

SEP 22 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: September 10, 1999

2. Device Names: GE Dasonics Gateway & Gateway FX Diagnostic Ultrasound with Harmonic Imaging Modification. Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN

3. Marketed Device: Dasonics Gateway & Gateway FX diagnostic ultrasound system, 510(k) Numbers K951998 and K961002, currently in commercial distribution.

4. Device Description: The GE Dasonics Gateway & Gateway FX with Harmonic Imaging are mobile consoles approximately 69 cm wide, 107 cm deep and 132 cm high equipped with a keyboard control panel, black and white video display monitor, 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 GE Dasonics Gateway & Gateway FX with Harmonic Imaging are general purpose ultrasound imaging systems 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: Ophthalmic, Fetal, Abdominal, Intraoperative, Small Organ, Neonatal Cephalic, Adult Cephalic, Cardiac, TR, TV, PV, and Musculo-skeletal Conventional & Superficial.

6. Comparison with Predicate Device: The GE Dasonics Gateway & Gateway FX with Harmonic Imaging are of a comparable type and substantially equivalent to the currently marketed Gateway or Gateway FX. They have the same technological characteristics, use the same design, construction and materials, are comparable in key safety and effectiveness features, and have 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 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 Dasonics Gateway & Gateway FX with harmonic imaging is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 22 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K993069
GE Diagnostics Gateway and Gateway FX Diagnostic Ultrasound System
Regulatory Class: II (TWO)
Product Code: 90-IYO and 90-ITX
21 CFR 892.1560
21 CFR 892.1570
Dated: September 10, 1999
Received: September 13, 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 GE Diagnostics Gateway and Gateway FX Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Numbers:

CLA/3.5MI/40

CLA/3.5MI/50-2D

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.

Page 2 – Mr. Allen Schuh

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:

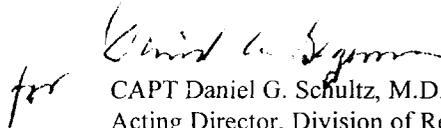
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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>".

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(s)

Diagnostic Ultrasound Indications for Use Form
GE Disonics Gateway and Gateway FX Systems

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		P	P	P		P	P		P	
Fetal		P	P	P		P	P		P	
Abdominal		P	P	P		P	P		P	
Intraoperative (specify)		P	P	P		P	P		P	
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		P	P	P		P	P		P	
Neonatal Cephalic		P	P	P		P	P		P	
Adult Cephalic		P	P	P		P	P		P	
Cardiac		P	P	P	P	P	P		P	
Transesophageal										
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)		N								

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

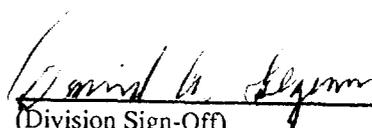
Additional Comments: Cardiac is Adult and Pediatric. Small Organ includes: breast, thyroid, testes and penis. Combined modes include B or M and Pulsed, Color or Power Doppler. Clearance via K951998.

Intraoperative (K961002) includes abdominal organs.

Harmonic Imaging (other feature) applies to CLA 3.5MI/40 & CLA 3.5/MI-50-2D probes in B mode only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K993069

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Diasonics Gateway and Gateway FX with CLA/3.5MI/40 Probe

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)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)		N								

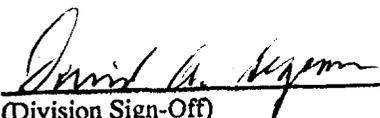
N= new indication; P= previously cleared by FDA via K951998; E= added under Appendix E

Additional Comments: Combined modes include B or M and Pulsed, Color or Power Doppler.

Harmonic Imaging (other feature) applies to B mode only.

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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 K993069

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Disonics Gateway FX with CLA/3.5M/50-2D Probe

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										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)		N								

N= new indication; P= previously cleared by FDA; E= added under Appendix E (24 OCT 1996)

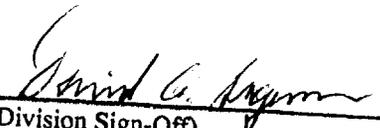
Additional Comments: Combined modes include B or M and Pulsed, Color or Power Doppler.

Harmonic Imaging (other feature) applies to B mode only.

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