

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 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. Device Name:** 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. Device Description:** 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. Indications for Use:** 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; Musculo-skeletal 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. 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.
- 2. Clinical Tests:** None required.
- 3. Conclusion:** 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>	<u>ERB Biplane</u>	<u>5S</u>
<u>3.5CS</u>	<u>i739 or t739</u>	<u>7S</u>
<u>4C</u>	<u>8L</u>	<u>8T</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>
<u>E8Cs</u>	<u>12L</u>	
<u>BE9C Biplane</u>	<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 Federal Register.

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

This 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" (21CFR 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,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ P5/A5 Ultrasound System

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

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other **
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	P	N
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	N
Pediatric	P	P	P	P	P	P	P	P	P	P	N
Small Organ ^[2]	P	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		
Cardiac ^[3]	P	P	P	P	P	P	P	P	P		
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	
Other ^[4]	P	P	P	P	P	P	P	P	P	P	N
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P		
Transrectal	P	P	P		P		P	P	P	P	
Transvaginal	P	P	P		P		P	P	P	P	
Transurethral											
Intraoperative ^[5]	P	P	P		P	P	P	P	N	P	
Intraoperative Neurological	P	P	P		P	N	P	P	N	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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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. [Signature]

(Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K060993

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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 Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P		P	P	P	P	P	P	
Abdominal ^[1]	P	P	P		P	P	P	P	P	P	
Pediatric											
Small Organ (specify)	P	P	P		P	P	P	P	P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	P	P	P		P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
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)

David A. Keyser

(Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K060993

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P5/A5 with 3.5CS Transducer

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

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P		P	P	P	P	P	P	
Abdominal ^[1]	P	P	P		P	P	P	P	P	P	
Pediatric											
Small Organ (specify)	P	P	P		P	P	P	P	P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	P	P	P		P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
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)

David R. Anderson

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

K060993

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ P5/A5 with 4C Transducer

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

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	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											
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											
Transvaginal											
Transurethral											
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)

David A. Segerson

(Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K060993

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ P5/A5 with 5Cs Transducer

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

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	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											
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	
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes: [1] Abdominal includes GYN/Pelvic;

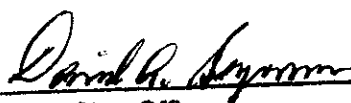
[4] Other use includes Urology/Prostate;

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

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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 K060993

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ P5/A5 with 8C Transducer

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

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

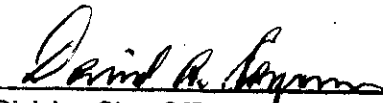
N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic;

[*] 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 120100993

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ P5/A5 with E8C Transducer

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

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

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

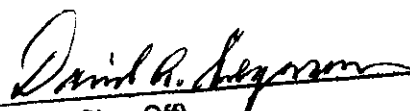
Notes: [1] Abdominal includes GYN/Pelvic;

[4] Other use includes Urology/Prostate;

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

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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 K060993

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ P5/A5 with E8Cs Transducer

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

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

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.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K060993

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P5/A5 with BE9C Biplane Transducer

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

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David R. Anderson
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number 2060993

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P5/A5 with ERB Biplane Transducer

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

Clinical Application Anatomy/ Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal	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											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes: [3] Cardiac is Adult and Pediatric.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K060993

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P5/A5 with i739 or t739 Transducer

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

Clinical Application Anatomy/ Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal	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]											
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											
Transurethral											
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.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David R. Seymour

(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

K060993

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ P5/A5 with 8L Transducer

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

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	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											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[5]	N	N	N		N	N	N	N	N	N	
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

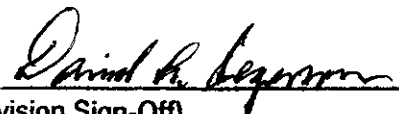
Notes: [2] Small organ includes breast, testes, thyroid.

[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)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K060993

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ P5/A5 with 9L Transducer

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

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	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											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[5]	N	N	N		N	N	N	N	N	N	
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.

[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)

David A. Seymour

(Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number 2060993

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P5/A5 with 10L Transducer

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

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

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

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

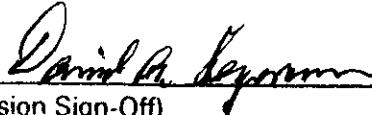
[5] Intraoperative includes abdominal, thoracic, and vascular.

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

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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 K060993

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P5/A5 with 11L Transducer

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

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	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											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[5]	N	N	N		N	N	N	N	N	N	
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.

[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)

David A. Ferguson

(Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K0160993

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ P5/A5 with 12L Transducer

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

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric	P	P	P		P	N	P	P	P	P	
Small Organ ^[2]	P	P	P		P	N	P	P	P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	N	P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P	N	P	P	P	P	
Musculo-skeletal Superficial	P	P	P		P	N	P	P	P	P	
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[5] (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/PWD, B/Color/PWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David B. Ferguson

(Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K060993

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ P5/A5 with 3S Transducer

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

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

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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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K060993

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ P5/A5 with 5S Transducer

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

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	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	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											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	N	N	N	N	N	N	N	N	N		
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number 2060993

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ P5/A5 with 7S Transducer

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

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

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

Notes: [1] Abdominal includes GYN;

[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)

David R. Ferguson

(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

K060993

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ P5/A5 with 8T Transducer

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

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

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)

David A. Segerson

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

5 - 4 - number

20060993

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P5/A5 with 4D3C Transducer

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

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	N	N	N		N	N	N	N	N		
Abdominal ^[1]	N	N	N		N	N	N	N	N		
Pediatric	N	N	N		N	N	N	N	N		
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	N	N	N		N	N	N	N	N		
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
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)

David A. Lyman
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K060993

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ P5/A5 with 2D Transducer

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

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

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

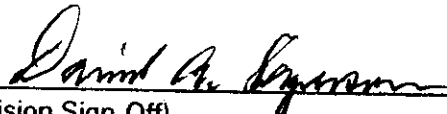
Notes: [3] Cardiac is Adult and Pediatric;

[*] Combined modes are B/M, B/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 K060993

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ P5/A5 with 6D Transducer

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

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

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

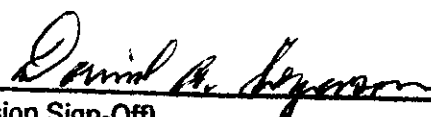
Notes: [4] [3] Cardiac is Adult and Pediatric;

[*] 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,

 STG Number 2060993