DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

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

May 30, 2017

Re: K163702
Trade/Device Name: Aplio i900/i800/i700 Diagnostic Ultrasound System, V2.1
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: April 21, 2017
Received: April 25, 2017

Dear Mr. Tadeo:

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163702

Device Name

Aplio i900/i800/i700 Diagnostic Ultrasound System, V2.1

Indications for Use *(Describe)*

The Diagnostic Ultrasound Systems Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800 and Aplio i700 Model TUS-AI700 are indicated for the visualization of structures, and dynamic processes with the human body using ultrasound and to provide image information for diagnosis in the following clinical applications: fetal, abdominal, intra-operative (abdominal), pediatric, small organs, trans-vaginal, trans-rectal, neonatal cephalic, adult cephalic, cardiac (both adult and pediatric), peripheral vascular, transesophageal, musculo-skeletal (both conventional and superficial) and laparoscopic.

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

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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

FOR FDA USE ONLY

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

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

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PRAStaff@fda.hhs.gov

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

System: Aplio i900, i800, i700 V2.1
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)**	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal	P	P	P		P	2	P	P			P			P		P	P	P	P	P				6,8
Abdominal	P	P	P	P	P	2,3	P	P			P		P	P	P	P	P	P	P	P	P	P		4,5,6,7,8
Intra-operative (Abdominal)	P	P	P		P	2	P	P			P									P				
Intra-operative (Neuro)																								
Laparoscopic	P	P	P		P	2	P	P			P		P	P										
Pediatric	P	P	P	P	P	2,3	P	P			P			P		P	P	P	P	P	P	P		6,8
Small Organ (Note 1)	P	P	P		P	2	P	P	P	P	P		P	P	P					P	P	P		6
Neonatal Cephalic	P	P	P	P	P	3	P				P													
Adult Cephalic	P	P	P	P	P	3					P													
Trans-rectal	P	P	P		P	2	P	P			P		P	P		P	P				P	P		8
Trans-vaginal	P	P	P		P	2	P	P			P		P	P		P	P				P	P		8
Trans-urethral																								
Trans-esoph. (non-Card.)																								
Musculo-skeletal(**Conventional**)	P	P	P		P	2	P	P	P	P	P		P	P						P	P	P		6
Musculo-skeletal (**Superficial**)	P	P	P		P	2	P	P	P	P	P		P	P						P	P	P		6
Intravascular																								
Other (Specify)																								
Cardiac Adult	P	P	P	P	P	3	P				P	P											N	7, 8
Cardiac Pediatric	P	P	P	P	P	3	P				P	P											N	7,8
Intravascular (Cardiac)																								
Trans-esoph. (Cardiac)	P	P	P	P	P	3	P					P											N	8
Intra-cardiac																								
Other (Specify)																								
Peripheral vessel	P	P	P	P	P	2	P	P	P	P	P		P	P						P	P	P		6
Other (Specify)																								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PSI-30BX
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) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																									
Fetal																									
Abdominal	P	P	P	P	P	3	P				P			P							P			
Intra-operative (Abdominal)																									
Intra-operative (Neuro)																									
Laparoscopic																									
Pediatric	P	P	P	P	P	3	P				P			P							P			
Small Organ (Note 1)																									
Neonatal Cephalic	P	P	P	P	P	3	P				P														
Adult Cephalic	P	P	P	P	P	3					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												N	7
Cardiac Pediatric	P	P	P	P	P	3	P				P	P												N	7
Intravascular (Cardiac)																									
Trans-esoph. (Cardiac)																									
Intra-cardiac																									
Other (Specify)																									
Peripheral vessel																									
Other (Specify)																									

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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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PSI-70BT
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) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																									
Fetal																									
Abdominal	P	P	P	P	P	3	P				P			P											
Intra-operative (Abdominal)																									
Intra-operative (Neuro)																									
Laparoscopic																									
Pediatric	P	P	P	P	P	3	P				P			P											
Small Organ (Note 1)																									
Neonatal Cephalic	P	P	P	P	P	3	P				P														
Adult Cephalic	P	P	P	P	P	3					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												N	7
Cardiac Pediatric	P	P	P	P	P	3	P				P	P												N	7
Intravascular (Cardiac)																									
Trans-esoph. (Cardiac)																									
Intra-cardiac																									
Other (Specify)																									
Peripheral vessel																									
Other (Specify)																									

