

SIEMENS

August 27, 1999

K992925

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Control Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Subject: 510(k) Submission for the Siemens AX Workstation DR-Viewer Option

Dear Document Control Clerk:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act, Siemens Medical Systems, Inc. is submitting, in duplicate, a Premarket Notification [510(k)] for the DR-Viewer Software Option, for use in viewing angiographic image data. The following information is provided in accordance with 21 CFR § 807.87 and the guidance document "Addendum: How to Submit a Premarket Notification [510(k)] March 1995" from the Center for Devices and Radiological Health.

1. **Reason for Submission:**
Siemens Medical Systems, Inc. intends to market, the DR-Viewer Software Option which is loaded and executed on the AX Workstation (K991972, currently under FDA review).

2. **Device Name and Classification:**
Trade Name: AX Workstation DR-Viewer Software Option
Classification Name: Accessory to Angiographic X-Ray System
Classification Panel: Radiology
CFR Section: 21 CFR § 892.1600
Device Class: Class II
Product Code: LLZ

3. **Importer/Distributor Establishment Registration Number: 2240869**
Facility:
Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ 08830

4. **Manufacturing Facility:**
Siemens AG
Bereich Med.
Siemensstrasse 1
91301 Forchheim
Germany

Siemens Medical Systems, Inc.

Sales and Service

186 Wood Avenue South
Iselin, NJ 08830

Tel: (732) 321-4500
Fax: (732) 494-2250

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5. Contact Person:

Ms. Malgorzata Stanek
Senior Technical Specialist
Phone: (732) 321-3950 Fax: (732) 321-4841

6. Substantial Equivalence:

The AX Workstation DR-Viewer Software Option uses a series of images of the anatomy (i.e. spine, legs, colon) generated with a radiographic, fluoroscopic, or angiographic x-ray system, and reconstructs the images into a single composite image format. After reconstruction of the image, the software provides the user with various measurement tools and post-processing functions.

The package is substantially equivalent to the following devices:

<i>Device Name</i>	<i>FDA Clearance Number</i>	<i>FDA Clearance Date</i>
Philips EasyVision Family Workstation Legs Option	K990455	5/12/99
Philips Spine Option for EasyVision Workstation	K963980	12/23/96

Information that substantiates this claim of equivalence is provided throughout this 510(k) submission and specific equivalence information is provided in Attachment 5.

7. 510(k) Summary:

In response to the requirements addressed by the SMDA of 1990 and 21 CFR § 807.92, I am enclosing, in Attachment 8, a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

8. Indications For Use:

The AX Workstation DR-Viewer Software Option offers the user the ability to visualize composite images of selected anatomy (i.e. spine, legs, colon). The images produced by the package, as well as the measurement tools of DR-Viewer, are intended to assist the physician in diagnosis and treatment of musculoskeletal disorders and conditions of the gastrointestinal tract.

The Indications for Use statement for the DR-Viewer Software Option is also provided in Attachment 9.

9. Truthful and Accurate Statement:

A Premarket Notification Truthful and Accurate Statement is provided in Attachment 1.

10. Labeling:

Information about the predicate devices is provided in Attachment 6. The Draft Operating Manual for DR-Viewer is provided in Attachment 7.

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Confidentiality

All items marked "CONFIDENTIAL" may be trade secret, confidential commercial or financial information as defined in 21 CFR § 20.61. Siemens requests that FDA not make public disclosure of this information without prior consultation with Siemens as provided by 21 CFR § 20.45.

We would appreciate your earliest attention to this 510(k) submission. Should you have any additional questions, please contact Ms. Malgorzata Stanek at (732) 321-3950. Her fax number is (732) 321-4841.

Sincerely,



Kathleen Rutherford
Manager, Regulatory Submissions

Attachments



Ms. Malgorzata Stanek
Senior Technical Specialist
Siemens Medical Systems, Inc.
186 Wood Avenue South
ISELIN NJ 08830

MAY - 7 2012

Re: K992925

Trade/Device Name: DR-Viewer Software Option for AX Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 27, 1999
Received: August 30, 1999

Dear Ms. Stanek:

This letter corrects our substantially equivalent letter of November 23, 1999.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

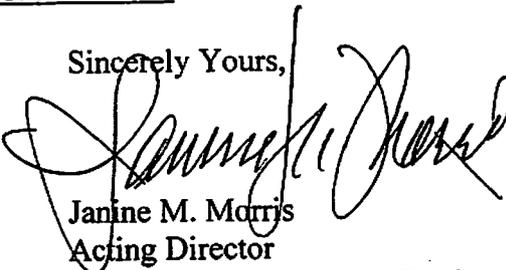
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

ATTACHMENT 9

INDICATIONS FOR USE

510(k) Number (if known): K992925
Device Name: DR-Viewer

Indications For Use:

The AX Workstation DR-Viewer Software Option offers the user the ability to visualize composite images of selected anatomy (i.e. spine, legs, colon). The images produced by the package, as well as the measurement tools of DR-Viewer, are intended to assist the physician in diagnosis and treatment of musculoskeletal disorders and gastrointestinal conditions.

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

Edward G. Keenan
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992925

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

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