



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

October 28, 2014

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

Re: K141459
Trade/Device Name: Aplio 500/400/300 Diagnostic Ultrasound System, V5.0
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: October 2, 2014
Received: October 3, 2014

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.

This determination of substantial equivalence applies to the following transducers intended for use with the Aplio 500/400/300 Diagnostic Ultrasound System, V5.0, as described in your premarket notification:

Transducer Model Number

PST-25BT	PST-30BT	PST-50BT
PST-65AT	PVT-375BT	PVT-375SC
PVT-375MV	PVT-382BT	PVT-382MV
PVT-661VT	PVT-781VT	PVT-674BT
PVT-675MV	PVT-675MVL	PVT-681MV
PVT-712BT	PVT-745BTF	PVT-745BTH
PVT-745BTV	PVT-770RT	PLT-604AT
PLT-704AT	PLT-704SBT	PLT-705BT
PLT-705BTF	PVT-705BTH	PLT-805AT

PLT-1005BT□	PLT-1202S	PLT-1204BT
PLT-1204BX	PLT-1204MV	PET-508MA
PET-510MB	PET-512MC	PET-805LA
PC-20M	PC-50M	

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 black ink, appearing to read "Janine M. Morris", is written over a large, faded, light gray watermark of the FDA logo. The logo consists of the letters "FDA" in a bold, sans-serif font, with a stylized triangle to the right.

for

Janine M. Morris
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)

K141459

Device Name

Aplio 500/400/300 V5.0 Diagnostic Ultrasound System

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: _____

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

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	THI	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
Abdominal	P	P	P	P	P	2,3	P	P	P		P	5,7,8,9,10,11,12,14,15,16,18
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			4,5,7,11
Intra-operative (Neuro)												
Laparoscopic	N	N	N		N	2	N	N	N			5,7
Pediatric	P	P	P	P	P	2,3	P	P	P		P	5,7,8,9,10,12,14,15,18
Small Organ (Note 1)	P	P	P		P	2	P	P	P			4,5,6,7,8,9,10,11,14,15,17,18
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
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			4,5,6,7,8,9,10,11,14,15,17,18
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
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducers: K133761, K123992, K121422 and 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

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PST-25BT

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

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PST-30BT

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

Clinical Application Specific (Tracks 3)	Mode of Operation												
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PST-50BT

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

Clinical Application Specific (Tracks 3)	Mode of Operation												[Note]
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other	
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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PST-65AT

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

Clinical Application Specific (Tracks 3)	Mode of Operation												Other	[Note]	
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D				
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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PVT-375BT

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

Clinical Application Specific (Tracks 3)	Mode of Operation												
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	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				5,7,11,12,15,16,18
Intra-operative (Abdominal)													
Intra-operative (Neuro)													
Laparoscopic													
Pediatric	P	P	P		P	2	P	P	P				5, 7,12,15,18
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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PVT-375SC

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

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal	N	N	N		N	2	N	N	N			5,7
Abdominal	N	N	N		N	2	N	N	N			5,7,11,12,15,16,18
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	N	N	N		N	2	N	N	N			5,7,12,15,18
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: 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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PVT-375MV

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

Clinical Application Specific (Tracks 3)	Mode of Operation												[Note]
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other	
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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PVT-382BT

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

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal	P	P	P		P	2	P	P	P			5, 7,18
Abdominal	P	P	P		P	2	P	P	P			5, 7,12,18
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			5, 7,12,18
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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PVT-382MV

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

Clinical Application Specific (Tracks 3)	Mode of Operation												Other	[Note]	
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D				
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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0
 Transducer: PVT-661VT

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

Clinical Application Specific (Tracks 3)	Mode of Operation												
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other	[Note]
Ophthalmic													
Fetal													
Abdominal													
Intra-operative (Abdominal)													
Intra-operative (Neuro)													
Laparoscopic													
Pediatric													
Small Organ (Specify) (1)													
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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0
 Transducer: PVT-781VT

