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

September 18, 2019

Re: K191663
Trade/Device Name: Aplio a550, Aplio a450 and Aplio a, 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: June 20, 2019
Received: June 21, 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,

For

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191663

Device Name

Aplio a550, Aplio a450 and Aplio a,Diagnostic Ultrasound System, V4.0

Indications for Use *(Describe)*

The Diagnostic Ultrasound Systems Aplio a550 Model CUS-AA550, Aplio a450 Model CUS-AA450, and Aplio a Model CUS-AA000 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 a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: _____
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal	P	P	P		P	2	P	P			P	N		P		P	P	P	P	P		P		4,6
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(N)
Intra-operative (Abdominal)	P	P	P		P	2	P	P			P			P						P	P			4
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		4,6
Small Organ (Note 1)	P	P	P		P	2	P	P	P	P	P		P	P	P					P	P	P		4
Neonatal Cephalic	P	P	P	P	P	2,3	P	P			P									P				
Adult Cephalic	P	P	P	P	P	3	N				P			N							N			4
Trans-rectal	P	P	P		P	2	P	P			P		P	P	P	P	P				P	P		4,6
Trans-vaginal	P	P	P		P	2	P	P			P		P	P	P	P	P				P	P		4,6
Trans-urethral																								
Trans-esoph. (non-Card.)																								
Musculo-skeletal(**Conventional**)	P	P	P		P	2	P	P	P	P	P		P	P						P	P	P		4
Musculo-skeletal (**Superficial**)	P	P	P		P	2	P	P	P	P	P		P	P						P	P	P		4
Intravascular																								
Other (Specify)																								
Cardiac Adult	P	P	P	P	P	3	P				P	P									N		P	5, 6
Cardiac Pediatric	P	P	P	P	P	3	P				P	P											P	5,6
Intravascular (Cardiac)																								
Trans-esoph. (Cardiac)	P	P	P	P	P	3	P					P											P	6
Intra-cardiac																								
Other (Specify)																								
Peripheral vessel	P	P	P	P	P	2	P	P	P	P	P		P	P						P	P	P		4
Other (Specify)																								

N = new indication; P = previously cleared by FDA; E = added under this appendix
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PST-25BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PST-28BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal	P	P	P	P	P	3	P				P			P							P			4,5,6
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			4
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	5,6
Cardiac Pediatric	P	P	P	P	P	3	P				P	P											P	5,6
Intravascular (Cardiac)																								
Trans-esoph. (Cardiac)																								
Intra-cardiac																								
Other (Specify)																								
Peripheral vessel																								
Other (Specify)																								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: 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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PST-30BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal	P	P	P	P	P	3	P				P			P										5
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	5
Cardiac Pediatric	P	P	P	P	P	3					P	P											P	5
Intravascular (Cardiac)																								
Trans-esoph. (Cardiac)																								
Intra-cardiac																								
Other (Specify)																								
Peripheral vessel																								
Other (Specify)																								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K182427 and 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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PST-50BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal	P	P	P	P	P	3	P				P			P										
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P	P	P	3	P				P			P										
Small Organ (Note 1)																								
Neonatal Cephalic	P	P	P	P	P	3					P													
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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Previous 510(k) of the transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PSI-70BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal	P	P	P	P	P	3	P				P			P										
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P	P	P	3	P				P			P										
Small Organ (Note 1)																								
Neonatal Cephalic	P	P	P	P	P	3	P				P													
Adult Cephalic	P	P	P	P	P	3					P													
Trans-rectal																								
Trans-vaginal																								
Trans-urethral																								
Trans-esoph. (non-Card.)																								
Musculo-skeletal(**Conventional**)																								
Musculo-skeletal (**Superficial**)																								
Intravascular																								
Other (Specify)																								
Cardiac Adult	P	P	P	P	P	3	P				P	P											P	5
Cardiac Pediatric	P	P	P	P	P	3	P				P	P											P	5
Intravascular (Cardiac)																								
Trans-esoph. (Cardiac)																								
Intra-cardiac																								
Other (Specify)																								
Peripheral vessel																								
Other (Specify)																								

