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

September 21, 2016

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

Re: K161843
Trade/Device Name: Aplio i900/i800/i700 Diagnostic Ultrasound System, V2.0
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: September 14, 2016
Received: September 15, 2016

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)*

K161843

Device Name

Aplio i900/i800/i700 Diagnostic Ultrasound System, V2.0

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.

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

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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 V2.0
Transducer: _____
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**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	N	N	N		N	2	N	N			N			N		N	N	N	N	N				6,8
Abdominal	N	N	N	N	N	2,3	N	N			N		N	N	N	N	N	N	N	N	N	N		4,5,6,7,8
Intra-operative (Abdominal)	N	N	N		N	2	N	N			N									N				
Intra-operative (Neuro)																								
Laparoscopic	N	N	N		N	2	N	N			N		N	N										
Pediatric	N	N	N	N	N	2,3	N	N			N			N		N	N	N	N	N	N	N		6,8
Small Organ (Note 1)	N	N	N		N	2	N	N	N	N	N		N	N	N					N	N	N		6
Neonatal Cephalic	N	N	N	N	N	3	N				N													
Adult Cephalic	N	N	N	N	N	3					N													
Trans-rectal	N	N	N		N	2	N	N			N		N	N		N	N				N	N		8
Trans-vaginal	N	N	N		N	2	N	N			N		N	N		N	N				N	N		8
Trans-urethral																								
Trans-esoph. (non-Card.)																								
Musculo-skeletal(**Conventional**)	N	N	N		N	2	N	N	N	N	N		N	N						N	N	N		6
Musculo-skeletal (**Superficial**)	N	N	N		N	2	N	N	N	N	N		N	N						N	N	N		6
Intravascular																								
Other (Specify)																								
Cardiac Adult	N	N	N	N	N	3	N				N	N												7
Cardiac Pediatric	N	N	N	N	N	3	N				N	N												7
Intravascular (Cardiac)																								
Trans-esoph. (Cardiac)	N	N	N	N	N	3	N					N												
Intra-cardiac																								
Other (Specify)																								
Peripheral vessel	N	N	N	N	N	2	N	N	N	N	N		N	N						N	N	N		6
Other (Specify)																								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducers: N/A
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 V2.0
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	N	N	N	N	N	3	N				N			N							N			
Intra-operative (Abdominal)																									
Intra-operative (Neuro)																									
Laparoscopic																									
Pediatric	N	N	N	N	N	3	N				N			N							N			
Small Organ (Note 1)																									
Neonatal Cephalic	N	N	N	N	N	3	N				N														
Adult Cephalic	N	N	N	N	N	3					N														
Trans-rectal																									
Trans-vaginal																									
Trans-urethral																									
Trans-esoph. (non-Card.)																									
Musculo-skeletal(**Conventional**)																									
Musculo-skeletal (**Superficial**)																									
Intravascular																									
Other (Specify)																									
Cardiac Adult	N	N	N	N	N	3	N				N	N													7
Cardiac Pediatric	N	N	N	N	N	3	N				N	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 V2.0
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	N	N	N	N	N	3	N				N			N										
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	N	N	N	N	N	3	N				N			N										
Small Organ (Note 1)																								
Neonatal Cephalic	N	N	N	N	N	3	N				N													
Adult Cephalic	N	N	N	N	N	3					N													
Trans-rectal																								
Trans-vaginal																								
Trans-urethral																								
Trans-esoph. (non-Card.)																								
Musculo-skeletal(**Conventional**)																								
Musculo-skeletal (**Superficial**)																								
Intravascular																								
Other (Specify)																								
Cardiac Adult	N	N	N	N	N	3	N				N	N												7
Cardiac Pediatric	N	N	N	N	N	3	N				N	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: N/A
