



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

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

July 9, 2015

Re: K151451

Trade/Device Name: Aplio 500/400/300 Diagnostic Ultrasound System, V6.0
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: May 26, 2015
Received: May 29, 2015

Dear Mr. Tadeo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink, reading "Robert D. O'Hara". The signature is written over a large, faint, stylized "FDA" logo.

For

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151451

Device Name

Aplio 500/400/300 Diagnostic Ultrasound System, V6.0

Indications for Use (Describe)

The Diagnostic Ultrasound System Aplio 500 Model TUS-A500, Aplio 400 Model TUS-A400 And Aplio 300 Model TUS-A300 is 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), pediatric, small organs, trans-vaginal, trans-rectal, neonatal cephalic, adult cephalic, cardiac (both adult and pediatric), peripheral vascular, transesophageal, musculo-skeletal (both conventional and superficial) and laparoscopic.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D)

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

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

FOR FDA USE ONLY

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

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

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System: Aplio 500, Aplio 400, Aplio 300 V6.0

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	PW D	CW D	Color Doppler	Combined (Specify) *	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal	P	P	P	P	P	2	P	P	P		P	5,7,8, 9,10,14,18,19
Abdominal	P	P	P	P	P	2,3	P	P	P		P	5,7,8, 9,10,11,12,14, 15,16,18,19
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			4,5,7,11,19
Intra-operative (Neuro)												
Laparoscopic	P	P	P		P	2	P	P	P			5,7
Pediatric	P	P	P	P	P	2,3	P	P	P		P	5,7,8,9,10,12,14,15, 18,19
Small Organ (Note 1)	P	P	P		P	2	P	P	P			4,5,6,7,8,9,10,11,14, 15,16(N),17,18,19
Neonatal Cephalic	P	P	P	P	P	3	P	P	P			
Adult Cephalic	P	P	P	P	P	3	P	P	P			
Trans-rectal	P	P	P		P	2	P	P	P		P	4,5,7,11,12,18
Trans-vaginal	P	P	P		P	2	P	P	P		P	4,5,7,11,12,18
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P			4,5,6,7,8,9,10,11,14, 15,17,18,19
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			4,5,6,7,8,9,10,11,14, 15,17,18,19
Intravascular												
Other (Specify)												
Cardiac Adult	P	P	P	P	P	3	P	P	P	P		4,13
Cardiac Pediatric	P	P	P	P	P	3	P	P	P	P		4,13
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	P	P	P	P	P	3	P					4,13
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P	P	P	2	P	P	P			4,5,6,7,8,9,10,11,14, 15,17,18,19
Other (Specify)												

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

Previous 510(k) of the transducers: K141459, K133761, K123992, K121422, K103629

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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			11
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		4,13
Cardiac Pediatric	P	P	P	P	P	3	P	P	P	P		4,13
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 transducer: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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			11	
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		4,13	
Cardiac Pediatric	P	P	P	P	P	3	P	P	P	P		4,13	
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 transducer: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: PST-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	Dynamic Flow	Power	CHI 2D	4D	Other	[Note]
Ophthalmic													
Fetal													
Abdominal	P	P	P	P	P	3	P	P	P			11	
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		4,13	
Cardiac Pediatric	P	P	P	P	P	3	P	P	P	P		4,13	
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 transducer: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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	P	P	P	P	P	3	P	P	P			11	
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		4,13	
Cardiac Pediatric	P	P	P	P	P	3	P	P	P	P		4,13	
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 transducer: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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			5,7,19
Abdominal	P	P	P		P	2	P	P	P			5,7,11,12,15,16,18,19
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			5, 7,12,15,18,19
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: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: PVT-375SC

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			5,7,19
Abdominal	P	P	P		P	2	P	P	P			5,7,11,12,15,16,18,19
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			5,7,12,15,18,19
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: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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
Abdominal	P	P	P		P	2	P	P	P		P	5,7,8,9,10
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
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: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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, 7,18,19
Abdominal	P	P	P		P	2	P	P	P			5, 7,12,18,19
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			5, 7,12,18,19
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: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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	5,7,9	
Abdominal	P	P	P		P	2	P	P	P		P	5,7,9	
Intra-operative (Abdominal)													
Intra-operative (Neuro)													
Laparoscopic													
Pediatric	P	P	P		P	2	P	P	P		P	5,7,9	
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: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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	P	P	P			4,5,7,11	
Trans-vaginal	P	P	P		P	2	P	P	P			4,5,7,11	
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: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: PVT-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	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			4,5,7,11,12,15,18	
Trans-vaginal	P	P	P		P	2	P	P	P			4,5,7,11,12,15,18	
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: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: PVT-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	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	N	N	N		N	2	N	N	N			4,5,7,11,12,15,18	
Trans-vaginal	N	N	N		N	2	N	N	N			4,5,7,11,12,15,18	
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: N/A

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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			5,7,14,15,19	
Abdominal	P	P	P		P	2	P	P	P			5,7,14,15,19	
Intra-operative (Abdominal)													
Intra-operative (Neuro)													
Laparoscopic													
Pediatric	P	P	P		P	2	P	P	P			5,7,14,15,19	
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: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: PVT-675MV

