

K041499

JUN 10 2004

**510(k) Summary of Safety and Effectiveness: 21 CFR 807.92**

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

**Device Proprietary Name:** SSA-770A, APLIO Version 5.5  
**Common Name:** Diagnostic Ultrasound System

**Classification:**

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

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

**Identification of Predicate Devices:**

Toshiba America Medical Systems believes that this device is substantially equivalent to:

- 1) Toshiba SSA-770A, Aplio Version 4.0 Diagnostic Ultrasound; 510(k) control number k032281
- 2) Siemens Medical Solutions Sequoia 8.0 Diagnostic Ultrasound System; 510(k) control number k032281

**Device Description:**

The APLIO Ultrasound System is a mobile system. This system is a Track 3 device that employs a wide array of probes that include flat linear array, convex linear array, and sector array with a frequency range of approximately 2 MHz to 12 MHz.

**Intended Use:**

The APLIO is intended to be used for the following type of studies; fetal, abdominal, intraoperative, pediatric, small organs, neonatal cephalic, adult cephalic, cardiac, transrectal, transvaginal, transesophageal, peripheral vascular, musculo-skeletal (both conventional and superficial) and laparoscopic.

**Safety Considerations:**

This device is designed and manufactured in conjunction with the Quality System Regulation, IEC 60601 (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.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 10 2004

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

Re: K041499  
Trade Name: APLIO Diagnostic Ultrasound System, Model SSA-770A  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulation Number: 21 CFR 892.1560  
Regulation Name: Ultrasonic pulsed echo imaging system  
Regulation Number: 21 CFR 892.1570  
Regulatory Name: Diagnostic ultrasonic transducer  
Regulatory Class: II  
Product Code: 90 IYN, IYO, and ITX  
Dated: June 4, 2004  
Received: June 7, 2004

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 Diagnostic Ultrasound System, Model SSA-770A, as described in your premarket notification:

Transducer Model Number

PST-25AT  
PVT-375AT  
PVT-661VT  
PST-805AT  
PST-20CT

PLT-1204AX  
PC-20M  
PET-510MB  
PLT-1202S  
PET-704LA

PST-37CT  
PST-30BT  
PLT-704AT  
PLT-1204AT  
PVT-375AX

PST-65AT  
PLT-604AT  
PST-50AT

PLT-308P  
PET-508MA  
PVT-770RT

PVT-375BT  
PVT-382BT

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.

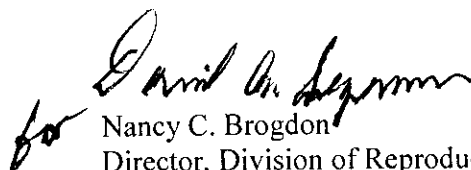
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,



Nancy C. Brogdon  
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 X Transducer \_\_\_\_\_  
 Model SSA-770A  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation											
	B	M	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI- Q
Ophthalmic												
Fetal	P	P	P	P	P	P	P	P	P			
Abdominal	P	P	P	P	P	P	P	P	P			
Intraoperative (Specify)**	P	P	P		P	P	P	P				
Intraoperative Neurological												
Pediatric	P	P	P	P	P	P	P	P	P			
Small Organ (Specify)***	P	P	P		P	P	P	P	P			
Neonatal Cephalic	P	P	P	P	P	P	P	P	P			
Adult Cephalic	P	P	P	P	P	P	P	P	P			
Cardiac	P	P	P	P	P	P	P	P	P	E <sup>1</sup>	P	P
Transesophageal	P	P	P	P	P	P	P	P	P	E <sup>1</sup>		P
Transrectal	P	P	P		P	P	P	P	P			
Transvaginal	P	P	P		P	P	P	P	P			
Transurethral												
Intravascular												
Peripheral Vascular	P	P	P		P	P	P	P	P			
Laparoscopic	P	P	P		P	P	P	P				
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P			
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P			