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Previous 510(k) of the transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PST-25BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																								
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D wMT**	**Other [Note]**
Ophthalmic																									
Fetal																									
Abdominal	P	P	P	P	P	3	P				P			P											
Intra-operative (Abdominal)																									
Intra-operative (Neuro)																									
Laparoscopic																									
Pediatric	P	P	P	P	P	3	P				P			P											
Small Organ (Note 1)																									
Neonatal Cephalic	P	P	P	P	P	3	P				P														
Adult Cephalic	P	P	P	P	P	3					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												N	
Cardiac Pediatric	P	P	P	P	P	3	P				P	P												N	
Intravascular (Cardiac)																									
Trans-esoph. (Cardiac)																									
Intra-cardiac																									
Other (Specify)																									
Peripheral vessel																									
Other (Specify)																									

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Previous 510(k) of the transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PST-30BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal	P	P	P	P	P	3	P				P			P										7
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P	P	P	3	P				P			P										
Small Organ (Note 1)																								
Neonatal Cephalic	P	P	P	P	P	3					P													
Adult Cephalic	P	P	P	P	P	3					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											N	7
Cardiac Pediatric	P	P	P	P	P	3					P	P											N	7
Intravascular (Cardiac)																								
Trans-esoph. (Cardiac)																								
Intra-cardiac																								
Other (Specify)																								
Peripheral vessel																								
Other (Specify)																								

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Prescription Use Only (Per 21 CFR 801.109)

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

Note 4 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PST-50BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal	P	P	P	P	P	3	P				P			E										
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P	P	P	3	P				P			E										
Small Organ (Note 1)																								
Neonatal Cephalic	P	P	P	P	P	3					P													
Adult Cephalic	P	P	P	P	P	3					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											N	
Cardiac Pediatric	P	P	P	P	P	3					P	P											N	
Intravascular (Cardiac)																								
Trans-esoph. (Cardiac)																								
Intra-cardiac																								
Other (Specify)																								
Peripheral vessel																								
Other (Specify)																								

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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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PVI-475BT
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) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal	P	P	P		P	2	P	P			P			P						P				
Abdominal	P	P	P		P	2	P	P			P		P	P	E					P	P	P		6,7
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P		P	2	P	P			P			P						P	P	P		6
Small Organ (Note 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)																								

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

Note 4 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PVI-475BX
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) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal	P	P	P		P	2	P	P			P			P						P				
Abdominal	P	P	P		P	2	P	P			P		P	P	P					P	P	P		4,5,6,7
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P		P	2	P	P			P			P						P	P	P		6
Small Organ (Note 1)																								
Neonatal Cephalic																								
Adult Cephalic																								
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Musculo-skeletal(**Conventional**)																								
Musculo-skeletal (**Superficial**)																								
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Cardiac Adult																								
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Intravascular (Cardiac)																								
Trans-esoph. (Cardiac)																								
Intra-cardiac																								
Other (Specify)																								
Peripheral vessel																								
Other (Specify)																								

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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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PVT-375BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal	P	P	P		P	2	P	P			P			P						P				
Abdominal	P	P	P		P	2	P	P			P		P	P	P					P	P	P		4, 5, 6, 7
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P		P	2	P	P			P			P						P	P	P		6
Small Organ (Note 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 transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PVT-375SC
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal	P	P	P		P	2	P	P			P			P						P				6
Abdominal	P	P	P		P	2	P	P			P		P	P	P					P	P	P		4,5,67
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P		P	2	P	P			P			P						P	P	P		6
Small Organ (Note 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 transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PVT-382BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal	P	P	P		P	2	P	P			P			P						P		P		6
Abdominal	P	P	P		P	2	P	P			P			P						P	P	P		6,7
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P		P	2	P	P			P			P						P	P	P		6
Small Organ (Note 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 transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PVT-674BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal	P	P	P		P	2	P	P			P			P						P				
Abdominal	P	P	P		P	2	P	P			P			P						P				7
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P		P	2	P	P			P			P						P				
Small Organ (Note 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 transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PVT-675MVL
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal	P	P	P		P	2	P	P			P			P		P	P	P	P					8
Abdominal	P	P	P		P	2	P	P			P			P		P	P	P	P					8
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P		P	2	P	P			P			P		P	P	P	P					8
Small Organ (Note 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 transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PVT-681MVL
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal	P	P	P		P	2	P	P			P													7
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric																								
Small Organ (Note 1)																								
Neonatal Cephalic																								
Adult Cephalic																								
Trans-rectal	P	P	P		P	2	P	P			P		P	P		P	P							8
Trans-vaginal	P	P	P		P	2	P	P			P		P	P		P	P							8
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)																								

