DEC 2 9 2011



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: December 14, 2011

Submitter: GE Healthcare

9900 W. Innovation Dr. Wauwatosa, WI 53226

Primary Contact Person: Bryan Behn

Regulatory Affairs Manager

GE Healthcare T:(414)721-4214 F:(414)918-8275

Secondary Contact Person: Yalan Wu

Regulatory Affairs Manager

GE Healthcare

T: +86 510 8527 8652 F: +86 510 8527 7347

<u>Device:</u> <u>Trade Name:</u> LOGIQ i, LOGIQ e, Vivid e <u>Common/Usual Name:</u> LOGIQ i, LOGIQ e, Vivid e

Classification Names: Class II

Product Code: Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550 90-

IYN Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21 CFR 892.1570,

90-ITX

Predicate Device(s): LOGIQ i, LOGIQ e, Vivid e, K102256

LOGIQ E9 K110943

Device Description:

The LOGIQ i/e & Vivid e is a full-featured, compact and extremely portable ultrasound system consisting of a main console chassis with integrated keyboard, a color video LCD type display and several interchangeable electronic-array transducers. It has digital acquisition, processing and display capability and operates from an integrated battery or a separate power supply/charger. It is used primarily where portability, size and convenience are essential and is available in three variations: LOGIQ e is for general purpose radiology imaging having a variety of options to tailor it for use by the medical specialist for use in various departments and patient care areas (e.g., OR,



GE Healthcare

510(k) Premarket Notification Submission

ER & outpatient care). Accordingly it has various configurations (Software option/standard and probes supporting) for different packages (Nerve, ED, and GI). LOGIQ i is a full-featured premium radiology system suitable for physician rounds in a hospital, nursing home where a broader range of high performance is needed.

Vivid e is similar to the LOGIQ e with an emphasis on cardiology examinations.

Intended Use:

The LOGIQ i/e & Vivid e is a general purpose ultrasound system intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Intra-operative (abdominal, thoracic and PV), Musculo-skeletal Conventional & Superficial, Transesophageal, Transrectal and Transvaginal, and Thoracic/Pleural for motion/sliding and fluid detection.

Technology:

The LOGIQ i/e & Vivid e employs the same fundamental scientific technology as its predicate.

<u>Determination o</u> Substantial Equivalence

<u>Determination of Summary of Non-Clinical Tests:</u>

Substantial Equivalence: The LOGIQ i/e & Vivid e 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)
- Performance testing (Verification)
- Safety testing (Verification
- Simulated use testing (Validation)

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



GE Healthcare

510(k) Premarket Notification Submission

Summary of Clinical Tests:

The subject of this premarket submission, LOGIQ i/e & Vivid e, did not require clinical studies to support substantial equivalence.

Conclusion:

GE Healthcare considers the LOGIQ i/e & Vivid e to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).



Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

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

JAN 19 2012

Re: K113690

Trade/Device Name: GE LOGIQ I, LOGIQ e and Vivid e Diagnostic Ultrasound

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: December 14, 2011 Received: December 15, 2011

Dear Mr. Behn:

This letter corrects our substantially equivalent letter of December 29, 2011.

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 I, LOGIQ e and Vivid e Diagnostic Ultrasound, as described in your premarket notification:

Transducer Model Number

4C-RS	12L-RS	<u>6S-RS</u>
8C-RS	16L-RS	P2D
E8C-RS	<u>i12L-RS</u>	<u>6Tc-RS</u>
8L-RS	<u>i/t739-RS</u>	<u>L8-18i-RS</u>
9L-RS	<u>3S-RS</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 895. 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 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 Michael O'Hara at (301) 796-0294.

Sincerely Yours,

Mary S. Pastel, Sc.D.

Director

Division of Radiological Devices Office of In Vitro Diagnostic Device

huld DOKkun for

Evaluation and Safety

Center for Devices and Radiological Health

Enclosure(s)



- GE Healthcare 510(k) Premarket Notification Submission

510(k) Number (if known):

Device Name:

GE LOGIQ I, LOGIQ e and Vivid e Diagnostic Ultrasound

Indications for Use:

The LOGIQ i/e & Vivid e is a general purpose ultrasound system intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Intraoperative (abdominal, thoracic and PV), Musculo-skeletal Conventional & Superficial, Transesophageal, Transrectal and Transvaginal, and Thoracic/Pleural for motion/sliding and fluid detection.

Prescription Use_x	AND/OR	Over-The-Counter Use_N/A_
(Part 21 CFR 801 Subpart D)		(Part 21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE I	BELOW THIS LIN	E - CONTINUE ON ANOTHER PAGE

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

IF NEEDED)

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) Number____

Page 1 of 1

GE Healthcare



510(k) Premarket Notification Submission

Indications For Use Forms

The following Indication for Use forms are attached.

System: GE LOGIQ i/e & Vivid e

Transducer: 4C-RS

Transducer: 8C-RS

Transducer: E8C-RS

Transducer: 8L-RS

Transducer: 9L-RS

Transducer: 12L-RS

Transducer: 16L-RS

Transducer: i12L-RS

Transducer: i/t739-RS

Transducer: 3S-RS

Transducer: 6S-RS

Transducer: P2D

Transducer: 6Tc-RS

Transducer: L8-18i-RS

The following forms represent indications with clinical applications and exam types along with the modes of operation for the LOGIQ i/e & Vivid e system and for all of its probe/mode combinations. Combinations identified by "N" are new while "P" represents those previously cleared with the unmodified LOGIQ i/e & Vivid e. The subject modification does not alter the previously cleared system level indications or clinical applications.

