K993364

NOV - 5 1999

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: October 5, 1999

2. Device Name: GE LOGIQ 700 Diagnostic Ultrasound with coded excitation (CE) modification.
Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO

3. Marketed Device: GE Medical Systems LOGIQ 700 diagnostic ultrasound system, 510(k) Numbers K930768, K960527, K964617, K964886 and K990226, currently in commercial distribution.

4. Device Description: The GE LOGIQ 700 with CE is a mobile console approximately 70 cm wide, 120 cm deep and 120 cm high that provides full 128 channel capability and assorted probes. The user interface is an adjustable height keyboard, small A/N display panel and a color video display monitor. Optional image storage or hard-copy devices are integrated into the design. Coded Excitation is useful for enhancing B or M mode performance characteristics providing improved high frequency depth penetration without loss of spatial resolution.

5. Indications for Use: The GE LOGIQ 700 with CE 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; intraoperative abdominal and neurological; pediatric; small organ including breast, testes, thyroid; neonatal cephalic; cardiac adult and pediatric; TR; TV; PV; urological; and conventional and superficial musculo-skeletal.

6. Comparison with Predicate Device: The GE LOGIQ 700 Diagnostic Ultrasound System with CE is of a comparable type and substantially equivalent to the currently marketed GE LOGIQ 700. It has the same technological characteristics, is comparable in key safety and effectiveness features, uses the same basic design, construction, and materials, and has the same intended uses, operating modes and probes 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. Coded Excitation 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, ISO 9001 and EN 46001 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with 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 700 with CE is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 1999

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

Re: K993364
GE Logiq 700 Diagnostic Ultrasound System with Coded Excitation
Dated: October 5, 1999
Received: October 6, 1999
Regulatory class: II
21 CFR 892.1560/Procode: 90 IYO
21 CFR 892.1570/Procode: 90 ITX

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 Ultrasound Imaging and Doppler Fluid Flow Measurements of the Human Body, as described in your premarket notification:

Transducer Model Number

548c, M7c, 618e, 618c, 739L

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 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".

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

Sincerely yours,

for

CAPT. Daniel G. Schultz, M.D.
Acting 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 700 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	
Intraoperative (specify)		P	P	P		P	P		P	
Intraoperative Neurological		P	P	P		P	P		P	
Pediatric		P	P	P		P	P		P	
Small Organ (specify)		P	P	P		P	P		P	
Neonatal Cephalic		P	P	P		P	P		P	
Adult Cephalic										
Cardiac		P	P	P		P	P		P	
Transesophageal										
Transrectal		P	P	P		P	P		P	
Transvaginal		P	P	P		P	P		P	
Transuretheral										
Intravascular										
Peripheral Vascular		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	

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 is urological. Combined includes B/M, B/Color, B/PWD, B/Color/PWD, Color includes Color M, Intraoperative includes abdominal organs, added via K964886. Musculo-skeletal added via K960527 3D Imaging added via K964617. B-mode includes B-flow imaging K990226. Initial 510(k): K930768 B and M modes include coded excitation for limited probes and scan conditions.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legrom

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993364

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ 700 with 548c 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		P	P	P		P	P		P	
Abdominal		P	P	P		P	P		P	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		P	P	P		P	P		P	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transuretheral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)		P	P	P		P	P		P	

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

Additional Comments: Small organ includes breast, testes, thyroid. Other includes urological.

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

B and M modes include coded excitation (CE) capability.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993364

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ 700 with 618e 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		P	P	P		P	P		P	
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P		P	P		P	
Transvaginal		P	P	P		P	P		P	
Transuretheral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)		P	P	P		P	P		P	

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

Additional Comments: Combined modes are B/M, B/Color, B/PWD, B/Color/PWD

Other includes urological. B and M modes include coded excitation (CE) capability.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993364

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ 700 with 618c 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										
Intraoperative (specify)		P	P	P		P	P		P	
Intraoperative Neurological		P	P	P		P	P		P	
Pediatric		P	P	P		P	P		P	
Small Organ (specify)										
Neonatal Cephalic		P	P	P		P	P		P	
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transuretheral										
Intravascular										
Peripheral Vascular		P	P	P		P	P		P	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: Combined modes are B/M, B/Color, B/PWD, B/Color/PWD

Intraoperative includes abdominal organs. K964886

B and M modes include coded excitation (CE) capability.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993364

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ 700 with 739L 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		P	P	P		P	P		P	
Abdominal										
Intraoperative (specify)		P	P	P		P	P		P	
Intraoperative Neurological		P	P	P		P	P		P	
Pediatric		P	P	P		P	P		P	
Small Organ (specify)		P	P	P		P	P		P	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transuretheral										
Intravascular										
Peripheral Vascular		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	

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

Additional Comments: Small organ includes breast, testes, thyroid. Other includes urological.

Combined modes are B/M, B/Color, B/PWD, B/Color/PWD, Musculo-skeletal added via K960527

Intraoperative includes abdominal organs. K964886,

B and M modes include B-flow (K990226) with or without CE type coding.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Segmn

vision Sign-Off)
ision of Reproductive, Abdominal, ENT,
Radiological Devices
Number K993364

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ 700 with M7c 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		E	E	E		E	E		E	
Abdominal		E	E	E		E	E		E	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E	E		E	E		E	
Small Organ (specify)		E	E	E		E	E		E	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transuretheral										
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: Combined modes are B/M, B/Color, B/PWD, B/Color/PWD

Small organ my include breast and testes.

B and M modes include coded excitation (CE) capability.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993364

Prescription User (Per 21 CFR 801.109)