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Previous 510(k) of the transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PVT-712BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal	P	P	P		P	2	P	P			P			P						P				
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P		P	2	P	P			P			P						P				
Small Organ (Note 1)																								
Neonatal Cephalic	P	P	P		P	2	P	P			P									P				
Adult Cephalic																								
Trans-rectal																								
Trans-vaginal																								
Trans-urethral																								
Trans-esoph. (non-Card.)																								
Musculo-skeletal(**Conventional**)																								
Musculo-skeletal (**Superficial**)																								
Intravascular																								
Other (Specify)																								
Cardiac Adult																								
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 transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PVT-745BTF
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal	P	P	P		P	2	P	P			P			P						P				7
Intra-operative (Abdominal)	P	P	P		P	2	P	P			P									P				
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric																								
Small Organ (Note 1)	P	P	P		P	2	P	P			P			P						P				
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 transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PVT-745BTH
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal	P	P	P		P	2	P	P			P			P						P				7
Intra-operative (Abdominal)	P	P	P		P	2	P	P			P									P				
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric																								
Small Organ (Note 1)	P	P	P		P	2	P	P			P			P						P				
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 transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PVT-745BTV
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal	P	P	P		P	2	P	P			P			P						P				
Intra-operative (Abdominal)	P	P	P		P	2	P	P			P									P				
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric																								
Small Organ (Note 1)	P	P	P		P	2	P	P			P			P						P				
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 transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PVT-781VT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal	P	P	P		P	2	P	P			P			P										7
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric																								
Small Organ (Note 1)																								
Neonatal Cephalic																								
Adult Cephalic																								
Trans-rectal	P	P	P		P	2	P	P			P		P	P							P	P		6
Trans-vaginal	P	P	P		P	2	P	P			P		P	P							P	P		6
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 transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PVT-781VTE
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal	P	P	P		P	2	P	P			P			P										7
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric																								
Small Organ (Note 1)																								
Neonatal Cephalic																								
Adult Cephalic																								
Trans-rectal	P	P	P		P	2	P	P			P		P	P							P	P		6
Trans-vaginal	P	P	P		P	2	P	P			P		P	P							P	P		6
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 transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PVL-715RST
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal	P	P	P		P	2	P	P			P													7
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric																								
Small Organ (Note 1)																								
Neonatal Cephalic																								
Adult Cephalic																								
Trans-rectal	P	P	P		P	2	P	P			P		P	P							P	P		6
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 transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PLI-1205BX
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) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal	P	P	P		P	2	P	P			P													7
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric																								
Small Organ (Note 1)	P	P	P		P	2	P	P	P	P	P		P	P	P					P	P	P		6
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	P		P	P						P	P	P		6
Musculo-skeletal (**Superficial**)	P	P	P		P	2	P	P	P	P	P		P	P						P	P	P		6
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	P		P	P						P	P	P		6
Other (Specify)																								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PLI-2004BX
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) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal																								
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric																								
Small Organ (Note 1)	P	P	P		P	2	P	P		P	P		P	P						P	P	P		6
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		P	P						P	P	P		6
Musculo-skeletal (**Superficial**)	P	P	P		P	2	P	P		P	P		P	P						P	P	P		6
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		P	P						P	P	P		
Other (Specify)																								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PLT-704SBT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal	P	P	P		P	2	P	P			P													7
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric																								
Small Organ (Note 1)	P	P	P		P	2	P	P		P	P			P						P				
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			P						P				
Musculo-skeletal (**Superficial**)	P	P	P		P	2	P	P		P	P			P						P				
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			P						P				
Other (Specify)																								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PLT-705BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal	P	P	P		P	2	P	P			P													7
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric																								
Small Organ (Note 1)	P	P	P		P	2	P	P		P	P			P						P				
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			P						P				
Musculo-skeletal (**Superficial**)	P	P	P		P	2	P	P		P	P			P						P				
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			P						P				
Other (Specify)																								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PLT-1005BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal	P	P	P		P	2	P	P			P													7
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric																								
Small Organ (Note 1)	P	P	P		P	2	P	P		P	P		P	P	P					P	P	P		6
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		P	P						P	P	P		6
Musculo-skeletal (**Superficial**)	P	P	P		P	2	P	P		P	P		P	P						P	P	P		6
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		P	P						P	P	P		6
Other (Specify)																								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PLT-1204BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal	P	P	P		P	2	P	P			P													7
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric																								
Small Organ (Note 1)	P	P	P		P	2	P	P		P	P		P	P						P				
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		P	P						P				
Musculo-skeletal (**Superficial**)	P	P	P		P	2	P	P		P	P		P	P						P				
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		P	P						P				
Other (Specify)																								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PET-508MA
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal																								
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric																								
Small Organ (Note 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					P											N	
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 transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PET-512MD
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) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal																								
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric																								
Small Organ (Note 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					P											N	
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 transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PET-805LA
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal	P	P	P		P	2	P	P			P													7
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic	P	P	P		P	2	P	P			P		P	P										
Pediatric																								
Small Organ (Note 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 transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PC-20M
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal																								
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric				P																				
Small Organ (Note 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 transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

