



July 19, 2019

Canon Medical Systems Corporation
% Orlando Tadeo, Jr.
Sr. Manager, Regulatory Affairs
Canon Medical Systems USA, Inc.
2441 Michelle Drive
TUSTIN CA 92780

Re: K191467

Trade/Device Name: Aplio i900/i800/i700/i600 Diagnostic Ultrasound System, V4.0
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: May 31, 2019
Received: June 3, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K191467

Device Name

Aplio i900/i800/i700/i600 Diagnostic Ultrasound System, V4.0

Indications for Use (Describe)

The Diagnostic Ultrasound Systems Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800, Aplio i700 Model TUS-AI700 and Aplio i600 Model TUS-AI600 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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System: Aplio i900, i800, i700, i600 V4.0

Transducer: _____

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

Clinical Application	Mode of Operation																							Other	[Note]
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		
Ophthalmic																									
Fetal	P	P	P		P	2	P	P			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						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	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				P			P		P					P			6,	
Trans-rectal	P	P	P		P	2	P	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	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		6,8(N)	
Musculo-skeletal(Superficial)	P	P	P		P	2	P	P	P	P	P		P	P						P	P	P		6,8(N)	
Intravascular																									
Other (Specify)																									
Cardiac Adult	P	P	P	P	P	3	P				P	P				P	P				P		P	7,8,9,10	
Cardiac Pediatric	P	P	P	P	P	3	P				P	P				P	P						P	7,8,9,10	
Intravascular (Cardiac)																									
Trans-esoph. (Cardiac)	P	P	P	P	P	3	P					P				P	P						P	8,10,11	
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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700,i600 V4.0

Transducer: PST-28BT*

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

Clinical Application	Mode of Operation																							Other	[Note]
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		
Ophthalmic																									
Fetal																									
Abdominal	P	P	P	P	P	3	P	P			P			P							P			6(P),7(P),8(P)	
Intra-operative (Abdominal)																									
Intra-operative (Neuro)																									
Laparoscopic																									
Pediatric																									
Small Organ (Note 1)																									
Neonatal Cephalic	P	P	P	P	P	3	P				P														
Adult Cephalic	P	P	P	P	P	3	P				P			P							P			6(P)	
Trans-rectal																									
Trans-vaginal																									
Trans-urethral																									
Trans-esoph. (non-Card.)																									
Musculo-skeletal(Conventional)																									
Musculo-skeletal (Superficial)																									
Intravascular																									
Other (Specify)																									
Cardiac Adult	P	P	P	P	P	3	P				P	P									P		P	7(P),8(P)	
Cardiac Pediatric	P	P	P	P	P	3	P				P	P											P	7(P),8(P)	
Intravascular (Cardiac)																									
Trans-esoph. (Cardiac)																									
Intra-cardiac																									
Other (Specify)																									
Peripheral vessel																									
Other (Specify)																									

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Previous 510(k) of the transducers: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

*This transducer Model Name was incorrectly listed as “PSI-28BT” in predicate submission K182679. The correct reference was provided to FDA in “Add to file_K182679”.

System: Aplio i900, i800, i700 V4.0

Transducer: PSI-30BX

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

Clinical Application	Mode of Operation																							Other	[Note]
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		
Ophthalmic																									
Fetal																									
Abdominal	P	P	P	P	P	3	P				P			P							P	P		6(P)	
Intra-operative (Abdominal)																									
Intra-operative (Neuro)																									
Laparoscopic																									
Pediatric	P	P	P	P	P	3	P				P			P							P	P		6(P)	
Small Organ (Note 1)																									
Neonatal Cephalic	P	P	P	P	P	3	P				P														
Adult Cephalic	P	P	P	P	P	3	P				P			P							P			6(P)	
Trans-rectal																									
Trans-vaginal																									
Trans-urethral																									
Trans-esoph. (non-Card.)																									
Musculo-skeletal(Conventional)																									
Musculo-skeletal (Superficial)																									
Intravascular																									
Other (Specify)																									
Cardiac Adult	P	P	P	P	P	3	P				P	P		P							P		P	7	
Cardiac Pediatric	P	P	P	P	P	3	P				P	P		P							P		P	7	
Intravascular (Cardiac)																									
Trans-esoph. (Cardiac)																									
Intra-cardiac																									
Other (Specify)																									
Peripheral vessel																									
Other (Specify)																									

