



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

Toshiba Medical Systems Corporation
% Mr. Orlando Tadeo, Jr.
Manager, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

November 19, 2014

Re: K143046
Trade/Device Name: Xario 100, V3.0 (Models: TUS-X100 and TUS-X100S)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN
Dated: October 21, 2014
Received: October 22, 2014

Dear Mr. Tadeo:

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 100 TUS-X100, TUS-X100S V3.0 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

PSU-25BT	PSU-30BT	PSU-50BT
PVU-375BT	PVU-382BT	PVU-674BT
PVU-674MV	PVU-712BT	PVU-745BTF
PVU-745BTH	PVU-745BTV	PVU-681MVL
PVU-770ST	PVU-781VT	PVL-715RS
PLU-704BT	PLU-1005BT	PLU-1204BT
PET-512MC	PET-805LA	PC-20M
PC-50M		

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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, large watermark of the letters "FDA" in a light gray color.

for

Janine M. Morris
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)

K143046

Device Name

Xario 100 TUS-X100 and TUS-X100S, V3.0

Indications for Use (Describe)

The Diagnostic Ultrasound System Xario 100 Model TUS-X100 and Xario 100 Model TUS-X100S 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), laparoscopic, pediatric, small organs, neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional), musculo-skeletal (superficial), cardiac adult, cardiac pediatric, trans-esoph (cardiac) and peripheral vessel.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

System: Xario 100 TUS-X100, TUS-X100S V3.0

Transducer: _____

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	P	P	P		P	2	P	P	P		P	4,5,6,7,8
Abdominal	P	P	P	P	P	2,3	P	P	P		P	4,5,6,7,8
Intra-operative (Abdominal)	N	N	N		N	2	N	N	N			5,6,7,8
Intra-operative (Neuro)												
Laparoscopic	N	N	N		N	2	N	N	N			5,7
Pediatric	P	P	P	P	P	2,3	P	P	P		P	4,5,6,7,8
Small Organ (Note 1)	P	P	P		P	2	P	P	P			4,5,6,7,8,9,10
Neonatal Cephalic	P	P	P	P	P	3	P	P	P			5,6,7,8
Adult Cephalic	P	P	P	P	P	3	P	P	P			7
Trans-rectal	P	P	P		P	2	P	P	P		N	4,5,6,7,8
Trans-vaginal	P	P	P		P	2	P	P	P		N	4,5,6,7,8
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P			4,5,6,7,8,9,10
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			4,5,6,7,8,9,10
Intravascular												
Other (Specify)												
Cardiac Adult	P	P	P	P	P	3	P	P	P			4, 7
Cardiac Pediatric	P	P	P	P	P	3	P	P	P			4, 7
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	N	N	N	N	N	3	N					4,7
Intra-cardiac												
Other (Specify)												
Peripheral vascular	P	P	P	N	P	2	P	P	P			4,5,6,7,8,9,10
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

Note 9 Elastography

Note 10 BEAM

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100, TUS-X100S V3.0
 Transducer: PSU-25BT

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												
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 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

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

Note 9 Elastography

Note 10 BEAM

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100.TUS-X100S V3.0

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	P	P	P	P	P	3	P	P	P			7
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P	P	P	3	P	P	P			7
Small Organ (Specify) (1)												
Neonatal Cephalic	P	P	P	P	P	3	P	P	P			7
Adult Cephalic	P	P	P	P	P	3	P	P	P			7
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult	P	P	P	P	P	3	P	P	P			4, 7
Cardiac Pediatric	P	P	P	P	P	3	P	P	P			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
 Previous 510(k) of the transducers: K133277

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

Note 9 Elastography

Note 10 BEAM

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100, TUS-X100S V3.0

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 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

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

Note 9 Elastography

Note 10 BEAM

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100,TUS-X100S V3.0

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	P	P	P		P	2	P	P	P			4,5,6,7,8
Abdominal	P	P	P		P	2	P	P	P			4,5,6,7,8
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			4,5,6,7,8
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
Previous 510(k) of the transducers: K133277

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

Note 9 Elastography

Note 10 BEAM

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100, TUS-X100S V3.0
 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 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

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

Note 9 Elastography

Note 10 BEAM

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100, TUS-X100S V3.0
 Transducer: PVU-674BT

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 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

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

Note 9 Elastography

Note 10 BEAM

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100,TUS-X100S V3.0

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	P	P	P		P	2	P	P	P		P	5,6,7,8
Abdominal	P	P	P		P	2	P	P	P		P	5,6,7,8
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P		P	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
 Previous 510(k) of the transducers: K133277

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

Note 9 Elastography

Note 10 BEAM

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100, TUS-X100S V3.0

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 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

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

Note 9 Elastography

Note 10 BEAM

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100, TUS-X100S V3.0

Transducer: PVU-745BTF

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 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

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

Note 9 Elastography

Note 10 BEAM

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100, TUS-X100S V3.0

Transducer: PVU-745BTH

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 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

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

Note 9 Elastography

Note 10 BEAM

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100, TUS-X100S V3.0

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 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

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

Note 9 Elastography

Note 10 BEAM

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100, TUS-X100S V3.0

Transducer: PVU-681MVL

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		N	5,6,7,8
Trans-vaginal	N	N	N		N	2	N	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 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

