K133277
Page 1 of 3

## 510(k) SUMMARY

JAN 17 2014

1. **SUBMITTER'S NAME:**
   Toshiba America Medical Systems, Inc.

2. **ADDRESS:**
   2441 Michelle Drive
   Tustin, CA. 92780-2068

3. **ESTABLISHMENT REGISTRATION:**
   2020563

4. **CONTACT PERSON:**
   Charlemagne Chua
   Manager, Regulatory Affairs
   (714) 669-7896

5. **U.S AGENT:**
   Paul Biggins
   Director, Regulatory Affairs
   (714) 730-5000

6. **Date Prepared:**
   October 23, 2013

7. **TRADE NAME(S):**
   Diagnostic Ultrasound System
   Xario 100 Model TUS-X100 and TUS-X100S, SW V1.0

8. **COMMON NAME:**
   System, Diagnostic Ultrasound

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

10. **PREDICATE DEVICE:**

| Product | Marketed by | 510(k) Number | Clearance Date |
|---|---|---|---|
| Xario 200 (TUS-X200 and TUS-X200S), v1.0 | Toshiba America Medical Systems | K131507 | August 28, 2013 |

## 11. REASON FOR SUBMISSION:

New device.

## 12. DEVICE DESCRIPTION:

The Xario 100 Model TUS-X100 and 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, and sector array with frequency ranges between approximately 3 MHz to 10 MHz.

## 13. SUMMARY OF INTENDED USES:

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

## 14. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the Xario 200 Diagnostic Ultrasound System, K131507, marketed by Toshiba America Medical Systems. The **Xario 100 Model TUS-X100 and TUS-X100S, SW Version 1.0**, functions in a manner similar to and is intended for the same use as the predicate device. The subject device is a compact diagnostic ultrasound system by implementing latest technologies.

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

## 15. SAFETY:

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

## 16. TESTING

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

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 17, 2014

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

Re: K133277
Trade/Device Name: Xario 100, TUS-X100 and TUS-X100S V1.0
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: October 23, 2013
Received: October 24, 2013

Dear Mr. Chua:

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 and Xario 100 TUS-X100S Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

| | | |
|---|---|---|
| PSU-30BT | PVU-375BT | PVU-674MV |
| PVU-781VT | PLU-704BT | PLU-1005BT |

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
*See PRA Statement on last page.*

510(k) Number *(if known)*
K133277

Device Name
Xario 100 TUS-X100 and TUS-X100S, v1.0

Indications for Use *(Describe)*

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

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)*

System: Xario 100 TUS-X100.TUS-X100S V1.0
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 | N | N | N | | N | 2 | N | N | N | | N | 5,6,7,8 |
| Abdominal | N | N | N | N | N | 2,3 | N | N | N | | N | 5,6,7,8 |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | N | N | N | N | N | 2,3 | N | N | N | | N | 5,6,7,8 |
| Small Organ (Note 1) | N | N | N | | N | 2 | N | N | N | | | 5,6,7,8,9 |
| 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 | N | N | N | | N | 2 | N | N | N | | | 4,5,7 |
| Trans-vaginal | N | N | N | | N | 2 | N | N | N | | | 4,5,7 |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | N | N | N | | N | 2 | N | N | N | | | 5,6,7,8,9 |
| Musculo-skeletal (Superficial) | N | N | N | | N | 2 | N | N | N | | | 5,6,7,8,9 |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | N | N | N | N | N | 3 | N | N | N | | | 4, 7 |
| Cardiac Pediatric | N | N | N | N | N | 3 | N | N | N | | | 4, 7 |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vascular | N | N | N | | N | 2 | N | N | N | | | 5,6,7,8,9 |
| 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

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100,TUS-X100S V1.0
Transducer: PSU-30BT

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

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

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

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 ApliPure Plus
Note 7 Precision Imaging
Note 8 Differential THI
Note 9 Elastography

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100,TUS-X100S V1.0
Transducer: PVU-375BT

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

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

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

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 ApliPure Plus
Note 7 Precision Imaging
Note 8 Differential THI
Note 9 Elastography

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100,TUS-X100S V1.0
Transducer: PVU-674MV

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

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

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

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100,TUS-X100S V1.0
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 | N | N | N | | N | 2 | N | N | N | | | 4.5.7 |
| Trans-vaginal | N | N | N | | N | 2 | N | N | N | | | 4.5.7 |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

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

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 ApliPure Plus
Note 7 Precision Imaging
Note 8 Differential THI
Note 9 Elastography

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100,TUS-X100S V1.0
Transducer: PLU-704BT

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

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

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

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 ApliPure Plus
Note 7 Precision Imaging
Note 8 Differential THI
Note 9 Elastography

Prescription Use Only (Per 21 CFR 801.109)

System: Xario 100 TUS-X100,TUS-X100S V1.0
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) | N | N | N | | N | 2 | N | N | N | | | 5,6,7,9 |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | N | N | N | | N | 2 | N | N | N | | | 5,6,7,9 |
| Musculo-skeletal (Superficial) | N | N | N | | N | 2 | N | N | N | | | 5,6,7,9 |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vascular | N | N | N | | N | 2 | N | N | N | | | 5,6,7,9 |
| 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

Prescription Use Only (Per 21 CFR 801.109)