JUL 31 1998

K981397

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: PowerVision 7000
Common Name: Ultrasound Imaging System

Classification:

Regulatory Class: II
Review Category: Tier II
Ultrasonic Pulsed Doppler Imaging System Accessory
[Fed.Reg.No.:892.1550,Pro.Code:90-IYN]

Identification of Predicate Devices:

Toshiba America Medical Systems believes that the SSA-380A PowerVision 7000 is substantially equivalent to:

1) HP Sonos 2500 510(k) K964309 found to be SE on April 22, 1997
2) ATL Level 10 HDI 510k) K961459 found to SE on March 26,1997
3) Diasonics/Vingmed System 5 510(k) K963315 found to be SE on March 17, 1997
4) Toshiba SSA-380A PowerVision 510(k)s K933473 & K943303

Device Description:

Functionality: This modification will allow the existing SSA-380A system to transmit at one frequency and receive the returning echo at a different frequency.

Scientific Concept: Rayleigh's theory predicts that a bubble in an ultrasonic field will radiate harmonic echoes that are multiples of the incident beam. This theory also stipulates that the second resonated frequency echoed could possibly be higher that the echoed fundamental frequency. This modification equips the SSA-380A to detect and process those harmonic echoes.

Description of Modification: The modification includes the addition of several new/modified circuit boards and modifications to the software to allow two existing transducers to operate in this manner.

Significant Safety Concerns: None. The FDA is currently evaluating the use of contrast agents for their Safety and Effectiveness. This modification does not change the amount of acoustic output required in conventional ultrasonography. The modification is to provide and existing device with the capability of receiving echoes at a frequency different than the transmitted frequency.

Statement of Intended Use:

Intended use remains unchanged from the SSA-380A.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 1998

Paul Bigggins
Regulatory Affairs Specialist
Toshiba America Medical Systems, Inc.
P.O. Box 2068
2441 Michelle Drive
Tustin, CA 92781-2068

Re: K981397
Trade Name: Harmonic Imaging and Flash Echo Imaging Function for the SSA-380A Diagnostic Ultrasound System (PowerVision 7000)
Regulatory Class: II/21 CFR 892.1550/21 CFR 892.1570
Product Code: 90 IYN/90 ITX
Dated: July 1, 1998
Received: July 2, 1998

Dear Mr. Biggins:

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-380A Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

PSK - 25AT
PVT - 357AT

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket 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.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Diagnostic Ultrasound Indications For Use Form

System _X_ Transducer___
Model SSA-380A
510(k) Number(s) K933743, K943303, K964865, K970047

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Tissue Harmonics	Harmonics w/Contrast	FEI
Ophthalmic												
Fetal		p	p	p	p	p	p	p	*	n		
Abdominal		p	p	p	p	p	p	p	*	n		
Intraoperative (Abdominal)		e	e	e	e	e	e	e	*			
Intraoperative Neurological												
Pediatric		p	p	p	p	p	p	p	*	n		
Small Organ -Breast -Testicle -Thyroid		p	p	p	p	p	p	p	*			
Neonatal Cephalic		p	p	p	p	p	p	p	*			
Adult Cephalic		p	p	p	p	p	p	p	*			
Cardiac		p	p	p	p	p	p	p	*	n	n	n
Transesophageal		p	p	p	p	p	p	p	*			
Transrectal		p	p	p	p	p	p	p	*			
Transvaginal		p	p	p	p	p	p	p	*			
Transurethral		p	p	p	p	p	p	p	*			
Intravascular												
Peripheral Vascular		p	p	p	p	p	p	p	*	n		
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: Combinations B/M, BDF/MDF, B/PWD, BDF/PWD, B-TDI,M-TDI

The SSA-380A is ready for use with Contrast Agents for their approved uses.

~~(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON OTHER PAGES IF NEEDED)~~

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

William Yin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981397

Diagnostic Ultrasound Indications For Use Form

System __ Transducer X
Model PSK-25AT
510(k) Number(s) K933743

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Tissue Harmonics	Harmonics w/Contrast	FEI
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Abdominal)												
Intraoperative Neurological												
Pediatric												
Small Organ -Breast -Testicle -Thyroid												
Neonatal Cephalic												
Adult Cephalic												
Cardiac		p	p	p	p	p	p	p	*	n	n	n
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: Combinations B/M, BDF/MDF, B/PWD, BDF/PWD, B-TDI,M-TDI

The PSK-25AT is ready for use with Contrast Agents for their approved uses.

~~(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON OTHER PAGES IF NEEDED)~~

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981397

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X
Model PVK-357AT
510(k) Number(s) K943303

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Tissue Harmonics	Harmonics w/Contrast	FEI
Ophthalmic												
Fetal		p	p	p	p	p	p	p	*	n		
Abdominal		p	p	p	p	p	p	p	*	n		
Intraoperative (Abdominal)												
Intraoperative Neurological												
Pediatric		p	p	p	p	p	p	p	*	n		
Small Organ -Breast -Testicle -Thyroid		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	*	n		
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: Combinations B/M, BDF/MDF, B/PWD, BDF/PWD, B-TDI,M-TDI

The PVK-357AT is ready for use with Contrast Agents for their approved uses.

~~(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON OTHER PAGES IF NEEDED)~~

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981397