Division of Radiological Devices

Chico of in Vitro Diagnostic Device Evaluation and Safety

510K 5 13 690

Confidential and Privileged. This document contains confidential and privileged trade secrets and other a information of General Electric Co. and as such may not be disclosed to others not employed by General Electric Co. All rights reserved

GE Compact Ultrasound System LOGIO i, LOGIO e, Vivid e

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

ļ	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	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other	
Ophthalmic												
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	P		
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	 	
Pediatric	P	P_	P	P	P	P	P	P	P	P	 	
Small Organ ^[2]	P	P	P		P		P	P	P	P		
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	P	ļ	
Peripheral Vascular	P	P	P	P	P		P	P	P	P	ļ	
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P		
Musculo-skeletal Superficial	P	P	P		P		P	P	P	P		
Thoracic/Pleural(specify)[4]	P	P	P	P	P	P	P	P	P	P		
Other ^[5]	P	P	P	P	P	P	P	P	P	P	<u> </u>	
Exam Type, Means of Access		_										
Transesophageal	P	P	P	P	P	P	P	P	P	P	1	
Transrectal	P	Р	P		P		P	P	P	_	_	
Transvaginal	P	P	P		P		P	P	P	↓	1	
Transurethral										1	1	
Intraoperative(specify)[6]	P	P	P		P		P	P	P	Р	1_	
Intraoperative Neurological										·	\perp	
Intravascular				_		1		ļ	1	↓	↓	
Laparoscopic					<u> </u>			<u> </u>	<u> </u>	<u> </u>	<u> </u>	

Laparo	scopic						<u> </u>			<u> </u>	
N = nev	v indication; P = prev	iously cleare	d by FDA;	E = adde	d under A	ppendix	E			_	
	· · · · · · · · · · · · · · · · · · ·	ides GYN and ludes breast, and Pediatri fluid and ple les Urology/I icludes abdor	d Urologica testes, thyro c. sural motion Prostate minal, thora	d id. /sliding; cic and p	eripheral;	Office	7	ivision of I	sion Sign-Off Radiological stic Device E	Devices	and Safety
	[*] Coded Pulse is f	or digitally e	ncoded harm	nonics.	,						

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

GE Compact Ultrasound LOGIO i, LOGIO e, Vivid e with 4C-RS Transducer

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

1						Mode of					
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Dopples	Combined Modes	Harmonid Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P	ļ	P		P	P	P	P	
Abdominal ^[1]	P	P	P		P	ļ	P	P	P	P	<u> </u>
Pediatric	P	P	P		P	<u> </u>	P	P	P	P	
Small Organ [2]			<u> </u>								ļ
Neonatal Cephalic											ļ
Adult Cephalic			<u> </u>	<u> </u>	<u> </u>						
Cardiac ^[3]											<u> </u>
Peripheral Vascular									ļ		<u> </u>
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural(specify)[4]	P	P	P		P	<u> </u>	P	P	P	P	
Other[5]	P	P	P		P		P	P	P	P	
Exam Type, Means of Access									<u>.</u>		<u> </u>
Transesophageal						<u> </u>		<u> </u>			
Transrectal					<u> </u>	<u> </u>	<u> </u>	<u></u>	<u> </u>		<u> </u>
Transvaginal								<u> </u>	<u> </u>		
Transurethral											ļ
Intraoperative (specify)[6]		L.		ļ					<u> </u>		
Intraoperative Neurological			<u></u>								
Intravascular				<u> </u>	ļ					<u> </u>	
Laparoscopic						1	1	1	l		

Intrava	scuar				4					
Laparo	scopic				<u> </u>	i				
N = nev	v indication; P = prev				r Appendi	хE	_			
Notes:	[1] Abdominal inclu	ides GYN an	d Urological				ממר	_	Qu.	n
	[2] Small organ incl	udes breast,	testes, thyroi	d.			lac	<u>, </u>	/ with	
	[3] Cardiac is Adult	and Pediatri	c.					rision Sign		
	[4] For detection of	fluid and ple	ural motion/s	sliding;	•	Office of In	Division o	of Radiclog Postic David	ical Device	s on and Safety
	[5] Other use includ	es Urology/F	rostate		_)	VIIO DIUg.		~ <i>^</i>	,,, <u></u>
	[6] Intraoperative in	cludes abdor	ninal, thorac	ic and peripher	al;	510K_	<u> SI</u>	136	<u>40.</u>	
	[*] Combined mode	s are B/M, B	/PWD, B/Co	lor/PWD, B/P	ower/PWD				_, ,	
	[*] Coded Pulse is for	or digitally e	ncoded harm	onics.						
				-						
	(PLEASE DO NOT	WRITE BEI	OW THIS L	INE - CONTI	NUE ON A	ANOTH	ER PAGE	IF NEED	ED)	

Prescription Use (Per 21 CFR 801.109)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

