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.



FEB 2 3 2005

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

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 <u>Federal Register</u>.

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,

Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

System X Transducer	
Model SSA-660A	
510(k) Number(s)	

		Mode of Operation												
Clinical Application	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI- Q		
Ophthalmic											ļ			
Fetal	N	Z	N		N	N	N	N	N		ļ	ļ		
Abdominal	Z	Ν	N	N	N	N	N	N	N			<u> </u>		
Intraoperative (Specify)											ļ	ļ		
Intraoperative Neurological														
Pediatric	N	N	N	Z	N	N	N	N	N					
Small Organ (Specify)*	N	N	Z		N	N	N	N	N					
Neonatal Cephalic									:					
Adult Cephalic				,								ļ		
Cardiac	N	N	N	Z	N	N	N	N	N	N	N	N		
Transesophageal	N	N	Z	N	N	N	N	N	N	N		N		
Transrectal	N	Ν	Z		N	N	N	N	N					
Transvaginal	N	N	N		N	N	N	N	N					
Transurethral														
Intravascular												ļ		
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; BI	DF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;	
CHI/2D; FEI/2D; CHI/BDI	F; FEI/BDF	
*: For example: thyroid, par	rathyroid, breast, scrotum and penis	

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Prescription Use (Per 21 CFR 801.109)11

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Division of Reproductive, Abdominal,

and Radiological Devices

System Transducer X	
Model PVT-375BT	
510(k) Number(s)	

	Mode of Operation													
Clinical Application	В	М	P W	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI- Q		
Ophthalmic														
Fetal	Z	N	Z		N	N	N	N	N	1				
Abdominal	N	N	Z		N	N	N	N	N					
Intraoperative (Specify)														
Intraoperative Neurological														
Pediatric	N	Ν	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 1	Modes: B/M; B	<u>/PWD;</u>	
BDF/PWD; BDF/MDF; B	DF/MDF/PWD;B	-TDI; M-TDI;	2D/CWD; BDF/CWD:	, 1
CHI/2D; FEI/2D; CHI/BI	OF; FEI/BDF			-
Previous 510(k) for this	device k013633			

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Prescription Use (Per 21 CFR 801.109)

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		Mode of Operation													
Clinical Application	В	М	P C W V D D	Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI Q				
Ophthalmic					1										
Fetal															
Abdominal															
Intraoperative (Specify)															
Intraoperative Neurological															
Pediatric															
Small Organ (Specify)															
Neonatal Cephalic				1											
Adult Cephalic															
Cardiac			$\neg \vdash$												
Transesophageal															
Transrectal	N	N	N	N	N	N	N	N							
Transvaginal	N	N	N	N	N	N	N	N							
Transurethral					-										
Intravascular			1						***						
Peripheral Vascular															
Laparoscopic										***·					
Musculo-skeletal															
Superficial															
Musculo-skeletal															
Conventional															
N= new indication;	P =	Pr	eviou	sly Cleare	ed by FDA;	E = Adc	led under	Appendix I	E (LTF)						
Additional Comme BDF/PWD; BDF/N CHI/2D; FEI/2D; G	<u>1DF;</u>	BD	F/M	DF/PWD;				F/CWD;							

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal, and Radiological Devices

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

		Mode of Operation													
Clinical Application	В	М	P W D	O N D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI- Q			
Ophthalmic												†			
Fetal												†			
Abdominal				П							<u> </u>	1			
Intraoperative (Specify)									·		-	ł			
Intraoperative Neurological						••••••••••••••••••••••••••••••••••••••									
Pediatric								† 		~ ~		 			
Small Organ (Specify)	N	N	N		N	N	N	N	N			·			
Neonatal Cephalic															
Adult Cephalic												 			
Cardiac															
Transesophageal															
Transrectal								731.2		*************					
Transvaginal			$\neg \uparrow$		1							<u> </u>			
Transurethral					~~										
Intravascular			一		7.17							 -			
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;
CHV2D; FEV2D; CHVBDF; FEVBDF

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and Radiological Devices

						V	Mode o	f Operati	on			
Clinical Application	В	M	P W D	, ,	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RS1	TDI Q
Ophthalmic	_	1	-				mugnig				 	
Fetal	+				1 7017							
Abdominal			 									
Intraoperative (Specify)		\vdash										
Intraoperative Neurological												-
Pediatric	7				-						<u> </u>	
Small Organ (Specify)	N	N	N		N	N	N	N	N			-
Neonatal Cephalic		ļ									<u> </u>	
Adult Cephalic												-
Cardiac										······································		
Transesophageal						"						<u> </u>
Transrectal												<u> </u>
Transvaginal												<u> </u>
Transurethral	\top			1								
Intravascular						77						<u> </u>
Peripheral Vascular	N	N	N		N	N	N	N	N			
Laparoscopic				$\neg \uparrow$								
Musculo-skeletal	N	N	N		N	N	N	N	N			
Superficial												
Musculo-skeletal	Z	N	N		N	N	N	N	N			
Conventional N= new indication;			1							_		

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Prescription Use (Per 21 CFR 801.109)

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and Radiological Devices

		Mode of Operation													
	+						lviode o	Operau	ION		<u> </u>	<u> </u>			
Clinical Application	В	M	P W D	C W D	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	1	H	i	N		<u> </u>	·····	-							
Small Organ (Specify)			-												
Neonatal Cephalic	$\dagger -$			T											
Adult Cephalic	+		\neg	-											
Cardiac	1		Ì	N											
Transesophageal	\dagger		1	7											
Transrectal	\Box		$\neg \uparrow$						•			 -			
Transvaginal		1	1	1											
Transurethral	† †		\neg	_											
Intravascular			_	\dashv											
Peripheral Vascular				+											
Laparoscopic				-											
Musculo-skeletal	1 1	1		1											
Superficial			-												
Musculo-skeletal						***									
Conventional				l						İ	ĺ				
N= new indication; Additional Comment BDF/PWD; BDF/MI CHI/2D; FEI/2D; CI	s: DF;	BD	F/N	<u>C</u>	ombined F/PWD;E	Modes: B/I	M; B/PWI	Э;		E (LTF)	_				
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Prescription Use (Per		Co	ncur	ren	ce of CDRH	, Office of Dev	ice Evaluatio	(Division Si	gn-Off) Reproductiv	Ly 1 mm ve, Abdomir					

