



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Toshiba Medical Systems Corporation
Mr. Charlemagne Chua
Manager, Regulatory Affairs
2441 Michelle Drive
TUSTIN CA 92780

August 28, 2015

Re: K131507
Trade/Device Name: Xario 200 TUS-X200 and TUS-X200S, v1.0
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: May 22, 2013
Received: May 30, 2013

Dear Mr. Chua:

This letter corrects our substantially equivalent letter of August 28, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Xario 200 TUS-X200 and TUS-X200S, v1.0, as described in your premarket notification:

Transducer Model Number

PSU-25BT	PSU-30BT	PSU-50BT
PVU-375BT	PVU-382BT	PVU-674MV
PVU-712BT	PVU-745BTV	PVU-770ST
PLU-704BT	PET-512MC	PC-20M

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert A. Ochs". The signature is written in a cursive style. Behind the signature, there is a faint, semi-transparent watermark of the FDA logo.

Robert Ochs, Ph.D.
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131507

Device Name: Xario 200 TUS-X200 and TUS-X200S, v1.0

Indications For Use:

The **Diagnostic Ultrasound System Xario 200 Model TUS-X200 and TUS-X200S** are indicated for the visualization of structures, and dynamic processes with the human body using ultrasound and to provide image information for diagnosis in the following clinical applications: fetal, abdominal, intra-operative (abdominal), pediatric, small organs, trans-vaginal, trans-rectal, neonatal cephalic, adult cephalic, cardiac (both adult and pediatric), peripheral vascular, transesophageal, and musculo-skeletal (both conventional and superficial).

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)



(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostic and Radiological Health

510(k): K131507

System: Xario 200 TUS-X200,TUS-X200S V1.0

Transducer: _____

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

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Advanced Dynamic Flow	Power	CHI	4D	Other [Note]
Ophthalmic												
Fetal	N	N	N		N	2	N	N	N		N	5,6,7,8
Abdominal	N	N	N	N	N	2,3	N	N	N		N	5,6,7,8
Intra-operative (Abdominal)	N	N	N		N	2	N	N	N			5,6,7,8
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N	N	N	2,3	N	N	N		N	5,6,7,8
Small Organ (Note 1)	N	N	N		N	2	N	N	N			5,6,7,8
Neonatal Cephalic	N	N	N	N	N	2,3	N	N	N			5,6,7,8
Adult Cephalic	N	N	N	N	N	3	N	N	N			7
Trans-rectal	N	N	N		N	2	N	N	N			5,6,7,8
Trans-vaginal	N	N	N		N	2	N	N	N			5,6,7,8
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	N	N	N		N	2	N	N	N			5,6,7,8
Musculo-skeletal (Superficial)	N	N	N		N	2	N	N	N			5,6,7,8
Intravascular												
Other (Specify)												
Cardiac Adult	N	N	N	N	N	3	N	N	N	N		4, 7
Cardiac Pediatric	N	N	N	N	N	3	N	N	N	N		4, 7
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	N	N	N	N	N	3	N					4, 7
Intra-cardiac												
Other (Specify)												
Peripheral vascular	N	N	N	N	N	2	N	N	N			5,6,7,8
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

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 ApliPure Plus

Note 7 Precision Imaging

Note 8 Differential THI

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V1.0

Transducer: PSU-25BT

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	Advanced Dynamic Flow	Power	CHI	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	N	N	N	N	N	3	N	N	N			7
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N	N	N	3	N	N	N			7
Small Organ (Specify) (1)												
Neonatal Cephalic	N	N	N	N	N	3	N	N	N			7
Adult Cephalic	N	N	N	N	N	3	N	N	N			7
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	N	3	N	N	N	N		4, 7
Cardiac Pediatric	N	N	N	N	N	3	N	N	N	N		4, 7
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vascular												
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

