FEB 2 3 2005 K050380

510(k) Summary of Safety and Effectiveness: 21 CFR 807.92

Submitter's Name: Toshiba America Medical Systems, Inc.
Address: PO Box 2068,2441 Michelle Drive Tustin, CA 92781-2068
Contact: Paul Biggins, Sr. Manager of Regulatory Affairs
Telephone No.: (714) 730-5000

Device Proprietary Name: SSA-660A, Xario Version 1.00
Common Name: Diagnostic Ultrasound System

Classification:

Regulatory Class: II
Review Category: Tier II

Ultrasonic Pulsed Doppler Imaging System – Product Code: 90-IYN
[Fed.Reg.No.:892.1550]
Ultrasonic Pulsed Echo Imaging System – Product Code: 90-IYO
[Fed.Reg.No.:892.1560]
Diagnostic Ultrasonic Transducer – Product Code: 90-ITX
[Fed. Reg. No.: 892.1570]

Identification of Predicate Devices:

Toshiba America Medical Systems believes that this device is substantially equivalent to:

1) Toshiba SSA-770A, Aplio Version 5.5 Diagnostic Ultrasound; 510(k) control number k041499

Device Description:

The Xario Ultrasound System is a mobile system. This system is a Track 3 device that employs a wide array of probes that include flat linear array, convex linear array, and sector array with a frequency range of approximately 2 MHz to 12 MHz.

Intended Use:

The Xario is intended to be used for the following type of studies; fetal, abdominal, pediatric, small organs, cardiac, transrectal, transvaginal, transesophageal, peripheral vascular and musculo-skeletal (both conventional and superficial).

Safety Considerations:

This device is designed and manufactured in conjunction with the Quality System Regulation, IEC 60601-1 (applicable portions), IEC 60601-1-2 (applicable portion), IEC60601-2-37 (applicable portions), and the AIUM-NEMA UD2 Output Measurement Standard as applied to Track 3 Ultrasound systems and the AIUM-NEMA UD3 Output Display Standard.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 3 2005

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K050380
Trade Name: XARIO Diagnostic Ultrasound System, Model SSA-660A
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: II
Product Code: 90 IYN, IYO, and ITX
Dated: February 11, 2005
Received: February 15, 2005

Dear Mr. Job:

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 XARIO Diagnostic Ultrasound System, Model SSA-660A, as described in your premarket notification:

Transducer Model Number

PVT-375BT
PVT-661VT

PLT-805AT
PLT-1204AT
PC-20M
PET-510MB
PST-30BT
PLT-704AT
PLT-604AT

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 (240) 276-0120. Also, please note the regulation entitled,

"Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

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

Sincerely yours,

David A. Lepmm

for Nancy C. Brogdon
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

System _X__ Transducer___
Model___SSA-660A_____
510(k) Number(s)

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI-Q
Ophthalmic												
Fetal	N	N	N		N	N	N	N	N			
Abdominal	N	N	N	N	N	N	N	N	N			
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric	N	N	N	N	N	N	N	N	N			
Small Organ (Specify)*	N	N	N		N	N	N	N	N			
Neonatal Cephalic												
Adult Cephalic												
Cardiac	N	N	N	N	N	N	N	N	N	N	N	N
Transesophageal	N	N	N	N	N	N	N	N	N	N		N
Transrectal	N	N	N		N	N	N	N	N			
Transvaginal	N	N	N		N	N	N	N	N			
Transurethral												
Intravascular												
Peripheral Vascular	N	N	N		N	N	N	N	N			
Laparoscopic												
Musculo-skeletal Superficial	N	N	N		N	N	N	N	N			
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N			

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

* : For example: thyroid, parathyroid, breast, scrotum and penis

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)11

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050380

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer _X_
Model ___PVT-375BT_____
510(k) Number(s)

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI-Q
Ophthalmic												
Fetal	N	N	N		N	N	N	N	N			
Abdominal	N	N	N		N	N	N	N	N			
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric	N	N	N		N	N	N	N	N			
Small Organ (Specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

Previous 510(k) for this device k013633

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050380

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer _X_
Model PVT-661VT
510(k) Number(s)

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI-Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal	N	N	N		N	N	N	N	N			
Transvaginal	N	N	N		N	N	N	N	N			
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050380

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer _X_
Model PLT-805AT
510(k) Number(s)

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI-Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)	N	N	N		N	N	N	N	N			
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular	N	N	N		N	N	N	N	N			
Laparoscopic												
Musculo-skeletal Superficial	N	N	N		N	N	N	N	N			
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N			

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050380

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer _X_
Model PLT-1204AT
510(k) Number(s)

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI-Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)	N	N	N		N	N	N	N	N			
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular	N	N	N		N	N	N	N	N			
Laparoscopic												
Musculo-skeletal Superficial	N	N	N		N	N	N	N	N			
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N			

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050380

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer _X_
Model PC-20M
510(k) Number(s)

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI-Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric				N								
Small Organ (Specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac				N								
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050380

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer _X_
Model PET-510MB
510(k) Number(s)

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI-Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal	N	N	N	N	N	N	N	N	N	N		N
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050380

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer _X_
Model PST-30BT
510(k) Number(s)

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q
Ophthalmic												
Fetal												
Abdominal	N	N	N	N	N	N	N	N	N			
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric	N	N	N	N	N	N	N	N	N			
Small Organ (Specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac	N	N	N	N	N	N	N	N	N	N	N	N
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

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Division of Reproductive, Abdominal, and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

510(k) Number K050380

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer _X_
Model PLT-704AT
510(k) Number(s)

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)	N	N	N		N	N	N	N	N			
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular	N	N	N		N	N	N	N	N			
Laparoscopic												
Musculo-skeletal Superficial	N	N	N		N	N	N	N	N			
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N			

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

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Prescription Use (Per 21 CFR 801.109)

David A. Lyon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050380

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer _X_
Model___PLT-604AT_____
510(k) Number(s)
_____

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)	N	N	N		N	N	N	N	N			
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular	N	N	N		N	N	N	N	N			
Laparoscopic												
Musculo-skeletal Superficial	N	N	N		N	N	N	N	N			
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N			

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Legrow
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050380