
Transuretheral			<u></u>								
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic	ł	ł			ł	1	1	.	Ì	1	

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices #032/82

Prescription Use (Per 21 CFR 801.109)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

GE LOGIQ 7 with i8L Transducer

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

					Mode	of Ope	ration				
Clinical Application Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics				ļ							
Abdominal ^[1]	P	Р	P		P	P	Р	P	Р		
Pediatric			J					<u> </u>			
Small Organ (specify)											
Neonatal Cephalic							<u> </u>				
Adult Cephalic											
Cardiac ^[3]	Р	Р	P		Р	P	P	P	P		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)	<u>. </u>										
Exam Type, Means of Access											
Transesophageal				<u></u>				<u> </u>			
Transrectal											
Transvaginal											
Transuretheral			<u> </u>								
Intraoperative ^[5]	Р	Р	Р		Р	Р	Р	Р	Р		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

Laparoscopic]		i			
N = new indication; P = pr	eviously	cleared	by FDA	; E = ac	lded und	ler Appe	ndix E			;
Notes: [1] Abdominal is v	ia Intrao	perative	;							
[3] Cardiac is Adu	lt and Pe	ediatric v	ia Intrad	perative) ;					
[5] Intraoperative i	ncludes	abdomi	nal, thor	acic, and	d vascula	ar.				
Notes: [1] Abdominal is via Intraoperative; [3] Cardiac is Adult and Pediatric via Intraoperative; [5] Intraoperative includes abdominal, thoracic, and vascular. [*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.										
								<u>. – </u>	 	
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	Co	ncurren	ce of CD	RH. Offic	e of Dev	ice Evalu	ation (O	DE)		

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number

GE LOGIQ 7 with i12L Transducer

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

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

N = ne	w indication: P = pre	viously cleared b	v FDA· F	= added	Lunder /	Annendix I	Ξ

Tr = Not indication, r = provided by r bri, E = added and r ripperialix E	
Notes: [1] Abdominal is via Intraoperative; [3] Cardiac is Adult and Pediatric via Intraoperative; [5] Intraoperative includes abdominal, thoracic, and vascular. [*] 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 Device Evaluation (ODE)	

Prescription Use (Per 21 CFR 801.109)

of Reproductive, Abdominal, orological Devices 1032/82