	Mode of Operation												
Clinical Application	В	М	P W D		Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI Q	
Ophthalmic												 -	
Fetal								1				-	
Abdominal		L										_	
Intraoperative (Specify)											<u> </u>	 	
Intraoperative	-								· · · · · · · · · · · · · · · · · · ·	 -			
Neurological													
Pediatric	<u> </u>			\rightarrow									
Small Organ (Specify)													
Neonatal Cephalic		Ш											
Adult Cephalic	\perp			_	·	·							
Cardiac	_												
Transesophageal	N	N	N	N	N	N	N	N	N	N		N	
Transrectal				_									
Transvaginal	1			_									
Transurethral											-		
Intravascular													
Peripheral Vascular		[
Laparoscopic													
Musculo-skeletal	11	1											
Superficial	1-1		\perp										
Musculo-skeletal		- 1											
Conventional										İ			
N= new indication; Additional Commen BDF/PWD; BDF/M CHI/2D; FEI/2D; C	ts: DF;]	BD	F/M	<u>Co</u>	ombined VPWD;E	Modes: B/l	М: B/PWГ).		C(LTF)			
											 		
Prescription Use (Per		Co	ncur	renc	e of CDRH	is Line - Contin , Office of Dev	ice Evaluatio (Div Divis	ision Sign-Cadiological	Off) roductive, A	ymn_ Abdominal,		, ' <u>, , , , , , , , , , , , , , , , , ,</u>	

510(k) Number__

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

Clinical Application		Mode of Operation												
	В	М	P W D		Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RS1	TDI-Q		
Ophthalmic			}					<u> </u>						
Fetal									77.					
Abdominal	N	N	N	N	N	N	N	N	N					
Intraoperative (Specify)														
Intraoperative Neurological														
Pediatric	N	N	N	N	N	N	N	N	N			<u> </u>		
Small Organ (Specify)														
Neonatal Cephalic								_						
Adult Cephalic												<u></u>		
Cardiac	N	N	Ν	N	N	N	N	N	N	N	N	Ñ		
Transesophageal								-						
Transrectal														
Transvaginal	\prod													
Transurethral														
Intravascular														
Peripheral Vascular				\Box		****								
Laparoscopic														
Musculo-skeletal			1		·									
Superficial										İ		ŀ		
Musculo-skeletal														
Conventional							ľ	Ī		Ī				

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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510(k) Number ______

Prescription Use (Per 21 CFR 801.109)

Clinical Application	. [- 1	Mode of Operation												
11	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-(
Ophthalmic	+	1	_	_			2111261118	7.1.11				<u> </u>			
Fetal		1							-						
Abdominal	1	\top				7 787 7		1							
Intraoperative (Specify)	\top	\dashv	\neg	\neg						· · · · · · · · · · · · · · · · · · ·					
Intraoperative Neurological					,										
Pediatric	1	7													
Small Organ (Specify)	V	N	N		N	N	N	N	N						
Neonatal Cephalic		7			ĺ				··-						
Adult Cephalic		T													
Cardiac	T	丁									-				
Transesophageal		7					1.6.4								
Transrectal		T		T											
Transvaginal		\top									······································				
Transurethral	1	1													
Intravascular	T	1	T												
Peripheral Vascular	1	٧Ì	N		N	N	N	N	N.						
Laparoscopic	1	+	\dashv												
	1 1	7	N		N	N	N	N	N						
	1	1	N	\top	N	N	N	N	N						
Conventional	- 1	- 1			1	i				1		'			

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ad Radiological Devices

	Mode of Operation												
Clinical Application	В	М	P W D	W	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-0	
Ophthalmic	1	 					illuging						
Fetal		 -						 					
Abdominal												ļ	
ntraoperative (Specify)	1				———								
ntraoperative	1												
Veurological		ĺ											
Pediatric Pediatric													
Small Organ (Specify)	N	N	N		N	N	N	N	N			<u> </u>	
Neonatal Cephalic													
Adult Cephalic													
Cardiac							······································						
`ransesophageal					-								
ransrectal							·····						
ransvaginal										~			
ransurethral													
ntravascular													
eripheral Vascular	N	N	N		N	N	N	N	N				
aparoscopic	1												
Iusculo-skeletal	N	N	N		N	N	N	N	N				
uperficial Iusculo-skeletal	N	Ŋ	N		N	N	N	N	N				
onventional	'`	'`	17		14	14	14	14	N	1			
N= new indication;	<u> Р</u> –	Pre	evi		y Cleare	d by FDA:	E = 4dd	lad undar A	nnondiu I	7 (I 'min')			
Additional Commen BDF/PWD; BDF/MI CHI/2D; FEI/2D; C	ts: DF;	BD	F/I	C MD	ombined F/PWD;I	Modes: B/	M; B/PWI	<u>);</u>					
	(PLEA	SE O	O NO	T WP	ITE BELOW?	HIS LINE - CONTIN	THE ON OTHER !	DACED IN NOVES	D)				
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Prescription Use (Per	: 21	CF	R 8	801.	109)	Divisio	on Sign-Off on of Reprod	luctive, Abo	y y m lominal	<u>~</u>			

510(k) Number