K060993

Special 510(k) Premarket Notification GE Healthcare - LOGIQ P5/A5 Ultrasound System April 7, 2006

MAY 3 2006

Attachment B:

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



GE Healthcare

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

Section a):

1

Submitter: GE He

GE Healthcare

PO Box 414

Milwaukee, WI 53201

Contact Person:

Allen Schuh,

Manager, Safety and Regulatory Engineering Telephone: 414-721-3992; Fax: 414-721-3868

Date Prepared:

April 7, 2006

2. <u>Device Name</u>:

GE LOGIQ P5/A5 Diagnostic Ultrasound System

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

3. Marketed Device:

GE LOGIQ 5 PRO diagnostic ultrasound system, 510(k) Numbers K032974

currently in commercial distribution.

- 4. <u>Device Description</u>: The GE LOGIQ P5 & A5 are full-featured, general-purpose diagnostic ultrasound systems consisting of a mobile console approximately 49 cm wide, 64 cm deep and 135-141 cm high that provide digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls and color video LCD display. The modification combines features of the unmodified system with additional features from other systems currently marketed by GE Healthcare to provide users with a smaller, more convenient ultrasound system.
- 5. <u>Indications for Use</u>: The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications: Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculoskeletal Conventional and Superficial; Urology (including prostate); Transesophageal (TE); Transrectal (TR); Transvaginal (TV); and Intraoperative (abdominal, thoracic, vascular and neurological).
- 6. Comparison with Predicate Device: The GE LOGIQ P5/A5 are of a comparable type and substantially equivalent to the current GE LOGIQ 5 PRO. They have the same technological characteristics, are comparable in key safety and effectiveness features, utilize similar design, construction, and materials, and have the same intended uses and basic operating modes as the predicate device.

Section b):

- 1. <u>Non-clinical Tests</u>: 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.
- 2. Clinical Tests: None required.
- 3. <u>Conclusion</u>: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms to 21 CFR 820, ISO 9001 and 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 P5/A5 Diagnostic Ultrasound are substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



MAY 3 2006

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Mr. Allen Schuh
Manager, GE Ultrasound Safety and Regulatory Engineering
General Electric Company
GE Medical Systems, Ultrasound and Primary Care Diagnostics, LLC
9900 Innovation Drive
WEST MILWAUKEE WI 53219

Re: K060993

Trade Name: GE LOGIQ P5/A5 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: IYN, IYO, and ITX

Dated: April 7, 2006 Received: April 11, 2006

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 P5/A5 Ultrasound System, as described in your premarket notification:



Protecting and Promoting Public Health

Transducer Model Number

<u>3.5C</u>	ERB Biplane	<u>5S</u>
3.5CS	<u>i739 or t739</u>	<u>7S</u>
4C	<u>8L</u>	<u>8T</u>
<u>4C</u> <u>5Cs</u>	<u>9L</u>	<u>4D3C</u>
<u>8C</u>	<u>10L</u>	<u>2D</u>
<u>E8C</u>	<u>11L</u>	<u>6D</u>
E8Cs	<u>12L</u>	
BE9C Biplane	<u>3S</u>	

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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

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

Sincerely yours,

Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

GE LOGIQ P5/A5 Ultrasound System

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

					Mod	e of Oper	ration				
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppier	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	P	P	Р	P	Р	Р	P	Р	Р	P	N
Abdominal ^[1]	Р	P	Р	Р	Р	Р	P	Р	P	Р	N
Pediatric	P	P	P	P	Р	P	P	Р	P	P	N
Small Organ ^[2]	Р	P	P		Р	P	P	Р	₽	Р	
Neonatal Cephalic	P	P	Р	P	Р	P	P	Р	P	P	
Adult Cephalic	P	₽	Р	P	P	P	P	Р	P		
Cardiac ^[3]	Р	P	P	P	P	P	Р	Р	P		
Peripheral Vascular	Р	P	P	Р	P	P	P	Р	P	Р	
Musculo-skeletal Conventional	Р	P	P		Р	Р	Р	Р	P	Р	
Musculo-skeletal Superficial	Р	P	P		Р	P	Р	P	P	P	
Other ^[4]	P	P	P	Р	Р	Р	Р	P	P	P	N
Exam Type, Means of Access											
Transesophageal	Р	Р	P	Р	Р	P	P	P	P		
Transrectal	P	P	P		Р		Р	P	P	P	
Transvaginal	Р	P	P		Р		P	P	P	P	
Transuretheral											
Intraoperative ^[5]	P	P	Р		Р	Р	Р	Р	N	P	
Intraoperative Neurological	P	P	Р		Р	N	Р	Р	Ņ	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, 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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Dr. 1A K

