

JUN 9 1999

Special 510(k) Premarket Notification
GE Medical Systems - LOGIQ 500 with Harmonic Imaging Modification
May 7, 1999

K991611

Attachment B:

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



GE Medical Systems

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

Section a):

1. Submitter: GE Medical Systems
PO Box 414
Milwaukee, WI 53201

Contact Person: Allen Schuh,
Manager, Safety and Regulatory Engineering
Telephone: 414-647-4385; Fax: 414-647-4090

Date Prepared: May 7, 1999

2. Device Name: GE LOGIQ 500 Diagnostic Ultrasound with Harmonic Imaging Modification.
Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO

3. Marketed Device: GE Medical Systems LOGIQ 500 diagnostic ultrasound system, 510(k) Numbers K933202 and K970901, currently in commercial distribution.

4. Device Description: The LOGIQ 500 with Harmonic Imaging is a mobile console approximately 53 cm wide, 94 cm deep and 130 cm high equipped with a keyboard control panel, small A/N display panel, color video display monitor, assorted transducers and optional image storage or hard-copy devices. Harmonic imaging enhances or highlights the imaging of nonlinear tissue characteristics and contrast media.

5. Indications for Use: The LOGIQ 500 with Harmonic Imaging is a general purpose ultrasound imaging system intended for use in the evaluation of soft tissue and vascular disease in the head, neck, chest, abdomen, pelvis, male and female reproductive organs, limbs and pregnant uterus. Specific indications are: fetal, abdominal, pediatric, small organ, cephalic, cardiac, transesophageal, transrectal, transvaginal, peripheral vascular, intra-operative, neurological, urological, and musculo-skeletal.

6. Comparison with Predicate Device: The GE LOGIQ 500 Diagnostic Ultrasound System with Harmonic Imaging is of a comparable type and substantially equivalent to the currently marketed GE LOGIQ 500. It has the same technological characteristics, is comparable in key safety and effectiveness features, uses the same design, construction, and materials, and has the same intended uses, operating modes and transducers as the predicate device.

Section b):

1. Non-clinical Tests: The device has been evaluated for acoustic output, biocompatibility, and thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards. Harmonic imaging is implemented with conventional digital image processing technology.

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 with 21 CFR 820 Quality System Regulation and ISO 9001 & EN 46001 quality system standards. The product is designed to conform with 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 500 with harmonic imaging is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



JUN 9 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Allen Schuh
Manager
GE Ultrasound Safety & Regulatory Engineering
General Electric Co.
GE Medical Systems, Inc.
P.O. Box 414
Milwaukee, Wisconsin 53201

Re: K991611
GE LOGIQ 500 (Harmonic Imaging)
Dated: May 7, 1999
Received: May 10, 1999

Dear Mr. Schuh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the LOGIQ 500 System as described in your premarket notification:

Transducer Model Number(s):

C358, S317 and S222

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Please be advised that the determination above is based on the fact that no medical devices have been demonstrated to be safe and effective for in vitro fertilization or percutaneous umbilical blood sampling, nor have any devices been marketed for these uses in interstate commerce prior to May 28, 1976, or reclassified into class I (General Controls) or class II (Special Controls). FDA considers devices specifically intended for in vitro fertilization and percutaneous umbilical blood sampling to be investigational, and subject to the provision of the investigational device exemptions (IDE) regulations, 21 CFR, Part 812. Therefore, your product labeling must be consistent with FDA's position on this use.

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

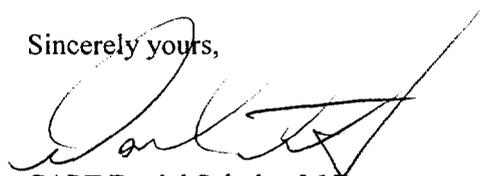
This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Page -3 – Mr, Allen Schuh

If you have any questions regarding the content of this letter, please contact Robert Phillips, Ph.D at (301) 594-1212.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Daniel Schultz", with a long, sweeping horizontal stroke extending to the right.

CAPT Daniel Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ 500 System

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	P		P	
Abdominal		P	P	P	P	P	P		P	
Intraoperative (specify)		P	P	P		P	P		P	
Intraoperative Neurological		P	P	P		P	P		P	
Pediatric		P	P	P	P	P	P		P	
Small Organ (specify)		P	P	P		P	P		P	
Neonatal Cephalic		P	P	P	P	P	P		P	
Adult Cephalic		P	P	P	P	P	P		P	
Cardiac		P	P	P	P	P	P		P	
Transesophageal		P	P	P	P	P	P		P	
Transrectal		P	P	P		P	P		P	
Transvaginal		P	P	P		P	P		P	
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P	P	P	P		P	
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		P	
Musculo-skeletal Superficial		P	P	P		P	P		P	
Other (specify)		P	P	P	P	P	P		P	

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

Additional Comments: Cardiac is Adult and Pediatric. Small organ includes breast, testes, thyroid.

Other includes urological. Combined modes are B/M, B/Color, B/PWD, B/Color/PWD, Color/M K970901

HARMONIC IMAGING

(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)

Rachael Pally
 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number K991611

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ 500 with S222 Transducer

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		E	E	E	E	E	E		E	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic		E	E	E	E	E	E		E	
Cardiac		E	E	E	E	E	E		E	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)		E	E	E	E	E	E		E	

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

Additional Comments: Other includes urology. Cardiac includes adult and pediatric.

Combined modes are B/M, B/Color, B/PWD, B/Color/PWD, Color/M K970901

Harmonic Imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Ra-C Paey
 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number K991611

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ 500 with S317 Transducer

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		P	P	P	P	P	P		P	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

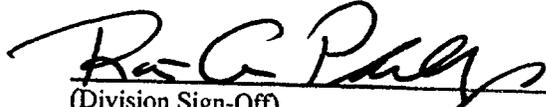
Additional Comments: Cardiac is Adult and Pediatric. Small organ includes breast, testes, thyroid.

Combined modes are B/M, B/Color, B/PWD, B/Color/PWD, Color/M K970901

HARMONIC IMAGING

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Concurrence of CDRH, Office of Device Evaluation (ODE)


 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number K991611

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