K092948

OCT - 9 2009

510(k) Summary

Submitter's Name: Toshiba America Medical Systems, Inc.
Address: 2441 Michelle Drive Tustin, CA 92780
Contact: Paul Biggins, Director Regulatory Affairs
Telephone No.: (714) 730-5000

Device Proprietary Name: DIAGNOSTIC ULTRASOUND SYSTEM APLIO MX MODEL SSA-780A Version 1.0

Common Name: Diagnostic Ultrasound System

Classification:
- **Regulatory Class:** II
- **Review Category:** Tier II

- Ultrasonic Pulsed Doppler Imaging System – Product Code: 90-IYN [Fed. Reg. No.: 892.1550]
- Ultrasonic Pulsed Echo Imaging System – Product Code: 90-IYO [Fed. Reg. No.: 892.1560]
- Diagnostic Ultrasonic Transducer – Product Code: 90-ITX [Fed.Reg. No.: 892.1570]

Identification of Predicate Devices:
Toshiba America Medical Systems believes that this device is substantially equivalent to:
1. Toshiba DIAGNOSTIC ULTRASOUND SYSTEM APLIO XG MODEL SSA-790A v4.0R001 – 510(k) K092179
2. Toshiba DIAGNOSTIC ULTRASOUND SYSTEM APLIO XG MODEL SSA-790A v4.0 – 510(k) K091295

Device Description:
The DIAGNOSTIC ULTRASOUND SYSTEM APLIO XG MODEL SSA-780A is a mobile system. This system is a Track 3 device that employs a wide array of probes that include flat linear array, convex linear array, and sector array with a frequency range of approximately 2 MHz to 12 MHz.

Intended Use:
The DIAGNOSTIC ULTRASOUND SYSTEM APLIO MX MODEL SSA-780A is intended to be used for the following type of studies; fetal, abdominal, intraoperative, pediatric, small organs, neonatal cephalic, adult cephalic, cardiac, transrectal, transvaginal, transesophageal, peripheral vascular and musculo-skeletal (both conventional and superficial).

Declaration of Conformity:
This device is designed and manufactured in conjunction with the Quality System Regulation, IEC 60601-1 (applicable portions), IEC 60601-1-1 (applicable portion), IEC 60601-1-2 (applicable portion), IEC 60601-1-4 (applicable portion), IEC60601-2-37 (applicable portions), IEC 62304 (applicable portion) and the AIUM-NEMA UD2 Output Measurement Standard as applied to Track 3 Ultrasound systems and the AIUM-NEMA UD3 Output Display Standard.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

OCT - 9 2009

Re: K092948
Trade/Device Name: Aplio MX v1.0 SSA-780A
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: September 23, 2009
Received: September 24, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the Aplio MX v1.0 SSA-780A, as described in your premarket notification:

Transducer Model Number

PST-25BT	PVT-375MV	PVT-681MV
PST-30BT	PVT-382BT	PVT-745BTV
PST-50AT	PVT-382MV	PVT-770RT
PST-65AT	PVT-575MV	PLT-604AT
PST-20CT	PVT-674BT	PLT-704AT
PVT-375BT	PVT-661VT	PLT-704SBT

PLT-705BTH	PLT-1204AT	PET-508MA
PLT-705BTF	PLT-1204BT	PC-20M
PLT-805AT	PLT-1204MV	PC-50M
PLT-1202S	PET-510MB	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

for Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

System: Aplio MX v1.0 SSA-780A
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**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal	N	N	N	N	N	N	N	N	N		N	5,7,8,9,10
Abdominal	N	N	N	N	N	2,3	N	N	N		N	5,7,8,9,10
Intra-operative (Abdominal)	N	N	N	N	N	2	N	N	N			4,5
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N	N	N	2,3	N	N	N		N	5,7,8,9,10
Small Organ (Note 1)	N	N	N		N	2	N	N	N			4,5,6,7,9,11
Neonatal Cephalic	N	N	N	N	N	N	N	N	N			
Adult Cephalic	N	N	N	N	N	3	N	N	N			
Trans-rectal	N	N	N		N	2	N	N	N		N	4,5,7,11
Trans-vaginal	N	N	N		N	2	N	N	N		N	4,5,7
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**	N	N	N		N	2	N	N	N			4,5,6,7,9,11
Musculo-skeletal **(Superficial)**	N	N	N		N	2	N	N	N			4,5,6,7,9,11
Intravascular												
Other (Specify)												
Cardiac Adult	N	N	N	N	N	3	N	N	N	N		4
Cardiac Pediatric	N	N	N	N	N	3	N	N	N	N		4
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	N	N	N	N	N	3	N					4
Intra-cardiac												
Other (Specify)												
Peripheral vessel	N	N	N	N	N	2	N	N	N			4,5,6,7,9,11
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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092948