(Division Sign-Off)

Division of Reproductive, Abdominal,

Prescription User (Per 21 CFR 801.109) and Radiological Devices

510(k) Number:

GE LOGIQ P5/A5 with 3.5C Transducer

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

Clinical Application B M PW CW Color Color M Power Combined Harmonic Coded Ott											
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppier	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	Р	Р	Р		Р	Р	Р	P	Р	Р	
Abdominal ^[1]	Р	P	Р		Р	. P	Р	P	Р	Р	
Pediatric											
Small Organ (specify)	P	Р	P		Р	P	Р	Р	P	Р	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	Р	Р		P	Р	Р	Р	P	Р	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	P	Р	Р		٠Р	P	Р	Р	Р	Р	
Exam Type, Means of Access											
Transesophageal							,				
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes: [1] Abdominal includes GYN;
[4] Other use includes Urology;
[*] Combined modes are B/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

Prescription User (Per 21 CFR 801.109)

510(k) Number.

GE LOGIQ P5/A5 with 3.5CS Transducer

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

											
					Mod	le 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	Other
Ophthalmic											
Fetal / Obstetrics	Р	Р	P		Р	Р	Р	P	P	P	
Abdominal ^[1]	P	P	P		Р	Р	P	Р	Р	P	
Pediatric											
Small Organ (specify)	P	Р	Р		Р	P	Р	Р	Р	P	
Neonatal Cephalic											
Adult Cephalic					,	:					
Cardiac					~						
Peripheral Vascular	Р	Р	Р		P	Р	₽	Р	Р	Р	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial			<u> </u>								
Other ^[4]	P	Р	Р		P	Р	P	Р	Р	Р	
Exam Type, Means of Access											
Transesophageal											·
Transrectal											
Transvaginal				:							
Transuretheral				:							
Intraoperative (specify)											
Intraoperative Neurological					j						
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E		
Notes: [1] Abdominal includes GYN;		
[4] Other use includes Urology;		
[*] Combined modes are B/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 P5/A5 with 4C Transducer

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

·					Mod	e 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	Other
Ophthalmic											
Fetal / Obstetrics	N	N	N		N	N	N	N	N	N	
Abdominal ^[1]	N	N	N		N	N	N	N	N	N	
Pediatric	N	N	N_		N	N	N	N	N	N	
Small Organ (specify)			<u> </u>								
Neonatal Cephalic			<u> </u>								
Adult Cephalic								ļ			
Cardiac			<u></u>		<u> </u>						
Peripheral Vascular	N	N	N		N	N	N	N	N	N	
Musculo-skeletal Conventional								<u> </u>			
Musculo-skeletal Superficial								<u> </u>			
Other ^[4]	N	N	N		· N	N	N	N	N	N	<u> </u>
Exam Type, Means of Access						<u> </u>			٠.		
Transesophageal								<u> </u>	<u> </u>		ļ
Transrectal				ļ		ļ					
Transvaginal					ļ			ļ	ļ		
Transuretheral				<u> </u>	<u> </u>	· ·					<u> </u>
Intraoperative (specify)				<u> </u>	<u> </u>						1
Intraoperative Neurological				<u> </u>	ļ						ļ <u>.</u>
Intravascular			<u> </u>			ļ		1	ļ	ļ	<u> </u>
Laparoscopic				<u> </u>			<u> </u>				<u></u>

N = new indication; P = previously cleared by FDA; E = added under Appendix E	
Notes: [1] Abdominal includes GYN;	
[4] Other use includes Urology;	
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.	
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(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number_

