



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 1999

Mr. David Simard
Quality Assurance
and Regulatory Affairs
Siemens Medical Systems, Inc.
16 Electronics Avenue
Danvers, MA 01923

Re: K990563
Siemens SC 8000 Bedside Monitor with Advanced
Communication Option
Regulatory Class: III (three)
Product Code: MXH
Dated: February 19, 1999
Received: February 22, 1999

Dear Mr. Simard:

This letter corrects our substantially equivalent letter of March 19, 1999, regarding the enclosure to the letter. We erroneously enclosed the Intended Use Statement in place of the Indications for Use Statement.

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 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). 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 Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 continue 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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (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
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Siemens SC 8000 Bedside Monitor with Advanced Communication Option

Indications for Use:

The SC 8000 Bedside monitor with Advanced Communication Option is capable of monitoring:

- Heart rate
- Respiration rate
- Invasive pressure
- Non-invasive pressure
- Arrhythmia
- Temperature
- Cardiac output
- Arterial oxygen saturation
- Pulse rate
- (central) apnea
- ST Segment Analysis
- 12-Lead ST Segment Analysis

With the MultiGas™ and MultiGas+™ modules the SC8000 is capable of measuring:

- Respiration rate
- Inspired and expired Carbon Dioxide (CO2)
- Inspired and expired Oxygen (MultiGas+™ only)
- Average inspired Oxygen (MultiGas™ only)
- Inspired and expired gas concentrations of Enflurane, Halothane, Isoflurane, Desflurane, Sevoflurane, and Nitrous Oxide.

The SC 8000 Bedside Monitor can interface with third party devices.

The device is intended to be used in the environment where patient care is provided by Healthcare Professionals, i.e. Physicians, Nurses, and Technicians, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

The device is intended to be used on Adult, Pediatric and Neonatal populations, *with the exception of the parameter Cardiac Output and ST Segment Analysis which are intended for use in the adult and pediatric populations only; Arrhythmia which is intended for use in the adult population only; and tcpO2 which is to be used in the neonatal population only when the patient is not under gas anesthesia.*

MRI Compatibility Statement:

The Siemens SC 8000 Bedside Monitor is not compatible for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____

[Signature]
 (Division Sign-Off) (Optional Format 1-2-96)
 Division of Cardiovascular, Respiratory,
 and Neurological Devices
 510(k) Number K990563