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Previous 510(k) of the transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PVT-375BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal	P	P	P		P	2	P	P			P			P						P				
Abdominal	P	P	P		P	2	P	P			P		P	P	P					P	P	P		4, 5
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P		P	2	P	P			P			P						P	P	P		4
Small Organ (Note 1)																								
Neonatal Cephalic																								
Adult Cephalic																								
Trans-rectal																								
Trans-vaginal																								
Trans-urethral																								
Trans-esoph. (non-Card.)																								
Musculo-skeletal(**Conventional**)																								
Musculo-skeletal (**Superficial**)																								
Intravascular																								
Other (Specify)																								
Cardiac Adult																								
Cardiac Pediatric																								
Intravascular (Cardiac)																								
Trans-esoph. (Cardiac)																								
Intra-cardiac																								
Other (Specify)																								
Peripheral vessel																								
Other (Specify)																								

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Previous 510(k) of the transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PVT-375SC
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**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				4
Abdominal	P	P	P		P	2	P	P			P		P	P	P					P	P	P		4,5
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P		P	2	P	P			P			P						P	P	P		4
Small Organ (Note 1)																								
Neonatal Cephalic																								
Adult Cephalic																								
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Trans-urethral																								
Trans-esoph. (non-Card.)																								
Musculo-skeletal(**Conventional**)																								
Musculo-skeletal (**Superficial**)																								
Intravascular																								
Other (Specify)																								
Cardiac Adult																								
Cardiac Pediatric																								
Intravascular (Cardiac)																								
Trans-esoph. (Cardiac)																								
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Other (Specify)																								
Peripheral vessel																								
Other (Specify)																								

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Previous 510(k) of the transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PVT-382BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																								
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**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		4
Abdominal	P	P	P		P	2	P	P			P			P						P	P	P		4,5
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P		P	2	P	P			P			P						P	P	P		4
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 transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PVT-475BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																								
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal	P	P	P		P	2	P	P			P			P						P				
Abdominal	P	P	P		P	2	P	P			P		P	P	P					P	P	P		4, 5,7(N)
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P		P	2	P	P			P			P						P	P	P		4
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 transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: 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**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**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				4
Abdominal	P	P	P		P	2	P	P			P			P						P	P	P		4,5
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P		P	2	P	P			P			P						P	P	P		4
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 transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PVT-574BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																								
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**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	4,6
Abdominal	P	P	P		P	2	P	P			P			P	P					P	P	P		4,5,6
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P		P	2	P	P			P			P						P	P	P		4,6
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 transducer: 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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PVT-674BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal	P	P	P		P	2	P	P			P			P						P				
Abdominal	P	P	P		P	2	P	P			P			P						P				5
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P		P	2	P	P			P			P						P				
Small Organ (Note 1)																								
Neonatal Cephalic																								
Adult Cephalic																								
Trans-rectal																								
Trans-vaginal																								
Trans-urethral																								
Trans-esoph. (non-Card.)																								
Musculo-skeletal(**Conventional**)																								
Musculo-skeletal (**Superficial**)																								
Intravascular																								
Other (Specify)																								
Cardiac Adult																								
Cardiac Pediatric																								
Intravascular (Cardiac)																								
Trans-esoph. (Cardiac)																								
Intra-cardiac																								
Other (Specify)																								
Peripheral vessel																								
Other (Specify)																								

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Previous 510(k) of the transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PVT-675MVL
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal	P	P	P		P	2	P	P			P			P		P	P	P	P					6
Abdominal	P	P	P		P	2	P	P			P			P		P	P	P	P					6
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P		P	2	P	P			P			P		P	P	P	P					6
Small Organ (Note 1)																								
Neonatal Cephalic																								
Adult Cephalic																								
Trans-rectal																								
Trans-vaginal																								
Trans-urethral																								
Trans-esoph. (non-Card.)																								
Musculo-skeletal(**Conventional**)																								
Musculo-skeletal (**Superficial**)																								
Intravascular																								
Other (Specify)																								
Cardiac Adult																								
Cardiac Pediatric																								
Intravascular (Cardiac)																								
Trans-esoph. (Cardiac)																								
Intra-cardiac																								
Other (Specify)																								
Peripheral vessel																								
Other (Specify)																								