GE LOGIQ P5/A5 with 5Cs Transducer

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

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

N = new inc	dication; $P = previously cleared by FDA; E = a$	added under Appendix E	
Notes: [1]	Abdominal includes GYN/Pelvic;		
[4]	Other use includes Urology/Prostate;		
[7]	Combined modes are B/M, B/PWD, B/Color/P	WD, B/Power/PWD.	
-			
***************************************	(D) EASE DO NOT WRITE DELOW THIS LIN	IE - CONTINUE ON ANOTHER PAGE IF NEEDED)	
	Concurrence of CDRH, Off	fice of Device Evaluation (ODE)	

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices KOGO 5.93

GE LOGIQ P5/A5 with 8C Transducer

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

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

Laparoscopic					<u> </u>	<u> </u>	<u>i </u>	1	1		
N = new indic	ation; P = pr	eviously	cleared	by FDA	; E = a	dded und	der App	endix E	·		
Notes: [1] Ab	odominal incl	udes GY	N/Pelvi	c;							
[*] Co	mbined mod	les are B	3/M, B/P	WD, B/0	Color/PW	D, B/Pc	wer/PW	/D.			
							-				
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	•	Co	ncurren	ce of CD	RH, Offic	e of Dev	ice Eval	uation (O	DE)	 	

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number _____/L0(0)993

GE LOGIQ P5/A5 with E8C Transducer

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

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

M = NA	windication, P - previously cleared by PDA, E - added under Appendix E
Notes:	[1] Abdominal includes GYN/Pelvic;
	[4] Other use includes Urology/Prostate;
	[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

GE LOGIQ P5/A5 with E8Cs Transducer

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

Ĺ					Mod	e of Ope	ration				
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	N	N	N		N		N	N	N	N	
Abdominal ^[1]	N	N	N		N		N	N	N	N	
Pediatric											
Small Organ (specify)											
Neonatal Cephalic			<u> </u>								
Adult Cephalic											
Cardiac						`			:		<u> </u>
Peripheral Vascular								<u>. </u>			
Musculo-skeletal Conventional											
Musculo-skeletal Superficial										·	<u>.</u>
Other ^[4]	N	N	N		N		N	N.	N	N	
Exam Type, Means of Access						<u> </u>					
Transesophageal							<u> </u>				
Transrectal	N	N	N		N		N	N	N	N	ļ
Transvaginal	N	N	N.		N		N	N	N	N	
Transuretheral											
Intraoperative (specify)							<u> </u>				<u> </u>
Intraoperative Neurological				<u> </u>	<u> </u>	ļ		ļ			
Intravascular					<u> </u>	<u> </u>			<u> </u>		<u> </u>
Laparoscopic						<u> </u>		<u> </u>			

N = new indication; P = previously cleared by FDA; E = added under Appendix E
Notes: [1] Abdominal includes GYN/Pelvic;
[4] Other use includes Urology/Prostate;
[*] Combined modes are B/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 User (Per 21 CFR 801.109)

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

GE LOGIQ P5/A5 with BE9C Biplane Transducer

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

					Mod	e of Ope	ration				
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	Р	Р		Р		Р	Р	P	Р	
Abdominal	Р	Р	Р		Р		Р	Р	Р	P	
Pediatric			<u> </u>								
Small Organ (specify)											
Neonatal Cephalic			ļ		<u> </u>						
Adult Cephalic											
Cardiac											
Peripheral Vascular									·		
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)	P	P	P		P		Р	Р	Р	Р	
Exam Type, Means of Access											
Transesophageal											
Transrectal	Р	Р	P		P		P	Р	P	Р	
Transvaginal	Р	P	Р		Р		P	Р	Р	P	
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular				ļ							
Laparoscopic								<u> </u>			

Laparos	соріс	1			1	<u> </u>	1	<u> </u>	<u> </u>	<u> </u>	
N = nev	/ indication; P = pr	eviously clea	red by FDA	۹; E = a	dded und	ler Appe	endix E				
Notes:	[1] Abdominal inc	cludes GYN/F	Pelvic;								
	[4] Other use incl	ludes Urology	y/Prostate;								
	[*] Combined mo	des are B/M,	B/PWD, B	/Color/P	WD, B/P	ower/PV	۷D				
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		Concur	rence of CE	ORH, Offic	ce of Dev	ice Evalu	uation (O	DE)			_