System: Aplio MX v1.0 SSA-780A
Transducer: PST-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	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	P	P	P	P	P	3	P	P	P			
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P	P	P	3	P	P	P			
Small Organ (Note 1)												
Neonatal Cephalic	P	P	P	P	P	3	P	P	P			
Adult Cephalic	P	P	P	P	P	3	P	P	P			
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	P		4
Cardiac Pediatric	P	P	P	P	P	3	P	P	P	P		4
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 transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092948

System: Aplio MX v1.0 SSA-780A
Transducer: PST-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	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	P	P	P	P	P	3	P	P	P			
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P	P	P	3	P	P	P			
Small Organ (Specify) (1)												
Neonatal Cephalic	P	P	P	P	P	3	P	P	P			
Adult Cephalic	P	P	P	P	P	3	P	P	P			
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	P		4
Cardiac Pediatric	P	P	P	P	P	3	P	P	P	P		4
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 transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092948

Prescription Use Only (Per 21 CRF801.109)

System: Aplio MX v1.0 SSA-780A
Transducer: PST-50AT

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 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Note 1)												
Neonatal Cephalic	P	P	P	P	P	3	P					
Adult Cephalic												
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					4
Cardiac Pediatric	P	P	P	P	P	3	P					4
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 transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092948

Prescription Use Only (Per 21 CRF801.109)

System: Aplio MX v1.0 SSA-780A
Transducer: PST-65AT

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 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Note 1)												
Neonatal Cephalic	P	P	P	P	P	3	P	P	P			
Adult Cephalic												
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
Cardiac Pediatric	P	P	P	P	P	3	P	P	P			4
IPtravascular (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 transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092948

System: Aplio MX v1.0 SSA-780A
Transducer: PST-20CT

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 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal	P	P	P	P	P	3	P	P	P			
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P	P	P	3	P	P	P			
Small Organ (Note 1)												
Neonatal Cephalic	P	P	P	P	P	3	P	P	P			
Adult Cephalic	P	P	P	P	P	3	P	P	P			
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	P		4
Cardiac Pediatric	P	P	P	P	P	3	P	P	P	P		4
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 transducer: Letter filed as a compatible transducer to Xario XG SSA-680A V1.1 K072918

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092948

Prescription Use Only (Per 21 CRF801.109)

System: Aplio MX v1.0 SSA-780A
Transducer: PVT-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**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal	P	P	P		P	2	P	P	P			5, 7
Abdominal	P	P	P		P	2	P	P	P			5, 7
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			5, 7
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (**Conventional**)												
Musculo-skeletal (**Superficial**)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092948

Prescription Use Only (Per 21 CRF801.109)

System: Aplio MX v1.0 SSA-780A
Transducer: PVT-375MV

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 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal	P	P	P		P	2	P	P	P		P	5,7,8,9,10
AbdomiPal	P	P	P		P	2	P	P	P		P	5,7,8,9,10
IPtra-operative (AbdomiPal)												
IPtra-operative (Peuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P		P	5,7,8,9,10
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (**Conventional**)												
Musculo-skeletal (**Superficial**)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092948

Prescription Use Only (Per 21 CRF801.109)

System: Aplio MX v1.0 SSA-780A
Transducer: PVT-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**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal	P	P	P		P	2	P	P	P			5
AbdomiPal	P	P	P		P	2	P	P	P			5
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			5
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (**Conventional**)												
Musculo-skeletal (**Superficial**)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092948

Prescription Use Only (Per 21 CRF801.109)

System: Aplio MX v1.0 SSA-780A
Transducer: PVT-382MV

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 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal	P	P	P		P	2	P	P	P		P	5,7
Abdominal	P	P	P		P	2	P	P	P		P	5,7
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P		P	5,7
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (**Conventional**)												
Musculo-skeletal (**Superficial**)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092948

Prescription Use Only (Per 21 CRF801.109)

System: Aplio MX v1.0 SSA-780A
Transducer: PVT-575MV

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 2D	4D	Other [Note]
Ophthalmic												
Fetal	P	P	P		P	2	P	P	P		P	5,7,8
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
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 transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092948

Prescription Use Only (Per 21 CRF801.109)

System: Aplio MX v1.0 SSA-780A
Transducer: PVT-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	Dynamic Flow	Power	CHI 2D	4D	Other {Note}
Ophthalmic												
Fetal	P	P	P		P	2	P	P	P			5
Abdominal	P	P	P		P	2	P	P	P			5
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			5
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092948

Prescription Use Only (Per 21 CRF801.109)