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Previous 510(k) of the transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PVT-675MVS
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																						
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal	P	P	P		P	2	P	P			P			P		P	P	P	P					6
Abdominal	P	P	P		P	2	P	P			P			P		P	P	P	P					6
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric	P	P	P		P	2	P	P			P			P		P	P	P	P					6
Small Organ (Note 1)																								
Neonatal Cephalic																								
Adult Cephalic																								
Trans-rectal																								
Trans-vaginal																								
Trans-urethral																								
Trans-esoph. (non-Card.)																								
Musculo-skeletal(**Conventional**)																								
Musculo-skeletal (**Superficial**)																								
Intravascular																								
Other (Specify)																								
Cardiac Adult																								
Cardiac Pediatric																								
Intravascular (Cardiac)																								
Trans-esoph. (Cardiac)																								
Intra-cardiac																								
Other (Specify)																								
Peripheral vessel																								
Other (Specify)																								

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Previous 510(k) of the transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PVT-681MVL
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**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													5
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)																								

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Previous 510(k) of the transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PVT-712BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PVT-745BTF
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**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				5
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 transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PVT-745BTH
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**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				5
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 transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PVT-745BTV
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PVT-770RT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**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	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 transducer: 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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PVT-781VT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**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										5
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	P		4
Trans-vaginal	P	P	P		P	2	P	P			P		P	P	P						P	P		4
Trans-urethral																								
Trans-esoph. (non-Card.)																								
Musculo-skeletal(**Conventional**)																								
Musculo-skeletal (**Superficial**)																								
Intravascular																								
Other (Specify)																								
Cardiac Adult																								
Cardiac Pediatric																								
Intravascular (Cardiac)																								
Trans-esoph. (Cardiac)																								
Intra-cardiac																								
Other (Specify)																								
Peripheral vessel																								
Other (Specify)																								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PVT-781VTE
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**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										5
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	P		4
Trans-vaginal	P	P	P		P	2	P	P			P		P	P	P						P	P		4
Trans-urethral																								
Trans-esoph. (non-Card.)																								
Musculo-skeletal(**Conventional**)																								
Musculo-skeletal (**Superficial**)																								
Intravascular																								
Other (Specify)																								
Cardiac Adult																								
Cardiac Pediatric																								
Intravascular (Cardiac)																								
Trans-esoph. (Cardiac)																								
Intra-cardiac																								
Other (Specify)																								
Peripheral vessel																								
Other (Specify)																								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PVL-715RST
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**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													5
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		4
Trans-vaginal																								
Trans-urethral																								
Trans-esoph. (non-Card.)																								
Musculo-skeletal(**Conventional**)																								
Musculo-skeletal (**Superficial**)																								
Intravascular																								
Other (Specify)																								
Cardiac Adult																								
Cardiac Pediatric																								
Intravascular (Cardiac)																								
Trans-esoph. (Cardiac)																								
Intra-cardiac																								
Other (Specify)																								
Peripheral vessel																								
Other (Specify)																								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PLT-704SBT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**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													5
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 transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PLT-705BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																								
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**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				5
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 transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PLT-705BTF
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**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 transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: 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**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**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 transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PLT-1005BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**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													5
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric																								
Small Organ (Note 1)	P	P	P		P	2	P	P	P	P	P		P	P	P					P	P	P		4
Neonatal Cephalic																								
Adult Cephalic																								
Trans-rectal																								
Trans-vaginal																								
Trans-urethral																								
Trans-esoph. (non-Card.)																								
Musculo-skeletal(**Conventional**)	P	P	P		P	2	P	P	P	P	P		P	P						P	P	P		4
Musculo-skeletal (**Superficial**)	P	P	P		P	2	P	P	P	P	P		P	P						P	P	P		4
Intravascular																								
Other (Specify)																								
Cardiac Adult																								
Cardiac Pediatric																								
Intravascular (Cardiac)																								
Trans-esoph. (Cardiac)																								
Intra-cardiac																								
Other (Specify)																								
Peripheral vessel	P	P	P		P	2	P	P	P	P	P		P	P						P	P	P		4
Other (Specify)																								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PLT-1202BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**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)	P	P	P		P	2	P	P			P			P						P	P			4
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric																								
Small Organ (Note 1)	P	P	P		P	2	P	P			P			P						P	P			4
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			4
Musculo-skeletal (**Superficial**)	P	P	P		P	2	P	P			P			P						P	P			4
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 transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PLT-1204BT
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**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				5
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric																								
Small Organ (Note 1)	P	P	P		P	2	P	P	P		P		P	P						P				
Neonatal Cephalic																								
Adult Cephalic																								
Trans-rectal																								
Trans-vaginal																								
Trans-urethral																								
Trans-esoph. (non-Card.)																								
Musculo-skeletal(**Conventional**)	P	P	P		P	2	P	P	P		P		P	P						P				
Musculo-skeletal (**Superficial**)	P	P	P		P	2	P	P	P		P		P	P						P				
Intravascular																								
Other (Specify)																								
Cardiac Adult																								
Cardiac Pediatric																								
Intravascular (Cardiac)																								
Trans-esoph. (Cardiac)																								
Intra-cardiac																								
Other (Specify)																								
Peripheral vessel	P	P	P		P	2	P	P	P		P		P	P						P				
Other (Specify)																								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K182427 and 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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PLT-1204BX
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**Shear wave**	**4D**	**3D Color (Volume color)**	**STIC**	**STIC Color**	**Smart 3D**	**Fusion**	**Smart Navigation**	**2D WMT**	**Other [Note]**
Ophthalmic																								
Fetal																								
Abdominal	N	N	N		N	2	N	N			N			N						N				5(N)
Intra-operative (Abdominal)																								
Intra-operative (Neuro)																								
Laparoscopic																								
Pediatric																								
Small Organ (Note 1)	P	P	P		P	2	P	P	N	P	P		N	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	N	P	P		N	P						P				
Musculo-skeletal (**Superficial**)	P	P	P		P	2	P	P	N	P	P		N	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	N	P	P		N	P						P				
Other (Specify)																								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K151451
Prescription Use Only (Per 21 CFR 801.109)