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

Clinical Application Specific (Tracks 3)	Mode of Operation												
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PVT-674BT

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

Clinical Application Specific (Tracks 3)	Mode of Operation												Other	[Note]	
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D				
Ophthalmic															
Fetal	P	P	P		P	2	P	P	P					5,7,14,15	
Abdominal	P	P	P		P	2	P	P	P					5,7,14,15	
Intra-operative (Abdominal)															
Intra-operative (Neuro)															
Laparoscopic															
Pediatric	P	P	P		P	2	P	P	P					5,7,14,15	
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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PVT-675MV

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

Clinical Application Specific (Tracks 3)	Mode of Operation												
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other	[Note]
Ophthalmic													
Fetal	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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PVT-675MVL

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

Clinical Application Specific (Tracks 3)	Mode of Operation												[Note]
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other	
Ophthalmic													
Fetal	N	N	N		N	2	N	N	N		N	5,7,8,9,10	
Abdominal	N	N	N		N	2	N	N	N		N	5,7,8,9,10	
Intra-operative (Abdominal)													
Intra-operative (Neuro)													
Laparoscopic													
Pediatric	N	N	N		N	2	N	N	N		N	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: 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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PVT-681MV

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

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PVT-712BT

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

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
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	P	P	P		P	2	P	P	P			5,7
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: K133761

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

System: Aplio 300, Aplio 400, Aplio 500 V5.0

Transducer: PVT-745BTF

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

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	P	P	P		P	2	P	P	P			5,7
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			5,7
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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PVT-745BTH

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

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	P	P	P		P	2	P	P	P			5,7
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			5,7
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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PVT-745BTV

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

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	P	P	P		P	2	P	P	P			5,7
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			5,7
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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PVT-770RT

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

Clinical Application Specific (Tracks 3)	Mode of Operation												
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other	[Note]
Ophthalmic													
Fetal													
Abdominal													
Intra-operative (Abdominal)													
Intra-operative (Neuro)													
Laparoscopic													
Pediatric													
Small Organ (Specify) (1)													
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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PLT-604AT

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

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			5,7,17
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
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,7,17
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
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducer: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PLT-704AT

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

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			5,7,17
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
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,7
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
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducer: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PLT-704SBT

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

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			5,7,14,15,17
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
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,7,14,15,17
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
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducer: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PLT-705BT

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

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	N	N	N		N	2	N	N	N			5,7,15,17
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	N	N	N		N	2	N	N	N			5,7,15,17
Musculo-skeletal (Superficial)	N	N	N		N	2	N	N	N			5,7,15,17
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	N	N	N		N	2	N	N	N			5,7,15,17
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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PLT-705BTF

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

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	P	P	P		P	2	P	P	P			5,7
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			5,7
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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PVT-705BTH

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

Clinical Application Specific (Tracks 3)	Mode of Operation											Other [Note]
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	
Ophthalmic												
Fetal												
Abdominal	P	P	P		P	2	P	P	P			5,7
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			5,7
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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PLT-805AT

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

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			5,6,7,11,17
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
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,6,7,11,17
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
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducer: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PLT-1005BT

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

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynami c 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, 17,18
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
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,6,7,11,12,14,15, 17,18
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
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducer: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PLT-1202S

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

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)	P	P	P		P	2	P		P			4,5,11
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	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	2	P		P			4,5,11
Musculo-skeletal (Superficial)	P	P	P		P	2	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			4,5,11
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducer: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PLT-1204BT

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

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	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
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
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			4,5,6,7,11,15,17
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
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducer: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0
 Transducer: PLT-1204BX

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

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			5,7,15,17
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
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,7,15,17
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
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducer: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PLT-1204MV

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

Clinical Application Specific (Tracks 3)	Mode of Operation											
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PET-508MA

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

Clinical Application Specific (Tracks 3)	Mode of Operation											Other [Note]	
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D		
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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PET-510MB