GE Compact Ultrasound LOGIO i, LOGIO e, Vivid e with 8C-RS Transducer

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

						ode of O			r		
Clinical Application	В	M	PW	CW	Color	Color M	Power	Combined	Harmonic	Coded Pulse	Other
Anatomy/Region of Interest			Doppler	Doppler	Doppler	Doppler	Doppler	Modes	Imaging	ruise	
Ophthalmic			<u> </u>								
Fetal / Obstetrics			ļ					<u> </u>			
Abdominal ^[1]	Р	P	P		P		P	P	P		
Pediatric	P	P	P		P		P	P	P		
Small Organ [2]	P	P	P	<u> </u>	P		P	P	P	<u> </u>	
Neonatal Cephalic	₽	P	P	ļ	P		P	P	P		
Adult Cephalic			1			ļ			<u> </u>		
Cardiac ^[3]	P	P	P		P		P	P	P	<u> </u>	
Peripheral Vascular	P	P	P	<u> </u>	P		P	P	P		L
Musculo-skeletal Conventional	P	P	P		P		P	P	P		
Musculo-skeletal Superficial	N	N	N		N		N	N	N		
Thoracic/Pleura(specify)[4]	P	P	P	<u> </u>	P		P	P	P		<u> </u>
Other[5]				}				<u> </u>		ļ	
Exam Type, Means of Access											
Transesophageal											
Transrectal									<u> </u>		
Transvaginal							ļ				
Transurethral											
Intraoperative (specify)[6]							<u></u>				
Intraoperative Neurological											
Intravascular											
Laparoscopic	1				1 ~		1	1			

Laparosc	opic											
N = new ir	ndication; P = prev	iously	cleared	by FDA	E = adde	d under	Appendia	¢Ε				-
Notes: [i] Abdominal inclu	ides G	YN and	Urologic	al		_	<u> </u>	_		2 4	
[2] Small organ incl	udes t	oreast, tes	tes, thyr	oid.	•		N	7 a.	SK	~~!!	
[3] Cardiac is Adult	and P	ediatric.				_		(District	Sign-Off)	ar_	
[4	For detection of	fluid a	and pleur	al motio	n/sliding;			Div	ision of Rad	iological De	evices	
. [5	Other use includ	es Un	ology/Pro	state			Office	of In Vitro	Diagnostic	Device Eva	luation an	d Safety
[6	Intraoperative in	clude	abdomi	nal, thor	acic and p	eripheral	;	¥	くロス	600)	
•]] Combined mode	s are l	B/M, B/P	WD, B/	Color/PW	D, B/Pov	ver/PWI	<u>рк — 1</u>	يىلىد.	$Q \gamma V$	<u>′ </u>	
Ĭ,	Coded Pulse is 6	or digi	tally enc	oded har	monics .							

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

GE Compact Ultrasound LOGIQ i, LOGIQ e, Vivid e with E8C-RS 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 Dopplet	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic		•									
Fetal / Obstetrics	P	P	P		P		P	P	P		
Abdominal ^[1]	P	P	P		P		P	P	P		
Pediatric				<u> </u>					ļ		
Small Organ [2]						 					
Neonatal Cephalic				<u> </u>		<u> </u>			ļ		<u> </u>
Adult Cephalic						ļ	ļ		ļ		<u> </u>
Cardiac					<u> </u>	<u> </u>	<u> </u>				
Peripheral Vascular					ļ		ļ		_		
Musculo-skeletal Conventional											L
Musculo-skeletal Superficial											
Thoracic/Pleura(specify)[4]										<u> </u>	
Other[5]	P	P	P		P		P	P	P		L
Exam Type, Means of Access					_						
Transesophageal								<u> </u>	<u> </u>	<u> </u>	<u> </u>
Transrectal	P	P	P		P		P	P	P	<u> </u>	L
Transvaginal	P	P	P		P		P	P	P	<u> </u>	<u> </u>
Transurethral										<u> </u>	<u> </u>
Intraoperative (specify) [6]			J						<u> </u>	ļ	
Intraoperative Neurological											
Intravascular							<u> </u>	<u> </u>			
Laparoscopic								1			

Lapare	oscopic			<u> </u>					
i = nev	w indication; $P = previously cleared by FDA; E = ac$	ded under Appendix	<u> </u>	0 1					
Votes:	[1] Abdominal includes GYN and Urological	•	m	SHI	9				
	[2] Small organ includes breast, testes, thyroid.		- Mary	sion Sign-Off)					
	[3] Cardiac is Adult and Pediatric.			Radiological Device	3				
	[4] For detection of fluid and pleural motion/sliding	3; Of	Office of In Vitro Diagnostic Device Evaluation and Saf						
	[5] Other use includes Urology/Prostate		KII.	スムのの					
	[6] Intraoperative includes abdominal, thoracic and	peripheral;	510K)() <u> </u>					
	[*] Combined modes are B/M, B/PWD, B/Color/P' [*] Coded Pulse is for digitally encoded harmonics.		•						

