JUN 17 2005

K 051500

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-530A, FAMIO
Common Name: Diagnostic Ultrasound System

Classification:

Regulatory Class: II
Review Category: Tier II

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 NEMIO SSA-550A, Diagnostic Ultrasound; 510(k) control numbers are K010631 and K043078.

Device Description:

The FAMIO SSA-530A Diagnostic 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 and convex array with a frequency range of approximately 3.75MHz to 12MHz.

Intended Use:

The FAMIO SSA-530A is intended to be used for the following type of studies; fetal, abdominal, intraoperative, pediatric, small organs, neonatal cephalic, cardiac, transrectal, transvaginal, 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), 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

JUN 17 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: K051500
Trade Name: FAMIO Diagnostic Ultrasound System, Model SSA-530A
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasound transducer
Regulatory Class: II
Product Code: IYO and ITX
Dated: June 4, 2005
Received: June 7, 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 FAMIO Diagnostic Ultrasound System, Model SSA-530A, as described in your premarket notification:

Transducer Model Number

PVQ-375A
PVQ-641V
PLQ-805A
PLQ-1203A
PVQ-662A
PLF-308P
PVQ-381A

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 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/industry/support/index.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

Enclosure(s)

Diagnostic Ultrasound Indications For Use Form

System _X_ Transducer___
Model___SSA-530A_____
510(k) Number(s)
_____

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

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

Additional Comments: Combined Modes: B/M;

* Tissue Harmonic Imaging does not use contrast agents
** Abdominal
*** 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

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051500

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X
Model PVQ-375A
510(k) Number(s)

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Tissue Harmonic Imaging*
Ophthalmic									
Fetal	N	N						N	N
Abdominal	N	N						N	N
Intraoperative (Specify)									
Intraoperative Neurological									
Pediatric	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

* Tissue Harmonic Imaging does not use contrast agents

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510(k) Number K051500

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer _X_
Model___PVQ-641V_____
510(k) Number(s)

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Tissue Harmonic Imaging
Ophthalmic									
Fetal									
Abdominal									
Intraoperative (Specify)									
Intraoperative Neurological									
Pediatric									
Small Organ (Specify)									
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transesophageal									
Transrectal	N	N						N	
Transvaginal	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

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✓ Prescription Use (Per 21 CFR 801.109)

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510(k) Number K031500

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X
Model___ PLQ-805A
510(k) Number(s)

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

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Additional Comments: Combined Modes: B/M

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510(k) Number K051500

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X
Model PLQ-1203A
510(k) Number(s)

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

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Additional Comments: Combined Modes: B/M;

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510(k) Number K051500

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X
Model PVQ-662A
510(k) Number(s)

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

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Additional Comments: Combined Modes: B/M

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510(k) Number K057500

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X
Model PLF-308P
510(k) Number(s)

Clinical Application	Mode of Operation									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Tissue Harmonic Imaging	
Ophthalmic										
Fetal										
Abdominal	N	N						N		
Intraoperative (Specify)	N	N						N		
Intraoperative Neurological										
Pediatric	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

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510(k) Number K051500

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X
Model PVQ-381A
510(k) Number(s)

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

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Additional Comments: Combined Modes: B/M

* Tissue Harmonic Imaging does not use contrast agents

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