

Siemens SC9000 / SC9015 Series Surgical Display Controller

4. Predicate Device Identification:

The Siemens SC9000/9015 Series Surgical Display Controller is substantially equivalent to the Siemens SC9000/9015 Series SC9015 Display.

5. Device Description

The SC9000/9015 Series Surgical Display Controller enables SC9000/9015 monitoring functions to be displayed on a Siemens 15 inch Remote Display or on a standard video display.

6. Intended Use:

The intended use of the Siemens SC9000/9015 Series Surgical Display Controller is to display SC9000/9015 Bedside Monitor functions on a Siemens Remote Display or on a standard video display.

7. Table of device similarities and differences to predicate device

	Substantial Equivalent Device: Siemens Medical Systems SC 9000/9015 Series SC9015 Display	Applicant: Siemens Medical Systems SC 9000/9015 Series Surgical Display Controller
Manufacturer	Siemens Medical Systems Electromedical Group	Siemens Medical Systems Electromedical Group
510K Number	K946306	K970348
Intended Population	Same as Siemens Component Monitoring System	Same
Displayed Parameters	Same as bedside monitor	Same
Measuring Methods	None: Information and data generated in bedside monitor	Same
Waveform Display	Dependent on the bedside monitor's primary display	Same

8. Assessment of non-clinical performance data for equivalence:

The Siemens 9000/9015 Series Surgical Display Controller is substantially equivalent to the predicate device: Siemens 9000/9015 Series SC9015 display.

9. Assessment of clinical performance data for equivalence:

Not applicable; device is substantially equivalent to predicate device.

10. **Biocompatibility:** Not applicable

11. **Sterilization:** Not applicable

Siemens Medical Systems, Inc.

Electromedical Group

16 Electronics Avenue
Danvers, MA 01923
USA

Tel: (508) 750-7500
Fax: (508) 777-3398
Telex: 511958 (Siemensm SD)



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

AUG 15 1997

Mr. David Simard
Siemens Medical Systems, Inc.
16 Electronics Avenue
Danvers, Massachusetts 01923

Re: K970348
Siemens SC9000/SC9015 Series Surgical Display Controller
Regulatory Class: III (three)
Product Code: 74 DSI
Dated: May 16, 1997
Received: May 19, 1997

Dear Mr. Simard:

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 (Pre-market 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 pre-market 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.

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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) 594-4648. 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indicated Use Statement

The Siemens SC9000/SC9015 Series Surgical Display Controller is indicated for use in an environment where patient care is provided by healthcare professionals (e.g. surgeons and other operating room personnel). It will be used whenever the professional determines that parameters and functions generated by the SC 9000/9015 Bedside Monitor should be displayed on a remote terminal.

MRI Compatibility Statement:

The Siemens SC9000/9015 Series Surgical Display Controller is not intended for use in an MRI environment.

Prescription Use ✓

Cristy Foreman for AAC

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K970348

Company Confidential

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Electromedical Group

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Danvers, MA 01923
USA

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Fax: (508) 777-3398
Telex: 511958 (Siemensm SD)