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: \_\_\_\_\_ Combined Modes: B/M; B/PWD;  
 BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;  
 CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

E<sup>1</sup> - Added via LTF against SSA-700A 510(k) control number K022400  
 Previous 510(k) for this device k013633

\*\* Abdominal

\*\*\* For example: thyroid, parathyroid, breast, scrotum and penis

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 Concurrence of CDRII, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)11

*David A. Bejman*  
 \_\_\_\_\_  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K041499

## Diagnostic Ultrasound Indications For Use Form

System \_\_\_\_\_ Transducer X  
 Model PST-25AT  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation											
	B	M	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI- Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric	P	P	P	P	P	P	P	P	P			
Small Organ (Specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac	P	P	P	P	P	P	P	P	P	E <sup>1</sup>		P
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: \_\_\_\_\_ Combined Modes: B/M; B/PWD;  
 BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;  
 CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

E<sup>1</sup> - Added via LTF against SSA-700A 510(k) control number K022400  
 Previous 510(k) for this device k013633

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Seymour*  
 \_\_\_\_\_  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K044499

## Diagnostic Ultrasound Indications For Use Form

System \_\_\_ Transducer X  
 Model PVT-375AT  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation											
	B	M	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI- Q
Ophthalmic												
Fetal	P	P	P		P	P	P	P	P			
Abdominal	P	P	P		P	P	P	P	P			
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric	P	P	P		P	P	P	P	P			
Small Organ (Specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												


N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: \_\_\_\_\_ Combined Modes: B/M; B/PWD;  
 BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;  
 CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

Previous 510(k) for this device k013633

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 Concurrence of CDRII, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

  
 \_\_\_\_\_  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K041499

## Diagnostic Ultrasound Indications For Use Form

System \_\_\_ Transducer X  
 Model PVT-661VT  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation											
	B	M	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI- Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal	P	P	P		P	P	P	P	P			
Transvaginal	P	P	P		P	P	P	P	P			
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: \_\_\_\_\_ Combined Modes: B/M; B/PWD;  
 BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;  
 CHI/2D; FEI/2D; CHI/BDF; FEI/BDF  
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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David R. Deperson*  
 \_\_\_\_\_  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number       K041499

## Diagnostic Ultrasound Indications For Use Form

System \_\_\_\_\_ Transducer X

Model PLT-805AT

510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation											
	B	M	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI- Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)	P	P	P		P	P	P	P	P			
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular	P	P	P		P	P	P	P	P			
Laparoscopic												
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P			
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P			


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Additional Comments: \_\_\_\_\_ Combined Modes: B/M; B/PWD;  
 BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;  
 CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

Previous 510(k) for this device k013633

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 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K041499



## Diagnostic Ultrasound Indications For Use Form

System \_\_\_\_\_ Transducer X  
 Model PST-20CT  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation											
	B	M	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI- Q
Ophthalmic												
Fetal	P	P	P	P	P	P	P	P	P			
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)												
Neonatal Cephalic	P	P	P	P	P	P	P	P	P			
Adult Cephalic												
Cardiac	P	P	P	P	P	P	P	P	P			
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

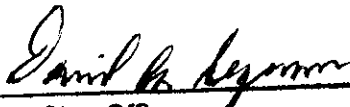
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 BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;  
 CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

Previous 510(k) for this device k013633

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 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K041499

## Diagnostic Ultrasound Indications For Use Form

System      Transducer X  
 Model PLT-1204AX  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation											
	B	M	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI- Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)	P	P	P		P	P	P	P	P			
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular	P	P	P		P	P	P	P	P			
Laparoscopic												
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P			
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P			

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: \_\_\_\_\_ Combined Modes: B/M; B/PWD;  
BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;  
CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

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Prescription Use (Per 21 CFR 801.109)

*David A. Seymour*  
 \_\_\_\_\_  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K011499