System: Aplio MX v1.0 SSA-780A
Transducer: PVT-661VT

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 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal	P	P	P		P	2	N	P	P			4,5,11
Trans-vaginal	P	P	P		P	2	P	P	P			4,5
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 transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092948

Prescription Use Only (Per 21 CRF801.109)

System: Aplio MX v1.0 SSA-780A
Transducer: PVT-681MV

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 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal	P	P	P		P	2	P	P	P		P	4,5,7,11
Trans-vaginal	P	P	P		P	2	P	P	P		P	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 vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092948

System: Aplio MX v1.0 SSA-780A
Transducer: PVT-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	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	P	P	P		P	2	P	P	P			5
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			5
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			5
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			5
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 transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092948

System: Aplio MX v1.0 SSA-780A
Transducer: PVT-770RT

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 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal	P	P	P		P	2	P	P	P			5
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 transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092948

Prescription Use Only (Per 21 CRF801.109)

System: Aplio MX v1.0 SSA-780A
Transducer: PLT-604AT

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 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			5
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
Musculo-skeletal (**Superficial**)	P	P	P		P	2	P	P	P			5
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
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092948

System: Aplio MX v1.0 SSA-780A
Transducer: PLT-704AT

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 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			5
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
Musculo-skeletal **(Superficial)**	P	P	P		P	2	P	P	P			5
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
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092948

Prescription Use Only (Per 21 CRF801.109)

System: Aplio MX v1.0 SSA-780A
Transducer: PLT-704SBT

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 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			5
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
Musculo-skeletal **(Superficial)**	P	P	P		P	2	P	P	P			5
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
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092948

Prescription Use Only (Per 21 CRF801.109)

System: Aplio MX v1.0 SSA-780A
Transducer: PLT-705BTH

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 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal	P	P	P		P	2	P	P	P			5
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			5
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			5
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			5
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 transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092948

Prescription Use Only (Per 21 CRF801.109)

System: Aplio MX v1.0 SSA-780A
Transducer: PLT-705BTF

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 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal	P	P	P		P	2	P	P	P			5
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			5
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			5
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			5
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 transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092948

System: Aplio MX v1.0 SSA-780A
Transducer: PLT-805AT

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 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			5,6,7,11
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			5,6,7,11
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,6,7,11
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			5,6,7,11
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography
Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092948

System: Aplio MX v1.0 SSA-780A
Transducer: PLT-1202S

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 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			4,5,11
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			4,5,11
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (**Conventional**)	P	P	P		P	P	P	P	P			4,5,11
Musculo-skeletal (**Superficial**)	P	P	P		P	2	P	P	P			4,5,11
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			4,5,11
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092948

Prescription Use Only (Per 21 CRF801.109)

System: Aplio MX v1.0 SSA-780A
Transducer: PLT-1204AT

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 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			4,5,6,7,11
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			4,5,6,7,11
Musculo-skeletal **(Superficial)**	P	P	P		P	2	P	P	P			4,5,6,7,11
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			4,5,6,7,11
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092948

Prescription Use Only (Per 21 CRF801.109)

System: Aplio MX v1.0 SSA-780A
Transducer: PLT-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**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			4,5,6,11
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			4,5,6,11
Musculo-skeletal **(Superficial)**	P	P	P		P	2	P	P	P			4,5,6,11
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			4,5,6,11
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092948

Prescription Use Only (Per 21 CRF801.109)

System: Aplio MX v1.0 SSA-780A
Transducer: PLT-1204MV

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 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P		P	5,7,9
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		P	5,7,9
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P		P	5,7,9
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		P	5,7,9
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092948

Prescription Use Only (Per 21 CRF801.109)

System: Aplio MX v1.0 SSA-780A
Transducer: PET-510MB

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 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	P	P	P	P	P	3	P					4
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 transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092948

Prescription Use Only (Per 21 CRF801.109)

System: Aplio MX v1.0 SSA-780A
Transducer: PET-508MA

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 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	P	P	P	P	P	3	P					4
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 transducer: Letter filed as a compatible transducer to Xario XG SSA-680A V1.1 K072918

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092948

Prescription Use Only (Per 21 CRF801.109)

System: Aplio MX v1.0 SSA-780A
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**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult				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 transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092948

Prescription Use Only (Per 21 CRF801.109)

System: Aplio MX v1.0 SSA-780A
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**	**Dynamic Flow**	**Power**	**CHI 2D**	**4D**	**Other [Note]**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult				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 transducer: K092179

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 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D Color (Volume Color)
Note 10 STIC Color
Note 11 Elastography

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092948

Prescription Use Only (Per 21 CRF801.109)