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

GE Compact Ultrasound LOGIO i, LOGIO e, Vivid e with 8L-RS Transducer

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

.			, ,			Mode of O					0.1
Clinical Application	В	M	PW	CW	Color	Color M	Power	Combined	Harmonic Imaging	Coded Pulse	Other
Anatomy/Region of Interest		_	Doppler	Doppler	Doppler	Doppler	Dopplet	IVIUUES	magnig	1 disc	
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	_ <u>P_</u>	P	P		P		P	P	P	P	
Pediatric	P	P	P		P		P	P	P	P	
Small Organ [2]	P	P	P		P		P	P	P	P	
Neonatal Cephalic					ļ						ļ
Adult Cephalic			<u> </u>						<u> </u>		
Cardiac ^[3]	P	P	P		P		P	P	P		
Peripheral Vascular	P	P	P		P		P	P	P	P	<u> </u>
Musculo-skeletal Conventional	P	P	P		P		P	P	P		
Musculo-skeletal Superficial											
Thoracic/Pleural(specify) [4]							<u> </u>		<u> </u>		<u> </u>
Other ^[5]										<u> </u>	
Exam Type, Means of Access											
Transesophageal								<u></u>		<u> </u>	
Transrectal							<u> </u>				ļ
Transvaginal				<u> </u>						<u> </u>	<u> </u>
Transurethral											<u> </u>
Intraoperative (specify) [6]	P	P	P		P		P	P	P		
Intraoperative Neurological											
Intravascular											
Laparoscopic	[Į				1		1		1

	scopic					<u> </u>	<u> </u>	<u> </u>	<u> </u>			
N = nev	v indication; P = prev	iously	cleared	by FDA	; E = ado	led unde	r Appendi	x E			0	
Notes:	[1] Abdominal inch	ıdes G	YN and	l Urologi	cal				Mar.	.5/	~~X	
	[2] Small organ incl	udes b	reast, to	estes, thy	roid.		•		(Dive	ion Sign-O	HI)	
	[3] Cardiac is Adult	and P	ediatric					·	Division of R	adiologice	1 Davison	
	[4] For detection of	fluid a	ind pleu	ıral moti	on/sliding	;	Off	ice of in v	itro Diagnos	tic Device	Evaluation	and Safety
	[5] Other use include	es Uro	logy/Pr	rostate					K11.2	6a1	ን	
	[6] Intraoperative in	cludes	abdom	inal, tho	racic and	peripher	al;	510K	1110	<u> </u>	<u></u>	
	[*] Combined mode [*] Coded Pulse is f					/D, B/P	ower/PWD).				

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

GE Compact Ultrasound LOGIQ i, LOGIQ e, Vivid e with 9L-RS Transducer

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

Į					M	ode of Op				,	
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 [1]	P	P	P		P		P	P	P	P	
Pediatric	P	P	P		P	 	P	P	P	P	
Small Organ [2]	P	P	P	<u></u>	P		P	P	P	P	
Neonatal Cephalic						ļ			ļ		
Adult Cephalic				<u> </u>			ļ			 	
Cardiac ^[3]							<u> </u>			ļ	<u> </u>
Peripheral Vascular	P	P_	P		P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P	<u> </u>	P		P	P	P	P	
Musculo-skeletal Superficial	N	N	N		N		N	N	N	N	
Thoracic/Pleural(specify)[4]	N	N	N		N		N	N	N	N	
Other[5]					<u> </u>		<u> </u>			<u> </u>	
Exam Type, Means of Access											
Transesophageal					<u> </u>	<u> </u>					
Transrectal					<u> </u>	<u></u>	ļ	<u> </u>	<u> </u>	 	
Transvaginal					<u> </u>	<u> </u>	<u> </u>	<u> </u>	ļ	 	<u> </u>
Transurethral					<u> </u>	<u> </u>		ļ		↓	
Intraoperative (specify)[6]	P	P	P	<u> </u>	P		P	P	P	P	-
Intraoperative Neurological					ļ						
Intravascular	L.,						}			 	
Laparoscopic		1		l		1		<u></u>	<u> </u>		<u>L, , , , , , , , , , , , , , , , , , , </u>

N = new	indication; P = prev	viously cleare	d by FDA	; E = ado	led under	Appendix	E			
	[1] Abdominal inclu [2] Small organ inc [3] Cardiac is Adult [4] For detection of [5] Other use includ [6] Intraoperative in [*] Combined mode [*] Coded Pulse is f	ludes breast, it and Pediatri fluid and ple des Urology/F ncludes abdor es are B/M, B	testes, thyr c. ural motio Prostate ninal, thor VPWD, B/	roid. in/stiding acic and Color/PV	peripheral	; 51(of in Vitro	(Division sion of Radio		nd Safety
	PLEASE DO NOT	WRITE BEI	OW THIS	S LINE -	CONTIN	UE ON A	NOTHE	R PAGE IF	NEEDED)	
	Cone	currence of (CDRH, O	ffice of I	a Vitro Di	agnostic l	Devices ((OIVD)		

