

510(k) Summary

K093171

Submitter's Name: Toshiba America Medical Systems, Inc. **DEC - 4 2009**
Address: PO Box 2068, 2441 Michelle Drive Tustin, CA 92781-2068
Contact: Paul Biggins, Director Regulatory Affairs
Telephone No.: (714) 730-5000

Device Proprietary Name: VIAMO MODEL SSA-640A Version 1.2
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:

- Toshiba Ultrasound Diagnostic System Aplio XG MODEL SSA-790A V4.0 - 510(k)
K091295

Device Description:

The Viamo is a mobile system. It is a Track 3 device that employs a wide range of probes that include flat linear array, convex array and sector array with a frequency range of approximately 2.5 MHz to 7.5 MHz.

Intended Use:

The Viamo SSA-640 v1.2 Ultrasound System is indicated for the visualization of structures, characteristics, and dynamic processes with the human body using ultrasound and to provide image information for diagnosis in the following clinical applications: fetal, abdominal, pediatric, small organs, neonatal cephalic, adult cephalic, cardiac, peripheral vascular, and musculo-skeletal (both conventional and superficial).

Declaration of Conformity:

This device is designed and manufactured in conjunction with the Quality System Regulation, IEC 60601-1 (applicable portions), IEC 60601-1-1 (applicable portion), IEC 60601-1-2 (applicable portion), IEC 60601-1-4 (applicable portion), IEC60601-2-37 (applicable portions), IEC 62304 (applicable portion) 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
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

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

DEC - 4 2009

Re: K093171

Trade/Device Name: VIAMO SSA-640 v1.2 Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: November 19, 2009
Received: November 20, 2009

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 VIAMO SSA-640 v1.2 Ultrasound System, as described in your premarket notification:

Transducer Model Number

PST-25ST
PVT-375ST
PLT-704ST
PLT-805AT
PVT-382BT

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.

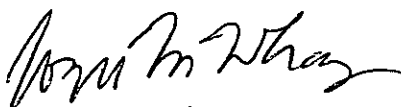
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,


for Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

510(k) Number (if known): K093171

Device Name: Viamo SSA-640 v1.2 Ultrasound System

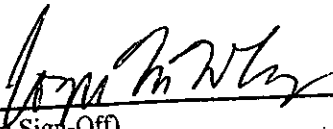
Indications for Use:

The Viamo SSA-640 v1.2 Ultrasound System is indicated for the visualization of structures, characteristics, and dynamic processes within the human body using ultrasound and to provide image information for diagnosis in the following clinical applications: fetal, abdominal, pediatric, small organs, neonatal cephalic, adult cephalic, cardiac, peripheral vascular and musculo-skeletal (both conventional and superficial).

Prescription Use Only (Per 21 CFR801.109)

(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,
and Radiological Devices

510(k) Number

K093171

System: Viamo v1.2 SSA-640A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:


Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal	N	N	N		N	2	N		N			
Abdominal	N	N	N		N	2	N		N			
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N		N	2	N		N			
Small Organ (Note 1)	N	N	N		N	2	N		N			
Neonatal Cephalic	N	N	N		N	2	N		N			
Adult Cephalic	N	N	N		N	2	N		N			
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	N	N	N		N	2	N		N			
Musculo-skeletal (Superficial)	N	N	N		N	2	N		N			
Intravascular												
Other (Specify)												
Cardiac Adult	N	N	N		N	2	N		N			
Cardiac Pediatric	N	N	N		N	2	N		N			
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	N	N	N		N	2	N		N			
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer:

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K093171

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Viamo (v1.2) SSA-640A Ultrasound System

System: Viamo v1.2 SSA-640A

Transducer: PST-25ST

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

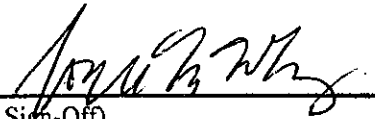
Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	N	N	N		N	2	N		N			
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N		N	2	N		N			
Small Organ (Note 1)												
Neonatal Cephalic	N	N	N		N	2	N		N			
Adult Cephalic	N	N	N		N	2	N		N			
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult	N	N	N		N	2	N		N			
Cardiac Pediatric	N	N	N		N	2	N		N			
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

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

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093171

System: Viamo v1.2 SSA-640ATransducer: PVT-375ST

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

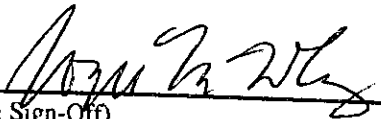
Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal	N	N	N		N	2	N		N			
Abdominal	N	N	N		N	2	N		N			
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N		N	2	N		N			
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

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

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Prescription Use Only (Per 21 CFR801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K093171

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Viamo (v1.2) SSA-640A Ultrasound System

System: Viamo v4.0 SSA-640A

Transducer: PLT-704ST

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

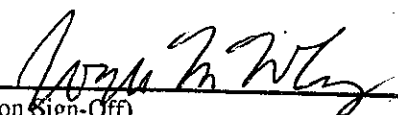
Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify *)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	N	N	N		N	2	N		N			
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	N	N	N		N	2	N		N			
Musculo-skeletal (Superficial)	N	N	N		N	2	N		N			
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	N	N	N		N	2	N		N			
Other (Specify)												

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

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Prescription Use Only (Per 21 CFR801.109)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093171

System: Viamo v1.2 SSA-640A
Transducer: PLT-805AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

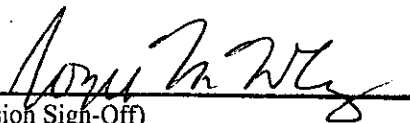
Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P		P			
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P		P			
Musculo-skeletal (Superficial)	P	P	P		P	P	P		P			
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P		P	2	P		P			
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K091295

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Prescription Use Only (Per 21 CFR801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K093191

System: Viamo v1.2 SSA-640A
Transducer: PVT-382BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal	P	P	P		P	2	P		P			
Abdominal	P	P	P		P	2	P		P			
Intra-operative (Abdominal)									P			
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P		P			
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

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Previous 510(k) of the transducer: K091295

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Prescription Use Only (Per 21 CFR801.109)

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