SIEMENS

SEP - 3 1997

ATTACHMENT 11

K971717

510(k) Summary

Siemens Fly Through Software Package

May 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:** Fly Through
- **Common Name:** PACS software
- **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:**

The Siemens Fly Through is a software package that provides 3D, MPR of anatomic structures, and interactive endoscopic views of organs with cavities. By navigating within the 3D imaging data, the user can tour the patient anatomy and make adjustments to provide the best view.

Fly Through can be installed onto medical viewing and post-processing workstations that meet minimum system requirements such as patient database, filming, and networking, 24 bits true color graphics display, real-time polygon rendering graphics, and real-time texture mapping graphics.

- **Intended Use:**
  The Fly Through application is intended to provide physicians with a training tool, and means to help evaluate from CT or MR datasets the feasibility of conducting actual endoscopic procedures. The application is also intended to assist diagnosis from Multi-Planar-Reconstructions (MPRs): the Fly Through tool can help the user to position and visualize the 3-dimensional location of the MPR within the segmented dataset.

- **Technological Characteristics as compared to the Predicate Device:**
  The Fly Through has the same technological characteristics as GE's Navigator. 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 view the anatomy in different viewpoints. Siemens Fly Through also provides the MPR is relation to the 3D model thus making it easier for the user to position and visualize the 3-dimensional location of the MPR within the segmented dataset.

  The Fly Through has the same technological characteristics as the Prominence Workstation. FT is installed as an option on the Prominence. They share the same segmentation module, patient data, MPR, user interface, filming, and storage. FT has the added ability to show 3D surface shading and tetrahedral models.

- **Substantial Equivalence:**
  Siemens Fly Through is substantially equivalent to the following devices:
  1. Advantage Windows 3D with Navigator
     GE
  2. Prominence Workstation (Silhouette)
     ISG Technologies

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

5/8/97
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 3 1997

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

Re: K971717
Fly Through (3D CT/MR Reconstruction Software)
Dated: August 7, 1997
Received: August 8, 1997
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK

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

Indications For Use

510(k) Number (if known): K971717
Device Name: Fly Through Software Package

Indications For Use:

From user specified sets of CT or MR images, Fly Through can be used for

- 3D presentation of segmented anatomic models (e.g., tracheas, bones, vessels, colon, etc.);
- navigating interactively through 3D segmented models that represent body cavities (e.g., vessels, colon, spine, lung, etc.);
- for viewing the inner surface of organ models (vessels, colon, etc.). Fly Through offers advantages over real endoscopy. For example, Fly Through can be performed within models of organs or blood vessels inaccessible to a real endoscope;
- a training tool for surgeons to practice endoscopic procedures;
- surgical planning;
- feasibility study of an actual endoscopic procedure; and
- a 3D positioning and orientation tool for Multiplanar reconstruction, thus assisting diagnosis from Multi-Planar-Reconstructions (MPRs): the Fly Through tool can help the user to position and visualize the 3-dimensional location of the MPR within the segmented dataset.

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

Concurrence of the CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971717

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)