510(k) Summary

Submitter's Name: Toshiba America Medical Systems, Inc.
Address: PO Box 2068, 2441 Michelle Drive, Tustin, CA 92781-2068
Contact: Paul Biggins, Director of Regulatory Affairs
Telephone No.: (714) 730-5000

Device Proprietary Name: Aplio Artida v2.0 SSH-880CV
Common Name: Diagnostic Ultrasound System

Classification:

- **Regulatory Class:** II
- **Review Category:** Tier II

- Ultrasonic Pulsed Doppler Imaging System – Product Code: 90-IYN [Federal Reg. No.: 892.1550]
- Ultrasonic Pulsed Echo Imaging System – Product Code: 90-IYO [Federal Reg. No.: 892.1560]
- Diagnostic Ultrasonic Transducer – Product Code: 90-ITX [Federal Reg. No.: 892.1570]

Identification of Predicate Devices:
Toshiba America Medical Systems believes that this device is substantially equivalent to:

- Toshiba Ultrasound Diagnostic System Aplio Artida v2.0 SSH-880CV; 510(k) K080160.
- Toshiba Ultrasound Diagnostic System Aplio XG SSA-790A V3.0; 510(k) K082119.

Device Description:
This device is a mobile system. This system is a Track 3 device that employs a wide range of probes that include flat linear array and sector array with a frequency range of approximately 2.5 MHz to 7.5 MHz.

Indication of Use:
This device is intended to be used for the following type of studies; cardiac, transesophageal, abdominal and peripheral vascular.

Declaration of Conformity:
This device is designed and manufactured in conjunction with the Quality System Regulation, IEC 60601-1 (applicable portions), IEC 60601-1-1 (applicable portions), IEC 60601-1-2 (applicable portion), IEC 60601-1-4 (applicable portions), IEC60601-2-37 (applicable portions), and the AIUM-NEMA UD2 Output Measurement Standard as applied to Track 3 Ultrasound systems and the AIUM-NEMA UD3 Output Display Standard.

Standards Form:
Please see the attached standard form of the IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4 and IEC 60601-2-37.

Reason for Submission:
There is no new clinical application. The indication of use "abdominal" is added to the Indication of Use.

Submission Type:
This device is a Track 3 device. The submission type is Track 3.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

FEB - 6 2009

Re: K090158
Trade/Device Name: Aplio Artida v2.0 SSH-880CV
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: January 21, 2009
Received: January 22, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Aplio Artida v2.0 SSH-880CV, as described in your premarket notification:

Transducer Model Number

PST-25SX
PST-30BT
PST-30SBT
PST-50BT
PST-65AT
PLT-704SBT

PET-511BTM
PC-20M

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact John Chen at (240) 276-3666.

Sincerely yours,

for Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications For Use Form

System: Aplio Artida v2.0 SSH-880CV
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) ***	**THI**	**Dynamic Flow**	**Power**	**TDI**	**CHI 2D**	**4D (Realtime 3D)**
Ophthalmic												
Fetal												
Abdominal	N	N	N	N	N	N	N	N	N	N	N	
Intra-operative (Specify)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	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	P	P	P	P			
Musculo-skeletal **(Superficial)**	P	P	P		P	P	P	P	P			
Intravascular												
Other (Specify)												
Cardiac Adult	P	P	P	P	P	P	P	N	N	P	P	P
Cardiac Pediatric	P	P	P	P	P	P	P	N	N	P	P	P
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	P	P	P	P	P	P	P			P		
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P	P	P	P	P	P	P			
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
*Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Previous 510(k) of the transducer: K080160

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090158

Diagnostic Ultrasound Indications For Use Form

System: Aplio Artida v2.0 SSH-880CV
Transducer: PST-25SX

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) ***	**THI**	**Dynamic Flow**	**Power**	**TDI**	**CHI 2D**	**4D (Realtime 3D)**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Specify)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult	P						P					P
Cardiac Pediatric	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
*Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Previous 510(k) of the transducer: K080160

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K090158

Diagnostic Ultrasound Indications For Use Form

System: Aplio Artida v2.0 SSH-880CV
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) ***	**THI**	**Dynamic Flow**	**Power**	**TDI**	**CHI 2D**	**4D (Realtime 3D)**
Ophthalmic												
Fetal												
Abdominal	N	N	N	N	N	N	N	N	N	N	N	
Intra-operative (Specify)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult	N	N	N	N	N	N	N	N	N	N	N	
Cardiac Pediatric	N	N	N	N	N	N	N	N	N	N	N	
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
*Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090158

Diagnostic Ultrasound Indications For Use Form

System: Aplio Artida v2.0 SSH-880CV
Transducer: PST-30SBT

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) ***	**THI**	**Dynamic Flow**	**Power**	**TDI**	**CHI 2D**	**4D (Realtime 3D)**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Specify)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (**Conventional**)												
Musculo-skeletal (**Superficial**)												
Intravascular												
Other (Specify)												
Cardiac Adult	P	P	P	P	P	P	P			P	P	
Cardiac Pediatric	P	P	P	P	P	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
*Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Previous 510(k) of the transducer: K080160

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090158

Diagnostic Ultrasound Indications For Use Form

System: Aplio Artida v2.0 SSH-880CV
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) ***	**THI**	**Dynamic Flow**	**Power**	**TDI**	**CHI 2D**	**4D (Realtime 3D)**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Specify)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult	N	N	N	N	N	N	N			N		
Cardiac Pediatric	N	N	N	N	N	N	N			N		
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
*Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090158

Diagnostic Ultrasound Indications For Use Form

System: Aplio Artida v2.0 SSH-880CV
Transducer: PST-65AT

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) ***	**THI**	**Dynamic Flow**	**Power**	**TDI**	**CHI 2D**	**4D (Realtime 3D)**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Specify)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult	N	N	N	N	N	N	N			N		
Cardiac Pediatric	N	N	N	N	N	N	N			N		
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
*Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090158

Diagnostic Ultrasound Indications For Use Form

System: Aplio Artida v2.0 SSH-880CV
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) ***	**THI**	**Dynamic Flow**	**Power**	**TDI**	**CHI 2D**	**4D (Realtime 3D)**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Specify)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	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	P	P	P	P			
Musculo-skeletal **(Superficial)**	P	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	P	P	P	P			
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
*Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Previous 510(k) of the transducer: K080160

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090158

Diagnostic Ultrasound Indications For Use Form

System: Aplio Artida v2.0 SSH-880CV
Transducer: PET-511BTM

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) ***	**THI**	**Dynamic Flow**	**Power**	**TDI**	**CHI 2D**	**4D (Realtime 3D)**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Specify)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	P	P	P	P	P	P	P			P		
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
*Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Previous 510(k) of the transducer: K080160

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090158

Diagnostic Ultrasound Indications For Use Form

System: Aplio Artida v2.0 SSH-880CV
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) ***	**THI**	**Dynamic Flow**	**Power**	**TDI**	**CHI 2D**	**4D (Realtime 3D)**
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Specify)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal **(Conventional)**												
Musculo-skeletal **(Superficial)**												
Intravascular												
Other (Specify)												
Cardiac Adult				P								
Cardiac Pediatric				P								
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)												
Peripheral vessel				P								
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
*Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Previous 510(k) of the transducer: K080160

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090158