

K97277!

FEB 11 1998

510(k) Summary

Submitter's Name: Toshiba America Medical Systems, Inc.
Submitter's Address: P.O. Box 2068, 2441 Michelle Drive, Tustin CA 92781-2068
Submitter's Contact: Steven M. Kay, Regulatory Affairs Specialist, (714) 730-5000
Establishment Registration Number: 2020563

Device Proprietary Name: Phased Array Transducer - - PVF-375DT
Common Name: Diagnostic Ultrasound Transducer
[Fed. Reg. No.: 892.1570, Pro. Code: 90-ITX]

Regulatory Class: II
514 Performance Standards: None
Special Controls: None
Prescription Status: Prescription Device

Reason for Submission: Modification of the PVF-375MT

Substantial Equivalence Summary:

The PVF-375DT volume imaging transducer is a modification of the PVF-375MT convex transducer that was cleared for the SSA-340A, SSA-270A and SSH-140A diagnostic ultrasound imaging systems. It will add volume imaging to conventional diagnostic ultrasound images. Volume imaging is due to the physical characteristics of the device and is intended to assist with patient education during an examination.

The PVF-375DT follows previously cleared software verification and validation procedures and employs the same general technology as that most lately cleared for the PVF-375MT. It does not affect cleared patient contact materials or acoustic output intensities. Based on a review of TAMS Complaint and MDR files for similar transducers, any potential failure of this transducer is not expected to result in an injury to the patient.

TAMS believes that the PVF-375DT is substantially equivalent to the PVF-375MT because it does not change the cleared safety and effectiveness attributes or the indications for use of the PVF-375MT.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 1998

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

Re: K972771
Phased Array Transducer – PVF-375DT
Dated: November 7, 1997
Received: November 13, 1997
Regulatory class: II
21 CFR 892.1570/Procode: 90 ITX

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 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. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SSA-340A, SSA-270 and SSA-140A Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

PVF-375DT

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:

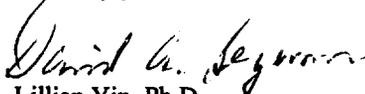
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 Phillips, Ph.D. at (301) 594-1212.

Sincerely yours,

for 
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

510(k) Number (if known):

K972771

Device Name:

PVF-375DT convex phased array transducer

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		✓	✓	✓						
Abdominal		✓	✓	✓						
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-Esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal										
Other (Specify)										

Additional Comments:

This transducer is indicated for adjunctive non-quantitative visualization of the target study area.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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, ENT,
 Radiological Devices
 510(k) Number K972771