K040251

FEB 2 0 2004

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, Ultrasound and Primary Care Diagnostics, LLC
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: January 30, 2004

2. Device Name: GE LOGIQ 9 Diagnostic Ultrasound BT04,
Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO
Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN

3. Marketed Device: GE LOGIQ 9 Diagnostic Ultrasound System K011188/K030934/K032656
A device currently in commercial distribution.

4. Device Description: The GE LOGIQ 9 is a full featured general purpose diagnostic ultrasound system. It consists of a mobile console approximately 64 cm wide, 90 cm deep and 140-160 cm (adjustable) high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls and a color video CRT and LCD display. This modification will provide users with additional probe options, improved user interface and productivity.

5. Indications for Use: The device is intended for use by a qualified physician for ultrasound evaluation of 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); Transrectal; Transvaginal; and Intraoperative (abdominal, thoracic, vascular and neurosurgical).

6. Comparison with Predicate Device: The GE LOGIQ 9 BT04 is of a comparable type and substantially equivalent to the current GE LOGIQ 9 and GE Voluson. It has the same technological characteristics, key safety and effectiveness features, physical design, construction, and materials, and has 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 with 21 CFR 820, ISO 9001:2000 and ISO 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 9 BT04 Diagnostic Ultrasound 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

FEB 2 0 2004

Mr. Allen Schuh
Manager, GE Ultrasound Safety
and Regulatory Engineering
GE Medical Systems,
Ultrasound and Primary Care Diagnostics, LLC
4855 West Electric Avenue
MILWAUKEE WI 53219

Re: K040251
Trade Name: GE LOGIQ 9 Ultrasound System with BT04 Modification
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: Class II
Product Code: 90 IYN, IYO, and ITX
Dated: January 30, 2004
Received: February 3, 2004

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 9 Ultrasound System, as described in your premarket notification:

Transducer Model Number

4D3C

4D10L
4DE7C
P8D

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 (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 Part 807.97). Other general information on your responsibilities under the

Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C Brogdon

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

Enclosures

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ 9 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	
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	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	
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	
Exam Type, Means of Access											
Transesophageal											
Transrectal	P	P	P		P	P	P	P	P	P	
Transvaginal	P	P	P		P	P	P	P	P	P	
Transuretheral											
Intraoperative[5]	P	P	P		P	P	P	P	P	P	
Intraoperative Neurological	P	P	P		P	P	P	P	P	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, 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.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040251

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ 9 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											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes: [1] Abdominal includes renal, GYN/Pelvic

[*] 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)

Maryann Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040251

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ 9 with 4D10L 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]	N	N	N		N		N	N	N	N	
Pediatric	N	N	N		N		N	N	N	N	
Small Organ[2]	N	N	N		N		N	N	N	N	
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	N	N	N		N		N	N	N	N	
Musculo-skeletal Conventional	N	N	N		N		N	N	N	N	
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative	N	N	N		N		N	N	N	N	
Intraoperative Neurological	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.

[*] 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)

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

510(k) Number K040251

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ 9 with 4DE7C 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]											
Pediatric[6]	N	N	N		N		N	N	N	N	
Small Organ[2]											
Neonatal Cephalic[6]	N	N	N		N		N	N	N	N	
Adult Cephalic											
Cardiac[3]											
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	
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes: [4] Other use includes Urology/Prostate

[6] Probe used in surface scanning only

[*] 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)

Nancy C Brogdon

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

510(k) Number K040251

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ 9 with P8D 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	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular				N							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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

Notes:

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