Canon Medical Systems Corporation
Orlando Tadeo, Jr.
Sr. Manager, Regulatory Affairs
2441 Michelle Drive
TUSTIN, CA 92780

November 2, 2018

Re: K182596
Trade/Device Name: Xario200G and Xario100G, Software V1.1 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: September 18, 2018
Received: September 20, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Michael D. O'Hara 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182596

Device Name

Xario200G and Xario100G, Software V1.1 Diagnostic Ultrasound System

Indications for Use *(Describe)*

The Diagnostic Ultrasound System Xario200G Model CUS-X200G and Xario100G Model CUS-X100G 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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PRAStaff@fda.hhs.gov

"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: Xario200G and Xario100G, Software V1.1
Transducer: _____

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		N	4,5,6,7,8,9,11,12
Abdominal	N	N	N	N	N	2,3	N	N	N		N	4,5,6,7,8,9,11,12,14
Intra-operative (Abdominal)	N	N	N		N	2	N	N	N			5,6,7,8,11
Intra-operative (Neuro)												
Laparoscopic	N	N	N		N	2	N	N	N			5,7
Pediatric	N	N	N	N	N	2,3	N	N	N		N	4,5,6,7,8,9,11,12
Small Organ (Note 1)	N	N	N		N	2	N	N	N			4,5,6,7,8,9,10,11,12
Neonatal Cephalic	N	N	N	N	N	2,3	N	N	N			5,6,7,8,11
Adult Cephalic	N	N	N	N	N	3	N	N	N			7
Trans-rectal	N	N	N		N	2	N	N	N		N	4,5,6,7,8,9,12
Trans-vaginal	N	N	N		N	2	N	N	N		N	4,5,6,7,8,9,12
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (**Conventional**)	N	N	N		N	2	N	N	N			4,5,6,7,8,9,10,11,12
Musculo-skeletal (**Superficial**)	N	N	N		N	2	N	N	N			4,5,6,7,8,9,10,11,12
Intravascular												
Other (Specify)												
Cardiac Adult	N	N	N	N	N	3	N	N	N			4, 7, 13
Cardiac Pediatric	N	N	N	N	N	3	N	N	N			4, 7, 13
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	N	N	N	N	N	3	N					4, 7, 13
Intra-cardiac												
Other (Specify)												
Peripheral vessel	N	N	N	N	N	2	N	N	N			4,5,6,7,8,9,10,11,12
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
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: Xario200G and Xario100G, Software V1.1
Transducer: PSU-25BT

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	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
Cardiac Pediatric	P	P	P	P	P	3	P	P	P			4, 7, 13
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: K172276

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: Xario200G and Xario100G, Software V1.1
Transducer: PSU-30BT

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	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
Cardiac Pediatric	P	P	P	P	P	3	P	P	P			4, 7, 13
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: K172276

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: Xario200G and Xario100G, Software V1.1
Transducer: PSU-50BT

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	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
Cardiac Pediatric	P	P	P	P	P	3	P	P	P			4, 7, 13
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

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Previous 510(k) of the transducers: K172276

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: Xario200G and Xario100G, Software V1.1
Transducer: PSU-70BT

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	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
Cardiac Pediatric	P	P	P	P	P	3	P	P	P			4, 7, 13
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

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Previous 510(k) of the transducers: K172276

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: Xario200G and Xario100G, Software V1.1
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	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: K172276

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: Xario200G and Xario100G, Software V1.1
Transducer: PVU-382BT

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	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: K172276

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
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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: Xario200G and Xario100G, Software V1.1
Transducer: PVU-674BT

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	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)												

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Previous 510(k) of the transducers: K172276

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
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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: Xario200G and Xario100G, Software V1.1
Transducer: PVU-674MV

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	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												
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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: K172276

Note 1 Small organ includes thyroid, breast and testicle.
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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: Xario200G and Xario100G, Software V1.1
Transducer: PVU-712BT

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 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: K172276

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: Xario200G and Xario100G, Software V1.1
Transducer: PVU-745BTF

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	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: K172276

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: Xario200G and Xario100G, Software V1.1
Transducer: PVU-745BTH

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	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: K172276

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: Xario200G and Xario100G, Software V1.1
Transducer: PVU-745BTV

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	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: K172276

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: Xario200G and Xario100G, Software V1.1
Transducer: PVU-681MVL

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 (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: K172276

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: Xario200G and Xario100G, Software V1.1
Transducer: PVU-770ST

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 (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: K172276

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: Xario200G and Xario100G, Software V1.1
Transducer: PVU-781VT

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 (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: K172276

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: Xario200G and Xario100G, Software V1.1
Transducer: PVU-781VTE

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 (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: K172276

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: Xario200G and Xario100G, Software V1.1
Transducer: PVL-715RS

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 (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: K172276

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: Xario200G and Xario100G, Software V1.1
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 (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: K172276

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: Xario200G and Xario100G, Software V1.1
Transducer: PLU-1005BT

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 (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: K172276