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 V2.0
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	N				P			N										
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P	P	P	3	N				P			N										
Small Organ (Note 1)																								
Neonatal Cephalic	P	P	P	P	P	3	N				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	N				P	P												
Cardiac Pediatric	P	P	P	P	P	3	N				P	P												
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: K151451
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 V2.0
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	N				P			N										7(N)
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P	P	P	3	N				P			N										
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												7
Cardiac Pediatric	P	P	P	P	P	3					P	P												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 V2.0
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	N				P													
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P	P	P	3	N				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												
Cardiac Pediatric	P	P	P	P	P	3					P	P												
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 V2.0
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	N	N	N		N	2	N	N			N			N						N				
Abdominal	N	N	N		N	2	N	N			N		N	N						N	N	N		6,7
Intra-operative (Abdominal)																									
Intra-operative (Neuro)																									
Laparoscopic																									
Pediatric	N	N	N		N	2	N	N			N			N						N	N	N		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 V2.0
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	N	N	N		N	2	N	N			N			N						N				
Abdominal	N	N	N		N	2	N	N			N		N	N	N					N	N	N		4,5,6,7
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	N	N	N		N	2	N	N			N			N						N	N	N		6
Small Organ (Note 1)																								
Neonatal Cephalic																								
Adult Cephalic																								
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Trans-vaginal																								
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Musculo-skeletal (**Superficial**)																								
Intravascular																								
Other (Specify)																								
Cardiac Adult																								
Cardiac Pediatric																								
Intravascular (Cardiac)																								
Trans-esoph. (Cardiac)																								
Intra-cardiac																								
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 V2.0
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			N						P				
Abdominal	P	P	P		P	2	P	P			P		P	P	P					P	P	P		4(N), 5(N), 6(N), 7(N)
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P		P	2	P	P			P			P						P	P	P		6(N)
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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Previous 510(k) of the transducers: K151451
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 V2.0
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			N						P				6(N)
Abdominal	P	P	P		P	2	P	P			P		P	P	P					P	P	P		4(N),5(N),6(N),7(N)
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P		P	2	P	P			P			P						P	P	P		6(N)
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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Previous 510(k) of the transducers: K151451
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 V2.0
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			N						P		P		6(N)
Abdominal	P	P	P		P	2	P	P			P			P						P	P	P		6(N),7(N)
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P		P	2	P	P			P			P						P	P	P		6(N)
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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Previous 510(k) of the transducers: K151451
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 V2.0
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(N)
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)																									