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	
Abdominal	P	P	P		P	2	P	P	P		P	5,7,8,9,10	
Intra-operative (Abdominal)													
Intra-operative (Neuro)													
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: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: PVT-675MVL

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
Abdominal	P	P	P		P	2	P	P	P		P	5,7,8,9,10
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
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: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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	4,5,7,9,11	
Trans-vaginal	P	P	P		P	2	P	P	P		P	4,5,7,9,11	
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: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: PVT-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	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	N	N	N		N	2	N	N	N		N	4,5,7,9,11,15
Trans-vaginal	N	N	N		N	2	N	N	N		N	4,5,7,9,11,15
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: N/A

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: PVT-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	Dynamic Flow	Power	CHI 2D	4D	Other	[Note]
Ophthalmic													
Fetal													
Abdominal	P	P	P		P	2	P	P	P			5,7,19	
Intra-operative (Abdominal)													
Intra-operative (Neuro)													
Laparoscopic													
Pediatric	P	P	P		P	2	P	P	P			5,7,19	
Small Organ (Specify) (1)													
Neonatal Cephalic	P	P	P		P	2	P	P	P			5,7,19	
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: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 300, Aplio 400, Aplio 500 V6.0Transducer: PVT-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	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	P	P	P		P	2	P	P	P			5,7,19
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			5,7,19
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: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: PVT-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	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	P	P	P		P	2	P	P	P			5,7,19
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			5,7,19
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: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: PVT-745BTB

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			5,7,19
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			5,7,19
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: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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			4,5,7,11	
Trans-vaginal	P	P	P		P	2	P	P	P			4,5,7,11	
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: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: PVT-715RST

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	N	N	N		N	2	N	N	N			5,7,12,15,18	
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: N/A

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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			5,7,17,19	
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			5,7,17,19	
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,7,17,19	
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			5,7,17,19	
Other (Specify)													

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducer: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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			5,7,17,19
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			5,7,17,19
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,7,19
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			5,7,17,19
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducer: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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			5,7,14,15,17,19	
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			5,7,14,15,17,19	
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,7,14,15,17,19	
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			5,7,14,15,17,19	
Other (Specify)													

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducer: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: PLT-705BT

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			5,7,15,17,19
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			5,7,15,17,19
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,7,15,17,19
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			5,7,15,17,19
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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			5,7,19
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			5,7,19
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: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: PVT-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			5,7,19
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			5,7,19
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: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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			5,6,7,11,17,19	
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			5,6,7,11,17,19	
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,6,7,11,17,19	
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			5,6,7,11,17,19	
Other (Specify)													

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducer: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: PLT-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	PW D	CW D	Color Doppler	Combine d (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			5,6,7,11,12,14,15, 16(N), 17,18,19
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			5,6,7,11,12,14,15, 17,18,19
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,6,7,11,12,14,15, 17,18,19
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			5,6,7,11,12,14,15, 17,18,19
Other (Specify)												

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

Previous 510(k) of the transducer: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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			4,5,11,19	
Intra-operative (Neuro)													
Laparoscopic													
Pediatric													
Small Organ (Specify) (1)	P	P	P		P	2	P		P			4,5,11,19	
Neonatal Cephalic													
Adult Cephalic													
Trans-rectal													
Trans-vaginal													
Trans-urethral													
Trans-esoph. (non-Card.)													
Musculo-skeletal (Conventional)	P	P	P		P	2	P		P			4,5,11,19	
Musculo-skeletal (Superficial)	P	P	P		P	2	P		P			4,5,11,19	
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			4,5,11,19	
Other (Specify)													

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducer: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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			4,5,6,7,11,15,17,19	
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			4,5,6,7,11,15,17,19	
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			4,5,6,7,11,15,17,19	
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			4,5,6,7,11,15,17,19	
Other (Specify)													

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: PLT-1204BX

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			5,7,15,17,19
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			5,7,15,17,19
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,7,15,17,19
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			5,7,15,17,19
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducer: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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	5,7,8,9,10
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P		P	5,7,8,9,10
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P		P	5,7,8,9,10
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	5,7,8,9,10
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducer: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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					4,13	
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 transducer: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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					4,13	
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 transducer: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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	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					4,13	
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 transducer: K103629

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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 2D	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 (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: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V6.0Transducer: 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: K141459

Note 1 Small organ includes thyroid, breast and testicle

Note 7 Precision Imaging

Note 13 2D WMT

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD

Note 8 STIC

Note 14 Boost

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD;
BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 9 3D Color (Volume Color)

Note 15 SMI

Note 4 TDI

Note 10 STIC Color

Note 16 Shear wave

Note 5 ApliPure

Note 11 Elastography

Note 17 BEAM

Note 6 MicroPure

Note 12 Fusion

Note 18 Smart Navigation

Note 19 Smart 3D

Prescription Use Only (Per 21 CFR 801.109)