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: Xario200G and Xario100G, Software V1.1
Transducer: PLU-1202BT

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)	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			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**)	P	P	P		P	2	P	P	P			4,5,6,7,8,9,11,12
Musculo-skeletal (**Superficial**)	P	P	P		P	2	P	P	P			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	P	P	P		P	2	P	P	P			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: K172276

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: Xario200G and Xario100G, Software V1.1
Transducer: PLU-1204BT

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 (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: K172276

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: Xario200G and Xario100G, Software V1.1
Transducer: PET-512MC

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 (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
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: K172276

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: Xario200G and Xario100G, Software V1.1
Transducer: PET-512MD

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 (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
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: Xario200G and Xario100G, Software V1.1
Transducer: PET-805LA

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**	**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: K172276

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: Xario200G and Xario100G, Software V1.1
Transducer: PC-20M

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 (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: K172276

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: Xario200G and Xario100G, Software V1.1
Transducer: PC-50M

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 (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: K172276

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
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Note 7 Precision Imaging
Note 8 Differential THI
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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)

K182596

510(k) SUMMARY

1. **SUBMITTER'S NAME:**
   Canon Medical Systems Corporation
   1385 Shimoishigami
   Otawara-shi, Tochigi-ken, Japan 324-8550

2. **OFFICIAL CORRESPONDENT**
   Naofumi Watanabe

3. **ESTABLISHMENT REGISTRATION:**
   9614698

4. **CONTACT PERSON:**
   Orlando Tadeo, Jr.
   Sr. Manager, Regulatory Affairs
   Canon Medical Systems USA, Inc
   2441 Michelle Drive
   Tustin, CA 92780
   (714) 669-7459

5. **DATE PREPARED:**
   September 7, 2018

6. **DEVICE NAME:**
   Xario200G and Xario100G, Software V1.1 Diagnostic Ultrasound System

7. **TRADE NAME(S):**
   Diagnostic Ultrasound System Xario200G Model CUS-X200G
   Diagnostic Ultrasound System Xario100G Model CUS-X100G

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 Diagnostic Ultrasound System V6.0	Canon Medical Systems USA, Inc	K172276	December 12, 2017

11. REASON FOR SUBMISSION:

New device

12. DEVICE DESCRIPTION:

The Xario200G Model CUS-X200G and Xario100G Model CUS-X100G 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.

13. INDICATIONS FOR USE:

The Diagnostic Ultrasound System Xario200G Model CUS-X200G and Xario100G Model CUS-X100G 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.

14. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the Xario200 V6.0 Diagnostic Ultrasound System, 510(k) cleared under K172276, marketed by Canon Medical Systems USA, Inc. The Xario200G and Xario100G, Software V1.1 Diagnostic Ultrasound System functions in a manner similar to and is intended for the same use as the predicate devices referenced within this submission. The subject device is a compact diagnostic ultrasound system that implements the latest technologies.

	Xario200G/Xario100G Model CUS-X200G Model CUS-X100G, v1.1	Xario200 Model TUS-X200 v6.0	Comments
510(K) Control Number	**This Submission (Subject)**	**K172276**	
Scanning Method	Electronic Convex, Electronic Sector, Electronic Linear/Trapezoid, Pencil	Electronic Convex, Electronic Sector, Electronic Linear/Trapezoid, Pencil	Same
Probe Selector	A/B/C Channels 3 connections and Pencil	A/B/C Channels 3 connections and Pencil	Same
	Xario200G/Xario100G Model CUS-X200G Model CUS-X100G, v1.1	**Xario200 Model TUS-X200 v6.0**	**Comments**
B-Mode Depth	1cm (min.), 40 cm (max.)	1cm (min.), 40 cm (max.)	Same
Transmission/Reception Circuitry **Beam Formation Control** **Processing** **Summation** **Maximum Transmission Channels**	 Digital Parallel processing Quad Processing 128 Channels (Xario200G) 64 Channels (Xario100G)	 Digital Parallel processing Quad Processing 128 Channels	 Same Same Same Same for Xario200G
Transmission Frequency	Multiple frequencies are selectable	Multiple frequencies are selectable	Same
Observation Monitor	21.5-inch LCD (LED backlight)	19-inch LCD (LED backlight)	Change
Reference signal: ECG **Wired** **Wireless**	 Yes Yes (Xario200G) / No (Xario100G)	 Yes No	 Same Change
Foot switch **Wired** **Wireless**	 Yes Yes (Xario200G) / No (Xario100G)	 Yes No	 Same Change
Battery pack	Yes	No	Change
Mounting kit for Battery pack	Yes (Xario200G) / No (Xario100G)	No	Change

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

16. TESTING

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

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

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

No clinical studies were required to demonstrate safety and efficacy of the Xario200G/Xario100G systems.

17. CONCLUSION

The **Xario200G and Xario100G, Software V1.1 Diagnostic Ultrasound System** are substantially equivalent to the predicate device. The subject devices function in a manner similar to and is intended for the same use as the predicate device, as described in the labeling. Based upon the 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.