DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 29 1997

D. Duersteler
Technology Product Assurance
GE Medical Systems
General Electric Company
P.O. Box 414
Milwaukee, WI 53201

Re: K964886
GE LOGIQ 700 Diagnostic Ultrasound System
Dated: June 18, 1997
Received: June 19, 1997
Regulatory class: II
21 CFR 892.1550/Procode: 90 IYN
21 CFR 892.1570/Procode: 90 ITX

Dear Mr. Duersteler:

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 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. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the GE LOGIQ 700 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

618C	739I
LA39	739L
	739T

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 regulation (CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (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.

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 February 17, 1993 "Revised 510(k) Diagnostic Ultrasound Guidance for 1993." 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".

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

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K964886

JUL 29 1997

GE Medical Systems

510(k) Summary of Safety and Effectiveness: GE LOGIQ 700

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Identification of Submitter: GE Medical Systems
PO Box 414
Milwaukee, WI 53201

Contact : D. Duersteler
Safety/Regulatory Project Engineer
414-647-4385

Date Prepared: June 18, 1997

Product Identification: GE LOGIQ 700 diagnostic ultrasound system including intra-operative and neurosurgical uses.

Marketed Devices: The LOGIQ 700 with intra-operative and neurosurgical uses is of a comparable type and substantially equivalent to the GE Medical Systems LOGIQ 700 diagnostic ultrasound system, 510(k) Number K930768, currently in commercial distribution:

Device Description: The LOGIQ 700 including intra-operative and neurosurgical uses is the same in all other aspects as the currently marketed LOGIQ 700, consisting of a mobile console approximately 70 cm wide, 120 cm deep and 120 cm high that provides full 128 channel capability, and assorted transducers. 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.

Indications for Use: The GE LOGIQ 700 including intra-operative and neurosurgical uses is a general purpose ultrasound imaging system intended for use by or under the direction of a qualified physician for Diagnostic ultrasound imaging or Doppler analysis of the human body as follows: Fetal, Abdominal, Intra-operative of abdominal organs, Neurosurgical, Pediatric, Small Organ including breast, testes, thyroid, Neonatal Cephalic, Cardiac Adult, Cardic Pediatric, Trans-rectal, Trans-vaginal, and Peripheral vessel.

Comparison with Predicate Device: The LOGIQ 700 including intra-operative and neurosurgical uses is comparable in key safety and effectiveness features, uses the same design, construction, and materials, and has the same operating modes as the predicate device. The intended uses are the same except for the addition of intra-operative use.

Summary of Studies: 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.

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 GMP standards. The product is designed to conform with applicable medical device safety standards and compliance is verified through independent evaluation. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Medical Systems that the LOGIQ 700 including intra-operative uses is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

Ultrasound Device Indications Statement

510(k) Number (if known): K964886

Device Name: LOGIQ 700 **618C** Transducer

Fill out one form for each ultrasound system or transducer

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Opthalmic										
Fetal and Other										
Abdominal										
Intra-operative		X	X	X		X	X		X	
Neurosurgical		X	X	X		X	X		X	
Pediatric		X	X	X		X	X		X	
Small Organ (Specify)										
Neonatal Cephalic		X	X	X		X	X		X	
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Trans-esophageal										
Trans-rectal										
Trans-vaginal										
Intra-luminal										
Trans-urethral										
Peripheral vessel		X	X	X		X	X		X	
Laparoscopic										

Other Indications or Modes: Small organ includes breast, testes, thyroid. Intra-operative includes abdominal organs. Combined modes are B/M, B/Color, B/PWD, B/Color/PWD.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K964886