K041499

JUN 1 0 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 0 2004

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th 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	PLT-1204AX	PST-37CT
PVT-375AT	PC-20M	PST-30BT
PVT-661VT	PET-510MB	PLT-704AT
PLT-805AT	PLT-1202S	PLT-1204AT
PST-20CT	PET-704LA	PVT-375AX

PST-65AT	PLT-308P	PVT-375BT
PLT-604AT	PET-508MA	PVT-382BT
PST-50AT	PVT-770RT	

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,

for David A. Lepmm

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	PWD	CWD	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'	P	P
Transesophageal	P	P	P	P	P	P	P	P		E'		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'-- 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 CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)11

David A. Legan

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K044499

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer_X__
Model__PST-25AT_____
510(k) Number(s)
_____

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	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'		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' – 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. Lyon

(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	PWD	CWD	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 CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Legreen
(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)
_____

	Mode of Operation											
Clinical Application	B	M	PWD	CWD	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

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 R. Legrom

(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	PWD	CWD	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

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)

(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-20CT
510(k) Number(s)

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	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												

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. Lyerly
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041199

Diagnostic Ultrasound Indications For Use Form

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

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	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

Previous 510(k) for this device k013633

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerson

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 PC-20M
510(k) Number(s)

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	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												

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. Lyerman

(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	PWD	CWD	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												

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. Legan
(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	PWD	CWD	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			

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. Lyerson

(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	PWD	CWD	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. Lehrman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021499

Diagnostic Ultrasound Indications For Use Form

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

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	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. Legorm
(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-30BT_____
510(k) Number(s)
_____

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	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)

(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	PWD	CWD	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. Legorm
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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-1204AT
510(k) Number(s)

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	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 Seguin
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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 PVT-375AX
510(k) Number(s)

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	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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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Legstrom
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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	PWD	CWD	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 CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seymour
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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041495

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer _X_
Model PLT-604AT
510(k) Number(s)

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	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 Lyon

(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	PWD	CWD	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 A. Lyon

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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	PWD	CWD	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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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyon

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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 PET-508MA
510(k) Number(s)

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	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 CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lagomarsino
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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 PVT-770RT
510(k) Number(s)

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	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. Legum
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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041459

Diagnostic Ultrasound Indications For Use Form

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

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	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 Lagomarsino
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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041469

Diagnostic Ultrasound Indications For Use Form

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

Clinical Application	Mode of Operation											
	B	M	PWD	CWD	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. Segerson

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