



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

December 12, 2017

Re: K172276

Trade/Device Name: Xario 200 Diagnostic Ultrasound System V6.0
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: July 26, 2017
Received: July 28, 2017

Dear Orlando 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.

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

 For

Robert A. 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)

K172276

Device Name

Xario 200 Diagnostic Ultrasound System V6.0

Indications for Use (Describe)

The Diagnostic Ultrasound System Xario 200 Model TUS-X200 and Xario 200 Model 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), 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 200 TUS-X200,TUS-X200S V6.0

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	4,5,6,7,8,9,11,12
Abdominal	P	P	P	P	P	2,3	P	P	P		P	4,5,6,7,8,9,11,12,14
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			5,6,7,8,11
Intra-operative (Neuro)												
Laparoscopic	P	P	P		P	2	P	P	P			5,7
Pediatric	P	P	P	P	P	2,3	P	P	P		P	4,5,6,7,8,9,11,12
Small Organ (Note 1)	P	P	P		P	2	P	P	P			4,5,6,7,8,9,10,11,12
Neonatal Cephalic	P	P	P	P	P	2,3	P	P	P			5,6,7,8,11
Adult Cephalic	P	P	P	P	P	3	P	P	P			7
Trans-rectal	P	P	P		P	2	P	P	P		P	4,5,6,7,8,9,12
Trans-vaginal	P	P	P		P	2	P	P	P		P	4,5,6,7,8,9,12
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P			4,5,6,7,8,9,10,11,12
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			4,5,6,7,8,9,10,11,12
Intravascular												
Other (Specify)												
Cardiac Adult	P	P	P	P	P	3	P	P	P			4, 7, 13(N)
Cardiac Pediatric	P	P	P	P	P	3	P	P	P			4, 7, 13(N)
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	P	P	P	P	P	3	P					4, 7, 13(N)
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P	P	P	2	P	P	P			4,5,6,7,8,9,10,11,12
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0

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	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 (Note 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, 13(N)
Cardiac Pediatric	P	P	P	P	P	3	P	P	P			4, 7, 13(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
Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0

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 (Note 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, 13(N)
Cardiac Pediatric	P	P	P	P	P	3	P	P	P			4, 7, 13(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
Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0
 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	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 (Note 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, 13(N)
Cardiac Pediatric	P	P	P	P	P	3	P	P	P			4, 7, 13(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
 Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0

Transducer: PSU-70BT

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 (Note 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, 13(N)
Cardiac Pediatric	P	P	P	P	P	3	P	P	P			4, 7, 13(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
 Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0
 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			4,5,6,7,8,9,11,12
Abdominal	P	P	P		P	2	P	P	P			4,5,6,7,8,9,11,12,14
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			4,5,6,7,8,9,11,12
Small Organ (Note 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
 Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0

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	P	P	P		P	2	P	P	P			5,6,7,8,11
Abdominal	P	P	P		P	2	P	P	P			5,6,7,8,11
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			5,6,7,8,11
Small Organ (Note 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 transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0

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	P	P	P		P	2	P	P	P			5,6,7,8,11,12
Abdominal	P	P	P		P	2	P	P	P			5,6,7,8,11,12
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			5,6,7,8,11,12
Small Organ (Note 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
 Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0

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 (Note 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 transducers: K143027

- Note 1 Small organ includes thyroid, breast and testicle.
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- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
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- Note 8 Differential THI
- Note 9 Elastography
- Note 10 BEAM
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0

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	P	P	P		P	2	P	P	P			5,6,7,8,11
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			5,6,7,8,11
Small Organ (Note 1)												
Neonatal Cephalic	P	P	P		P	2	P	P	P			5,6,7,8,11
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
 Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0

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	P	P	P		P	2	P	P	P			5,6,7,8,11
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			5,6,7,8,11
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Note 1)	P	P	P		P	2	P	P	P			5,6,7,8,11
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
 Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0

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	P	P	P		P	2	P	P	P			5,6,7,8,11
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			5,6,7,8,11
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Note 1)	P	P	P		P	2	P	P	P			5,6,7,8,11
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
 Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0
 Transducer: PVU-745BTU

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	2	P	P	P			5,6,7,8,11
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			5,6,7,8,11
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Note 1)	P	P	P		P	2	P	P	P			5,6,7,8,11
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
 Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0

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 (Note 1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal	P	P	P		P	2	P	P	P		P	5,6,7,8,12
Trans-vaginal	P	P	P		P	2	P	P	P		P	5,6,7,8,12
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
 Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0

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 (Note 1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal	P	P	P		P	2	P	P	P			4,5,6,7,8,9
Trans-vaginal	P	P	P		P	2	P	P	P			4,5,6,7,8,9
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
 Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0

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	Advanced Dynamic Flow	Power	CHI>	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Note 1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal	P	P	P		P	2	P	P	P			4,5,6,7,8,9,12
Trans-vaginal	P	P	P		P	2	P	P	P			4,5,6,7,8,9,12
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
 Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0

Transducer: PVU-781VTE

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 (Note 1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal	P	P	P		P	2	P	P	P			4,5,6,7,8,9,12
Trans-vaginal	P	P	P		P	2	P	P	P			4,5,6,7,8,9,12
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
 Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0
 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 (Note 1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal	P	P	P		P	2	P	P	P			5,6,7,8,12
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
 Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0
 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 (Note 1)	P	P	P		P	2	P	P	P			5,6,7,8,10,11,12
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			5,6,7,8,10,11,12
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,6,7,8,10,11,12
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	P			5,6,7,8,10,11,12
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0