## Diagnostic Ultrasound Indications For Use Form

System \_\_\_ Transducer X  
 Model PC-20M  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation											
	B	M	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI- Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric				P								
Small Organ (Specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac				P								
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

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 CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

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Prescription Use (Per 21 CFR 801.109)

*David A. Seymour*  
 \_\_\_\_\_  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number       K041499

**Diagnostic Ultrasound Indications For Use Form**

System \_\_\_\_ Transducer X  
 Model PET-510MB  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation											
	B	M	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI- Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal	P	P	P	P	P	P	P	P	P	E		P
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

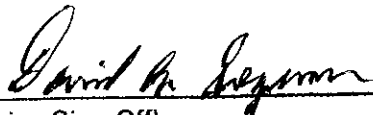
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BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;  
CHI/2D; FEI/2D; CHI/BDF; FEI/BDF  
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Prescription Use (Per 21 CFR 801.109)

  
 \_\_\_\_\_  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K041499

## Diagnostic Ultrasound Indications For Use Form

System \_\_\_\_\_ Transducer X  
 Model PLT-1202S  
 510(k) Number(s) \_\_\_\_\_

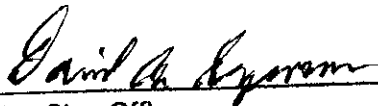
Clinical Application	Mode of Operation											
	B	M	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI- Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)	P	P	P		P	P	P	P	P			
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)	P	P	P		P	P	P	P	P			
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular	P	P	P		P	P	P	P	P			
Laparoscopic												
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P			
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P			

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Additional Comments: \_\_\_\_\_ Combined Modes: B/M; B/PWD;  
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 CHI/2D; FEI/2D; CHI/BDF; FEI/BDF  
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Prescription Use (Per 21 CFR 801.109)

  
 \_\_\_\_\_  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number           K041499

## Diagnostic Ultrasound Indications For Use Form

System \_\_\_\_\_ Transducer X  
 Model PET-704LA  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation											
	B	M	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI- Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic	P	P	P		P	P	P	P				
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: \_\_\_\_\_ Combined Modes: B/M; B/PWD;  
 BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;  
 CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

Previous 510(k) for this device k013633

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Sepperson*  
 \_\_\_\_\_  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K0211499

## Diagnostic Ultrasound Indications For Use Form

System \_\_\_ Transducer X  
 Model PST-37CT  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation											
	B	M	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q
Ophthalmic												
Fetal	E	E	E	E	E	E	E	E	E			
Abdominal	E	E	E	E	E	E	E	E	E			
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric	E	E	E	E	E	E	E	E	E			
Small Organ (Specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: \_\_\_\_\_ Combined Modes: B/M; B/PWD;  
BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;  
CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Legarom*  
 \_\_\_\_\_  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number 2041499

## Diagnostic Ultrasound Indications For Use Form

System \_\_\_ Transducer X  
 Model PST-30BT  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation											
	B	M	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q
Ophthalmic												
Fetal												
Abdominal	E	E	E	E	E	E	E	E	E			
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric	E	E	E	E	E	E	E	E	E			
Small Organ (Specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac	E	E	E	E	E	E	E	E	E	E	P	P
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: \_\_\_\_\_ Combined Modes: B/M; B/PWD;  
 BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;  
 CHI/2D; FEI/2D; CHI/BDF; FEI/BDF  
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 Concurrence of CDRH, Office of Device Evaluation (ODE)

*David R. Ferguson*

(Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K041499

Prescription Use (Per 21 CFR 801.109)



## Diagnostic Ultrasound Indications For Use Form

System \_\_\_\_\_ Transducer X  
 Model PLT-704AT  
 510(k) Number(s) \_\_\_\_\_

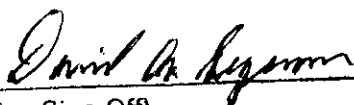
Clinical Application	Mode of Operation											
	B	M	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)	E	E	E		E	E	E	E	E			
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular	E	E	E		E	E	E	E	E			
Laparoscopic												
Musculo-skeletal Superficial	E	E	E		E	E	E	E	E			
Musculo-skeletal Conventional	E	E	E		E	E	E	E	E			