Prescription User (Per 21 CFR 801.109)

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

GE LOGIQ P5/A5 with ERB Biplane Transducer

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

				·	Mod	le 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	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal	N	N	N		N		N	N	N	N	
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic							,				
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)	N	N	N		N		N	N	N	N	
Exam Type, Means of Access											
Transesophageal											
Transrectal	N	N	N		N		N	N	N	N	
Transvaginal											
Transuretheral					:						
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic	. –										

N = new indication; P = pr	reviously cleared b	y FDA; E = a	added und	er Apper	ndix E			800 C 800 Node
Notes: [3] Cardiac is Adu	It and Pediatric.							
				-				
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	Concurrence	of CDRH, Off	ice of Devi	ce Evalua	ation (Ol	DE)		

Prescription User (Per 21 CFR 801.109)

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

510(k) Number _

GE LOGIQ P5/A5 with i739 or t739 Transducer

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

					Mod	e 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	Other
Ophthalmic									: : : : : : : : : : : : : : : : : : :		
Fetal / Obstetrics											
Abdominal	N	N	N		N	N	N	N	N	N	
Pediatric	N	N	N		N	N	N	N	N	N	
Small Organ (specify)	N	N	N		N	N	N	N	N	N	
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]						20					
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	
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal	•										
Transvaginal											
Transuretheral											
Intraoperative (specify)	N	N	N		N	N	N	N	N	N	
Intraoperative Neurological	N	N	N		N	N	N	N	N	N	
Intravascular											
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.	
[*] Combined modes are B/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 User (Per 21 CFR 801.109)

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

GE LOGIQ P5/A5 with 8L Transducer

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

					Mod	e of Ope	ration				
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	Other
Ophthalmic											
Fetal / Obstetrics	N	N	N		N	N	N	N	N	N.	
Abdominal	N	N	N		N	N	N	N	N	N	
Pediatric	N	N	N		N	N	N	N	N	N	
Small Organ ^[2]	N	N	N		N	N	N	N	N	N	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
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	
Other (specify)										"	
Exam Type, Means of Access			<u> </u>								
Transesophageal											
Transrectal											
Transvaginal					:			,			
Transuretheral											
Intraoperative ^[5]	N	N	N		N	N	N	N	N	N	
Intraoperative Neurological											
Intravascular											
Laparoscopic	:										

$M = ue_i$	w 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.
	[*] Combined modes are B/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 1/11/100

510(k) Number _____

GE LOGIQ P5/A5 with 9L 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	Other		
Ophthalmic													
Fetal / Obstetrics	N_	N	N		N	N	N	N	N	N			
Abdominal	N	N	N		N	N	N	N	N	N			
Pediatric	N	N	N		N	N	N	N	N	N			
Small Organ ^[2]	N	N	N		N	N	N	N	N	N	<u> </u>		
Neonatal Cephalic													
Adult Cephalic													
Cardiac													
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			
Other (specify)													
Exam Type, Means of Access											<u> </u>		
Transesophageal			1										
Transrectal													
Transvaginal			ļ										
Transuretheral													
Intraoperative ^[5]	N	N	N		N	N	N	N	N	N			
Intraoperative Neurological													
Intravascular													
Laparoscopic		 		<u> </u>							<u> </u>		

Lupuio	acopio									 <u></u>	
N = ne	w indication; P =	previous	y cleared	by FDA	; E = a	ded und	ler Appe	endix E			
Notes:	[2] Small organ i	includes l	breast, te	stes, th	yroid.						
	[5] Intraoperative	e include:	s abdomi	nal, tho	racic, an	d vascul	ar.				
	[*] Combined mo	odes are	B/M, B/P	WD, B/0	Color/PV	/D, B/Pa	wer/PW	D.			
	-									 	
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Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number