Note 1 Small organ includes thyroid, breast and testicle
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PET-508MA
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**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	
Intra-cardiac																								
Other (Specify)																								
Peripheral vessel																								
Other (Specify)																								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PET-512MC
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																								
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**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	
Intra-cardiac																								
Other (Specify)																								
Peripheral vessel																								
Other (Specify)																								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PET-512MD
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																								
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**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	
Intra-cardiac																								
Other (Specify)																								
Peripheral vessel																								
Other (Specify)																								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PET-805LA
LA
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation																							
Specific (Tracks 3)	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify) ***	**Precision Imaging**	**Apli Pure**	**Micro Pure**	**BEAM**	**Power**	**TDI**	**Elastography**	**SMI**	**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													5
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 transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550, Aplio a450 and Aplio a, SoftwareV4.0
Transducer: PC-20M
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

System: Aplio a550 and a450, Software V2.8
Transducer: PC-50M
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K182427
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 Smart Sensor 3D
Note 5 CHI (Per FDA approved contrast agent prescribing information)
Note 6 Shadow Glass
Note 7 ATI

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:**
   Orlando Tadeo, Jr.
   Sr. Manager, Regulatory Affairs
   Canon Medical Systems USA, Inc
   2441 Michelle Drive
   Tustin, CA 92780
   (714) 669-7459

5. **DATE PREPARED:**
   June 20, 2019

6. **DEVICE NAME:**
   Aplio a550/a450/a Diagnostic Ultrasound System, V4.0

7. **TRADE NAME(S):**
   Diagnostic Ultrasound System Aplio a550, Model CUS-AA550
   Diagnostic Ultrasound System Aplio a450, Model CUS-AA450
   Diagnostic Ultrasound System Aplio a, Model CUS-AA000

8. **COMMON NAME:**
   System, Diagnostic Ultrasound

9. **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]

10. **PREDICATE DEVICE:**

Product	Marketed by	510(k) Number	Clearance Date
Aplio a550 and a450, Software V2.8 Diagnostic Ultrasound System	Canon Medical Systems USA, Inc	K182427	November 2, 2018

11. REASON FOR SUBMISSION:

Modification of a cleared device

12. DEVICE DESCRIPTION:

The Aplio a550 Model CUS-AA550, Aplio a450 Model CUS-AA450 and Aplio a Model CUS-AA000 are mobile diagnostic ultrasound systems. These systems are Track 3 devices that employ a wide array of probes including flat linear array, convex linear array, and sector array with frequency ranges between approximately 2 MHz to 20 MHz.