GE Compact Ultrasound LOGIQ i, LOGIQ e, Vivid e with 12L-RS Transducer

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

į					M	ode of Op					
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Dopplet	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic					<u> </u>						
Fetal / Obstetrics											<u> </u>
Abdominal	N	N	N		N		N	N	N	N	
Pediatric	P	P	P		P		P	P	P	P	<u> </u>
Small Organ [2]	P	P	P		P		P	P	P	P	<u> </u>
Neonatal Cephalic			<u> </u>								<u> </u>
Adult Cephalic			<u> </u>	<u> </u>							<u> </u>
Cardiac										ļ	<u> </u>
Peripheral Vascular	P	P	P		P	<u> </u>	P	Р	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	L
Musculo-skeletal Superficial	P	P	P		P		P	P	P	P	L
Thoracic/Pleural(specify)[4]	P	P	P		Р		P	P	P	P	
Other (specify) [5]											
Exam Type, Means of Access											
Transesophageal											L.,
Transrectal											
Transvaginal											
Transurethral								<u> </u>	<u> </u>	<u> </u>	
Intraoperative(specify) [6]						<u></u>				<u></u>	L
Intraoperative Neurological											
Intravascular											L
Laparoscopic N = new indication: P = new					1	1	1				

Intravascular							
Laparoscopic							
N = new indication; P = p	reviously cleared by l	FDA; E = added und	ler Appendix E				
Notes: [1] Abdominal in	cludes GYN and Uro	logical	•	\mathcal{M}_{ϵ}	< PL	1	
(2) Small organ i	ncludes breast, testes,	, thyroid.	<u> </u>	- any	2/400		
[3] Cardiac is Ad	ult and Pediatric.			Division of R	ion Sign-Off) Iadiological Devi	004	
[4] For detection	of fluid and pleural n	notion/sliding;	Office of t	n Vitro Diagnos	tic Device Evalua	ation and	Safety
[5] Other use inc	ludes Urology/Prostat	te		KIL	2600		•
[6] Intraoperative	includes abdominal,	thoracic and periphe	ral; 610K		MAGI		
[*] Combined mo	odes are B/M, B/PWI	D, B/Color/PWD, B/	Power/PWD.				
[] Coded Pulse i	s for digitally encode	d harmonics.					

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

GE Compact Ultrasound LOGIO i, LOGIO e, Vivid e with 16L-RS Transducer

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

					M	ode of Op	_				
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Dopplet	Combined Modes	Harmonic Imaging		
Ophthalmic								ļ			
Fetal / Obstetrics								ļ			
Abdominal						 _					_
Pediatric	P	P	P		P		P	P	P	P	
Small Organ [2]	P	P	P		P		P	P	P	P	
Neonatal Cephalic								<u></u>			<u> </u>
Adult Cephalic							<u> </u>		<u> </u>	<u> </u>	<u> </u>
Cardiac					<u> </u>		ļ	ļ	<u> </u>	 	<u> </u>
Peripheral Vascular	P	P	P		P	<u> </u>	P	P	P_	P	 —
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	_
Musculo-skeletal Superficial	P	P	P		P		P	P	P	P	
Thoracic/Pleural(specify)[4]]	<u> </u>					ļ
Other (specify) [5]					<u> </u>	<u> </u>	<u> </u>		<u> </u>	<u> </u>	_
Exam Type, Means of Access					<u> </u>					ļ	_
Transesophageal		Ĺ		<u> </u>	<u> </u>	1	1		<u> </u>		<u> </u>
Transrectal				<u> </u>	ļ		1	<u> </u>		 -	-
Transvaginal				<u> </u>	ļ		<u> </u>	ļ	<u> </u>	<u> </u>	-
Transurethral		<u> </u>		<u> </u>	ļ		ļ	<u> </u>		ļ	↓_
Intraoperative(specify) [6]		<u>L</u> _		<u> </u>			 	<u> </u>	<u> </u>	1	1
Intraoperative Neurological									<u> </u>		
Intravascular		<u> </u>			<u> </u>						╄
Laparoscopic			1	<u> </u>	1	- A mandi	L	<u> </u>	Ц		

Intraoperative Neurological					<u></u>			<u>. </u>		
Intravascular			ļ	<u> </u>						
Laparoscopic				1				<u> </u>		
N = new indication; P = pre Notes: [1] Abdominal incl	udes GYN a	nd Urolog	pical	ded under	Appendix	E	Mary	5/4	SH	
[2] Small organ inc [3] Cardiac is Adul	t and Pediatr	ic.			~ ~		(Dylis Nvision of R tro Diagnos	on Sign-Of ediological	Devices	end Safatu
[4] For detection of [5] Other use include	des Urology/	Prostate	_			,	Kil	360	10	trici Salety
[6] Intraoperative in [*] Combined mod					1;	51CK	للماساسا		<u> </u>	
[*] Coded Pulse is	for digitally	encoded h	armonics.							
(PLEASE DO NOT	WRITE BE	LOW TH	IS LINE .	CONTIN	UE ON A	NOTHE	R PAGE IF	NEEDEL	2)	
Con Prescription Use (Per 21 CF	currence of R 801.109)	CDRH, (Office of I	n Vitro D	iagnostic l	Devices ((OIVD)			