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 ApliPure Plus

Note 7 Precision Imaging

Note 8 Differential THI

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V1.0

Transducer: PSU-30BT

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	Advanced Dynamic Flow	Power	CHI	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	N	N	N	N	N	3	N	N	N			7
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N	N	N	3	N	N	N			7
Small Organ (Specify) (1)												
Neonatal Cephalic	N	N	N	N	N	3	N	N	N			7
Adult Cephalic	N	N	N	N	N	3	N	N	N			7
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	N	3	N	N	N	N		4, 7
Cardiac Pediatric	N	N	N	N	N	3	N	N	N	N		4, 7
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vascular												
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

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 ApliPure Plus

Note 7 Precision Imaging

Note 8 Differential THI

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V1.0

Transducer: PSU-50BT

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	Advanced Dynamic Flow	Power	CHI	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	N	N	N	N	N	3	N	N	N			7
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N	N	N	3	N	N	N			7
Small Organ (Specify) (1)												
Neonatal Cephalic	N	N	N	N	N	3	N	N	N			7
Adult Cephalic	N	N	N	N	N	3	N	N	N			7
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	N	3	N	N	N	N		4, 7
Cardiac Pediatric	N	N	N	N	N	3	N	N	N	N		4, 7
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vascular												
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

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 ApliPure Plus

Note 7 Precision Imaging

Note 8 Differential THI

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V1.0
 Transducer: PVU-375BT

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	Advanced Dynamic Flow	Power	CHI	4D	Other [Note]
Ophthalmic												
Fetal	N	N	N		N	2	N	N	N			5,6,7,8
Abdominal	N	N	N		N	2	N	N	N			5,6,7,8
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N		N	2	N	N	N			5,6,7,8
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 vascular												
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

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 ApliPure Plus

Note 7 Precision Imaging

Note 8 Differential THI

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V1.0
Transducer: PVU-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	Advanced Dynamic Flow	Power	CHI	4D	Other [Note]
Ophthalmic												
Fetal	N	N	N		N	2	N	N	N			5,6,7,8
Abdominal	N	N	N		N	2	N	N	N			5,6,7,8
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N		N	2	N	N	N			5,6,7,8
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 vascular												
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

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 ApliPure Plus

Note 7 Precision Imaging

Note 8 Differential THI

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V1.0
 Transducer: PVU-674MV

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	Advanced Dynamic Flow	Power	CHI	4D	Other [Note]
Ophthalmic												
Fetal	N	N	N		N	2	N	N	N		N	5,6,7,8
Abdominal	N	N	N		N	2	N	N	N		N	5,6,7,8
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N		N	2	N	N	N		N	5,6,7,8
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 vascular												
Other (Specify)												

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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

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 ApliPure Plus

Note 7 Precision Imaging

Note 8 Differential THI

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V1.0

Transducer: PVU-712BT

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	Advanced Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	N	N	N		N	2	N	N	N			5,6,7,8
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N		N	2	N	N	N			5,6,7,8
Small Organ (Specify) (1)												
Neonatal Cephalic	N	N	N		N	2	N	N	N			5,6,7,8
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 vascular												
Other (Specify)												

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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

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 ApliPure Plus

Note 7 Precision Imaging

Note 8 Differential THI

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V1.0
 Transducer: PVU-745BTV

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	Advanced Dynamic Flow	Power	CHI	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	N	N	N		N	2	N	N	N			5,6,7,8
Intra-operative (Abdominal)	N	N	N		N	2	N	N	N			5,6,7,8
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	N	N	N		N	2	N	N	N			5,6,7,8
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 vascular												
Other (Specify)												

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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

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 ApliPure Plus

Note 7 Precision Imaging

Note 8 Differential THI

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V1.0

Transducer: PVU-770ST

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	Advanced Dynamic Flow	Power	CHI	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal	N	N	N		N	2	N	N	N			5,6,7,8
Trans-vaginal	N	N	N		N	2	N	N	N			5,6,7,8
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 vascular												
Other (Specify)												

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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

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 ApliPure Plus

Note 7 Precision Imaging

Note 8 Differential THI

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V1.0

Transducer: PLU-704BT

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	Advanced Dynamic Flow	Power	CHI	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	N	N	N		N	2	N	N	N			5,6,7,8
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	N	N	N		N	2	N	N	N			5,6,7,8
Musculo-skeletal (Superficial)	N	N	N		N	2	N	N	N			5,6,7,8
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vascular	N	N	N		N	2	N	N	N			5,6,7,8
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

