

FEB 13 1998

510(k) Summary

K974307

Date: November 13, 1997

Submitter: Gary J. Allsebrook, Regulatory Affairs
for/ TERARECON, INC.
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Contact: Gary J. Allsebrook, Regulatory Affairs
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Device Name: RTR-2000 Medical Image Reconstruction and
Processing Systems

Common Name: Image Processing Workstation

Classification Name: System, Image Processing

Classification: Class II

Procode: 90LLZ

Establishment
Registration Number: Application in Process

Predicate Device: Toshiba TSFX-001A, Real-Time Reconstruction
System Option for Xpress/SX CT System, K950972

Device Description: The TERARECON, INC. RTR-2000 real-time image reconstruction system acquires medical image data from such medical imaging devices as CT and reconstructs the "raw" data into visible images. The RTR-2000 system reconstructs images with such high performance that the images are viewed in real-time. This stand-alone high performance image reconstruction system is offered as an upgrade to existing imaging devices, and is not intended to replace the devices' existing reconstruction system. Rather, it is intended to serve as an alternative means of viewing medical images, particularly where real-time visualization of images is beneficial.

Intended Use of this Device: The intended use of the device is to provide solutions to various medical image reconstruction throughput problems through the application of high speed image image processing devices and software, specifically, 2D and 3D reconstructions for CT scanners, MRI scanners and Ultrasound and other related radiological image host systems. It will allow for near real-time viewing, in turn, supporting existing system clinical uses by offering enhanced operator flexibility.

Comparison to Predicate Device: The RTR-2000 is similar to the Toshiba Real-Time Reconstruction System Model TSXF-001A, K950972, in that it is an upgraded version (supplement) of the host viewing system. As in the predicate device, the features provide user flexibility and improvements to the image processing throughput. Other than dramatically speeding up the image reconstruction process, there are no perceived or imagined new intended uses which will affect the safety and effectiveness of the host system.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850TeraRecon, Inc.
c/o Gary J. Allesbrook
Regulatory Management Services
16303 Panoramic Way
San Leandro, CA 94578-1116Re: K974307
RTR-2000 (Image Processing
Workstation)
Dated: November 13, 1997
Received: November 17, 1997
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. Allesbrook:

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 requirement, 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/cdrb/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): K974307

Device Name: TeraRecon RTR-2000 Image Reconstruction System

Indications for Use:

The TeraRecon RTR-2000 Image Reconstruction System should be used when it is desirable to view scanned medical images immediately, rather than wait long periods of time for reconstruction. Indications would include monitoring of radiological examinations for patient movement. It is possible that patient movement during the middle of an examination, which may require re-scanning, would not be detected until after the completion of the exam when all of the images are reconstructed and thus visualized. High speed image reconstruction allows for real-time visualization of the images. Such real-time visualization of images gives the immediate visual feedback necessary to monitor the progress of examinations in efforts to maximize scanning accuracy and minimize radiation dose to the patient.

In short, real-time visualization of images is indicated in cases where the user prefers immediate visual feedback as opposed to having to wait long periods of time for image reconstruction.

(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 901.109)

OR

Over-the-Counter Use

David A. Beynon (Optional Format 1-2-96)
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

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