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Previous 510(k) of the transducers: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0

Transducer: PSI-70BT

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

Clinical Application	Mode of Operation														Other	[Note]							
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appl 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
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										P	7
Cardiac Pediatric	P	P	P	P	P	3	P				P	P										P	7
Intravascular (Cardiac)																							
Trans-esoph. (Cardiac)																							
Intra-cardiac																							
Other (Specify)																							
Peripheral vessel																							
Other (Specify)																							

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Previous 510(k) of the transducers: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0

Transducer: PST-25BT

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

Clinical Application	Mode of Operation															Other	[Note]						
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Apl 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
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				P												
Trans-rectal																							
Trans-vaginal																							
Trans-urethral																							
Trans-esoph. (non-Card.)																							
Musculo-skeletal(Conventional)																							
Musculo-skeletal (Superficial)																							
Intravascular																							
Other (Specify)																							
Cardiac Adult	P	P	P	P	P	3	P				P	P											P
Cardiac Pediatric	P	P	P	P	P	3	P				P	P											P
Intravascular (Cardiac)																							
Trans-esoph. (Cardiac)																							
Intra-cardiac																							
Other (Specify)																							
Peripheral vessel																							
Other (Specify)																							

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Previous 510(k) of the transducers: K182679

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

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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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: PST-30BT

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

Clinical Application	Mode of Operation																						Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli Pure	Micro Pure	BEAM	Power	TDI	Elastography	SMI(ADF)	Shear wave	4D	3D Color (Volume color)	STIC	STIC Color	Smart 3D	Fusion	Smart Navigation		
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				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		7
Cardiac Pediatric	P	P	P	P	P	3					P	P										P		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

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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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: PST-50BT

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

Clinical Application	Mode of Operation																Other	[Note]					
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli 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
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												
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
Cardiac Pediatric	P	P	P	P	P	3					P	P											P
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)

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

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Note 8 Shadow Glass

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0

Transducer: PST-65BT

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

Clinical Application	Mode of Operation															Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Apfi Pure	Micro Pure	BEAM	Power	TDI	Elastography	SMI(ADF)	Shear wave		
Ophthalmic																	
Fetal																	
Abdominal																	
Intra-operative (Abdominal)																	
Intra-operative (Neuro)																	
Laparoscopic																	
Pediatric	N	N	N	N	N	3	N				N			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	N	N	N	N	N	3	N				N	N				N	
Cardiac Pediatric	N	N	N	N	N	3	N				N	N				N	
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)

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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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, V4.0Transducer: PSI-30VX

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

Clinical Application	Mode of Operation																							Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli 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		
Ophthalmic																									
Fetal																									
Abdominal	P	P	P	P	P	3	P				P			P		P	P			P	P			7	
Intra-operative (Abdominal)																									
Intra-operative (Neuro)																									
Laparoscopic																									
Pediatric	P	P	P	P	P	3	P				P			P		P	P			P	P				
Small Organ (Note 1)																									
Neonatal Cephalic																									
Adult Cephalic	P	P	P	P	P	3	P				P					P					P				
Trans-rectal																									
Trans-vaginal																									
Trans-urethral																									
Trans-esoph. (non-Card.)																									
Musculo-skeletal(Conventional)																									
Musculo-skeletal (Superficial)																									
Intravascular																									
Other (Specify)																									
Cardiac Adult	P	P	P	P	P	3	P				P	P				P	P						P	7,8,9,10	
Cardiac Pediatric	P	P	P	P	P	3	P				P	P				P	P						P	7,8,9,10	
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:K182679

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; BD/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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700 V4.0Transducer: PSI-40VX

