

3/2/99

K990490

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: JustVision 200 and JustVision 400
Common Name: Ultrasound Imaging System

Classification:

Regulatory Class: II
Review Category: Tier II
Ultrasonic Pulsed Echo Imaging System
[Fed.Reg.No.:892.1560,Pro.Code:90-IYO]

Identification of Predicate Devices:

Toshiba America Medical Systems believes that this device is substantially equivalent to the SSA-220A Capasee, 510(k) control number K933747

Device Description:

The JustVision Ultrasound System is available as a compact portable system or can be configured as a mobile system with a 12 inch monitor. This system is a Track 1 device that employs a wide array of probes that include flat linear array and convex linear array, with a frequency range of approximately 2 MHz to 10 MHz.

Intended Use:

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

Safety Considerations:

This device is designed and manufactured in conjunction with the Quality System Regulation, ISO- 60601 (applicable portions) and the AIUM-NEMA UD2 Output Measurement Standard as applied to Track 1 Ultrasound systems. This unit is similar to that of the Toshiba SSA-220A Capasee and engineering assessments identify no new issues of risk or safety.



MAR - 2 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Toshiba America Medical Systems, Inc.
C/o Carole Stamp
TUV Product Service
1775 Old Highway 8 NW, Suite 104
New Brighton, MN 55112-1891

Re: K990490
SSA-320A JustVision 200 and SSA-325A JustVision 400
Regulatory Class: II/ 21 CFR 892.1560/21 CFR 892.1570
Product Code: 90 IYO/ 90 ITX
Dated: February 11, 1999
Received: February 16, 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-320A JustVision 200 and SSA-325A JustVision 400, as described in your premarket notification:

Transducer Model Number

PVG-366M
PVG-381M
PVG-681S
PVG-600S
PVG-601V
PVG-720S
PVG-738F
PVF-738H
PVF-745V
PLG-308P
PLG-506M

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:

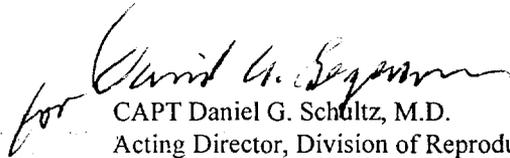
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 Robert A. 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

Enclosures

Diagnostic Ultrasound Indications For Use Form

System X Transducer _____
 Model SSA -320A/SSA-325A
 510(k) Number(s) _____

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

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

Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Squiman

 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number K990490

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications For Use Form

System _____ Transducer x _____

Model PVG-366M _____

510(k) Number(s) _____

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P						P	
Abdominal		P	P						P	
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
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 mode is B+M

Note: This transducer was originally cleared with the SSA-220A via 510(k) control number K933747

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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 K990490

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications For Use Form

System _____ Transducer x

Model PVG-381M

510(k) Number(s) _____

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

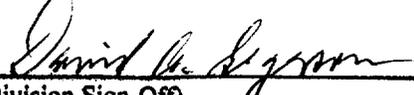
N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined mode is B+M

Note: This transducer was originally cleared with the SSA-220A via 510(k) control number K933747

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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 K990490

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications For Use Form

System _____ Transducer X

Model PVG-681S

510(k) Number(s) _____

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		N	N						N	
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic		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 mode is B+M

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number K990490

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications For Use Form

System _____ Transducer X

Model PVF-738F

510(k) Number(s) _____

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	
Intraoperative (Specify)		P	P						P	
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)		P	P						P	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P						P	
Laparoscopic										
Musculo-skeletal Superficial		N	N						N	
Musculo-skeletal Conventional		N	N						N	
Other (specify)										

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

Additional Comments: Combined mode is B+M

Note: This transducer was originally cleared as probe IOE-703F with the SSA-90A via 510(k) control number K852159

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Segerson

 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number K990490

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications For Use Form

System _____ Transducer X
 Model PVF-738H
 510(k) Number(s) _____

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		
Intraoperative (Specify)		P	P						P		
Intraoperative Neurological											
Pediatric											
Small Organ (Specify)		P	P						P		
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular		P	P						P		
Laparoscopic											
Musculo-skeletal Superficial		N	N						N		
Musculo-skeletal Conventional		N	N						N		
Other (specify)											

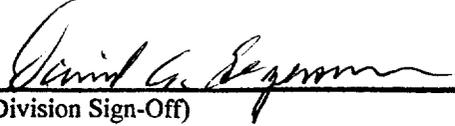
N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined mode is B+M

Note: This transducer was originally cleared as probe IOE-703H with the SSA-90A via 510(k) control number K852159

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Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number K990490

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications For Use Form

System _____ Transducer X

Model PLG-308P

510(k) Number(s) _____

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	
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

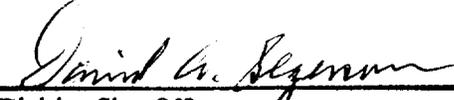
N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined mode is B+M

Note: This transducer was originally cleared as probe GCE -406M With the SSA-90A via 510(k) control number 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 K990490

Prescription Use (Per 21 CFR 801.109)