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: \_\_\_\_\_ Combined Modes: B/M; B/PWD;  
BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;  
CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

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Prescription Use (Per 21 CFR 801.109)

  
 \_\_\_\_\_  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number KD24499

## Diagnostic Ultrasound Indications For Use Form

System \_\_\_\_\_ Transducer X  
 Model PLT-1204AT  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation											
	B	M	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)	E	E	E		E	E	E	E	E			
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular	E	E	E		E	E	E	E	E			
Laparoscopic												
Musculo-skeletal Superficial	E	E	E		E	E	E	E	E			
Musculo-skeletal Conventional	E	E	E		E	E	E	E	E			

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: \_\_\_\_\_ Combined Modes: B/M; B/PWD;  
 BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;  
 CHI/2D; FEI/2D; CHI/BDF; FEI/BDF  
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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Segura*  
 \_\_\_\_\_  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K041489

## Diagnostic Ultrasound Indications For Use Form

System \_\_\_\_\_ Transducer X  
 Model PVT-375AX  
 510(k) Number(s) \_\_\_\_\_

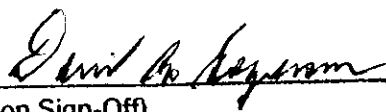
Clinical Application	Mode of Operation											
	B	M	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q
Ophthalmic												
Fetal	E	E	E		E	E	E	E	E			
Abdominal	E	E	E		E	E	E	E	E			
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric	E	E	E		E	E	E	E	E			
Small Organ (Specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: \_\_\_\_\_ Combined Modes: B/M; B/PWD;  
 BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;  
 CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

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Prescription Use (Per 21 CFR 801.109)

  
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 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K041499

## Diagnostic Ultrasound Indications For Use Form

System \_\_\_ Transducer X  
 Model PST-65AT  
 510(k) Number(s) \_\_\_\_\_

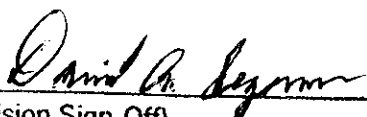
Clinical Application	Mode of Operation											
	B	M	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric	E	E	E	E	E	E	E	E	E			
Small Organ (Specify)												
Neonatal Cephalic	E	E	E	E	E	E	E	E	E			
Adult Cephalic												
Cardiac	E	E	E	E	E	E	E	E	E	E		
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N = new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: \_\_\_\_\_ Combined Modes: B/M; B/PWD;  
 BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;  
 CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

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 Concurrence of CDRII, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

  
 \_\_\_\_\_  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number 1K041499

## Diagnostic Ultrasound Indications For Use Form

System \_\_\_ Transducer X  
 Model PLT-604AT  
 510(k) Number(s) \_\_\_\_\_


Clinical Application	Mode of Operation											
	B	M	P	C	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)	E	E	E		E	E	E	E	E			
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular	E	E	E		E	E	E	E	E			
Laparoscopic												
Musculo-skeletal Superficial	E	E	E		E	E	E	E	E			
Musculo-skeletal Conventional	E	E	E		E	E	E	E	E			

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: \_\_\_\_\_ Combined Modes: B/M; B/PWD;  
 BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;  
 CHI/2D; FEI/2D; CHI/BDF; FEI/BDF  
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Prescription Use (Per 21 CFR 801.109)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number       K041499

# Diagnostic Ultrasound Indications For Use Form

System \_\_\_ Transducer X  
 Model PST-50AT  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation												
	B	M	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q	
Ophthalmic													
Fetal													
Abdominal													
Intraoperative (Specify)													
Intraoperative Neurological													
Pediatric	E	E	E	E	E	E	E	E	E				
Small Organ (Specify)													
Neonatal Cephalic	E	E	E	E	E	E	E	E	E				
Adult Cephalic													
Cardiac	E	E	E	E	E	E	E	E	E	E			P
Transesophageal													
Transrectal													
Transvaginal													
Transurethral													
Intravascular													
Peripheral Vascular													
Laparoscopic													
Musculo-skeletal Superficial													
Musculo-skeletal Conventional													

