SEP 2 2 1998

K982319

Attachment 10

510(k) Summary

CAREGRAPH Software Program for Image-Intensified Fluoroscopic X-ray System

Submitted by:

Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ 08830
Establishment Registration Number:
2240869

June 30, 1998

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

1. **Contact Person:**
Kathleen Rutherford
Phone: (732) 321-4779 Fax: (732) 321-4841

2. **Device Name and Classification:**

Trade Name:	CAREGRAPH
Classification Name:	Angiographic X-ray Systems and Image Intensified Fluoroscopic X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1600 and 21 CFR §892.1650
Device Class:	Class II
Device Code:	90IZZ

3. **Intended Use:**
CAREGRAPH is an angiographic system accessory for recording, displaying and documenting the regional distribution of the skin entry dose of a patient, depending on the relevant angulations in X-ray examination. The dose is calculated depending on the format size, the angulation and the table position and displayed on a graphical patient body surface.

4. **Substantial Equivalence:**
We believe within the meaning of the Safe Medical Devices Act of 1990, the CAREGRAPH Software Program for Angiographic X-ray Systems and Image Intensified Fluoroscopic X-ray Systems as addressed in this Premarket notification, is substantially equivalent to the following devices for Angiographic X-ray Systems and Image Intensified Fluoroscopic X-ray Systems currently in commercial distribution.

Device	Manufacturer	510(k) Number
Diamentor patient x-ray exposure indicator	Manufacturer: PTW - Freiburg Importer: Nuclear Associates	K853753
Diamentor M1/M2/M3	Manufacturer: PTW - Freiburg	exempt

This statement is based on the fact that the CAREGRAPH system is based a similar PTW detector system and complies with the same or equivalent standards and has the same intended uses as the aforementioned predicate devices. The software raises no new safety or effectiveness concerns.

5. Device Description:

CAREGRAPH is a PC program which provides a graphical display of the dose exposure to the patient as measured by a commercially available dose measurement system whose sensor is mounted in the imaging chain. CAREGRAPH can be used with all Siemens Angio and Fluoro systems that are configured with the ACS-, or XCS-interface. The software, which is delivered on CD-ROM, runs on Windows 95/Windows NT 4.0, and is designed to operate with existing Siemens dose counter features in products such as the cardiac workstations (marketed as Siemens Quantcor and Siemens ACOM.PC). The program follows the Microsoft conventions and can be configured by the customer. Minimum PC requirements are:

- Pentium 133 MHz (or better), 16 Mbyte RAM (or more) for Windows 95
- Pentium 133 MHz (or better), 32 Mbyte RAM (or more) for Windows NT 4.0.

The standard display is a two dimensional presentation of the radiation impact in a scaled window, with numerical indications at foci of skin doses for certain limits. The numerical value of the "Hot Spot" is focused in the graphical presentation, which is updated every 10 seconds. The radiation field must be presented within 2 seconds if relevant parameters have been changed. Calculation is done with an accuracy of ±5%.

The "Hot Spot" resolution shall be ≤ 5x5 mm^2 and limits and colors for the indication of the spot is configurable by the user. The program is operated with keyboard and mouse. The customer can set the skin dose alarm limit, though not higher than 2000 mGy. When a critical dose is reached an alarm sounds. The display of the dose area is possible without radiation. Patient data can be set parallel to data survey. It is possible to process the patient data afterwards and also generate a report on the patient and examination data. As a minimum, one week's patient reports shall be storable. Data may then be transferred and stored on another media.

6. Summary of Technological Characteristics of the Device Compared to the Predicate Devices:

The CAREGRAPH accessory has the same technological characteristics as the predicate PTW detector system and complies with the same or equivalent standards and has the same intended uses as the aforementioned predicate devices.

Kathleen Rutherford
Manager, Regulatory Submissions
Siemens Medical Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 1998

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

Re: K982319
Caregraph (Accessory to Angiographic X-ray
Systems and Image Intensified Fluoroscopic Systems
Dated: July 1, 1998
Received: July 2, 1998
Regulatory class: II
21 CFR 892.1650/Procode: 90 JAA

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 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

Attachment 1

Indications for Use

510(k) Number (if known): _____

Device Name: Siemens CAREGRAPH Accessory for Angiographic X-ray Systems and Image Intensified Fluoroscopic X-ray Systems

Indications for Use:

CAREGRAPH is an angiographic system accessory for recording, displaying and documenting the regional distribution of the skin entry dose of a patient, depending on the relevant angulations in X-ray examination. The dose is calculated depending on the format size, the angulation and the table position and displayed on a graphical patient body surface.

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

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

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982319