13. INDICATIONS FOR USE:

The Diagnostic Ultrasound Systems Aplio a550 Model CUS-AA550, Aplio a450 Model CUS-AA450 and Aplio a Model CUS-AA000 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.

14. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the Aplio a550 and Aplio a450 V2.8 Diagnostic Ultrasound System, 510(k) cleared under K182427, marketed by Canon Medical Systems USA, Inc. The Aplio a550 Model CUS-AA550 Version 4.0, Aplio a450 Model CUS-AA450 Version 4.0 and Aplio a Model CUS-AA000 Version 4.0 function in a manner similar to and is intended for the same use as the predicate device referenced within this submission. 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.

Transducers and hardware options added in this submission:

	Aplio a550/a450 Model CUS-AA550/AA450 Software V2.8	**Aplio a550/a450/a Models CUS-AA550, CUS-AA450, CUS-AA000 Software V4.0**	**Comments**
510(k) Control Number	**K182427 (Predicate)**	**This Submission (Subject)**	
PST-28BT	Not Available	Available	Previously cleared under K182679
PVT-574BT	Not Available	Available	Previously cleared under K182679
PVT-770RT	Not Available	Available	Previously cleared under K182679
PLT-1204BX	Not Available	Available	Previously cleared under K151451
Dynamic Micro Slice unit	Not Available	Available	Previously cleared under K182679
OLED Monitor	Not Available	Available	New option
Video Unit	Not Available	Available	New option

Improvements to previously cleared functionality:

	Aplio a550/a450 Model CUS-AA550/AA450 Software V2.8	**Aplio a550/a450/a Models CUS-AA550, CUS-AA450, CUS-AA000 Software V4.0**	**Comments**
510(k) Control Number	**K182427 (Predicate)**	**This Submission (Subject)**	
Doppler Luminance	Not Available	Available	Improved visibility of blood flow, Color Doppler imaging -Improvement
Auto E/A	Not Available	Available	Automation of previously manual measurements -Improvement
Volume rendering view (Mecha4D)	Not Available	Available	Previously only available in MPR view -Improvement
Auto EF (3ch)	Not Available	Available	Addition of 3 chamber view of Left Ventricle -Improvement
Stress Echo Color/Doppler	Not Available	Available	Applicability expanded to Color Doppler, PWD, M mode -Improvement
Vascularity Index	Not Available	Available	Expanded to include support of convex transducers and zoom -Improvement

Previously cleared software options being implemented to the subject device:

Application	**510(k) Clearance**	**Comments**
Attenuation Image	Previously cleared under K182679	No change from previous clearance
Breast Scan guide	Previously cleared under K182679	No change from previous clearance
Dynamic Micro Slice	Previously cleared under K182679	No change from previous clearance

15. 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 ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 , IEC 60601-1-2 (Ed. 4.0, 2014-02), IEC 60601-2-37 (Ed. 2.1, 2015), IEC 62304 (Ed 1.1, 2015-06), NEMA UD 2-2004 (R2009), NEMA UD3 -2004 (R2009), and ISO 10993 (Ed. 4.0, 2009-10-15) standards.

16. TESTING

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

16.1 Performance Testing – Bench Assessment of Doppler Luminance

This study confirmed that the subject function produces the intended 3D effect which realizes an improvement to blood flow visualization.

16.2 Performance Testing – Bench Assessment of Auto E/A

This study confirmed that the subject feature improves workflow through automation of previously

manual functionality which thereby reduces operation time.

16.3 Performance Testing – Bench Assessment of Measurement in volume rendering view established with Mechanical 4D Transducers

This study confirmed that the subject function realizes an improvement to existing functionality by expanding its applicability to volume rendering view.

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.

No clinical studies were required to demonstrate safety and efficacy of the Aplio a550, Aplio a450 and Aplio a systems.

17. CONCLUSION

The Aplio a550 Model CUS-AA550, Aplio a450 Model CUS-AA450 and Aplio a Model CUS-AA000 are substantially equivalent to the predicate device. The subject devices function in a manner similar to and is intended for the same use as the predicate device, as described in the labeling. Based upon the 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.