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

Note 9 Elastography

Note 10 BEAM

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100, TUS-X100S V3.0

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			4,5,6,7,8
Trans-vaginal	N	N	N		N	2	N	N	N			4,5,6,7,8
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 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

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

Note 9 Elastography

Note 10 BEAM

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100,TUS-X100S V3.0

Transducer: PVU-781VT

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

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducers: K133277

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

Note 9 Elastography

Note 10 BEAM

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100, TUS-X100S V3.0

Transducer: PVL-715RS

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												
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

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

Note 9 Elastography

Note 10 BEAM

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100,TUS-X100S V3.0

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)	P	P	P		P	2	P	P	P			5,6,7,8,10
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P			5,6,7,8,10
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,6,7,8,10
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vascular	P	P	P		P	2	P	P	P			5,6,7,8,10
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducers: K133277

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

Note 9 Elastography

Note 10 BEAM

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100,TUS-X100S V3.0
Transducer: PLU-1005BT

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												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			4,5,6,7,8,9,10
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P			4,5,6,7,8,9,10
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			4,5,6,7,8,9,10
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vascular	P	P	P		P	2	P	P	P			4,5,6,7,8,9,10
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducers: K133277

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

Note 9 Elastography

Note 10 BEAM

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100, TUS-X100S V3.0

Transducer: PLU-1204BT

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												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	N	N	N		N	2	N	N	N			4,5,6,7,8,9,10
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			4,5,6,7,8,9,10
Musculo-skeletal (Superficial)	N	N	N		N	2	N	N	N			4,5,6,7,8,9,10
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	N			4,5,6,7,8,9,10
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

Note 9 Elastography

Note 10 BEAM

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100, TUS-X100S V3.0
 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 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

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

Note 9 Elastography

Note 10 BEAM

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100, TUS-X100S V3.0
 Transducer: PET-805LA

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													
Intra-operative (Abdominal)													
Intra-operative (Neuro)													
Laparoscopic	N	N	N		N	2	N	N	N				5,7
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)													
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

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

Note 9 Elastography

Note 10 BEAM

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100, TUS-X100S V3.0
 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 vessel				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

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

Note 9 Elastography

Note 10 BEAM

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100, TUS-X100S V3.0
 Transducer: PC-50M

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 vessel				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

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

Note 9 Elastography

Note 10 BEAM

Prescription Use Only (Per 21 CFR 801.109)

510(k) SUMMARY

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5. Date Prepared:

October 21, 2014

6. TRADE NAME(S):

Diagnostic Ultrasound System
Xario100 Model TUS-X100 V3.0
Xario100 Model TUS-X100S V3.0

7. COMMON NAME:

System, Diagnostic Ultrasound

8. 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]

9. PREDICATE DEVICE:

Product	Marketed by	510(k) Number	Clearance Date
Xario100 Model TUS-X100, TUS-X100S, v1.0	Toshiba America Medical Systems	K133277	January 17,2014
MicroMaxx High Resolution Ultrasound System (C3 Series)	SonoSite, Inc.	K053069	February 24, 2006

10. REASON FOR SUBMISSION:

Modification of a cleared device

11. DEVICE DESCRIPTION:

The Xario100 Model TUS-X100 and Model TUS-X100S 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 12 MHz.

12. INDICATIONS FOR USE:

The **Diagnostic Ultrasound System Xario100 Model TUS-X100 and Xario100 Model TUS-X100S** 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), laparoscopic, pediatric, small organs, neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional), musculo-skeletal(superficial), cardiac adult, cardiac pediatric, trans-esoph(cardiac) and peripheral vessel.

13. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the Xario100 V1.0 Diagnostic Ultrasound System, 510(k) cleared under K133277, marketed by Toshiba America Medical Systems. The **Xario100 Model TUS-X100 Version 3.0 and Xario100 Model TUS-X100S Version 3.0** functions in a manner similar to and is intended for the same use as the predicate devices referenced within this submission.

Modifications include:

The introduction of a feature called BEAM which improves needle visualization during biopsy procedures.

Addition of transducers that are either already in the market or that are similar to transducers already in the market with regard to technological characteristics to include a laparoscopic transducer.

Addition of Laparoscopic, Intra-Operative (Abdominal) and Trans-esoph. (Cardiac) Use to the systems indications for use.

14. 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 60601-1-2:2007, IEC 60601-2-37 (2007), IEC 62304 (2006), AIUM RTD2-2004 Output Display and ISO 10993-1 standards.

15. TESTING

Design Control Activities including risk management following the ISO14971, verification/validation testing and Acoustic Output testing (UD3, 2004) were conducted and included in this submission. This documentation includes testing which demonstrates that the requirements for the features have been met.

Performance Testing – Bench

A study was conducted to compare an existing imaging mode with the needle enhancement feature and confirmed that the subject device improves needle visualization.

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 the modified system was conducted in accordance with the applicable standards published by the International Electrotechnical Commission (IEC) for Medical Devices.

16. CONCLUSION

The modifications incorporated into the **Xario100 Model TUS-X100 Version 3.0** and **Xario100 Model TUS-X100S Version 3.0** do not change the intended use of the device. Based upon bench testing, successful completion of software validation, application of risk management and design controls, it is concluded that this device is safe and effective for its intended use.