23

GE Compact Ultrasound LOGIO i, LOGIO e, Vivid e with i12L-RS Transducer

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

					M	ode of Op					
Clinical Application Anatomy/Region of Interest	В	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics				.							
Abdominal ^[1]	P	P	P		P		P	P	P	P	
Pediatric	P	P	P		P		P	P	P	P	
Small Organ [2]	P	P	P		P		P	P	P	P_	
Neonatal Cephalic			ļ			<u> </u>	ļ	<u> </u>	ļ	 	
Adult Cephalic										<u> </u>	
Cardiac ^[3]	P	P	P		P		P	Р.	P	ļ	
Peripheral Vascular	P	P	P	<u> </u>	P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P	<u> </u>	
Musculo-skeletal Superficial	P	P	P		P		P	P	P		
Thoracic/Pleural(specify)[4]			<u> </u>						<u> </u>	1	
Other[5]				<u> </u>			ļ				ļ
Exam Type, Means of Access											
Transesophageal						<u> </u>	ļ		<u> </u>	↓	<u> </u>
Transrectal								<u> </u>		↓	<u> </u>
Transvaginal		<u> </u>	ļ	<u> </u>	<u> </u>	<u> </u>	 		_		ļ
Transurethral			<u> </u>	ļ		<u> </u>	ļ	ļ	_	-	-
Intraoperative (specify) [6]	P	P	P		P	<u> </u>	P	P	P		ļ
Intraoperative Neurological				<u> </u>					ļ		
Intravascular	<u> </u>	<u> </u>		ļ			ļ	<u> </u>		↓	ļ
Laparoscopic	<u></u>		<u></u>	1	<u> </u>	<u></u>	<u> </u>	<u></u>		<u></u>	<u> </u>
N = new indication; P = prev Notes: [1] Abdominal inclu [2] Small organ inc	udes C	iYN ar	ıd Urologi	cal	led under			(Div Division of Vitro Diagno	sion Sign- Radiologic	Off) ad Device)8 :

4 - 116	w didication, r - previously cleared by t bit, E - above where	
lotes:	[1] Abdominal includes GYN and Urological	(Division Sign-Off)
	[2] Small organ includes breast, testes, thyroid.	Division of Radiological Devices Office of In Vitro Diagnostic Device Evaluation and Safe
	[3] Cardiac is Adult and Pediatric.	
	[4] For detection of fluid and pleural motion/sliding;	510K B 113690
	[5] Other use includes Urology/Prostate	

[6] Intraoperative includes abdominal, thoracic and peripheral;[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[*] Coded Pulse is for digitally encoded harmonics.

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

GE Compact Ultrasound LOGIO i, LOGIO e, Vivid e with i/t739-RS Transducers

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

l					M	ode of O	peration				
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler		Color M Doppler		Combined Modes	Harmonic Imaging		Other
Ophthalmic								<u></u>			
Fetal / Obstetrics									ļ		
Abdominal ^[1]	P	P	P		P		P	P	Р_	-	
Pediatric .	P	P	P		P		Р	P	P	ļ	
Small Organ [2]	P	P	P_		P		P	P	P		
Neonatal Cephalic				<u> </u>					ļ	 	
Adult Cephalic			<u> </u>							ļ	
Cardiac ^[3]	P	P	P		P		P	P	P	<u> </u>	
Peripheral Vascular	P	P	P		P	<u> </u>	P	P	P	ļ	
Musculo-skeletal Conventional			<u> </u>								
Musculo-skeletal Superficial											
Thoracic/Pleural(specify)[4]						<u>. </u>		<u> </u>	<u> </u>	<u> </u>	
Other ^[4]						<u> </u>		<u> </u>		<u> </u>	
Exam Type, Means of Access						ļ					
Transesophageal								<u> </u>	<u> </u>		<u> </u>
Transrectal					<u> </u>			<u> </u>	<u> </u>	<u> </u>	ļ
Transvaginal					<u> </u>		<u> </u>		ļ	 	↓ _
Transurethral					<u> </u>		<u> </u>	ļ			ļ
Intraoperative (specify) [6]	P	Р	P	<u> </u>	P	ļ	P	P	P		
Intraoperative Neurological											
Intravascular					1			ļ	1		1
Laparoscopic				1			<u> </u>				<u> </u>

							-				
Laparo				<u></u>	<u></u>		<u></u>				
N = new	v indication; P = prev	riously clea	red by FDA	; E = add	ed under	Appendi	ixE			_	
Notes:	[1] Abdominal inclu	udes GYN :	and Urologic	cal		•	YY	an '	5/!-	+0	
	[2] Small organ incl	ludes breas	t, testes, thy	roid.		•		Divisi	ion Sign-Off	<u> </u>	
	[3] Cardiac is Adult	and Pedia	ric.					Division of R	Rdinlonical () Dougous	
	[4] For detection of	fluid and p	leural motic	m/sliding;		Off	ice of In Vil	tro Diagnosi	tic Device Ev	valuation	end Safety
	[5] Other use includ	les Urology	/Prostate					KII	240	0	
	[6] Intraoperative in						510K		TELY.	<u>v </u>	
	[*] Combined mode	s are B/M,	B/PWD, B	'Color/PW	'D, B/Pov	ver/PWI	7.				
	[*] Coded Pulse is for	or digitally	encoded ha	rmonics.							

