K992886

NOV - 9 1999

510(k) Summary

Date:	25 August 1999
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:	PowerView Ultrasound Workstation, UIDM-400A
Common Name:	Picture Archiving and Communications System
Regulatory Class:	Class II per 21 CFR § 892.2050; 90LLZ
Predicate Device:	Toshiba Workstation, UIWS-300A (K982976) Dicomit Image Manager (K990248) Tomtec Echo-Scan (K963807)
Reason For Submission	New Product

Description of this Device:
The UIDM-400A, PowerView Ultrasound Workstation, is an all digital workstation that can be integrated with the 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, 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 UIDM-400A PowerView Ultrasound Workstation are similar to the functions included in the three predicate devices. This device does not offer any new functions that have not received previous market clearance from the Agency.

Safety Considerations:
The UIDM-400A is comprised of a personal computer that is mounted into the Toshiba PowerVision Ultrasound System. The software is comprised of various vendor programs that have received previous 510k clearances. The verification and validation testing is equivalent to that of the testing reported in previous 510k submissions. This system poses no new safety concerns or efficacy concerns that were not addressed in previous submissions. The manufacturing facility is ISO-9001 certified and follows the Quality System Regulations as administered by the Food and Drug Administration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Paul Biggins
Regulatory Affairs Specialist
Toshiba America Medical Systems, Inc.
2441 Michelle Dr.
Tustin, CA 92781

Re: K992886
PowerView Ultrasound Workstation
Model UIDM-400A
Dated: August 25, 1999
Received: August 26, 1999
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 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.

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,

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

510(k) Number (if known): K992886

Device Name: PowerView Ultrasound Workstation, UIDM-400A

Indications for Use:

Retrieval and storage of both passive and active ultrasound images.
Analysis of ultrasound images
Reconstruction and display of three dimensional images.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Gelperson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992886