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: \_\_\_\_\_ Combined Modes: B/M; B/PWD;  
 BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;  
 CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David G. Johnson*  
 \_\_\_\_\_  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number       K044199

## Diagnostic Ultrasound Indications For Use Form

System \_\_\_\_\_ Transducer X  
 Model PLT-308P  
 510(k) Number(s) \_\_\_\_\_

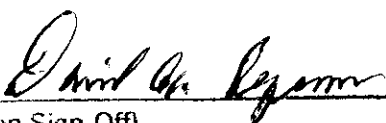
Clinical Application	Mode of Operation											
	B	M	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q
Ophthalmic												
Fetal												
Abdominal	E	E	E		E	E	E	E	E			
Intraoperative (Specify)	E	E	E		E	E	E	E	E			
Intraoperative Neurological												
Pediatric	E	E	E		E	E	E	E	E			
Small Organ (Specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: \_\_\_\_\_ Combined Modes: B/M; B/PWD;  
 BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;  
 CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

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Prescription Use (Per 21 CFR 801.109)

  
 \_\_\_\_\_  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K041499

## Diagnostic Ultrasound Indications For Use Form

System \_\_\_ Transducer X  
 Model PET-508MA  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation											
	B	M	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI- Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal	E	E	E	E	E	E	E	E	E	E		E
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N = new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: \_\_\_\_\_ Combined Modes: B/M; B/PWD;  
 BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;  
 CHI/2D; FEI/2D; CHI/BDF; FEI/BDF  
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 Concurrence of CDRII, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Seymour*  
 \_\_\_\_\_  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K041499



## Diagnostic Ultrasound Indications For Use Form

System \_\_\_\_\_ Transducer X  
 Model PVT-770RT  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation											
	B	M	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI- Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal	E	E	E		E	E	E	E	E			
Transvaginal	E	E	E		E	E	E	E	E			
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: \_\_\_\_\_ Combined Modes: B/M; B/PWD;  
 BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;  
 CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Rojman*  
 \_\_\_\_\_  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K041499

## Diagnostic Ultrasound Indications For Use Form

System \_\_\_\_\_ Transducer X  
 Model PVT-375BT  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation												
	B	M	P	C	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI-Q	
Ophthalmic													
Fetal	E	E	E		E	E	E	E	E				
Abdominal	E	E	E		E	E	E	E	E				
Intraoperative (Specify)													
Intraoperative Neurological													
Pediatric	E	E	E		E	E	E	E	E				
Small Organ (Specify)													
Neonatal Cephalic													
Adult Cephalic													
Cardiac													
Transesophageal													
Transrectal													
Transvaginal													
Transurethral													
Intravascular													
Peripheral Vascular													
Laparoscopic													
Musculo-skeletal Superficial													
Musculo-skeletal Conventional													

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: \_\_\_\_\_ Combined Modes: B/M; B/PWD;  
 BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;  
 CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Seymour*

(Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number 1041499

## Diagnostic Ultrasound Indications For Use Form

System \_\_\_\_\_ Transducer X  
 Model PVT-382BT  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation											
	B	M	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI- Q
Ophthalmic												
Fetal	E	E	E		E	E	E	E	E			
Abdominal	E	E	E		E	E	E	E	E			
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric	E	E	E		E	E	E	E	E			
Small Organ (Specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: \_\_\_\_\_ Combined Modes: B/M; B/PWD;  
 BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;  
 CHI/2D; FEI/2D; CHI/BDF; FEI/BDF  
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 Concurrence of CDRII, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Segerson*  
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 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number K041499