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

GE Compact Ultrasound LOGIQ i, LOGIQ e, Vivid e with 3S-RS Transducer

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

1					M	ode of O				, , ,	
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler		Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	P	
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	<u>P</u> _	P	P	P	<u>P</u>	P	P	P	P	
Small Organ [2]					ļ		<u> </u>	.	ļ	ļ	
Neonatal Cephalic								<u> </u>		ļ	
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac ^[3]	P	P	P	P	P	P	P	P	P_	P	
Peripheral Vascular	N	N	N	N	N	N	N	N	N	N	
Musculo-skeletal Conventional			ļ						ļ	ļ	
Musculo-skeletal Superficial											
Thoracic/Pleural(specify)[4]	P	P	P	P	P	P	P	P	P	P_	
Other[5]	P	P	P	P	P	P	P	P	P_	P	
Exam Type, Means of Access											
Transesophageal]	<u> </u>	<u> </u>		<u> </u>		<u> </u>		<u> </u>
Transrectal			J			<u> </u>	<u> </u>		<u> </u>	 	<u> </u>
Transvaginal									ļ	↓	<u> </u>
Transurethral			<u> </u>		<u> </u>	<u> </u>		_	ļ	 	<u> </u>
Intraoperative (specify) [6]		<u> </u>	<u> </u>	ļ		 			ļ	_	↓
Intraoperative Neurological									<u> </u>		
Intravascular						<u> </u>			↓	4—	
Laparoscopic			1						<u> </u>	<u></u>	<u> </u>

N = new	indication; P = previously cleared by FDA; E = added under App	pendix E
Notes:	[1] Abdominal includes GYN and Urological	Mansfath
	[2] Small organ includes breast, testes, thyroid.	Division Sign Con
	[3] Cardiac is Adult and Pediatric.	
	[4] For detection of fluid and pleural motion/sliding;	Office of In Vitro Diagnostic Devices Evaluation and Safety
	[5] Other use includes Urology/Prostate	510K 6 13690
	[6] Intraoperative includes abdominal, thoracic and peripheral;	

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

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

[*] Coded Pulse is for digitally encoded harmonics.

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

GE Compact Ultrasound LOGIQ i, LOGIQ e, Vivid e with 6S-RS 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	Power Doppled	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal ⁽¹⁾	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ [2]			ļ		ļ	ļ			<u> </u>	ļ	<u> </u>
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	P	 -
Peripheral Vascular			<u> </u>			<u> </u>	<u> </u>				
Musculo-skeletal Conventional	,								ļ		
Musculo-skeletal Superficial			ļ					_			<u> </u>
Thoracic/Pleural(specify)[4]			<u> </u>	<u> </u>					ļ		
Other[5]	P	P	P	P	P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal				<u> </u>			<u> </u>	<u> </u>	<u> </u>	ļ	<u> </u>
Transrectal		<u> </u>	<u> </u>	<u> </u>			<u> </u>	<u> </u>	-	<u> </u>	ļ
Transvaginal			<u> </u>	<u> </u>	ļ		 	<u> </u>	ļ	 	<u> </u>
Transurethral			<u> </u>	<u> </u>	1		igspace	<u> </u>		<u> </u>	}
Intraoperative (specify)[6]			ļ	<u> </u>		 	ļ	<u> </u>	<u> </u>	ļ	<u> </u>
Intraoperative Neurological											
Intravascular		ļ			<u> </u>	<u> </u>	<u> </u>	<u> </u>	ļ	ļ	<u> </u>
Laparoscopic			1	1			<u> </u>			<u> </u>	<u> </u>

N = nev	v indication; P = prev	iously cleared by FDA	E = added under App	endix E	5 Posts
Notes:	[1] Abdominal inclu	ides GYN and Urologic	al		2/10/-
	[2] Small organ incl	ludes breast, testes, thyr	V.G.	DIAMENTU OL KE	GICIOGICAI Devices
	[3] Cardiac is Adult	and Pediatric.		Office of In Vitro Diagnosti	Device Evaluation and Safety

- [3] Cardiac is Adult and Pediatric.
- [4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate

- [6] Intraoperative includes abdominal, thoracic and peripheral;
- [*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[*] Coded Pulse is for digitally encoded harmonics.

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

GE Compact Ultrasound LOGIO i, LOGIO e, Vivid e 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		Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics										L	
Abdominai ^[1]			<u> </u>								
Pediatric			<u> </u>								
Small Organ [2]						<u></u>					
Neonatal Cephalic			<u> </u>								
Adult Cephalic			<u> </u>								
Cardiac ^[3]			<u> </u>	P						L	
Peripheral Vascular				P							
Musculo-skeletai Conventional											
Musculo-skeletal Superficial						<u> </u>					
Thoracic/Pleural (specify)]	
Other ^[5]											
Exam Type, Means of Access											
Transesophageal			<u> </u>			<u> </u>				<u> </u>	<u> </u>
Transrectal		<u> </u>							ļ		
Transvaginal	<u></u>			<u> </u>		<u> </u>	<u> </u>				<u> </u>
Transurethral							<u> </u>			 	
Intraoperative (specify) [6]					<u> </u>	<u> </u>	<u> </u>		ļ	ļ	
Intraoperative Neurological											
Intravascular		<u> </u>	<u> </u>	ļ					<u> </u>	<u> </u>	<u> </u>
Laparoscopic N = new indication; P = pre	L]	<u> </u>		<u> </u>	<u> </u>	