System: Aplio i900, i800, i700 V2.1
Transducer: PC-50M
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI(ADF)**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal																								
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric				P																				
Small Organ (Note 1)																								
Neonatal Cephalic																								
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Musculo-skeletal(**Conventional**)																								
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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 transducers: K161843
Prescription Use Only (Per 21 CFR 801.109)

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Note 4 ATI

Note 5 Tissue Intensity Analysis

Note 6 Sensor3D

Note 7 CHI (Per FDA approved contrast agent prescribing information)

Note 8 Shadow Glass

510(k) SUMMARY

1. **SUBMITTER'S NAME:**
   Toshiba Medical Systems Corporation
   1385 Shimoishigami
   Otawara-shi, Tochigi-ken, Japan 324-8550

2. **OFFICIAL CORRESPONDENT**
   Akinori Hatanaka

3. **ESTABLISHMENT REGISTRATION:**
   9614698

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

5. **Date Prepared:**
   April 21, 2017

6. **TRADE NAME(S):**
   Diagnostic Ultrasound System
   Aplio i900 Model TUS-AI900 Software Version V2.1
   Aplio i800 Model TUS-AI800 Software Version V2.1
   Aplio i700 Model TUS-AI700 Software Version V2.1

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 i900/i800/i700 Diagnostic Ultrasound System, V2.0	Toshiba America Medical Systems	K161843	September 21, 2016
Aplio 500/400/300 Diagnostic Ultrasound System, V6.0	Toshiba America Medical Systems	K151451	July 9, 2016

10. REASON FOR SUBMISSION:

Modification of a cleared device

11. DEVICE DESCRIPTION:

The Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800 and Aplio i700 Model TUS-AI700, V2.1 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 20 MHz.

12. INDICATIONS FOR USE:

The Diagnostic Ultrasound Systems Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800 and Aplio i700 Model TUS-AI700 are indicated for the visualization of structures, and dynamic processes with the human body using ultrasound and to provide image information for diagnosis in the following clinical applications: fetal, abdominal, intra-operative (abdominal), pediatric, small organs, trans-vaginal, trans-rectal, neonatal cephalic, adult cephalic, cardiac (both adult and pediatric), peripheral vascular, transesophageal, musculo-skeletal (both conventional and superficial) and laparoscopic.

13. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the Aplio i900/i800/i700, Diagnostic Ultrasound System, V2.0, K161843, marketed by Toshiba America Medical Systems. The Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800 and Aplio i700 Model TUS-AI700, V2.1 function in a manner similar to and is intended for the same use as the predicate device. The subject device is a compact diagnostic ultrasound system that implements the latest technologies.

Device	Aplio A500/400/300 V6.0	Aplio i900/i800/i700 V2.0	Aplio i900/i800/i700 V2.1	Comment
510(k) Clearance Number	K151451 (Predicate)	K161843 (Predicate)	This Submission (Subject)	
2D WMT	Yes (Auto initial contour setting is not availble)	No	Yes (Auto initial contour setting is availble)	Previously cleared feature implemented on subject device (Auto initial contour setting is newly implemented in the subject device)

14. SAFETY:

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

15. TESTING

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

Performance Testing – Assessment of Workflow Improvement

The study concluded that the 2D WMT function is substantially equivalent to the predicate device with regard to the display of GLS, GCS, GRS and EDV/ESV/EF and the calculation/provision of global and segment strain in a Polar Map display. Additionally, it was also concluded that using the 2D WMT full-assist function on the subject device resulted in reduced operation time over that of the predicate device.

Performance Testing – Clinical Images

Representative clinical images were obtained and it was concluded that the 2D WMT implemented on the subject device performs as intended. More specifically, it enables the cardiac wall trace (initial contour setting), the local wall motion tracking and provides wall motion information analysis and display, cardiac volume measurement, and cardiac function analysis.

In a 10 patient study conducted by three clinicians, the measurement of the major parameters EDV, ESV, Long. Strain Inner, Radial Strain, Total and Circumferential Strain Inner was determined to have a less than 11% coefficient of variation. Additionally, the initial contour trace lines created by the clinicians showed little differences, of which may have been attributed to ultrasound image border recognition, read out conditions, and image frame selection differences.

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 this device was conducted in accordance with the applicable standards published by the International Electrotechnical Commission (IEC) for Medical Devices.

16. CONCLUSION

The Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800 and Aplio i700 Model TUS-AI700, V2.1 is substantially equivalent to the predicate devices. The subject devices function in a manner similar to and is intended for the same use as the predicate devices, as described in the labeling. Based upon the 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.