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Previous 510(k) of the transducers: K151451
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 V2.0
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			N		P	P	P	P					8(N)
Abdominal	P	P	P		P	2	P	P			P			N		P	P	P	P					8(N)
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P		P	2	P	P			P			N		P	P	P	P					8(N)
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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Previous 510(k) of the transducers: K151451
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 V2.0
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	N	N	N		N	2	N	N			N													7(N)
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(N)
Trans-vaginal	P	P	P		P	2	P	P			P		P	P		P	P							8(N)
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: K151451
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 V2.0
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			N						P				
Intra-operative (Abdominal)																									
Intra-operative (Neuro)																									
Laparoscopic																									
Pediatric	P	P	P		P	2	P	P			P			N						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)																									

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Previous 510(k) of the transducers: K151451
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 V2.0
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(N)
Intra-operative (Abdominal)	P	P	P		P	2	P	P			P									P				
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric																								
Small Organ (Note 1)	N	N	N		N	2	N	N			N			N						N				
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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Previous 510(k) of the transducers: K151451
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 V2.0
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			N						P				7(N)
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			N						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)																								

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Previous 510(k) of the transducers: K151451
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 V2.0
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			N						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			N						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)																								

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Previous 510(k) of the transducers: K151451
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 V2.0
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	N	N	N		N	2	N	N			N			N										7(N)
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(N)
Trans-vaginal	P	P	P		P	2	P	P			P		P	P							P	P		6(N)
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)																								
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Previous 510(k) of the transducers: K151451
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 V2.0
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	N	N	N		N	2	N	N			N			N										7(N)
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(N)
Trans-vaginal	P	P	P		P	2	P	P			P		P	P							P	P		6(N)
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: K151451
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 V2.0
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	N	N	N		N	2	N	N			N													7(N)
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		N	P							P	P		6(N)
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: K151451
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 V2.0
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	N	N	N		N	2	N	N			N													7
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric																								
Small Organ (Note 1)	N	N	N		N	2	N	N	N	N	N		N	N	N					N	N	N		6
Neonatal Cephalic																								
Adult Cephalic																								
Trans-rectal																								
Trans-vaginal																								
Trans-urethral																								
Trans-esoph. (non-Card.)																								
Musculo-skeletal(**Conventional**)	N	N	N		N	2	N	N	N	N	N		N	N						N	N	N		6
Musculo-skeletal (**Superficial**)	N	N	N		N	2	N	N	N	N	N		N	N						N	N	N		6
Intravascular																								
Other (Specify)																								
Cardiac Adult																								
Cardiac Pediatric																								
Intravascular (Cardiac)																								
Trans-esoph. (Cardiac)																								
Intra-cardiac																								
Other (Specify)																								
Peripheral vessel	N	N	N		N	2	N	N	N	N	N		N	N						N	N	N		6
Other (Specify)																								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducers: N/A
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 V2.0
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)	N	N	N		N	2	N	N		N	N		N	N						N	N	N		6
Neonatal Cephalic																									
Adult Cephalic																									
Trans-rectal																									
Trans-vaginal																									
Trans-urethral																									
Trans-esoph. (non-Card.)																									
Musculo-skeletal(**Conventional**)	N	N	N		N	2	N	N		N	N		N	N						N	N	N		6
Musculo-skeletal (**Superficial**)	N	N	N		N	2	N	N		N	N		N	N						N	N	N		6
Intravascular																									
Other (Specify)																									
Cardiac Adult																									
Cardiac Pediatric																									
Intravascular (Cardiac)																									
Trans-esoph. (Cardiac)																									
Intra-cardiac																									
Other (Specify)																									
Peripheral vessel	N	N	N		N	2	N	N		N	N		N	N						N	N	N		
Other (Specify)																									

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducers: N/A
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 V2.0
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	N	N	N		N	2	N	N			N													7(N)
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: K151451
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 V2.0
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	N	N	N		N	2	N	N			N													7(N)
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						N				
Other (Specify)																								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducers: K151451
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 V2.0
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	N	N	N		N	2	N	N			N													7(N)
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(N)
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(N)
Musculo-skeletal (**Superficial**)	P	P	P		P	2	P	P		P	P		P	P						P	P	P		6(N)
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(N)
Other (Specify)																								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducers: K151451
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 V2.0
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	N	N	N		N	2	N	N			N													7(N)
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: K151451
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 V2.0
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													
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: K151451
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 V2.0
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)	N	N	N	N	N	3	N					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: N/A
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 V2.0
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	N	N	N		N	2	N	N			N													7(N)
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: K151451
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 V2.0
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				N																				
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)																								
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Other (Specify)																								
Peripheral vessel				P																				
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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

System: Aplio i900, i800, i700 V2.0
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				N																				
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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)																								

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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:**
   September 16, 2016

6. **TRADE NAME(S):**
   Aplio i900/i800/i700 Diagnostic Ultrasound System, V2.0

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 V6.0	Toshiba America Medical Systems	K151451	July 7, 2015
Vivid E9 Diagnostic Ultrasound System	GE Healthcare	K131514	July 12, 2013

10. REASON FOR SUBMISSION:

New device

11. DEVICE DESCRIPTION:

The Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800 and Aplio i700 Model TUS-AI700, V2.0 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 500/400/300 V6.0 Diagnostic Ultrasound System, K151451, marketed by Toshiba America Medical Systems. The Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800 and Aplio i700 Model TUS-AI700, V2.0 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 by implementing latest technologies.