GE LOGIQ P5/A5 with 10L Transducer

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

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

N = ne	w 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.
	[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.
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	Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

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

GE LOGIQ P5/A5 with 11L 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		Harmonic Imaging	Coded Pulse	Other		
Ophthalmic											<u> </u>		
Fetal / Obstetrics	N	N	N		N	N	N	N	N	N			
Abdominal	N _	N	N		N	N	N	N	N	N	<u> </u>		
Pediatric	N	N	N		N	N	N	N	N	N			
Small Organ ^[2]	N	N	N		N	N	N	Ň	N	N	<u> </u>		
Neonatal Cephalic							<u></u>				ļ		
Adult Cephalic											<u> </u>		
Cardiac													
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	<u> </u>		
Other (specify)									<u> </u>				
Exam Type, Means of Access													
Transesophageal											<u> </u>		
Transrectal											<u> </u>		
Transvaginal											<u> </u>		
Transuretheral											<u> </u>		
Intraoperative ^[5]	N	N	N		N	N	N	N	Ň	N	L		
Intraoperative Neurological			<u> </u>					<u> </u>			<u> </u>		
intravascular											<u> </u>		
Laparoscopic						1							

N = new	indication; P = previously cleared by FDA; E = added under Appendix E
Notes: [2	2] Small organ includes breast, testes, thyroid.
[4	5] Intraoperative includes abdominal, thoracic, and vascular.
['	*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

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Prescription User (Per 21 CFR 801.109)

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

GE LOGIQ P5/A5 with 12L Transducer

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

Oliviant Application			Γ-	<u> </u>		e of Oper		L	I		F
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			ļ								
Fetal / Obstetrics											
Abdominal					·			ļ			ļ <u>.</u>
Pediatric	P	Р	P		Р	N	Р	Р	Р	P	
Small Organ ^[2]	Р	P	P		P	N	Р	Р	₽	Р	
Neonatal Cephalic					ļ						
Adult Cephalic											
Cardiac											ļ
Peripheral Vascular	Р	Р	Р		P	N	Р	Р	P	Р	
Musculo-skeletal Conventional	Р	P	P		P	N	Р	Р	P	Р	
Musculo-skeletal Superficial	Р	P	P		P_	N	Р	Р	Р	Р	
Other (specify)								<u> </u>			
Exam Type, Means of Access			<u> </u>					<u> </u>			<u> </u>
Transesophageal											<u> </u>
Transrectal			<u> </u>								<u> </u>
Transvaginal								ļ			<u> </u>
Transuretheral				ļ					ļ		<u> </u>
Intraoperative [5] (specify)			1	ļ	<u> </u>						
Intraoperative Neurological			ļ		ļ				<u> </u>		_
Intravascular			<u> </u>		<u> </u>						
Laparoscopic											

Laparoscopic					l			 	
N = new indication	r; P = previous	ly cleared by I	DA; E = 6	added und	ler Appe	endix E			
Notes: [2] Small of	organ includes	breast, testes	, thyroid.						
[*] Combir	ned modes are	B/M, B/PWD,	B/Color/P	WD, B/Po	wer/PW	D.			
					•				
	(PLEASI	DO NOT WRITE BI	LOW THIS LIN	E - CONTINU	E ON ANOT	HER PAGE	IF NEEDED)		
		Concurrence of	CDRH, Off	ice of Dev	ice Evalu	ation (O	DE)		

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Division of Reproductive, Abdominal,
and Radiological Devices

5 (O(k) Number _____

GE LOGIQ P5/A5 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	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											ļ
Fetal / Obstetrics	P	Р	P	P	Р	Р	Р	Р	P		<u> </u>
Abdominal ^[1]	P	Р	P	Р	Р	Р	Р	Р	Р		
Pediatric	Р	P	Р	P	P	P	P	P	Р		
Small Organ (specify)								ļ			<u> </u>
Neonatal Cephalic											
Adult Cephalic	Р	Р	Р	P	P	Р	Р	Р	Р		
Cardiac ^[3]	Р	Р	Р	Р	Р	P	Р	P	Р		<u> </u>
Peripheral Vascular				<u>.</u>							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial		<u> </u>									
Other ^[4]	P	Р	Р	P	Р	P	Р	P	Р		<u> </u>
Exam Type, Means of Access											<u> </u>
Transesophageal			<u> </u>	<u> </u>	<u> </u>	ļ					
Transrectal				<u> </u>				ļ			ļ
· Transvaginal				<u> </u>				ļ			
Transuretheral				<u> </u>		<u> </u>					
Intraoperative (specify)				<u> </u>			ļ	<u> </u>	<u> </u>		ļ
Intraoperative Neurological				<u> </u>	<u> </u>		<u> </u>	ļ			
Intravascular			<u>,</u>				<u> </u>				
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.