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	Advanced Dynamic Flow	Power	CHI	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Note 1)	P	P	P		P	2	P	P	P			4,5,6,7,8,9,10,11,12
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			4,5,6,7,8,9,10,11,12
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			4,5,6,7,8,9,10,11,12
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	P			4,5,6,7,8,9,10,11,12
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0

Transducer: PLU-1202BT

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)	N	N	N		N	2	N	N	N			5,6,7,8,11
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Note 1)	N	N	N		N	2	N	N	N			4,5,6,7,8,9,11,12
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			4,5,6,7,8,9,11,12
Musculo-skeletal (Superficial)	N	N	N		N	2	N	N	N			4,5,6,7,8,9,11,12
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			4,5,6,7,8,9,11,12
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0
 Transducer: PLU-1204BT

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 (Note 1)	P	P	P		P	2	P	P	P			4,5,6,7,8,9,10,11,12
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			4,5,6,7,8,9,10,11,12
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			4,5,6,7,8,9,10,11,12
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	P			4,5,6,7,8,9,10,11,12
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0

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 (Note 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)	P	P	P	P	P	3	P					4, 7, 13(N)
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0

Transducer: PET-512MD

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 (Note 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)	P	P	P	P	P	3	P					4, 7, 13(N)
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

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

Previous 510(k) of the transducers: N/A

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

Note 11 Smart 3D

Note 12 SMI

Note 13 2D Wall Motion Tracking

Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0

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	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic	P	P	P		P	2	P	P	P			5,7
Pediatric												
Small Organ (Note 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
 Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0

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 (Note 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				P								
Cardiac Pediatric				P								
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel				P								
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 200 TUS-X200, TUS-X200S V6.0

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 (Note 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				P								
Cardiac Pediatric				P								
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel				P								
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducers: K143027

- 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
- Note 11 Smart 3D
- Note 12 SMI
- Note 13 2D Wall Motion Tracking
- Note 14 Shear Wave

Prescription Use Only (Per 21 CFR 801.109)

510(k) SUMMARY**1. SUBMITTER'S NAME:**

Toshiba Medical Systems Corporation
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2. OFFICIAL CORRESPONDENT

Naofumi Watanabe

3. ESTABLISHMENT REGISTRATION:

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4. CONTACT PERSON:

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5. Date Prepared:

July 25, 2017

6. TRADE NAME(S):

Xario 200 Diagnostic Ultrasound System V6.0

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
Xario200, V5.0 (Models: TUS-X200 and TUS-X200S)	Toshiba America Medical Systems	K162155	October 14, 2016

10. REASON FOR SUBMISSION:

Modification of a cleared device

11. DEVICE DESCRIPTION:

The Xario200 Model TUS-X200 and Model 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 12 MHz.

12. INDICATIONS FOR USE:

The Diagnostic Ultrasound System Xario 200 Model TUS-X200 and Xario 200 Model 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), 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 Xario200 V5.0 Diagnostic Ultrasound System, 510(k) cleared under K162155, marketed by Toshiba America Medical Systems. The **Xario 200 Model TUS-X200 Version 6.0 and Xario200 Model TUS-X200S Version 6.0** functions in a manner similar to and is intended for the same use as the predicate devices referenced within this submission. The subject device includes modifications to the cleared device which improves upon existing features. Also, new features determined to be substantially equivalent to features cleared under the predicate devices referenced within this submission. A comparison table is included in this submission which details the similarities and differences between the predicate devices and the subject device.

	Xario 200 Model TUS-X200, TUS-X200S v5.0	Xario 200 Model TUS-X200 and TUS-X200S v6.0	Comment
510(K) Control Number	K162155 (Predicate Device)	N/A (Subject Device)	
Uninterruptible Power Supply (UPS)	Not Available	Available	New UPS
PLU-1202BT	Not Available	Available	New transducer

Previously cleared software options being implemented to the subject device:

Application	510(k) Clearance	Comments
Tissue Specific Optimization	Previously cleared under K151451	No change from previous clearance
2D Wall Motion Tracking	Previously cleared under K151451	No change from previous clearance
Shear wave	Previously cleared under K151451	No change from previous clearance. Available on TUS-X200 only
SMI Color	c-SMI previously cleared under K162155	SMI available on TUS-X200 only
Monochrome	m-SMI previously cleared under K151451	Addition of monochrome mapping

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, IEC 60601-1-2, IEC 60601-2-37, IEC 62304, AIUM RTD2-2004 Output Display and ISO 10993-1 standards.

15. TESTING

Design Control Activities including risk management following ISO14971, verification/validation testing and Acoustic Output testing (UD3, 2004) were conducted and included in this submission.

Performance Testing – Clinical Images

Representative clinical images of volunteers were obtained and it was concluded that the 2D WMT implemented on the subject device performs as intended in comparison to the predicate software. More specifically, 2D WMT enables the cardiac wall trace (initial contour setting), the local wall motion tracking and provides wall motion information analysis and display, cardiac volume measurement, and cardiac function analysis.

Performance Testing – Bench

Bench testing was done using an elasticity phantom to demonstrate that the implementation of Shear Wave onto the subject device performed as expected including measurement quantification accuracy and precision. As concluded in the study, Shear Wave performed as intended.

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 **Xario 200 Model TUS-X200 Version 6.0** and **Xario200 Model TUS-X200S Version 6.0** do not change the intended use of the device. Based upon bench testing, acquisition of representative clinical images, 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.