K991710

JUN 3 1999 **510(k) Summary of Safety and Effectiveness: 21 CFR 807.92**

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

Device Proprietary Name: SSA-370A/PowerVision 6000
Common Name: Ultrasound Imaging System

Classification:

Regulatory Class: II
Review Category: Tier II

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

Identification of Predicate Devices:
Toshiba America Medical Systems believes that this device is substantially equivalent to the SSA-380A/PowerVision 7000, 510(k) control numbers K933743,K943303, K963705, K964865,K970047, K981397

Device Description:
The PowerVision 6000 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 10 MHz.

Intended Use:
The PowerVision 6000 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, and musculo-skeletal (both conventional and superficial).

Safety Considerations:
This device is designed and manufactured in conjunction with the Quality System Regulation, IEC- 60601 (applicable portions), the AIUM-NEMA UD2 Output Measurement Standard as applied to Track 3 Ultrasound systems and the AIUM-NEMA UD3 Output Display Standard. This unit is similar to that of the Toshiba SSA-380A/PowerVision 7000 and engineering assessments identify no new issues of risk or safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 1999

Toshiba America Medical Systems
c/o Carole Stamp
TUV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891

Re: K991710
Trade Name: SSA-370A PowerVision 6000
Regulatory Class: 892.1560, 892.1560, 892.1570
Product Code: 90-IYO, 90-IYN, 90-ITX
Classification: II
Dated: May 18, 1999
Received: May 19, 1999

Dear Ms. Stamp:

We have reviewed your Section 510(k) 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 SSA-370A PowerVision 6000 as described in your premarket notification:

Transducer Model Numbers

PLM-703AT, PLM-503AT, PLM-805AT, PC-19M, PLF-308P, PSM-20CT, PSM-25AT, PSM-37AT, PSM-50AT, PSM-37CT, PVF-738F, PVF-738H, PVM-662AT, PEF-510MB, PVM-621VT, PVM-375AT, PVF-620ST.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval) 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Please be advised that the determination above is based on the fact that no medical devices have been demonstrated to be safe and effective for in vitro fertilization or percutaneous umbilical blood sampling, nor have any devices been marketed for these uses in interstate commerce prior to May 28, 1976, or reclassified into class I (General Controls) or class II (Special Controls). FDA considers devices specifically intended for in vitro fertilization and percutaneous umbilical blood sampling to be investigational, and subject to the provision of the investigational device exemptions (IDE) regulations, 21 CFR, Part 812. Therefore, your product labeling must be consistent with FDA's position on this use.

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 and additionally 809.10 for in vitro diagnostic devices), 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 Robert Phillips, Ph.D. at (301) 594-1212.

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
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-370A
510(k) Number(s) _____

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		n	n	n	n	n	n	n	n	n
Abdominal		n	n	n	n	n	n	n	n	n
Intraoperative (Specify)		n	n	n		n	n	n	n	
Intraoperative Neurological										
Pediatric		n	n	n	n	n	n	n	n	n
Small Organ (Specify)		n	n	n		n	n	n	n	
Neonatal Cephalic		n	n	n	n	n	n	n	n	
Adult Cephalic		n	n	n	n	n	n	n	n	
Cardiac		n	n	n	n	n	n	n	n	n
Transesophageal		n	n	n	n	n	n	n	n	
Transrectal		n	n	n		n	n	n	n	
Transvaginal		n	n	n		n	n	n	n	
Transurethral										
Intravascular										
Peripheral Vascular		n	n	n		n	n	n	n	
Laparoscopic										
Musculo-skeletal Superficial		n	n	n		n	n	n	n	
Musculo-skeletal Conventional		n	n	n		n	n	n	n	
Other (specify)										

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991710
Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PVF-620ST

510(k) Control Number: K964865

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
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	
Transvaginal		P	P	P		P	P	P	P	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

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

NOTE: Original model number was PVK-720ST

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(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991710