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Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number _

GE LOGIQ P5/A5 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 Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	N	N	N	N	N	N	N	N	N		
Abdominal ^[1]	N	N	N	N	N	N	N	N	N		
Pediatric	N	N_	N	N	N	N	N	N	N		
Small Organ (specify)											ļ
Neonatal Cephalic	N	N	N	N	N	N	N	N	N		
Adult Cephalic	N	N	N	N	N.	N	N	N	N		
Cardiac ^[3]	N_	N	N	N	N	N	N	N	N		
Peripheral Vascular			1								
Musculo-skeletal Conventional											
Musculo-skeletal Superficial				<u> </u>					ļ .		<u> </u>
Other ^[4]	N	N	N	N	N	N	N	N	N		ļ
Exam Type, Means of Access							<u></u>	<u> </u>			
Transesophageal											
Transrectal								ļ			ļ
Transvaginal											
Transuretheral				ļ				<u> </u>			ļ
Intraoperative (specify)				<u> </u>							
Intraoperative Neurological			<u> </u>	<u> </u>	<u> </u>					ļ	<u> </u>
Intravascular		<u> </u>	<u> </u>	ļ							<u> </u>
Laparoscopic					<u> </u>		<u> </u>				

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

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Notes: [1] Abdominal	l 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 User (Per 21 CFR 801.109)

GE LOGIQ P5/A5 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	Other	
Ophthalmic											ļ	
Fetal / Obstetrics	Р	P	P	Р	Р	Р	Р	P	P			
Abdominal ^[1]	Р	P	P	P	Р	Ρ	Р	Р	P		<u> </u>	
Pediatric	P	Р	P	Р	Р	P	Р	Р	Р			
Small Organ (specify)												
Neonatal Cephalic	Р	Р	Р	Р	Р	Р	Р	P	P			
Adult Cephalic	P	Р	Р	Р	P	Р	Р	Р	P			
Cardiac ^[3]	Р	Р	Р	Р	Р	P	Р	Р	Р		<u> </u>	
Peripheral Vascular											<u> </u>	
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other (specify)					1-							
Exam Type, Means of Access		ļ										
Transesophageal												
Transrectal												
Transvaginal												
Transuretheral												
Intraoperative (specify)												
Intraoperative Neurological				<u> </u>							<u> </u>	
Intravascular											<u> </u>	
Laparoscopic					<u> </u>			<u></u>			<u> </u>	

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	·
	[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
	• •
	[3] Cardiac is Adult and Pediatric.
votes.	: [1] Abdominal includes GYN;
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(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices \$10(k) Number ______

GE LOGIQ P5/A5 with 8T Transducer

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

			•· •· ·· •·		Mod	e 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	Other								
Ophthalmic																			
Fetal / Obstetrics								<u> </u>											
Abdominal ^[1]																			
Pediatric																			
Small Organ (specify)											L								
Neonatal Cephalic																			
Adult Cephalic								·											
Cardiac ^[3]	N	N	N	N	N	N	N	N	N										
Peripheral Vascular																			
Musculo-skeletal Conventional																			
Musculo-skeletal Superficial											<u> </u>								
Other (specify)									•		<u> </u>								
Exam Type, Means of Access									ļ										
Transesophageal	N	N	N	N	N	N	N	N	N										
Transrectal								<u> </u>			<u>L</u> _								
Transvaginal																			
Transuretheral								<u> </u>											
Intraoperative (specify)																			
Intraoperative Neurological																			
Intravascular																			
Laparoscopic																			