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

Clinical Application	Mode of Operation																							Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli 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		
Ophthalmic																									
Fetal	P	P	P		P	2					P			P		P	P								
Abdominal	P	P	P	P	P	3	P				P			P		P	P				P			7	
Intra-operative (Abdominal)																									
Intra-operative (Neuro)																									
Laparoscopic																									
Pediatric	P	P	P	P	P	3	P				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	P	P	P	P	P	3	P				P	P				P	P					P		7,8,9,10	
Cardiac Pediatric	P	P	P	P	P	3	P				P	P				P	P					P		7,8,9,10	
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: K182679

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; BD/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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700 V4.0Transducer: PSI-50VX

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

Clinical Application	Mode of Operation																						Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli 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	
Ophthalmic																								
Fetal	P	P	P		P	2					P			P		P	P							
Abdominal																								
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P	P	P	3	P				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	P	P	P	P	P	3	P				P	P				P	P					P	7,8,9,10	
Cardiac Pediatric	P	P	P	P	P	3	P				P	P				P	P					P	7,8,9,10	
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: K182679

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; BD/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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: PVI-475BT

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

Clinical Application	Mode of Operation																	Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli Pure	Micro Pure	BEAM	Power	TDI	Elastography	SMI(ADF)	Shear wave	4D	3D Color (Volume color)		
Ophthalmic																			
Fetal	P	P	P		P	2	P	P			P	P		P				P	
Abdominal	P	P	P		P	2	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	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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700 V4.0Transducer: PVI-475BX

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

Clinical Application	Mode of Operation																	Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli Pure	Micro Pure	BEAM	Power	TDI	Elastography	SMI(ADF)	Shear wave	4D	3D Color (Volume color)		
Ophthalmic																			
Fetal	P	P	P		P	2	P	P			P	P		P				P	
Abdominal	P	P	P		P	2	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	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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700 V4.0Transducer: PVI-482BX

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

Clinical Application	Mode of Operation																							Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appl Pure	Micro Pure	BEAM	Power	TDI	Elastography	SML(ADF)	Shear wave	4D	3D Color (Volume color)	STC	STC Color	Smart 3D	Fusion	Smart Navigation	2D WMT		
Ophthalmic																									
Fetal	N	N	N		N	2	N	N			N			N						N				6	
Abdominal	N	N	N		N	2	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)																									

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0

Transducer: PVT-574BT

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

Clinical Application	Mode of Operation																							Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Apfi 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		
Ophthalmic																									
Fetal	P	P	P		P	P	P	P			P	P		P						P			P	6(P), 8(P)	
Abdominal	P	P	P		P	P	P	P			P			P	P					P	P	P	P	6(P),7(P),8(P)	
Intra-operative (Abdominal)																									
Intra-operative (Neuro)																									
Laparoscopic																									
Pediatric	P	P	P		P	P	P	P			P			P						P	P	P		6(P),8(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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, V4.0

Transducer: PVI-574BX

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

Clinical Application	Mode of Operation																							Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Apili 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		
Ophthalmic																									
Fetal	P	P	P		P	2	P	P			P	P		P						P				P	6(P), 8(P)
Abdominal	P	P	P		P	2	P	P			P			P	P					P	P	P			6(P),7(P),8(P)
Intra-operative (Abdominal)																									
Intra-operative (Neuro)																									
Laparoscopic																									
Pediatric	P	P	P		P	2	P	P			P			P						P	P	P			6(P),8(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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: PVT-482BT

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	Appli 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		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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: PVT-375BT

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

Clinical Application	Mode of Operation																							Other	[Note]
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		
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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: PVT-375SC

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

Clinical Application	Mode of Operation																	Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Apfi Pure	Micro Pure	BEAM	Power	TDI	Elastography	SMI(ADF)	Shear wave	4D	3D Color (Volume color)		
Ophthalmic																			
Fetal	P	P	P		P	2	P	P			P			P				6	
Abdominal	P	P	P		P	2	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				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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: PVT-382BT

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

Clinical Application	Mode of Operation																							Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli 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		
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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0

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	Appli 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	
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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: PVT-675MVL

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

Clinical Application	Mode of Operation																	Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli Pure	Micro Pure	BEAM	Power	TDI	Elastography	SMI(ADF)	Shear wave	4D	3D Color (Volume color)		
Ophthalmic																			
Fetal	P	P	P		P	2	P	P			P			P		P	P	P	8
Abdominal	P	P	P		P	2	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	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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0