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

Clinical Application Specific (Tracks 3)	Mode of Operation												
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other	[Note]
Ophthalmic													
Fetal													
Abdominal													
Intra-operative (Abdominal)													
Intra-operative (Neuro)													
Laparoscopic													
Pediatric													
Small Organ (Specify) (1)													
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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PET-512MC

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

Clinical Application Specific (Tracks 3)	Mode of Operation												[Note]
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other	
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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PET-805LA

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

Clinical Application Specific (Tracks 3)	Mode of Operation												[Note]
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D	Other	
Ophthalmic													
Fetal													
Abdominal													
Intra-operative (Abdominal)													
Intra-operative (Neuro)													
Laparoscopic	N	N	N		N	2	N	N	N				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: 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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PC-20M

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

Clinical Application Specific (Tracks 3)	Mode of Operation												
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: PC-50M

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

Clinical Application Specific (Tracks 3)	Mode of Operation											[Note]	
	B	M	PWD	CWD	Color Doppler	Combined (Specify)*	THI	Dynamic Flow	Power	CHI 2D	4D		Other
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: K133761

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

Prescription Use Only (Per 21 CFR 801.109)

510(k) SUMMARY

1. SUBMITTER'S NAME:

Toshiba Medical Systems Corporation
1385 Shimoishigami
Otawara-shi, Tochigi-ken, Japan 324-8550

2. OFFICIAL CORRESPONDENT

Akinori Hatanaka

3. ESTABLISHMENT REGISTRATION:

9614698

4. CONTACT PERSON:

Orlando Tadeo, Jr.
Manager, Regulatory Affairs
Toshiba America Medical Systems, Inc
2441 Michelle Drive
Tustin, CA 92780
(714) 669-7459

5. Date Prepared:

May 27, 2014

6. TRADE NAME(S):

Diagnostic Ultrasound System
Aplio 500 Model TUS-A500 V5.0
Aplio 400 Model TUS-A400 V5.0
Aplio 300 Model TUS-A300 V5.0

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 V4.0	Toshiba America Medical Systems	K133761	April 22, 2014
AIXPLORER Ultrasound System	SuperSonic Imagine, S.A.	K112255	August 28, 2012
GE Logiq E9 BT2010 Diagnostic Ultrasound System	GE Healthcare	K092271	November 17, 2009
Electromagnetic Tracking System	CIVCO Medical Instruments Co., Inc.	K092619	November 13, 2009
MicroMaxx High Resolution Ultrasound System (C3 Series)	SonoSite, Inc.	K053069	February 24, 2006

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 V4.0 Diagnostic Ultrasound System, 510(k) cleared under K133761, marketed by Toshiba America Medical Systems. The **Aplio 500 Model TUS-A500 Version 5.0, Aplio 400 Model TUS-A400 Version 5.0 and Aplio 300 Model TUS-A300 Version 5.0** 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 improve upon image quality and existing features (Needle Enhancement). Also, new features determined to be substantially equivalent to features cleared under the predicate devices referenced within this submission including Shear wave and Smart Navigation and four new transducers (one of

which is indicated for laparoscopic use) are being added to the subject device. A comparison table is included in this submission which details the similarities and differences between the predicate devices and the subject device.

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.

Performance Testing – Bench

Three studies were conducted to demonstrate that the new features being implemented to the subject device performed as intended. One study compared an existing imaging mode with the needle enhancement feature and confirmed that the subject device improves needle visualization. Another study confirmed that the subject device accurately measured the shear wave speed and elasticity of known targets within an elasticity phantom while a third study demonstrated that the use of Smart Navigation successfully navigates needles to targets at various depths using a projected path displayed on the system.

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 5.0, Aplio 400 Model TUS-A400 Version 5.0 and Aplio 300 Model TUS-A300 Version 5.0** do not change the intended use of the device. Based upon bench testing, 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.