Laparo	scopic							<u> </u>			
N = ne	w indication; P = p	reviously clea	ared by FD	A; E=a	idded und	ler Appe	ndix E	**			
Notes:	[3] Cardiac is Adu	ult and Pediat	ric.								
	[*] Combined mod	des are B/M,	B/Color M	, B/PWD	or CWD,	B/Color	/PWD or	r CWD, E	B/Power/F	PWD.	
							,			· · · · · · · · · · · · · · · · · · ·	
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Division of Reproductive, Abdominal, and Radiological Devices

(Division Sign-Off)

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GE LOGIQ P5/A5 with 4D3C Transducer

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

L					Mod	e of Oper		· · · · ·	1		
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	Other
Ophthalmic											
Fetal / Obstetrics	N	N	N.		N	N	N	N	N		ļ
Abdominal ^[1]	N	N	N		N	N	N	N	N		
Pediatric	N	N	N		N	N	N	N	N		
Small Organ (specify)											ļ
Neonatal Cephalic			<u> </u>				<u> </u>		!		
Adult Cephalic											
Cardiac			<u> </u>								<u> </u>
Peripheral Vascular	J		ļ								
Musculo-skeletal Conventional					ļ						ļ
Musculo-skeletal Superficial				ļ .					<u> </u>		
Other ^[4]	N	N	N	<u>.</u>	N	N	N	N	N		<u> </u>
Exam Type, Means of Access											<u> </u>
Transesophageal			1	<u> </u>	ļ						<u> </u>
Transrectal					ļ						ļ
Transvaginal			<u> </u>					ļ	ļ		<u> </u>
Transuretheral				<u> </u>					<u> </u>		ļ
Intraoperative (specify)				ļ					<u> </u>		<u> </u>
Intraoperative Neurological		ļ		<u> </u>				ļ	<u> </u>		<u> </u>
Intravascular				<u> </u>		ļ		ļ	ļ		ļ
Laparoscopic			1								

N = new indication; P = previously cleared by FDA; E = added under Appendix E
Notes: [1] Abdominal includes GYN;
[4] Other use includes Urology;
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number_

KO60992

GE LOGIQ P5/A5 with 2D Transducer

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

Clinical Auntication	_		T			e of Oper					
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	Othe
Ophthalmic											
Fetal / Obstetrics											
Abdominal ⁽¹⁾											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac .				Р		;					
Peripheral Vascular				Р							
Musculo-skeletal Conventional			<u> </u>								
Musculo-skeletal Superficial											<u> </u>
Other ^[4]											
Exam Type, Means of Access		, , , , , , , , , , , , , , , , , , ,									<u> </u>
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological		<u> </u>									
Intravascular											
Laparoscopic				1	1						

- Lapar Goodpio												
N = new indication; P = property	eviously o	cleared	by FDA	; E = ad	lded und	er Appe	ndix E					
Notes: [3] Cardiac is Adult and Pediatric;												
[*] Combined mod	es are B/	M, B/PV	VD, B/C	olor/PW	D, B/Po	wer/PW	D.					
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	(PLEASE DO	NOT WRIT	TE BELOW	THIS LINE	- CONTINUE	ON ANOT	HER PAGE	F NEEDED)				
	Con	currenc	e of CDI	RH, Offic	e of Devi	ce Evalu	ation (O	DE)				

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices 200993

GE LOGIQ P5/A5 with 6D Transducer

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

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

Laparoscopic		<u> </u>								<u> </u>
N = new indication; P =	previously	cleared	by FDA	\;E≃a	dded und	er Appe	endix E			
Notes: [4] [3] Cardiac is	Adult and	d Pediati	ric;							
[*] Combined me	odes are E	3/M, B/P	WD, 8/0	Color/PV	D, B/Po	wer/PW	D.			
			_							
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	(PLEASE D	OO NOT WR	RITE BELOW	THIS LINE	- CONTINUI	E ON ANOT	HER PAGE	IF NEEDED)		
	Co	ncurren	ce of CD	RH, Offic	e of Dev	ice Eval	uation (O	DE)		