Transducer: PVT-675MVS

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

Clinical Application	Mode of Operation																	Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli Pure	Micro Pure	BEAM	Power	TDI	Elastography	SMI(ADF)	Shear wave	4D	3D Color (Volume color)		
Ophthalmic																			
Fetal	P	P	P		P	2	P	P			P			P		P	P	P	8
Abdominal	P	P	P		P	2	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	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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0

Transducer: PVT-681MVL

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

Clinical Application	Mode of Operation																							Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli 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 W/MT		
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)																									

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducers: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0

Transducer: PVT-712BT

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

Clinical Application	Mode of Operation																					Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli 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
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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: PVT-745BTF

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

Clinical Application	Mode of Operation																							Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli 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		
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						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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: PVT-745BTH

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

Clinical Application	Mode of Operation																							Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli 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		
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						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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0

Transducer: PVT-745BTv

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

Clinical Application	Mode of Operation																					Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli 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
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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: PVT-781VT

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

Clinical Application	Mode of Operation																	Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli Pure	Micro Pure	BEAM	Power	TDI	Elastography	SMI(ADF)	Shear wave	4D	3D Color (Volume color)		
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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: PVT-781VTE

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

Clinical Application	Mode of Operation																	Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli Pure	Micro Pure	BEAM	Power	TDI	Elastography	SMI(ADF)	Shear wave	4D	3D Color (Volume color)		
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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0

Transducer: PVL-715RST

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

Clinical Application	Mode of Operation																Other	[Note]					
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli Pure	Micro Pure	BE/AM	Power	TDI	Elastography	SMI(ADF)	Shear wave	4D	3D Color (Volume color)	STIC	STIC Color	Smart 3D	Fusion	Smart Navigation	2D WMT
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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: PVT-770RT

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

Clinical Application	Mode of Operation																							Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Apfi 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		
Ophthalmic																									
Fetal																									
Abdominal																									
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											
Trans-vaginal	P	P	P		P	2	P	P			P			P											
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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700 V4.0Transducer: PLI-1205BX

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

Clinical Application	Mode of Operation																	Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli Pure	Micro Pure	BEAM	Power	TDI	Elastography	SMI(ADF)	Shear wave	4D	3D Color (Volume color)		
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	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	6,8
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P	P	P		P	P				P	6,8
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	6
Other (Specify)																			

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducers: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700 V4.0

Transducer: PLI-2002BT

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

Clinical Application	Mode of Operation																							Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Apbi 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		
Ophthalmic																									
Fetal																									
Abdominal																									
Intra-operative (Abdominal)	P	P	P		P	2	P	P			P			P						P	P			6	
Intra-operative (Neuro)																									
Laparoscopic																									
Pediatric																									
Small Organ (Note 1)	P	P	P		P	2	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			6	
Musculo-skeletal (Superficial)	P	P	P		P	2	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			6	
Other (Specify)																									

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducers:K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700 V4.0Transducer: 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	Appli 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		6,8	
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P		P	P		P	P						P	P	P		6,8	
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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700 V4.0

Transducer: PLI-3003BX

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

Clinical Application	Mode of Operation																						Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Apfi 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	
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)	P	P	P		P	2	P	P			P			P						P	P		6(P)	
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P			P			P						P	P		6(P),8(P)	
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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: PLT-704SBT

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

Clinical Application	Mode of Operation																							Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli 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		
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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0

Transducer: PLT-705BT

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

Clinical Application	Mode of Operation																						Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli Pure	Micro Pure	BEAM	Power	TDI	Elastography	SMI(ADF)	Shear wave	4D	3D Color (Volume color)	STIC	STIC Color	Smart 3D	Fusion	Smart Navigation		
Ophthalmic																								
Fetal																								
Abdominal	P	P	P		P	2	P	P			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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: PLT-705BTF

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

Clinical Application	Mode of Operation																							Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli 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		
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						P					
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)																									
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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: PLT-705BTH

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	Appli 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						P				
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)																								
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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700 V4.0Transducer: PLI-705BX

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

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

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducers: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: PLT-1005BT

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

Clinical Application	Mode of Operation																							Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli 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		
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		6,8	
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P		P	P		P	P						P	P	P		6,8	
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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: PLT-1202BT

