

K133761

APR 22 2014

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:**
Mr. Charlemagne Chua
Manager, Regulatory Affairs
(714) 669-7896
- 5. Date Prepared:**
December 6, 2013
- 6. TRADE NAME(S):**
Diagnostic Ultrasound System
Aplio 500 Model TUS-A500 V4.0
Aplio 400 Model TUS-A400 V4.0
Aplio 300 Model TUS-A300 V4.0
- 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	K123992	February 6, 2013

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

13. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the Aplio 500/400/300 V3.0 Diagnostic Ultrasound System, 510(k) cleared under K123992, marketed by Toshiba America Medical Systems. The **Aplio 500 Model TUS-A500 Version 4.0, Aplio 400 Model TUS-A400 Version 4.0 and Aplio 300 Model TUS-A300 Version 4.0**, 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 including the image visualization of blood flow. 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 and the acquisition of representative clinical images included in this submission demonstrate 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 4.0, Aplio 400 Model TUS-A400 Version 4.0 and Aplio 300 Model TUS-A300 Version 4.0** do not change the indications for use or the intended use of the device. Based upon bench testing, acquisition of representative clinical images, 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 20993-0002

April 22, 2014

Toshiba Medical Systems Corporation
Paul Biggins
2441 Michelle Drive
TUSTIN CA 92780

Re: K133761

Trade/Device Name: Aplio 500/400/300 Diagnostic Ultrasound System V4.0
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: March 20, 2014
Received: March 21, 2014

Dear Mr. Biggins:

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 55/400/300 Diagnostic Ultrasound System V4.0, as described in your premarket notification:

Transducer Model Number

PST-25BT	PST-30BT	PST-50BT	PST-65AT
PVT-375BT	PVT-375MV	PVT-382BT	PVT-382MV
PVT-661VT	PVT-781VT	PVT-674BT	PVT-675MV
PVT-681MV	PVT-712BT	PVT-745BTF	PVT-745BTH
PVT-745BTV	PVT-770RT	PLT-604AT	PLT-704AT
PLT-704SBT	PLT-705BTF	PVT-705BTH	PLT-805AT
PLT-1005BT	PLT-1202S	PLT-1204BT	PLT-1204BX
PLT-1204MV	PET-508MA	PET-510MB	PET-512MC
	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 Small Manufacturers, International and Consumer Assistance 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance 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,



for

Janine 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)

K133761

Device Name

Aplio 500/400/300 V4.0 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, and musculo-skeletal (both conventional and superficial).

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.

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"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 V4.0

Transducer: _____

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

Clinical Application	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
Abdominal	P	P	P	P	P	2,3	P	P	P		P	5,7,8,9,10,11,12,14,15
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	5,7,8,9,10,12,14,15
Small Organ (Note 1)	P	P	P		P	2	P	P	P			4,5,6,7,8,9,10,11,14,15
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			4,5,6,7,8,9,10,11,14,15
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			4,5,6,7,8,9,10,11,14,15
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
Other (Specify)												

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

System: Aplio 500, Aplio 400, Aplio 300 V4.0
 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: K123992

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

Note 15 SMI

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V4.0
 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: K123992

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

Note 15 SMI

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V4.0

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: K123992

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

Note 15 SMI

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V4.0
 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: K123992

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

Note 15 SMI

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V4.0

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
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P			5, 7, 12, 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: K123992

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

Note 15 SMI

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V4.0
 Transducer: PVT-375MV

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

Clinical Application	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: K123992

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

Note 15 SMI

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V4.0
 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: K123992

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

Note 15 SMI

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V4.0
 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: K123992

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

Note 15 SMI

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V4.0
 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: K123992

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

Note 15 SMI

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V4.0
 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
Trans-vaginal	P	P	P		P	2	P	P	P			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: K123992

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

Note 15 SMI

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V4.0
 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: K123992

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

Note 15 SMI

System: Aplio 500, Aplio 400, Aplio 300 V4.0
 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: K123992

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

Note 15 SMI

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V4.0
 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: K123992

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

Note 15 SMI

System: Aplio 500, Aplio 400, Aplio 300 V4.0

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: K123992

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

Note 15 SMI

System: Aplio 300, Aplio 400, Aplio 500 V4.0
 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: K123992

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

Note 15 SMI

System: Aplio 500, Aplio 400, Aplio 300 V4.0

Transducer: PVT-745BTH

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

Clinical Application	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: K123992

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

Note 15 SMI

System: Aplio 500. Aplio 400. Aplio 300 V4.0

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: K123992

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

Note 15 SMI

System: Aplio 500, Aplio 400, Aplio 300 V4.0
 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: K123992

- 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
- Note 15 SMI

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V4.0

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: K123992

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

Note 15 SMI

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V4.0

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: K123992

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

Note 15 SMI

System: Aplio 500, Aplio 400, Aplio 300 V4.0

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
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
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,7,14,15
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
Other (Specify)												

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

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

Note 15 SMI

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V4.0
 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: K123992

- 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
- Note 15 SMI

System: Aplio 500, Aplio 400, Aplio 300 V4.0
 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: K123992

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

Note 15 SMI

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V4.0
 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: K123992

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

Note 15 SMI

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V4.0

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)	P	P	P		P	2	P	P	P			5,6,7,11,14,15
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			5,6,7,11,14,15
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,6,7,11,14,15
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			5,6,7,11,14,15
Other (Specify)												

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

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

Note 15 SMI

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V4.0
 Transducer: PLT-1202S

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

Clinical Application	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: K123992

- 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
- Note 15 SMI

System: Aplio 500, Aplio 400, Aplio 300 V4.0

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,
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
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			4,5,6,7,11, 15
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
Other (Specify)												

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

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

Note 15 SMI

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500 300 V4.0
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: K123992

- 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
- Note 15 SMI

System: Aplio 500, Aplio 400, Aplio 300 V4.0
 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: K123992

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

Note 15 SMI

System: Aplio 500, Aplio 400, Aplio 300 V4.0
 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: K123992

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

Note 15 SMI

System: Aplio 500, Aplio 400, Aplio 300 V4.0
 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: K123992

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

Note 15 SMI

System: Aplio 500, Aplio 400, Aplio 300 V4.0
 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: 103629

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

Note 15 SMI

System: Aplio 500, Aplio 400, Aplio 300 V4.0
 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: K123992

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

Note 15 SMI

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V4.0
 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: K123992

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

Note 15 SMI