

K123992

FEB 6 2013

TOSHIBA AMERICA MEDICAL SYSTEMS, INC.
2441 Michelle Drive, Tustin, CA 92780
Phone: (714) 730-5000

510(k) SUMMARY

- 1. SUBMITTER'S NAME:**
Toshiba America Medical Systems, Inc.
- 2. ADDRESS:**
2441 Michelle Drive
Tustin, CA. 92780-2068
- 3. ESTABLISHMENT REGISTRATION:**
2020563
- 4. CONTACT PERSON:**
Charlemagne Chua
Manager, Regulatory Affairs
(714) 669-7896
- 5. Date Prepared:**
December 21, 2012
- 6. TRADE NAME(S):**
Diagnostic Ultrasound System
Aplio 500 Model TUS-A500 V3.0
Aplio 400 Model TUS-A400 V3.0
Aplio 300 Model TUS-A300 V3.0
- 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	Toshiba America Medical Systems	K121422	August 16, 2012

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. SUMMARY OF INTENDED USES:

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, and musculo-skeletal (both conventional and superficial).

13. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the Aplio 500/400/300 Diagnostic Ultrasound System, K121422, marketed by Toshiba America Medical Systems. The **Aplio 500 Model TUS-A500 Version 3.0, Aplio 400 Model TUS-A400 Version 3.0 and Aplio 300 Model TUS-A300 Version 3.0**, functions in a manner similar to and is intended for the same use as the predicate device. The subject device includes modifications to the cleared device which improves upon existing features such as imaging and report/communication transfer. Additionally, two new transducers, a new 4D optional feature, Luminance, and new hardware items intended to improve ease of use, are now available with the subject device.

A comparison table is included in this submission detailing the similarities and differences between the predicate device 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, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-37, IEC 62304, NEMA UD3 Output Display and ISO 10993-1 standards.

15. TESTING

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

Software Documentation for a Moderate Level of Concern, per the FDA guidance

document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document" issued on May 11, 2005, is also included as part of this submission.

Additionally, testing of 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 3.0, Aplio 400 Model TUS-A400 Version 3.0 and Aplio 300 Model TUS-A300 Version 3.0** do not change the indications for use or 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.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 6, 2013

Toshiba America Medical Systems, Inc.
c/o Mr. Charlemagne Chua
Manager, Regulatory Affairs
2441 Michelle Drive
TUSTIN CA 92780-2068

Re: K123992

Trade/Device Name: Aplio™ 500/400/300 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: December 21, 2012
Received: December 26, 2012

Dear Mr. Chua:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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

Transducer Model Number

<u>PST-25BT</u>	<u>PVT-661VT</u>	<u>PVT-745BTV</u>	<u>PLT-1005BT</u>
<u>PST-30BT</u>	<u>PVT-781VT</u>	<u>PVT-770RT</u>	<u>PLT-1202S</u>
<u>PST-50BT</u>	<u>PVT-674BT</u>	<u>PLT-604AT</u>	<u>PLT-1204BT</u>
<u>PST-65AT</u>	<u>PVT-675MV</u>	<u>PLT-704AT</u>	<u>PLT-1204BX</u>
<u>PVT-375BT</u>	<u>PVT-681MV</u>	<u>PLT-704SBT</u>	<u>PLT-1204MV</u>
<u>PVT-375MV</u>	<u>PVT-712BT</u>	<u>PLT-705BTF</u>	<u>PET-508MA</u>
<u>PVT-382BT</u>	<u>PVT-745BTF</u>	<u>PVT-705BTH</u>	<u>PET-510MB</u>
<u>PVT-382MV</u>	<u>PVT-745BTH</u>	<u>PLT-805AT</u>	<u>PET-512MC</u>

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 such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Joshua Nipper at (301) 796-6524.

Sincerely Yours,

Sean M. Boyd -S for

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

Enclosure(s)

Indications for Use

510(k) Number (if known): _____

Device Name: Aplio 500/400/300 V3.0 Diagnostic Ultrasound System

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, and musculo-skeletal (both conventional and superficial).