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

Clinical Application	Mode of Operation																							Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli 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		
Ophthalmic																									
Fetal																									
Abdominal																									
Intra-operative (Abdominal)	P	P	P		P	2	P	P			P			P						P	P			6	
Intra-operative (Neuro)																									
Laparoscopic																									
Pediatric																									
Small Organ (Note 1)	P	P	P		P	2	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			6	
Musculo-skeletal (Superficial)	P	P	P		P	2	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				
Other (Specify)																									

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducers: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: PLT-1204BT

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

Clinical Application	Mode of Operation																							Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli 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		
Ophthalmic																									
Fetal																									
Abdominal	P	P	P		P	2	P	P			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			8		
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P		P	P		P	P						P			8		
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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: PET-508MA

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

Clinical Application	Mode of Operation																							Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli 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		
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										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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: PET-512MC

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

Clinical Application	Mode of Operation																							Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) *	Precision Imaging	Appli 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		
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											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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: PET-512MD

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

Clinical Application	Mode of Operation																							Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Precision Imaging Combined (Specify) *	Appli 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			
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											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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700 V4.0Transducer: PEI-512VX

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	Appli 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				P	P						P	8,9,10,11	
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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: 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	Appli 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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0

Transducer: PC-20M

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

Clinical Application	Mode of Operation																					Other	[Note]
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Precision Imaging Combined (Specify) *	Appli 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	
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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

System: Aplio i900, i800, i700, i600 V4.0Transducer: PC-50M

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

Clinical Application	Mode of Operation																							Other	[Note]
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		
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: K182679

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

Note 9 3D Wall Motion Tracking

Note 10 3D ACM

Note 11 Mitral Valve Analysis

510(k) SUMMARY**1. SUBMITTER'S NAME:**

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

2. OFFICIAL CORRESPONDENT

Naofumi Watanabe

3. ESTABLISHMENT REGISTRATION:

9614698

4. CONTACT PERSON:

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Canon Medical Systems USA, Inc.
2441 Michelle Drive
Tustin, CA 92780
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5. Date Prepared:

May 31, 2019

6. TRADE NAME(S):

Diagnostic Ultrasound System
Aplio i900 Model TUS-AI900 Software Version V4.0
Aplio i800 Model TUS-AI800 Software Version V4.0
Aplio i700 Model TUS-AI700 Software Version V4.0
Aplio i600 Model TUS-AI600 Software Version V4.0

7. COMMON NAME:

System, Diagnostic Ultrasound

8. DEVICE CLASSIFICATION:

Class II
Ultrasonic Pulsed Doppler Imaging System – Product Code: 90-IYN [per 21 CFR 892.1550]
Ultrasonic Pulsed Echo Imaging System – Product Code: 90-IYO [per 21 CFR 892.1560]
Diagnostic Ultrasonic Transducer – Product Code: 90-ITX [per 21 CFR 892.1570]

9. PREDICATE DEVICE:

Product	Marketed by	510(k) Number	Clearance Date
Aplio i900/i800/i700 Diagnostic Ultrasound System, V3.1 (Primary Predicate Device)	Canon Medical Systems USA	K182679	October 31, 2018
ACUSON SC2000 Diagnostic Ultrasound System	Siemens Medical Solutions USA, Inc	K181098	May 31, 2018
AIXPLORER® MACH Ultrasound Diagnostic Systems	Supersonic Imagine	K180572	May 29, 2018

10. REASON FOR SUBMISSION:

Modification of a cleared device

11. DEVICE DESCRIPTION:

The Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800, Aplio i700 Model TUS-AI700 and Aplio i600 Model TUS-AI600, V4.0 are mobile, compact diagnostic ultrasound systems which implement the latest technologies. 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 30 MHz.