	Aplio 500/400/300 V6.0	**Aplio i900/i800/i700 V2.0**	**Comment**
510(K) Control Number	**K151451**	**N/A (Subject Device)**	
Sensor 3D	No	Yes	New feature
Shadow Glass	No	Yes	New feature
Attenuation Imaging	No	Yes	New feature
Shear Wave Dispersion (SWD)	No	Yes	New feature
Tissue Intensity Analysis (Normalized Local Variance (NLV)/Ratio)	No	Yes	New feature
CHI (Contrast Harmonic Imaging) for Liver	No	Yes	New feature

	Aplio 500/400/300 V6.0	Aplio i900/i800/i700 V2.0	Comment
510(K) Control Number	**K151451**	**N/A (Subject Device)**	
Auto Volume Measurement	No	Yes	New feature
Fusion Auto Track	No	Yes	New feature
PSI-30BX transducer	No	Yes	New transducer
PSI-70BT transducer	No	Yes	New transducer
PVI-475BT transducer	No	Yes	New transducer
PVI-475BX transducer	No	Yes	New transducer
PLI-1205BX transducer	No	Yes	New transducer
PLI-2004BX transducer	No	Yes	New transducer

	Vivid E9 Diagnostic Ultrasound System	Aplio i900/i800/i700 V2.0	Comment
510(K) Control Number	**K131514**	**N/A (Subject Device)**	
Sensor 3D -Measurements Distance/Angle/Area/Volume	Yes (Tru3D(G))	Yes	New feature
Registration with OmniTRAX Active Patient Tracker (CIVCO Medical Instruments Co., Inc) - CT image - MR image	Yes	Yes (Fusion Auto Track)	New feature *CIVCO 510(k) clearance numbers CT: K092619 MR: K143396

Previously cleared features being implemented to the subject device:

Feature	510(k) Clearance	Comments
Shear Wave Elastography	Previously cleared under K151451	No change to basic function
Elastography	Previously cleared under K151451	No change to basic function
SMI	Previously cleared under K151451	No change to basic function
Smart Fusion	Previously cleared under K151451	No change to basic function
Smart Navigation	Previously cleared under K151451	No change to basic function
Auto-NT	Previously cleared under K151451	No change to basic function
MultiCast Beam Former	Previously cleared under K140729	Improvement to basic function (Histogram)
Tissue Intensity Analysis (Ratio)	Previously cleared under K991710	Improvement to basic function (Multiple focus)

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 – Bench

Various phantom studies were conducted to demonstrate that the new features and improvements to previously cleared features being implemented to the subject device performed as intended. The studies concluded the following:

- Sensor 3D provides the expected 3D images of phantom structures, measurement accuracy, hardness information and the frequency dispersion of the target of the 3D image with the shear wave function
- Accurate quantitative attenuation coefficient results can be obtained using Attenuation Imaging and that a color map is displayed to show the spatial distribution of attenuation coefficient
- NLV can be used to visualize the distribution of homogeneous and heterogeneous areas of various phantoms by displaying a color map
- Fusion Auto Track enables automatic fusion of real-time ultrasound images to previously acquired CT or MR data sets by using the OmniTRAX Active Patient Tracker
- Auto Volume Measurement improves workflow using volume transducers compared with the predicate device and that the measurement accuracy is within the specified range
- CHI can visualize the nonlinear signal including 2nd harmonic from the Contrast medium, the quantification of the peak intensity, the time to reach the peak intensity
- Shear Wave Dispersion (SWD) can visualize a frequency dependency of the shear wave speed (Phase velocity)
- Shadow Glass displays tissue and tissue with flow in a transparent manner

Performance Testing – Clinical Images

Clinical evaluations were conducted to demonstrate that the subject device performed as expected. In one study representative clinical images of volunteer livers were obtained and it was confirmed that Attenuation Imaging can display a color map of attenuation coefficient as well as numerical results in-vivo. In another study representative clinical images of volunteer livers were obtained and using NLV, the study confirmed that NLV displays acceptable color map images and mean NLV values, in-vivo.

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, V2.0 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.