510(k) SUMMARY

1. SUBMITTER'S NAME:

Toshiba Medical Systems Corporation
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2. OFFICIAL CORRESPONDENT

Akinori Hatanaka

3. ESTABLISHMENT REGISTRATION:

9614698

4. CONTACT PERSON:

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5. Date Prepared:

May 26, 2015 (Updated July 8, 2015)

6. TRADE NAME(S):

Diagnostic Ultrasound System
Aplio 500 Model TUS-A500 V6.0
Aplio 400 Model TUS-A400 V6.0
Aplio 300 Model TUS-A300 V6.0

7. COMMON NAME:

System, Diagnostic Ultrasound

8. DEVICE CLASSIFICATION:

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

9. PREDICATE DEVICE:

Product	Marketed by	510(k) Number	Clearance Date
Aplio 500/400/300 Diagnostic Ultrasound System, V5.0	Toshiba America Medical Systems	K141459	10/3/2014
Aplio XG Diagnostic Ultrasound System, Model SSA-790A version 2.0	Toshiba America Medical Systems	K072000	07/30/2007
Voluson i/e	GE Healthcare	K131937	09/24/2013
LOGIQ E9 Diagnostic Ultrasound System	GE Healthcare	K142160	10/10/2014

10. REASON FOR SUBMISSION:

Modification of a cleared device

11. DEVICE DESCRIPTION:

The Aplio 500 Model TUS-A500, Aplio 400 Model TUS-A400 and Aplio 300 Model TUS-A300 are mobile diagnostic ultrasound systems. These systems are Track 3 devices that employ a wide array of probes including flat linear array, convex linear array, and sector array with frequency ranges between approximately 2 MHz to 12 MHz.

12. INDICATIONS FOR USE:

The **Diagnostic Ultrasound System Aplio 500 Model TUS-A500, Aplio 400 Model TUS-A400 And Aplio 300 Model TUS-A300** is 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), pediatric, small organs, trans-vaginal, trans-rectal, neonatal cephalic, adult cephalic, cardiac (both adult and pediatric), peripheral vascular, transesophageal, musculo-skeletal (both conventional and superficial) and laparoscopic.

13. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the Aplio 500/400/300 V5.0 Diagnostic Ultrasound System, 510(k) cleared under K141459, marketed by Toshiba America Medical Systems. The **Aplio 500 Model TUS-A500 Version 6.0, Aplio 400 Model TUS-A400 Version 6.0 and Aplio 300 Model TUS-A300 Version 6.0** functions in a manner similar to and is intended for the same use as the predicate devices referenced within this submission. The subject device includes modifications to the cleared device which expands the Shear Wave indication and implements improvements to the Smart Navigation and SMI tools. Additionally, new features determined to be substantially equivalent to features cleared under the predicate devices referenced within this submission are being added including Auto-NT, Smart 3D and three new transducers.

Device	Aplio 500/400/300 V5.0	Aplio 500/400/300 V6.0	Comment
510(K) Control Number	K141459	This Submission	
Auto-NT	No	Yes	New Feature
Shear Wave (Small Organ)	No	Yes	New Indication
Smart 3D	No	Yes	New Feature
Shear Wave	Yes	Yes	Feature Improvement(s)
SMI	Yes	Yes	Feature Improvement(s)
Smart Navigation	Yes	Yes	Feature Improvement(s)
Smart Fusion	Yes	Yes	Feature Improvement(s)
OBR (On Board Report)	Yes	Yes	Feature Improvement(s)
OB Work Flow	Yes	Yes	Feature Improvement(s)
Elastography Kit	Aplio 500 and Aplio 400 only	Aplio 500, Aplio 400 and Aplio 300	Implemented on Aplio 300
PVT-781VTE	No	Yes	New Transducer
PVT-681MVL	No	Yes	New Transducer
PVL-715RST	No	Yes	New Transducer

14. SAFETY:

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

15. TESTING

Risk Analysis, Verification/Validation testing conducted through bench testing and clinical evaluation.

Performance Testing – Bench

Two studies were conducted to demonstrate that the new features and the improvements to existing features being implemented to the subject device performed as intended. One study demonstrated that the subject device accurately measured the shear wave speed and elasticity of known targets within an elasticity phantom and another study confirmed that the Smart 3D feature successfully displayed 3D images using existing 2D transducers.

Performance Testing – Clinical

Two clinical evaluations were conducted to demonstrate that the subject device performed as expected. In one study, representative clinical images of volunteers were obtained to confirm that the system provides acceptable images and numerical Shear wave results in-

vivo. Another study validated the performance of the Auto NT feature by demonstrating that the tool is able to equivalently measure Nuchal Translucency thickness when compared to manual measurement.

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

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

16. CONCLUSION

The modifications incorporated into the **Aplio 500 Model TUS-A500 Version 6.0, Aplio 400 Model TUS-A400 Version 6.0 and Aplio 300 Model TUS-A300 Version 6.0** do not change the intended use of the device. Based upon bench testing, clinical evaluations, 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.