Intravascular	<u> </u>								 	
Laparoscopic								<u> </u>	<u> </u>	
N = new indication; P = pre Notes: [1] Abdominal incl [2] Small organ inc [3] Cardiac is Adul [4] For detection of [5] Other use inclu [*] Combined mod [*] Coded Pulse is the	udes GYN and cludes breast, t t and Pediatric f fluid and pleated des Urology/P es are B/M, B	d Urologica estes, thyro c. ural motion rostate /PWD, B/O	al oid. n/sliding; Color/PW		Offi	ce of In V	(Division of Residue) Division of Residue Diagnostic	n Sign-Off diological to Device Ev	Da	and Safet
(PLEASE DO NOT	WRITE BEI	OW THIS	LINE -	CONTIN	UE ON A	NOTHE	R PAGE IF	NEEDED	»	
Con	currence of C	DRH, Off	ice of In	Vitro D	iagnostic	Devices	(OIVD)			

GE Compact Ultrasound LOGIO i, LOGIO e, Vivid e with 6Tc-RS 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											
Fetal / Obstetrics											
Abdominal ^[1]											
Pediatric				<u> </u>				L			
Smail Organ ^[2]			<u> </u>								
Neonatal Cephalic			ļ								
Adult Cephalic					<u> </u>						<u> </u>
Cardiac ^[3]	P	P	P	P	P	P	P	P_	P	P	<u> </u>
Peripheral Vascular			ļ				ļ		<u> </u>		<u> </u>
Musculo-skeletal Conventional											_
Musculo-skeletal Superficial											
Thoracic/Pleural (specify) [4]							Ĺ		<u></u>	<u> </u>	<u> </u>
Other ^[5]						<u> </u>			<u> </u>		<u> </u>
Exam Type, Means of Access							<u> </u>				ļ
Transesophageal	P	P	P	P	P	P	P	P	P	P	<u> </u>
Transrectal			<u> </u>				ļ	ļ			<u> </u>
Transvaginal		<u> </u>			<u> </u>					<u> </u>	↓
Transurethral			<u> </u>		<u> </u>	<u> </u>	ļ	<u> </u>	 		<u> </u>
Intraoperative (specify) ^[6]				1	<u> </u>	 	<u> </u>	 		 	 -
Intraoperative Neurological						<u> </u>				<u> </u>	_
Intravascular			<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>		ļ	_
Laparoscopic		<u> </u>	<u>. </u>		<u> </u>	1		<u> </u>		<u> </u>	

v indication; $P = previously$ cleared by PDA; $E = added$ under A	ppenaix E
[1] Abdominal includes GYN and Urological	m 0.10
[2] Small organ includes breast, testes, thyroid.	- Jan Slastel
[3] Cardiac is Adult and Pediatric.	Division of Register
[4] For detection of fluid and pleural motion/sliding;	Division of Radiological Devices Office of In Vitro Diagnostic Device Evaluation and Safety
[3] Office most mistages of cross By a resume	VIII COA
	510K_D1369()
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Powe	π/PWD.
[*] Coded Pulse is for digitally encoded harmonics.	
	 Abdominal includes GYN and Urological Small organ includes breast, testes, thyroid. Cardiac is Adult and Pediatric. For detection of fluid and pleural motion/sliding;

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

GE Compact Ultrasound LOGIQ i, LOGIQ e, Vivid e with L8-18i-RS Transducer

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

	Mode of Operation											
Clinical Application Anatomy/Region of	В	М	PW Doppler	CW Doppler		Color M Doppler		Combined Modes	Harmonio Imaging	Coded Pulse	Other	
Interest					<u> </u>	<u> </u> i	_					
Ophthalmic			ļ						ļ			
Fetal / Obstetrics			ļ		<u> </u>			ļ	ļ			
Abdominai ^[1]	N	N	N	· 	N		N	N	N	N		
Pediatric	N	N	N		N		N	N	N	N		
Smali Organ [2]	N	N	N		N		N	N	N	N		
Neonatal Cephalic												
Adult Cephalic									<u> </u>			
Cardiac ^[3]			<u> </u>									
Peripheral Vascular	N	N	Ŋ		N		N	N	N	N		
Musculo-skeletal Conventional	Z	N	N		N		N	N	N	N		
Musculo-skeletal Superficial	Z	N	N		N		N	N	N	N		
Thoracic/Pleural(specify) [4]	Z	N	N		И		N	N	N	N		
Other[5]					L							
Exam Type, Means of Access												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intraoperative (specify) [6]												
Intraoperative Neurological												
Intravascular												
Laparoscopic			1									

Lapare	scopic				L							
N = nev	v indication; P = prev	iously	cleared	by FDA	\; E = ado	ied under	Appendi	×Е		_		
Notes:	•	des G udes b and P fluid a es Uro cludes s are I	YN and reast, to ediatric and pleu llogy/Pa abdom B/M, B/	Urologicstes, thy in a motion of the content of the	ical roid. on/sliding racic and /Color/PV	; peripheral	Office 51	Divis of in Vitro I	(Ovision) (Ovisi	logical Dev	ices lation and	d Sefet
	(DI EASE DO NOT	WD FY	e ner	AU/TID	e i ma	CONTENT	III ON A	NOTE	DACETE	MEEDED		

Prescription Use (Per 21 CFR 801.109)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)