

ATTACHMENT 10

510(k) Summary

Siemens Realtime 3D Software Package

NOV 10 1997

August 8, 1997

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. General Information.

Establishment

- **Address:** Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ 08830
- **Contact Person:** Kathleen M. Rutherford
Manager, Regulatory Submissions
(908) 321-4779 phone
(908) 321-4841 fax

Device Name

- **Trade Name:** Realtime 3D Diagnostic Workstation
- **Common Name:** 3D CT/MR Post-processing Workstation
- **Classification Name:** Picture Archiving and Communication System (PACS)
- **Classification:** Class II
- **Performance Standards:** None established under Section 514 of the Food, Drug, and Cosmetic Act.

II. Information Supporting Substantial Equivalence Determination.

- **Device Description:**
Realtime 3D (RT3D) Diagnostic Workstation includes all the necessary hardware and software components for a medical imaging workstation that allows 3D visualization of tomographic dataset from either a CT or MR scanner together with Multiplanar Reconstructions (MPR), and allows the user to fly through or around the 3D image(s) in real time. The user can also view the 3D images in stereo and make measurements in the 3D images.
- **Intended Use:**
The Realtime 3D application is intended to provide the physician with additional diagnostic information through displaying the

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tomographic dataset in 3 dimensional space which can show the spatial relationship among different anatomical structures. It can also be used for pre-surgical and post-surgical evaluation by surgeons. Due to its real time performance, Realtime 3D provides the user with fast case-turnaround time which leads to improved patient care and cost savings.

- **Technological Characteristics as compared to the Predicate Device:**

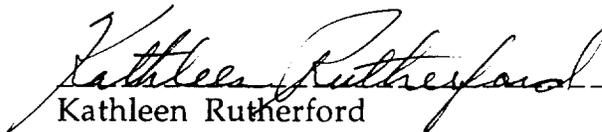
The Realtime 3D has the same technological characteristics as Vitrea™ 3D Medical Visualization System. They both provide the user with 3D and MPR of anatomic structures. They both provide the user with a navigation tool that can be used to "Fly around" or "Fly through" the anatomy of interest. Siemens Realtime 3D offers, in addition, interactive clip planes which provides the user with real time MPR, stereo display, 3D measurement, and an orientation view during Fly-through and fly-around for better orientation and navigation.

The Realtime 3D has the same technological characteristics as the MagicView Workstation. They have substantially similar MPRs, MIPs, and volume rendering algorithm. RT3D has the added ability to show 3D images in real time.

- **Substantial Equivalence:**

Siemens Realtime 3D is substantially equivalent to the following devices:

- Vitrea™ 3D Medical Visualization System
Vital Images
- MagicView Diagnostic Workstation
Siemens Medical Systems, Inc.



Kathleen Rutherford
Manager, Regulatory Submissions
Imaging Systems Group, Siemens Medical Systems

8/7/97

Date



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 1997

Kathleen Rutherford
Manager, Regulatory Submissions
Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ 08830

Re: K973010
Realtime 3D Diagnostic Workstation
Dated: August 8, 1997
Received: August 13, 1997
Regulatory class: Unclassified
Prococode: 90 LLZ

Dear Ms. Rutherford:

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/cdrh/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

ATTACHMENT 1(revision)

Indications For Use

510(k) Number (if known): K973010
Device Name: Realtime 3D Diagnostic Workstation

Indications For Use:

From user specified sets of CT or MR images, Realtime 3D can be used for

- 3D presentation of the complete anatomic structure (i.e. head, chest, abdomen) covered by the original CT or MR images for diagnosis and use in treatment planning;
- diagnosing as well as treatment planning from real time Multi-Planar-Reconstruction (MPR); the Realtime 3D tool can help the user to position and visualize the 3-dimensional location of the MPR within the 3D volume by using interactive clip planes in real time;
- CTA and MRA displaying enhanced vessels;
- measurement of anatomical structures in the 3D volume. Important for quantitative measurement of geometry and length of anatomy indices;
- displaying the position of anatomical structures in relationship to each other;
- navigating interactively through anatomical structures (e.g., vessels, colon, spine, lung, etc.) or inside the 3D volume;
- depth perception using the Stereo display option to visualize i.e. overlaying and underlying vessels;
- for viewing the inner surface of organs (vessels, colon, etc.);

(please do no write below this line- continue on another page if needed)

Prescription Use _____
(Per 21 CFR 801.109)

David G. Ferguson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973010