12. INDICATIONS FOR USE:

The Diagnostic Ultrasound Systems Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800, Aplio i700 Model TUS-AI700 and Aplio i600 Model TUS-AI600 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/i600, Diagnostic Ultrasound System, V3.1, K182679, marketed by Canon Medical Systems USA. The Aplio i900 Model TUS-AI900, Aplio i800 Model TUS-AI800, Aplio i700 Model TUS-AI700 and Aplio i600 Model TUS-AI600, V4.0 function in a manner similar to and is intended for the same use as the predicate devices. The subject device includes modifications to the cleared device which improves upon existing features. This submission also includes details regarding new features determined to be substantially equivalent to features cleared under the predicate devices referenced within this submission.

New features and Improvements to previously cleared functions:

Device	Aplio i900/i800/i700/i600 V4.0	ACUSON SC2000 Diagnostic Ultrasound System	AIXPLORER® MACH Ultrasound Diagnostic Systems	Comment
510(k) Clearance Number	Subject Device	K181098	K180572	
Aortic Valve Analysis (AV Analysis)	Yes (i900)	Yes		New Feature
BI-RADS Checklist	Yes		Yes	New Feature
TI-RADS Checklist	Yes		Yes	New Feature

	Aplio i900/i800/i700 V4.0	Aplio i600 V4.0	Comment
PST-65BT	Yes	Yes	New transducer
PVI-482BX	Yes	No	New transducer

Device	Aplio i900/i800/i700/i600 (V3.1)	Aplio i900/i800/i700 (V4.0)	Aplio i600 (v4.0)	Comment
510(k) Clearance Number	K182679	Subject Device	Subject Device	
Doppler Luminance	No	Yes	Yes	Improved visibility of blood flow, Color Doppler imaging -Improvement
Volume rendering view (Mecha4D)	No	Yes	Yes	Previously only available in MPR view -Improvement
2D WMT Fetal Heart-Fetal One cycle detection	No	Yes	Yes	Automated candidate heart cycle detection -Improvement
MVA (Mitral Valve Analysis) -A2/P2 length	No	Yes	No	Addition of parameters -Improvement
Auto E/A	No	Yes	Yes	Automation of previously manual measurements -Improvement

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 AAMI/ANSI ES60601-1:2012, IEC 60601-1-2 (2014), IEC 60601-2-37 (2015), IEC 62304 (2015), AIUM RTD2-2004 Output Display and ISO 10993-1(2009) standards.

15. TESTING

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

15.1 Performance Testing – Assessment of New Feature, Aortic Valve Analysis (AV Analysis)

Bench Assessment of AV Analysis

This study confirmed that AV Analysis provides measurement values of the aortic valve complex that are substantially equivalent to those by the predicate function.

Clinical Evaluation of AV Analysis

This study confirmed that that this function provides a faster and easier workflow in comparison to the predicate function.

15.2 Performance Testing – Assessment of New Feature, BI-RADS Checklist

This study confirmed the following: I) that this function provides a check list with options standardized according to ACR BI-RADS and that (II) this function establishes a worksheet displaying check items in the specified layout.

15.3 Performance Testing – Assessment of New Feature, TI-RADS Checklist

This study confirmed the following: I) that this subject function provides a check list with options standardized according to ACR TI-RADS and automatically provides clinical assessments (risk classification in terms of Thyroid cancer) standardized according to ACR TI-RADS and that (II) this function establishes a worksheet displaying check items in the specified layout.

15.4 Performance Testing – Assessment of Improved Feature, 2D Wall Motion Tracking for Fetal Heart one cycle detection

Bench Assessment of 2D Wall Motion Tracking for Fetal Heart one cycle detection

This study confirmed the following: that I) the measurement values by the subject function are substantially equivalent to the predicate function and (II) that the operation time is reduced as compared to the predicate function.

Clinical Evaluation of 2D Wall Motion Tracking for Fetal Heart one cycle detection

This study confirmed the following: I) that the subject function automatically provides a clinically appropriate candidate one heart cycle period and (II) that workflow is improved by comparison of the subject function to the predicate.

Additional performance testing, using test data and volunteer studies, was conducted to assess improvements to existing features including Color Doppler image processing, 4D measurements, Mitral Valve Analysis, and E/A measurements. Results of all these studies demonstrated that the improvements met specifications are performed as intended.

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, Aplio i700 Model TUS-AI700 and Aplio i600 Model TUS-AI600, V4.0 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, clinical evaluation, 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.