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 ApliPure Plus

Note 7 Precision Imaging

Note 8 Differential THI

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V1.0

Transducer: PET-512MC

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	Advanced Dynamic Flow	Power	CHI	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
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)	N	N	N	N	N	3	N					4, 7
Intra-cardiac												
Other (Specify)												
Peripheral vascular												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducer: 123992

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

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 ApliPure Plus

Note 7 Precision Imaging

Note 8 Differential THI

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V1.0

Transducer: PC-20M

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	Advanced Dynamic Flow	Power	CHI	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
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				N								
Cardiac Pediatric				N								
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vascular				N								
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducer: K123992

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

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 ApliPure Plus

Note 7 Precision Imaging

Note 8 Differential THI

Prescription Use Only (Per 21 CFR 801.109)

510(k) SUMMARY

1. SUBMITTER'S NAME:

Toshiba America Medical Systems, Inc.

2. ADDRESS:

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3. ESTABLISHMENT REGISTRATION:

2020563

4. CONTACT PERSON:

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(714) 669-7896

5. U.S AGENT:

Paul Biggins
Director, Regulatory Affairs
(714) 730-5000

6. Date Prepared:

May 22, 2013

7. TRADE NAME(S):

Diagnostic Ultrasound System
Xario 200 Model TUS-X200 and TUS-X200S, SW V1.0

8. COMMON NAME:

System, Diagnostic Ultrasound

9. DEVICE CLASSIFICATION:

Class II
Ultrasonic Pulsed Doppler Imaging System – Product Code: 90-IYN [per 21 CFR 892.1550]
Ultrasonic Pulsed Echo Imaging System – Product Code: 90-IYO [per 21 CFR 892.1560]
Diagnostic Ultrasonic Transducer – Product Code: 90-ITX [per 21 CFR 892.1570]

10. PREDICATE DEVICE:

Product	Marketed by	510(k) Number	Clearance Date
Aplio 500/400/300 Diagnostic Ultrasound System V3.0	Toshiba America Medical Systems	K123992	February 6, 2013

11. REASON FOR SUBMISSION:

New device.

12. DEVICE DESCRIPTION:

The Xario 200 Model TUS-X200 and TUS-X200S are mobile diagnostic ultrasound systems. These systems are Track 3 devices that employ a wide array of probes including flat linear array, convex linear array, and sector array with frequency ranges between approximately 2 MHz to 7.5 MHz.

13. SUMMARY OF INTENDED USES:

The **Diagnostic Ultrasound System Xario 200 Model TUS-X200 and TUS-X200S** are indicated for the visualization of structures, and dynamic processes with the human body using ultrasound and to provide image information for diagnosis in the following clinical applications: fetal, abdominal, intra-operative (abdominal), pediatric, small organs, trans-vaginal, trans-rectal, neonatal cephalic, adult cephalic, cardiac (both adult and pediatric), peripheral vascular, transesophageal, and musculo-skeletal (both conventional and superficial).

14. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the Aplio 500/400/300 Diagnostic Ultrasound System, K123922, marketed by Toshiba America Medical Systems. The **Xario 200 Model TUS-X200 and TUS-X200S, SW Version 1.0**, functions in a manner similar to and is intended for the same use as the predicate device. The subject device is a compact diagnostic ultrasound system by implementing latest technologies.

A comparison table is included in this submission detailing the similarities and differences between the predicate device and the subject device.

15. SAFETY:

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the IEC60601-1 (2005), IEC 60601-2-37 (2007), IEC 62304 (2006), AIUM RTD2-2004 Output Display and ISO 10993-1 standards.

16. TESTING

Risk Analysis, Verification/Validation testing conducted through bench testing which are included in this submission demonstrates that the requirements for the features have been met.

Software Documentation for a Moderate Level of Concern, per the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document" issued on May 11, 2005, is also included as part of this submission.

Additionally, testing of this device was conducted in accordance with the applicable standards published by the International Electrotechnical Commission (IEC) for Medical Devices.