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

Page 1 of 1

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123992

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 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	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	
Abdominal	P	P	P	P	P	2,3	P	P	P		P	5,7,8,9,10,11,12,14	
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			4,5,7,11	
Intra-operative (Neuro)													
Laparoscopic													
Pediatric	P	P	P	P	P	2,3	P	P	P		P	5,7,8,9,10,12,14	
Small Organ (Note 1)	P	P	P		P	2	P	P	P			4,5,6,7,8,9,10,11,14	
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	
Trans-vaginal	P	P	P		P	2	P	P	P		P	4,5,7,11,12	
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	
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			4,5,6,7,8,9,10,11,14	
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	
Other (Specify)													

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducers: K121422 and K103629

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k)

K123992

Sean M. Boyd -S

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
 Aplio 500/400/300 V3.0 Diagnostic Ultrasound System

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 Transducer: PST-25BT

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

Clinical Application (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: K121422

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

Sean M. Boyd -S

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123992

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 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: K121422

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off) **Sean M. Boyd -S**
 Division of Radiological Health
 Office of In Vitro Diagnostics and Radiological Health

510(k) K123992

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 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											
	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: K121422

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Sean M. Boyd - S

Prescription Use Only (Per 21 CFR 801.109)

510(k)

K123992

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 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											
	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: K121422

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
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- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

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 Division of Radiological Health
 Office of In Vitro Diagnostics and Radiological Health
Sean M. Boyd -S
 510(k) K123992

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 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
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			5, 7, 12
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: K121422

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
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- Note 13 2D WMT
- Note 14 Boost

Sean M. Boyd -S

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)
 Division of Radiological Health
 Office of In Vitro Diagnostics and Radiological Health
 510(k) K123992

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 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											
	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		N	5,7,8,9,10
Abdominal	P	P	P		P	2	P	P	P		N	5,7,8,9,10
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P		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: K121422

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

Sean M. Boyd -S

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k)

K12399-2

System: Aplio 500, Aplio 400, Aplio 300 V3.0
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
Abdominal	P	P	P		P	2	P	P	P			5, 7, 12
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			5, 7, 12
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: K121422

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off) **Sean M. Boyd -S**

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) 10123992

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 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											
	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: K121422

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off) **Sean M. Boyd -S**
 Division of Radiological Health
 Office of In Vitro Diagnostics and Radiological Health
 510(k) K123192

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
Aplio 500/400/300 V3.0 Diagnostic Ultrasound System

System: Aplio 500, Aplio 400, Aplio 300 V3.0
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: K121422

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

Sean M. Boyd -S

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)

Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

510(k) K123992

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 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	E	E	E		E	2	E	E	E			4,5,7,11,12
Trans-vaginal	E	E	E		E	2	E	E	E			4,5,7,11,12
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducer: N/A (This transducer is being added under this submission)

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

Sean M. Boyd - S
 Division of Radiological Health
 Office of In Vitro Diagnostics and Radiological Health

510(k) K123992

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 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											
	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
Abdominal	P	P	P		P	2	P	P	P			5,7,14
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			5,7,14
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: K121422

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

Sean M. Boyd -S

(Division Sign Off)
 Division of Radiological Health
 Office of In Vitro Diagnostics and Radiological Health

510(k) K123992

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 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: K121422

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)
 Division of Radiological Health
Sean M. Boyd, S
 Office of In Vitro Diagnostics and Radiological Health

510(k) K123992

System: Aplio 500, Aplio 400, Aplio 300 V3.0
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: K121422

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)
Division of Radiological Health
Sean M. Boyd - S
Office of In Vitro Diagnostics and Radiological Health

510(k) K123992

System: Aplio 500, Aplio 400, Aplio 300 V3.0
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		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: K121422

Note 1 Small organ includes thyroid, breast and testicle.