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PVM-375AT

510(k) Control Number: K943303

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
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										
Other (specify)										

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

Color Harmonic Imaging is applied to BDF and BDF/PWD modes

NOTE: Original model number was PVK-357AT

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Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K991710

Prescription Use (Per 21 CFR 801.109)

NEW TRANSDUCER TABLE

Transducer Model Number: PVM-621VT

510(k) Control Number:

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal		N	N	N		N	N	N	N	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

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

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Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991710

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PEF-510MB

510(k) Control Number: K964865

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
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	
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

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

NOTE: Original model number was PEF-511SA (K890969)

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Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991710

Prescription Use (Per 21 CFR 801.109)

NEW TRANSDUCER TABLE

Transducer Model Number: PVM-662AT

510(k) Control Number:

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N	N	N	
Small Organ (Specify)										
Neonatal Cephalic		N	N	N		N	N	N	N	
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

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

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Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K991710

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PVF-738H

510(k) Control Number: K990490

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P	P	P		P	P	P	P	
Intraoperative (Specify)		P	P	P		P	P	P	P	
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)		P	P	P		P	P	P	P	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

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

NOTE: Original model number was IOE-703H (K852159)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991710

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PVF-738F

510(k) Control Number: K990490

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P	P	P		P	P	P	P	
Intraoperative (Specify)		P	P	P		P	P	P	P	
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)		P	P	P		P	P	P	P	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

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

NOTE: Original model number was IOE-703F (K852159)

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Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991710

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PSM-37CT

510(k) Control Number: K933743

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
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										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		E	E	E	E	E	E	E	E	E
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

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

NOTE: Original model number was PSK-37CT

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991710

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PSM-50AT

510(k) Control Number: K933743

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric		E	E	E	E	E	E	E	E	
Small Organ (Specify)										
Neonatal Cephalic		E	E	E	E	E	E	E	E	
Adult Cephalic										
Cardiac		E	E	E	E	E	E	E	E	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

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

NOTE: Original model number was PSK-50LT

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991710

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PSM-37AT

510(k) Control Number: K933743

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
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
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

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

NOTE: Original model number was PSK-37AT

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K991710

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PSM-25AT

510(k) Control Number: K933743

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
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
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

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

Color Harmonic Imaging is applied to BDF and BDF/PWD modes

NOTE: Original model number was PSK-25AT

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K991710

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PSM-20CT

510(k) Control Number: K970047

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic		P	P	P	P	P	P	P	P	
Adult Cephalic		P	P	P	P	P	P	P	P	
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

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

NOTE: Original model number was PSK-20CT

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K991710

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PLF-308P
510(k) Control Number: K852159

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal		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	
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

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

NOTE: Original model number was GCE-406M

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991710

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PC-19M

510(k) Control Number: K933473

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
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										
Other (specify)										

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

Additional Comments:_____

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Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991710

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PLM-805AT
510(k) Control Number: K933743

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)		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	
Laparoscopic										
Musculo-skeletal Superficial		E	E	E		E	E	E	E	
Musculo-skeletal Conventional		E	E	E		E	E	E	E	
Other (specify)										

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

NOTE: Original model number was PLK-703AT

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(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991710

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PLM-503AT
510(k) Control Number: K933743

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)		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	
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional		E	E	E		E	E	E	E	
Other (specify)										

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

NOTE: Original model number was PLK-703AT

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K99 1710

Prescription Use (Per 21 CFR 801.109)

EXISTING TRANSDUCER TABLE

Transducer Model Number: PLM-703AT
510(k) Control Number: K933743

Clinical Application		Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)		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	
Laparoscopic										
Musculo-skeletal Superficial		P	P	P		P	P	P	P	
Musculo-skeletal Conventional		P	P	P		P	P	P	P	
Other (specify)										

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

NOTE: Original model number was PLK-703AT

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510(k) Number K991710

Prescription Use (Per 21 CFR 801.109)