

NOV 24 1998

## 510(k) Summary

K98 2976

**Date:** 25 August 1998

**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:** Paul Biggins, Regulatory Affairs Specialist, (714)730-5000

**Establishment Registration Number:** 2020563

**Device Proprietary Name:** Ultrasound Workstation, UIWS-300A

**Common Name:** Picture Archiving and Communications System

**Regulatory Class:** Class II per 21 CFR § 892.2050; 90LLZ

**Predicate Device:** Nova MicroSonics, Image View DCR

**Reason For Submission** New Product

### Description of this Device:

The UIWS-300A, Ultrasound Workstation, is an all digital workstation that can be connected to Toshiba PowerVision diagnostic ultrasound scanners. Its function is to provide the user with the ability to view images, annotate images, store image data and perform analysis on image data. The unit is comprised of a standard desktop type personal computer, keyboard, mouse, monitor and connecting cables.

### Summary of Intended Uses:

This device is to serve as a workstation for the capture, storage, review and analysis of ultrasound images, both still and dynamic. This device is designed to support functional diagnosis by performing display, processing, measurement and analysis of ultrasound images.

### Comparison to Predicate Device

The user features of the UIWS-300A Ultrasound Workstation and the Nova MicroSonics ImageVue DCR (K) are very similar.

### Conformance to Standards

The following standards apply to the design and manufacture of the UIWS-300A Ultrasound Workstation:

Image Storage:	DICOM SCU Storage
Monitor Testing:	JIS C6101
Safety:	IEC 60601-1-1 (AMD1) [1992]
Image Compression:	MJPEG: Compressed -AVI format Non-compressed - IMG format



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Paul Biggins  
Regulatory Affairs Specialist  
Toshiba America Medical Systems, Inc.  
2441 Michelle Drive  
PO Box 2068  
Tustin, CA 92781-2068Re: K982976  
Ultrasound Workstation, UIWS-300A  
Dated: August 25, 1998  
Received: August 26, 1998  
Regulatory class: II  
21 CFR 892.2050/Procode: 90 LLZ

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 (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.

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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) 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 the 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) 594-4613. 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 (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

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

Enclosure

510(k) Number (if known): K982976

Device Name: Ultrasound Workstation, UIWS-300A

Indications for Use:

Retrieval and storage of both passive and active ultrasound images  
Analysis of ultrasound images

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

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 K982976

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)