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

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

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Sean M. Boyd -S

Prescription Use Only (Per 21 CFR 801.109)

510(k)

K123192

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
 Aplio 500/400/300 V3.0 Diagnostic Ultrasound System

System: Aplio 300, Aplio 400, Aplio 500 v3.0
 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: K121422

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

(Division Sign Off)
 Division of Radiological Health
 Office of In Vitro Diagnostics and Radiological Health

Prescription Use Only (Per 21 CFR 801.109)

510(k) K123992 Sean M. Boyd -S

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 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: K121422

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)
 Division of Radiological Health
 Office of In Vitro Diagnostics and Radiological Health
Sean M. Boyd - S

510(k) 123992

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 Transducer: PVT-745BTU

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: K121422

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123992 Sean M. Boyd -S

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 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: K121422

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Prescription Use Only (Per 21 CFR 801.109)

510(k) K123992 Sean M. Boyd -S

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 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
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
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
Other (Specify)												

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

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123992 Sean M. Boyd -S

System: Aplio 500, Aplio 400, Aplio 300 V3.0
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
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
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
Other (Specify)												

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

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Sean M. Boyd -S
510(k) K123992

System: Aplio 500, Aplio 400, Aplio 300 V3.0
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
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
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,7,14
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
Other (Specify)												

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

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost
- Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Sean M. Boyd -S
510(k) K123992

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 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: K121422

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) M23992 Sean M. Boyd -S

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 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											
	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: K121422

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

(Division Sign Off)
 Division of Radiological Health
 Office of In Vitro Diagnostics and Radiological Health

510(k) K123442

Sean M. Boyd -S

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 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
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P			5,6,7,11
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,6,7,11
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P		P	2	P	P	P			5,6,7,11
Other (Specify)												

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

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

(Division Sign Off)

Division of Radiological Health:

Office of In Vitro Diagnostics and Radiological Health:

510(k)

K123992

Sean M. Boyd -S

System: Aplio 500, Aplio 400, Aplio 300 V3.0
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	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	E	E	E		E	2	E	E	E			5,6,7,11,14
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	E	E	E		E	2	E	E	E			5,6,7,11,14
Musculo-skeletal (Superficial)	E	E	E		E	2	E	E	E			5,6,7,11,14
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	E	E	E		E	2	E	E	E			5,6,7,11,14
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: N/A (This transducer is being added under this submission)

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Sean M. Boyd -S

Prescription Use Only (Per 21 CFR 801.109)

510(k)

K12 3992

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 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	N	N	N		N	2	N		N			4,5,11
Other (Specify)												

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

- Note 1, Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)
 Division of Radiological Health
 Office of In Vitro Diagnostics and Radiological Health
 510(k) K123992 Sean M. Boyd -S

System: Aplio 500, Aplio 400, Aplio 300 V3.0
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
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P			4,5,6,7,11
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			4,5,6,7,11
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel	N	N	N		N	2	N	N	N			4,5,6,7,11
Other (Specify)												

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

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123992 Sean M. Boyd -S

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500 V3.0
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
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
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
Other (Specify)												

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

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) K123997 Sean M. Boyd -S

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 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: K121422

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123992 Sean M. Boyd -S

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 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											
	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: K121422

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123992

Prescription Use Only (Per 21 CFR 801.109)

Sean M. Boyd -S

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 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: K121422

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

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 Division of Radiological Health
 Office of In Vitro Diagnostics and Radiological Health

510(k) K123992

Sean M. Boyd -S

System: Aplio 500, Aplio 400, Aplio 300 V3.0
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											
	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 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

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Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

510(k) 423912
Sean M. Boyd -S

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 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: K121422

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost

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 Division of Radiological Health
 Office of In Vitro Diagnostics and Radiological Health

510(k) 10123992

Toshiba America Medical Systems, Inc.

510(k) Premarket Notification
 Aplio 500/400/300 V3.0 Diagnostic Ultrasound System

System: Aplio 500, Aplio 400, Aplio 300 V3.0
 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											
	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: K121422

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
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510(k) K123992 Sean M. Boyd -S

Prescription Use Only (Per 21 CFR 801.109)